Radiochemistry Expert Committee (REC)
Meeting Summary

May 25, 2016

1. Roll Call and Minutes:

Bob Shannon, Chair, called the meeting to order at 1pm Eastern on May 25, 2016 by teleconference. Attendance is recorded in Attachment A – there were 6 members present. Associate Members: Jim Chambers, Joe Pardue.

The minutes for January, February and March were distributed by email for review. A motion was made by Marty to approve the minutes for 1/13/16, 1/27/16, 2/24/16 and 3/23/16 with the correction of the date in the file names. The motion was seconded by Dave and unanimously approved.

2. Summer Meeting in August

There is no need for the committee to meet in Orange County in August. A live training was done in Tulsa and it was recorded as a webinar. This training will be available to meeting attendees.

3. Subcommittee Updates

Assessor Training

Carolyn offered to pull together the Summary Document comments into the Standard and she will be getting started on this this month.

Assessor Checklist

Larry, Vas and Marty have moved forward with the checklist that was distributed to the committee (see Attachment D).

Comments:

- The media had not been listed for some of the methods – so this is being added.

- Include a space for listing the lab SOP. This highlights method modifications. ABs need to be sure they are accrediting to a modified method for many of the methods that have been modified to run soil. Lines could be added to the bottom of the table.

- The strikeouts and red text are changes from the previous meeting (see Attachment D).

- The checklist is now in the order of the Standard.

- Bob provided comments on the checklist and these were reviewed as the committee walked through the checklist with Larry (Attachment D). Any changes made during today's meeting were also added to the checklist.

- The Notes to assessors may be inappropriate. Too detailed. This should be part of the assessor training.

  The reason for giving the guidance was the thought that the statements in the Standard are too vague for some assessors to work with and they need some guidance. Bob did not think this was the appropriate place to put this guidance.

  Ilona noted that the Small Lab Handbook may be a document that can be used to put guidance. She also noted that if any suggestions or examples are given – multiple examples are needed so it is not thought it is the only way.

  The subcommittee will drop the notes.

- #19 is an example where Bob thought something was added to the Standard. Bob does not disagree with what is written, but it makes it confusing for an assessor. Do they write up a lab for #19 or a corrective action finding? Larry was OK with striking it.

- #21. A lot of the why in the Standard has been deleted from the checklist. This is why the text is striked.

- #22. Bob deleted his comment and this is reflected in Attachment D.

- Larry continued to review Bob's comments and changes will be reflected in the next checklist update.

- Marty sent some additions that will also be reflected in the next update.

Larry thinks the committee is now about 85% done. He is asking everyone to critically review the checklist as Drafts are sent.

<u>Laboratory Training</u>

Keith can no longer participate on this committee, so Carolyn is looking for another committee member. This committee has not gotten started yet. Marty will begin to work with this committee after he finishes with the checklist.

Small Laboratory Handbook

Dave is still working on this document. He hopes to have something out in the next two weeks. Ilona will send along what Micro is doing and ask Paul to provide anything he can send to help Dave. Dave will take a look at it and decide if Paul should be meeting with the committee in June when this is reviewed.

4. PT Needs

Joe Pardue is on the call representing PT. ABs are accrediting for Non-DW parameters. What needs to be done to expand Radiochemistry PTs beyond DW?

ERA is putting out some PTs that could be included in FoPT tables. These are outside of drinking water.

Ilona noted that the PTPEC has an application to add PTs to the FoPT table. Vas could complete this application as an AB.

Marty noted that there is the MAPEX PT Program that most commercial labs are involved in. They are ISO/IEC 17043 accredited.

Joe will look into this issue and discuss it with the two PT committees he works with. He will report at the next meeting.

5. New Business

None.

6. Action Items

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

7. Next Meeting and Close

Next months meeting will be scheduled by email. Bob may not be able to meet the regular meeting time.

