

Radiochemistry Expert Committee (REC)
Meeting Summary

December 23, 2020

1. Roll Call and Minutes:

Terry Romanko, Chair, called the meeting to order at 1pm Eastern on December 23, 2020 by teleconference. Attendance is recorded in Attachment A – there were 8 members present. Associate members in attendance: Chrystal Sheaff, Mary Beth Gustafson, Bob Shannon, Carl Kircher and Keith McCroan (Guest).

Meeting minutes are distributed by email for comment/revision for a week and then posted on the TNI website.

2. Proposed Changes to the Standard Summary

The Committee started with Line 22 that still needs to be closed out. See Attachment D for updated Summary of Changes Table.

Line 22

Bob put proposed language together for the Committee to consider:

- c) The QC program shall establish and maintain provisions for radionuclide standards.*
 - i. Radionuclide standards shall be fit for purpose; they shall be of appropriate chemical and physical form and stability, and be traceable to an NMI, with levels of uncertainty, purity that exceed those required to meet measurement quality objectives.*
 - ii. Reference standards used for instrument calibration shall be obtained from a national metrology institute (NMI), e.g. NIST in the USA or NPL in Great Britain, or from suppliers of NMI reference standards. Alternatively, reference standards may be obtained from reference material providers that conform to ANSI N42.22⁷ or other standards or programs that require intercomparison with an NMI similar to that specified in ANSI N42.22.*
 - iii. Reference materials used for quality control purposes may be obtained from providers described in 1.7.2.6 c) i. above or from providers that are accredited to ISO Guides 17034:2016⁶ or 17043:2010⁵.*
 - iv. Reference standards shall be accompanied with a certificate of calibration that meets the requirements of either ISO Guide 31:2000, or ANSI N42.22⁷, Section 8, Certificates, and shall include at least the following information: manufacturer, radionuclides calibrated, identification number, calibration method, activities or emission rates with associated uncertainties and the confidence limits, standard*

quantity, activity reference time (date or time as appropriate to the half-life of the radionuclide), physical and/or chemical description of the source, and radionuclide impurities.^[1]_{SEP}

⁵ *ISO Guide 17043:2010, Conformity assessment - General requirements for proficiency testing; International Organization for Standardization and International Electrotechnical Commission. Available from: <http://www.iso.org/>.*

⁶ *ISO Guide 17034:2016, General requirements for the competence of reference material producers; International Organization for Standardization and International Electrotechnical Commission. Available from: <http://www.iso.org/>.*

⁷ *ANSI N42.22-1995, American National Standard - Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control, Institute of Electrical and Electronics Engineers, 1995 (2005). Available at: <http://ieeexplore.ieee.org/>.*

Terry asked for feedback from the ABs on the call and there was general agreement with the recommended change. There was one concern that sometimes it is hard to get second source standards. NIST traceable is OK.

Bob just wanted to be sure all footnotes and references are current. Terry commented that this is being addressed.

Line 24:

Sherry did take a look at Module 2. She found it was similar for DOCs and it is similar to the other Modules. Terry recommended leaving the Module 6 language as is since it doesn't duplicate Module 2.

Line 25:

Terry met with QS and they aren't interested in adding anything to Module 2. Should leave what is there now. Discusses second source.

Line 27:

Terry reviewed the review of the footnote and references that he emailed the Committee with the Agenda. He thought the recommendations looked good and there was agreement to make the changes to the Standard. Thank-you Crystal and Candy

Section 1.7.2.4

Keith had one more concern. See section b) iii). He believes it was not the intent that you can take a second aliquot. Terry suggested a clarification is needed. This will be looked at in February.

3. Committee Membership

The Associate members were asked to step off the call so membership could be discussed.

Ron will rotate off the Committee after serving 2 terms. Terry thanked him for all his efforts.

One committee member has not been attending meetings, so Terry will work on having him removed as a voting member of the Committee. The person is welcome to continue as an associate member.

There are 3 members that are finishing their first term that have confirmed they would like to serve a second term: Brian Miller, Velinda Hebert and Terry Romanko.

A motion was made by Robert to approve Mary Beth Gustafson as a new voting member on the Committee . The motion was seconded by Greg and unanimously approved.

A motion was made by Stan to approve Chrystal Sheaff as a new voting member on the Committee. The motion was seconded by Velinda and unanimously approved.

4. New Business

Terry asked about an overview of the next steps in updating the Standard. Ilona reviewed the process in SOP 2-100: Procedures Governing Standards Development.

5. Action Items

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

6. Next Meeting and Close

There will be no meeting in January. The next meeting will be February 24, 2021 at 1pm Eastern.

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

The meeting was adjourned at 2:07 pm Eastern. (Motion: Greg Second: Amanda. Unanimously approved.)