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

The meeting was adjourned 2:04 pm Eastern. (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) **Absent**	Wadsworth Center, NY State DOH Albany, NY	AB	518-474-6071	thomas.semkow@health.ny.gov
Sreenivas (Vas) Komanduri **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 **Present**	Consultant Aiken, SC	Other	803-649-5268	dj1fauth@bellsouth.net
Carolyn Wong **Present**	Lawrence Livermore National Laboratory Livermore, CA	Lab	925-422-0398	CTWRACE@gmail.com
Keith McCroan **Absent**	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 **Present**	Sheibley Consulting, LLC	Other (Former AB)	651-485-1875	RHSHEIB111@yahoo.com
Ron Houck **Absent**	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
63	Send note to QS to ask them to consider making all references to "days" more clear by stating "calendar" days.	Bob	7/13/15	
68	Send common lab assessment findings to Dave for his use in preparing the chapter for the Small Lab Handbook.	All	10/20/15 Ongoing	
70	Send a request to get "Lesson Learned" ideas from committee and associate members.	Dave	11/17/15	
71	Follow-up with Ken and Shawn regarding PT Standard Issue.	Bob	11/17/15	
75	Prepare copy of Standard annotated with summary document language.	Carolyn	6/15/16	

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	

Assessment Checklist for Radiochemistry 5/20/2016 Draft

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

Methods Reviewed – complete as appropriate

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

Bob Shannon 5/24/2016 11:05 AM
Comment [1]: Suggest adding space for lab-developed – non-reference methods. Alternatively, add a column after the analyte for the method ID

Bob Shannon 5/23/2016 9:29 AM
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Bob Shannon 5/24/2016 11:05 AM
Comment [2]: Note that this method does not address preparation for solids/air

Bob Shannon 5/24/2016 11:05 AM
Comment [3]: Note that this method does not address preparation for solids or air. I suppose we could somehow inclide "modified"??

Assessment Checklist for Radiochemistry 5/20/2016 Draft

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

Item No.		Line of Inquiry	Status Y	N	n/a	Observations/Comments
Method Validation						
[At suggestion of the committee in the March meeting, the first 10 questions concerning SOPs were removed. The questions in the checklist now follow exactly the order that requirements are presented in the Standard.]						
1	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?~~ - Where applicable, activity range includes zero activity (e.g., a method blank) in the validation?				
2	V1M6, 1.5.1 b), 1.5.2 through 1.5.5	Does the laboratory, - 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: - Precision - Bias - Measurement Uncertainty, and - Selectivity				
3	V1M6, 1.5.1 c)	For each method for which documented data are not otherwise available, does the laboratory perform validation to demonstrate that the above requirements are met? If the laboratory refers to published method validation data for reference methods, are all required QC (including tracers and carriers, as applicable), acceptance criteria, and corrective action procedures for QC failures clearly specified?				
4	V1M6, 1.5.1 d)	Has the laboratory recorded the quality system matrix used in initial method validation studies?				
5	V1M6, 1.5.1 e)	Do the laboratory's method validations comply with the requirements at V1M2 5.4.5.1 through V1M2 5.4.5.3?				
6	V1M6, 1.5.1 f)	Do the laboratory documented 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?				

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Bob Shannon 5/23/2016 9:43 AM
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Bob Shannon 5/23/2016 9:44 AM
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Bob Shannon 5/24/2016 11:05 AM
Comment [4]: This is not address in 1.5.1 c)

Bob Shannon 5/23/2016 9:46 AM
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Bob Shannon 5/24/2016 11:05 AM
Comment [5]: This pushes the assessor a bit harder to go beyond reading an SOP and saying they require it - to looking at evidence.

Bob Shannon 5/23/2016 9:36 AM
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Bob Shannon 5/24/2016 10:54 AM
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Audit ID: _____ **Laboratory:** _____ **Assessor:** _____ **Date:** _____

Item No.		Line of Inquiry	Status Y	N	n/a	Observations/Comments
		Method Validation (continued)				
7	V1M6, 1.5.1 g)	Does the laboratory analyze, wherever available, externally-produced quality control samples from a nationally or internationally recognized source provider to determine its ability to produce acceptable data?				
8	V1M6, 1.5.4	Does method validation documentation include 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, 1.5.5	Does method validation documentation include a qualitative statement describing the means of evaluating selectivity during method validation?				
		Demonstration of Capability (DOC)				
10	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?				
11	V1M6, 1.6.2.1	Is documentation maintained for each initial DOC consistent with the minimum elements specified in Section 1.6.2.1 a) – g) ?				*[decided these elements are not unusual, and so it is not necessary to list them all here]*
12	V1M6, 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?				
13	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 accepted values, single blind to the analyst; b) another initial DOC; c) at least four (4) consecutive blank samples and 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; e) If a) through d) are not technically feasible, analysis of real-world samples with results within predefined acceptance criteria (defined by the laboratory or method)				
		Technical Requirements				
14	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				

Bob Shannon 5/24/2016 11:05 AM
Comment [6]: Need to address 1.5.2 and 1.5.3 and more detail on 1.5.4

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Bob Shannon 5/24/2016 11:05 AM
Comment [7]: Use language of standard

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Bob Shannon 5/24/2016 11:05 AM
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Assessment Checklist for Radiochemistry 5/20/2016 Draft

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

Item No.	Line of Inquiry		Status			Observations/Comments
			Y	N	n/a	
		Technical Requirements (continued)				
15	V1M6 1.7.1	~~Do procedures ensure~~ Does the lab's process ensure meeting appropriate regulatory or contractual specifications and support decision making?				
16	V1M6 1.7.1	Does the instrument QC program meet the requirements of method regulation, contract and or the TNI Standard? 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
17	V1M6, 1.7.1.1 a)	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
18	V1M6 1.7.1.1 b)	Does the laboratory document 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?				
19	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 perform corrective actions to determine and ameliorate any 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

Bob Shannon 5/23/2016 10:20 AM
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Bob Shannon 5/23/2016 10:21 AM
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Bob Shannon 5/25/2016 12:34 PM
Comment [10]: Larry is considering deleting the "assessor guides"

Bob Shannon 5/24/2016 11:05 AM
Comment [11]: Strongly suggest removing the note. I would leave it up to the assessor to find an instance of where this is not being met instead of loading the gun against the lab by requiring them to maintain positive proof of consistency. The checks we are doing with calibration, verification, backgrounds, should cover this.

Bob Shannon 5/24/2016 11:05 AM
Comment [12]: Again, I do not recommend including this comment rather leave the burden of proof on the assessor.

Bob Shannon 5/24/2016 11:05 AM
Comment [13]: Why the note???

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Bob Shannon 5/23/2016 10:32 AM
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Bob Shannon 5/24/2016 11:05 AM
Comment [16]: Recommend removing note

Bob Shannon 5/24/2016 11:05 AM
Comment [14]: Suggest deleting. This goes beyond the text of the standard

Bob Shannon 5/25/2016 12:37 PM
Comment [15]: Larry is included to strike this.

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

Item No.	Line of Inquiry	Status Y	Status N	Status n/a	Observations/Comments
Technical Requirements (continued)					
20	V1M6, 1.7.1.2 a)				

Does the laboratory perform radiation measurement systems calibration prior to initial use and any time the following conditions occur?

i) following replacement of a key detector element (e.g., a photomultiplier tube, silicon barrier detector, gas proportional detector chamber, germanium crystal, etc.)

ii) after a repair when subsequent performance checks indicate a change in performance

iii) after modification of system parameters that affect instrument response

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

v) when indicated by corrective actions

vi) when calibration is due according to a predetermined frequency

Does the laboratory document the criteria to initiate (re)calibration in its SOPs?

Bob Shannon 5/24/2016 11:05 AM
Comment [17]: Suggest moving the reference to column to the left

Bob Shannon 5/24/2016 11:05 AM
Comment [18]: Looks like this paragraph lost its number…I would number it as 1.7.1.2 a)

Bob Shannon 5/23/2016 10:41 AM
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Item No.		Line of Inquiry	Status Y	N	n/a	Observations/Comments
		Technical Requirements (continued)				
21	V1M6 1.7.1.2 b)	Does the laboratory perform multi-point calibrations, required, to correlate parameters (other than activity) such as the following cases? 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.				
22	V1M6 1.7.1.2 c)	Do instrument calibrations make use of reference standards based on physical measurements as defined in Section 1.7.2.6.c)? Do 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)].				
23	V1M6 1.7.1.2 d)	Does the laboratory use empirical techniques (e.g., gamma transmission) and/or computational techniques? (e.g., Monte Carlo or efficiency modeling techniques) to account for minor differences between physical characteristics of the calibration standard (i.e., geometry, density, coincidence-summing, etc.) and the samples to which the correction is to be applied ? If so, i) Has the laboratory performed documented validation of the correction method or model by physical measurement of reference standards as defined in Section 1.7.2.6.c)? i) Does the validation span the entire range of physical characteristics observed in samples to which the correction shall be applied (i.e., geometry, density, etc.) ? ii) Does the applied correction consistently minimize measurement bias across the range of physical characteristics? iii) Does the laboratory estimate and validate the uncertainty associated with the correction (see Section 1.5.4) and included it in the uncertainty reported with each associated sample result.				Note: Since Monte Carlo modeling techniques are relatively recent, the lab should have thorough documentation. The modeling techniques not applicable for drinking water analysis. Note: Lab should have detailed documentation.

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Bob Shannon 5/24/2016 11:05 AM
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Bob Shannon 5/23/2016 10:59 AM
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Bob Shannon 5/24/2016 11:05 AM
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Item No.		Line of Inquiry	Status Y	N	n/a	Observations/Comments
24	V1M6 1.7.1.2 e)	i) Does the laboratory establish and document in written procedures and in records the details of the initial instrument calibration including: 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) Does the laboratory 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, does the laboratory perform corrective actions? iv) Does the laboratory retain sufficient raw data records to permit reconstruction of the initial instrument calibration.				
		Technical Requirements (continued)				
25	V1M6 1.7.1.2 f)	Does the laboratory quantitate sample results only from the initial instrument calibrations unless otherwise allowed by regulation, method, or contract?				
26	V1M6, 1.7.1.3 a) & c)	Are initial instrument calibrations verified with either: a) i) a second set of calibration measurements compared to the first, or a) ii) quantifying a set of prepared standards using the initial calibration. a) Are standards used for calibration verification obtained from a source or lot independent of the reference standard used in the initial calibration (where available)?				*[Here it was felt that the detail was helpful]*
27	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~~?				*[Unnecessary detail removed]*
	V1M6,	Are instrument performance checks conducted using appropriate check				*[Not necessary to explain here the purpose of*

Comment [26]: Delete?
Bob Shannon 5/24/2016 11:05 AM
Comment [27]: Rephrase as questions?
Bob Shannon 5/23/2016 11:18 AM
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Bob Shannon 5/23/2016 11:16 AM
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Bob Shannon 5/23/2016 11:19 AM
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Audit ID: _____ **Laboratory:** _____ **Assessor:** _____ **Date:** _____

28	1.7.1.4 a) i) ii) & vi)	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~~?				*performance checks]*
29	V1M6, 1.7.1.4 a) vii)	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?				
30	V1M6, 1.7.1.4 a) iv) & v)	Do the performance check sources provide adequate counting statistics for a relatively short count time Is radioactive decay of the check source, where significant, taken into account when evaluating count-rate sensitive parameters such as efficiency?				
31	V1M6, 1.7.1.5 a) iii)	Are performance check sources prepared, handled, sealed or encapsulated to prevent damage, loss of activity and contamination?				
Item No.		**Line of Inquiry**	**Status Y**	**N**	**n/a**	**Observations/Comments**
Technical Requirements (continued)						
32	V1M6, 1.7.1.4 b) & c)	Are performance checks conducted consistent with the minimum required frequency? 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: - 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 - 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				

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Bob Shannon 5/24/2016 11:09 AM
Comment [32]: Cannot rephrase as suggested without changing the sense of the lnaguage. This was carefully worded to allow either decay correction or to allow limits to be corrected to compensate for decay.

Bob Shannon 5/24/2016 11:05 AM
Comment [33]: As rephrased, this would require use of sealed or encapsulated sources. This was not intended and could even be misinterpreted making alpha sources impossible. Instead, it is up to the lab to ensure that their sources are not compromised - and it allows the assessor to take action if weak practices are noted (e.g., sources scratched from reckless handling)

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		Exception: 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.				
33	V1M6, 1.7.1.4 d)	When detector systems are powered off between performance checks, are performance checks counted prior to the next Test Source measurement?				
34	V1M6, 1.7.1.5 d)	Does the laboratory have procedures for performing and evaluating subtraction background measurements that include the following: - 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?				
Item No.	**Line of Inquiry**		**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
Technical Requirements (continued)						
35	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)?				

36	V1M6, 1.7.1.5 a)	Are subtraction background measurements conducted consistent with the minimum required frequency:
		- Paired measurements performed 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 minimum frequency depending on the detector technology:
		  - Gamma spectrometry: monthly
		  - Alpha spectrometry: monthly
		  - Gas-proportional and semiconductor alpha/beta detectors: Quarterly.				

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Comment [34]: This does not capture to two cases. Long counts of samples and batches on automated changers

Bob Shannon 5/24/2016 11:10 AM
Comment [35]: Don't see backgrounds appropriate to method

Bob Shannon 5/24/2016 11:14 AM
Comment [36]: This section is not about background checks. While I agree with this in principle –I do not see this addressed in the standard. I thought it was there but don't see it. If I am overlooking it, move this to the approriate section

Bob Shannon 5/24/2016 11:15 AM
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Bob Shannon 5/24/2016 11:15 AM
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Bob Shannon 5/24/2016 11:05 AM
Comment [37]: Wrong reference. The language is also confusing and the fact that we are proposing three different options does nto come accross. The third option is missing.
Suggest sticking a little closer to words in the standard.

Bob Shannon 5/23/2016 12:06 PM
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Audit ID: _____ **Laboratory:** _____ **Assessor:** _____ **Date:** _____

		- Liquid scintillation detectors. • 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				
37	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)?				
38	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?				
Item No.	**Line of Inquiry**		**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
Technical Requirements (continued)						
39	V1M6, 1.7.1.6 a) – d)	Does the laboratory have a written procedure for performing short-term background checks that includes the following? - Establishes control or tolerance charts and acceptance criteria to monitor for significant changes; - Corrective actions and/or qualification of reported results when short-term background counts exceed established limits; - Short-term unquenched background counts performed each day of use for liquid scintillation detectors. - Frequency and length of checks, with possible following exceptions: ○ An uninterrupted count of an individual Test Source may be longer than the required interval between background counts if successful short-term backgrounds are performed prior to and after counting the Test Source. ○ An uninterrupted count of a group of Test Sources may also be longer than the required interval between background counts to allow for completion of the batch (Preparation or				*[Here we felt that the detail was helpful]*

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

		RMB) if the period between checks does not exceed seven (7) calendar days and successful checks are performed prior to and at the end of the measurement period.				
40	V1M6, 1.7.1.7	Does the laboratory have written procedures for corrective actions when radiation detectors have been contaminated, as determined by the subtraction background measurements, short-term background checks, or method blanks?				
41	V1M6, 1.7.2.1 a)	Does the laboratory follow a documented QC program that monitors and assesses the performance of the laboratory's analytical systems? Does the laboratory, at a minimum, incorporate the QA program imposed by regulation, method(s) and this Standard? Does the laboratory follow the imposed regulations when the regulations are more stringent than this Standard? (see Module 2, Section 5.9.3.c). If it is not apparent which requirement is more stringent, does the laboratory follow the requirements of the regulation or the mandated method? 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?				
Item No.	**Line of Inquiry**		**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
Quality Control for Radiochemistry – General Requirements						
42	V1M6 1.7.2.1 b)	Does the laboratory process batch and sample-specific quality controls to provide empirical evidence that demonstrates that the analytical system is in control? Does the laboratory use the results for these controls to assess the data quality of sample results produced by the analytical system?				
43	V1M6 1.7.2.1 c)	Does the laboratory employ either a sample Preparation Batch or a RMB to determine the grouping of samples and assignment of batch QC?				
		Does the laboratory initiate a Preparation Batch for samples that involves				

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44	V1M6 1.7.2.1 c) i)	physical or chemical processing which affects the outcome of the test? Does the laboratory prepare the QC samples together with the associated preparation batch using the same process, personnel, and lot(s) of reagents?				
45	V1M6 1.7.2.1 c) 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).				
46	V1M6 1.7.2.1 c) 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?				
Item No.		**Line of Inquiry**	**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
Quality Control for Radiochemistry – General Requirements						
47	V1M6 1.7.2.1 c) 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)				
48	V1M6 1.7.2.1 d)	Does the laboratory's QC program document the frequency required for quality controls?				
49	V1M6 1.7.2.1 e)	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				

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		reporting of results? *Note:* 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.				
50	V1M6 1.7.2.1 f)	Does the laboratory not use systematically or preferentially specific detectors, equipment or glassware for the analysis of QC samples? *Note:* 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.				
51	V1M6 1.7.2.1 g)	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?				
Item No.	**Line of Inquiry**		**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
Quality Control – General Requirements (continued)						
52	V1M6 1.7.2.1 h)	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?				
53	V1M6 1.7.2.1 i)	Does the laboratory track and trend the results of batch QC samples using statistical or tolerance control charts?				
54	V1M6 1.7.2.1 j)	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				

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		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?				
Item No.	**Line of Inquiry**		**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
		Quality Control – Negative Control				
55	V1M6 1.7.2.2 a)	Does the laboratory employ a minimum of one Method Blank (MB) per Preparation Batch or Radiation Measurement Batch?				
56	V1M6 1.7.2.2 b)	Are MBs prepared using a quality system matrix that is sufficiently analyte-free (to the extent possible), and using an aliquot of the matrix similar to that of routine samples? If sample aliquot sizes vary, do method blank acceptance criteria compensate for those differences?				
Item No.	**Line of Inquiry**		**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
		Quality Control – Negative Control (continued)				
57	V1M6 1.7.2.2 c)	Does the laboratory have procedures in place to determine if MB results are significantly different than zero or impacts sample analytical results (e.g., MB > sample-specific MDA)?				
58	V1M6 1.7.2.2 d)	Is corrective action taken when a method blank (MB) result is significantly different than zero and associated sample results are < 5 * MB?				
59	V1M6 1.7.2.2 e)	Are method blank results monitored for long term trends, absolute bias, possible contamination or interferences that may affect sample results?				
60	V1M6 1.7.2.2 f)	Batch-specific method blank (MB) results are not subtracted from sample results? Note: Average historical activity of MBs may be subtracted when systematic bias has been demonstrated.				

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Item No.	Line of Isample nquiry		Status			Observations/Comments
			Y	N	n/a	
		Quality Control – Positive Control				
61	V1M6 1.7.2.3 a)	Does the laboratory employ a minimum of one Laboratory Control Sample (LCS) per Preparation Batch or Radiation Measurement Batch (RMB)? Note: For RMBs, a calibration verification standard may be used in place of an LCS.				
62	V1M6 1.7.2.3 b)	Are LCSs prepared using a quality system matrix that is sufficiently analyte-free (to the extent possible), and using an aliquot of the matrix similar to that of routine samples? If sample aliquot sizes vary, do method blank acceptance criteria compensate for those differences?				
63	V1M6 1.7.2.3 d)	Are LCSs spiked at a level such that the uncertainty of the LCS result is < 1/3 * acceptance criteria?				
Item No.	**Line of Inquiry**		**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
		Quality Control – Positive Control (continued)				
64	V1M6 1.7.2.3 e)	Do the standards used to prepare LCSs conform to the requirements for reference standard provided in Section 1.7.2.6 c?				
65	V1M6 1.7.2.3 e) i-iii	Do LCSs include all of the radionuclide(s) being determined with the following allowed exceptions: - Gross alpha radionuclide(s) used to calibrate the detector - Alpha spectrometry radionuclide(s) with similar chemical characteristics - Gamma-ray spectrometric radionuclides with similar gamma energies or radionuclides representing at least the low and high ends of the energy range used for analysis.				
66	V1M6 1.7.2.3 f)	Are LCSs in each batch evaluated using a statistical technique that allows comparison to the lab's established acceptance criteria?				

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67	V1M6 1.7.2.3 g)	Where more than one analyte is spiked in the LCS, is each analyte evaluated against acceptance criteria?				
Item No.	**Line of Inquiry**		**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
Quality Control – Sample Specific QC Measures						
68	1.7.2.4	Does the laboratory document procedures for determining the effect of sample matrix on analytical results? Does the documented procedures relate to the analyses of specific QC samples? Are the QC samples designed as data quality indicators for a specific sample using the designated method? Examples of sample-specific QC include: Matrix Spike (MS); Matrix Spike Duplicate (MSD), Matrix Duplicate (MD), Tracers, and Carriers. Does the laboratory have procedures for, - tracking, - managing, - handling sample-specific QC criteria, - spiking radionuclides at appropriate activities, - calculating recoveries, - determining variability (e.g., relative percent difference and/or z-score), - evaluating results and - reporting results based on the performance of the QC samples?				Assessor(s) to review SOPs, QA Manual and real data of samples prior to answering the questions. Also, the analysts will be interviewed as necessary. ***[For group discussion. Do we want to include guidance to assessors as to where to look for evidence of compliance?]***
Item No.	**Line of Inquiry**		**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
Quality Control – Sample Specific QC Measures (continued)						
69	1.7.2.4 a) i)	Is the MS recovery an indication of matrix effects on the accuracy of sample results by using the selected method? Are the MS results reported to data users (customers) so that the customers evaluate the impact on their batch(s) samples? Note: MSs are not typically employed (or required) for non-destructive methods (e.g., gamma spectrometry or direct counting of samples for alpha or beta radioactivity), or for methods that employ a chemical yield tracer or carrier for each sample.				Review QC data for one or more sample batch(s) at random. Review one or more test report(s) at random ***[For group discussion. Do we want this level of specificity in guidance to assessors?]***

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

70	1.7.2.4a)ii)	Is the frequency for MS analysis specified by the method, or a regulation? Or, is it determined as part of the contract review process?				Interview the analyst, review documentation.
71	1.7.2.4a)iii)	Are the radionuclides to be spiked for MS specified in the mandated method, or a regulation? or Are they determined as part of the contract review process? At minimum, are they consistent with those specified for the LCS in Sections 1.7.2.3.e and 1.7.2.3.f of this Standard? (Module 6)				Review QC data of one or more sample batch(s) at random *[For group discussion. Guidance to assessors too specific?]*
72	1.7.2.4a)iv)	Is the aliquot used for MS similar to that of routine samples analyzed in the Preparation Batch? If the sample size in the Preparation Batch varies (e.g., due to restriction on the activity or mass residue that may be processed), does the laboratory apply appropriate corrections to compensate for differing aliquots when applying the acceptance criteria for MS?				Review one or more sample batch(s) at random
73	1.7.2.4a)v)	Is the lack of sufficient volume to perform an MS noted in the laboratory report when appropriate?				Review one or more sample batch(s) at random
74	1.7.2.4a)vi)	Is the activity of the MS analyte(s) greater than five (5) times the MDA?				Review one or more sample batch(s) at random
Item No.		**Line of Inquiry**	**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
Quality Control – Sample Specific QC Measures (continued)						
75	1.7.2.4a)vii)	Are the acceptance criteria for MS recoveries as established or specified in the method, regulation or contract? Where there are no mandatory acceptance criteria established in the method, regulation or contract, does the laboratory develop acceptance criteria based on industry practices and guidelines, or consistent with the guidelines of MARLAP[3] or other consensus standards? Are the criteria documented or referenced in the laboratory's quality manual?				Review SOPs and QA Manual
76	1.7.2.4a)viii	Is the standard used to prepare the MS meet the requirements for reference standard provided in Section 1.7.2.6.c., when possible? Is the final prepared MS acceptable even though not traceable to a				Review SOPs and QA Manual

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

		national standards organization?				
77	1.7.2.4a)ix)	Is the MS prepared by adding a known activity of target analyte prior to performing any processes that affect the analyte of interest? (e.g., chemical digestion, dissolution, ashing, separation, etc.).				Review SOP, Interview the analyst.
78	1.7.2.4b)i)	A duplicate is defined as a second aliquot of the same sample taken through the entire analytical procedure. The results of this analysis provide indications of the measurement precision of the analyte for the specific sample using the selected method.. Duplicate analyses provide a measure of precision only when the target analyte is present in the sample selected for duplication in the batch.				
79	1.7.2.4b)ii)	Is the acceptance criteria for duplicates as established or specified by the method, regulation or contract? Where there are no mandatory acceptance criteria established in the method, regulation or contract, does the laboratory develop the acceptance criteria based on industry practices and guidelines, such as - control charting developed by the laboratory, or - consistent with the guidelines of MARLAP[3] or other consensus standards? Are the criteria documented or referenced in the laboratory's quality manual?				Review SOPs and QA Manual
Item No.		**Line of Inquiry**	**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
Quality Control – Sample Specific QC Measures (continued)						
80	1.7.2.4b)iii)	At a minimum, does the laboratory analyze one MD per Preparation Batch or RMB (radiation measurement batch)? For RMBs, does the MD consist of a second measurement of the sample -on the same detector if only one detector is available, or -on a different detector if more than one detector available?				Review one or more sample batch(s) at random
		When samples have low-levels of activity (less than approximately three (3) times the MDA) does the laboratory, at its discretion, analyze MS/MSD				Review one or more sample batch(s) at random

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81	1.7.2.4b)iv)	to determine reproducibility within a Preparation Batch in place of a MD?.				
82	1.7.2.4b)v)	Based on specific project or program requirements or when there is insufficient sample available, does the laboratory choose to analyze a LCS in duplicate in place of a MD? The LCS and its duplicate will provide a measure of analytical precision, and not the information on matrix effects.				Review one or more sample batch(s) at random
83	1.7.2.4c)i)	For methods that employ a radioactive Tracer or a stable Carrier as a chemical yield monitor in the analysis, does the laboratory calculate and report the chemical yield for each sample? Is the chemical yield one of the quality control measures to be used to assess the associated sample result acceptance?				Review one or more sample batch(s) at random
84	1.7.2.4c)ii)	Does the selection of a Tracer or Carrier not significantly interfere with the analyte(s) of interest nor cause bias in its measurements? When such a Tracer or Carrier unavailable, is the interference or bias caused quantified and appropriate correction applied to the sample results? Does the laboratory have procedures to verify this requirement?				Review SOPs and interview the analyst.
Item No.		**Line of Inquiry**	**Status**			**Observations/Comments**
			Y	**N**	**n/a**	
Quality Control – Sample Specific QC Measures (continued)						
85	1.7.2.4c)iii)	Is the Tracer or Carrier used to monitor chemical yield added to the sample prior to performing any processes that affect the analyte of interest (e.g., chemical digestion, dissolution, ashing, separation, etc.) unless otherwise specified by the method?				Review SOPs and interview the analyst.
86	1.7.2.4c)iv)	Is the chemical yield assessed against acceptance criteria specified in the method, regulation, contract or laboratory SOP? Where there are no criteria, does the laboratory develop its criteria for data acceptance based on -guidelines established in the MARLAP[3] or -other criteria such control charting developed by the laboratory? Does the chemical yield assessment meet the required project or program MQOs (Section 1.3.1).				Review SOPs. Interview the analyst.

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

87	1.7.2.4c)v)	When the established chemical yield acceptance criteria are not met, does the laboratory follow the specified corrective action and contingencies? Is the occurrence of a failed chemical yield and the actions taken noted in the laboratory report?				Review SOPs and interview the analyst. Review one or more test reports at random.

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a)

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b)

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Page 3: [5] Comment [9] **Bob Shannon** **5/24/16 11:05 AM**

While these are needed to comply with this section, Is this an accurate reference for the question. There is no requirement as such in the preamble.

The only requirement I see is the flowdown of requirements from regulation, method, etc. which is addressed in the next question..

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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.[1]

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Page 6: [9] Comment [19] **Bob Shannon** **5/24/16 11:05 AM**

Suggest deleting leaving this text. Not a requirement

Page 6: [10] Comment [20] **Bob Shannon** **5/24/16 11:05 AM**

Problems with numbering. b) vs. i).

Also suggest keeping numbering in appropriate column?

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Where calibration standard characteristics do not exactly match sample characteristics,

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Where calibration standard characteristics do not exactly match sample characteristics,

Page 6: [14] Comment [21] **Bob Shannon** **5/24/16 11:05 AM**

As worded thsi soulds like a requirement to use modeling. Suggest this rewording.

Page 6: [15] Comment [22] **Bob Shannon** **5/24/16 11:05 AM**

Rephrasing changes meaning – stick to original language?

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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?

Does the laboratory document empirical or modeling techniques to

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Page 6: [22] Comment [24] **Bob Shannon** **5/24/16 11:05 AM**

Not sure I agree. These techniques, in many forms, have been around for a long time. ISOCS/LABSOC has made some of them more accessible to labs – but that it not new – nor do we want to focus this on proprietary software.

Before saying they will not accept, we should check with the Office of Water, perhaps, to see how they feel about this.

Page 6: [23] Comment [25] **Bob Shannon** **5/24/16 11:05 AM**

Suggest deleting this. Not sure it adds anything

Page 7: [24] Deleted **Bob Shannon** **5/23/16 11:18 AM**

Does the laboratory include the following essential elements for the initial instrument calibration? [2]

The

i)

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ii)

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iii)

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iv)

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v)

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vi)

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vii)

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The

viii)

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shall

ix)

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shall

x)

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The

xi)

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The

xii)

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Page 7: [33] Comment [29] **Bob Shannon** **5/24/16 11:05 AM**

Deviates from written text. Suggest sticking closer to original language

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second manufacturer or lot, if the lot from the manufacturer can be demonstrated as prepared independently from other lots

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Does the laboratory have a procedure stating the acceptance criteria, and were those criteria met?

Page 7: [39] Comment [30] **Bob Shannon** **5/24/16 11:05 AM**

Suggest inserting sections:

a) Does the laboratory have a procedure stating the acceptance criteria, and were those criteria met?

and

c) Does the laboratory specify calibration verification acceptance criteria in their SOPs?

Does the laboratory shall perform corrective action iIf the criteria for the calibration verification are not met?,.

Page 7: [40] Comment [31] **Bob Shannon** **5/24/16 11:06 AM**

I think it s important to ask if the same check source used to establish control charts was used to conduct periodic performance checks?

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