Attachment A
Participants
Radiochemistry Expert Committee

Members	Affiliation		Contact Information
Terry Romanko Chair (2021*) Present	TestAmerica Laboratories, Inc.	Lab	Terry.romanko@testamericainc.com
Sherry Faye (2022*) Present	Wadsworth Center, NY State DOH Albany, NY	AB	sherry.faye@health.ny.gov
Velinda Herbert (2021*) Present	National Analytical Environmental Laboratory	Lab	Herbert.velinda@epa.gov
Brian Miller (2021*) Present	ERA	Other	bmiller@eraqc.com
Ron Houck (2021) Absent	PA DEP/Bureau of Laboratories	AB	rhouck@pa.gov
Mark Johnson (2023*) Absent	Louisiana	AB	mark.johnson@la.gov
Stan Stevens (2023*) Present	Perma-Fix Environmental Services	Lab	stanws@aol.com
Amanda Fehr (2023*) Present	GEL	Lab	amanda.fehr@gel.com
Jim Chambers (2023*) Absent	Fluor-BWXT Portsmouth LLC	Other	jim.chambers@ports.pppo.gov
Greg Raspanti (2022*) Present	New Jersey Department of Environmental Protection	AB	Greg.Raspanti@dep.nj.gov
Robert Aullman (2022*) Present	Utah Department of Health	AB	aullman77@gmail.com
Ilona Taunton (Program Administrator) Present	The NELAC Institute	n/a	Ilona.taunton@nelac-institute.org

Attachment B**Action Items – REC**

	Action Item	Who	Target Completion	Completed
90	Send note about method codes and concerns to the PT Expert Committee. Is there a way to limit the codes a lab can use to report PT data?	Bob	TBD	
101	Check with Bob on Line 22 item.	Terry Bob	10/27/20	Complete
103	Review references in 2016 Standard that need to be updated.	Chrystal/ Candy	10/27/20	Complete
104	Compare Module 2 and 6 for Line 24.	Sherry	10/27/20	Complete
105	Review Charter	All	TBD (Feb or Mar)	
106	Prepare 2021 goals.	All	TBD (by mid January)	
107	Send new membership to Chair of CSDP EC for approval.	Terry Ilona	2/24/21	

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	From Action Item # 75: Prepare copy of Standard annotated with summary document language.		This is a project Carolyn was working on, but the committee decided it may duplicate the Small Lab Handbook. This project has been put on Hold.

Attachment D – Suggested Changes Summary Table – Volume 6 – v4

	Original Text	Suggested Change	Justification	Comments
	<i>Include reference and language.</i>	<i>Don't need to work on specific language - just summarize change needed.</i>	<i>Why does this need to be changed/updated?</i>	
3	1.7.1.5.c.ii.e - The subtraction background measurement shall be accomplished in one of the following ways: e. Solid-state scintillation detectors (e.g., zinc sulfide) used for non-spectrometric measurements: Day of use.	Possibly change "Day of use." to "Before each use"	This coul result in long counts (e.g. 24 hours) for which a background could not be counted the same day as the sample and therefore might not technically meet the requirement.	"Prior to use" may be most appropriate.

	Original Text	Suggested Change	Justification	Comments
4	<p>1.6.2.2.b - Where gamma-ray spectrometry is used to identify and quantify more than one analyte, <u>the Test Sample shall contain gamma-emitting radionuclides that represent the low (e.g., 241Am), medium (e.g., 137Cs), and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra.</u> As indicated by these examples, the nuclides need not exactly bracket the calibrated energy range or the range over which nuclides are identified and quantified.</p>	<p>"the Test Sample shall contain gamma-emitting radionuclides that, at a minimum, represent the low (e.g., 241Am) and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra. Commonly a medium energy radionuclide is also included in the LCS (e.g., 137Cs)."</p>	<p>To be consistent with 1.7.2.3.e.iii - the LCS shall contain gamma-emitting radionuclides that, at a minimum, represent the low (e.g., 241Am) and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra. Commonly a medium energy radionuclide is also included in the LCS (e.g., 137Cs). As indicated by these examples, the nuclides need not exactly bracket the calibration energy range or the range over which radionuclides are identified and quantified.</p> <p>This would also be consistent with ANSI N42-14 (above the knee and below the knee).</p>	<p>Not necessary to state what is not required.</p>

	Original Text	Suggested Change	Justification	Comments
5	Section 1.7.1.4.a.iii - The laboratory shall prepare, handle, seal and/or encapsulate check sources to prevent damage, loss of activity and contamination.	The Committee should evaluate the concern, and if determined to be needed develop a requirement in regard to a compromised check source.	No guidance is provided as to what to do if the instrument performance check source is compromised. ANSI N42.23 seems to state that if the instrument performance check is compromised, the detector "shall" be recalibrated.	Concept of verifying the current calibration with a LCS or other independent standard. Verify that the check source was actually compromised and document the investigation showing this. Employ a new check source with newly generated limits.
6	Page 3 - definition - Uncertainty, Counting: The component of Measurement Uncertainty attributable to the random nature of radioactive decay and radiation counting (<u>often estimated as the square root of observed counts</u>) (MARLAP3). Older references sometimes refer to this parameter as Error, Counting Error or Count Error (c.f., Total Uncertainty).	"(often estimated as Standard Uncertainty by means of the square root)"	Clarification, and to refer to other defined term (Standard Uncertainty).	No additional comments
7	1.5.2.1 - Minimal Detectable Activity (MDA)	"Minimum Detectable Activity (MDA)"	"Minimal" to "Minimum" as correction and for consistency	No additional comments
8	1.5.4.c - section is out of alignment	Fix formatting	Consistency and readability	No additional comments

	Original Text	Suggested Change	Justification	Comments
9	1.5.4.c.ii - A comparison of the experimentally-observed precision evaluation need not be performed for measurements that are required to be reported only with Counting Uncertainty per Section 1.5.4 a) ii).	Add something like "except as required by program/project specific requirements or regulations". Use language similar as in other places this type of language is used.	New EPA procedure in EPA 815-B-17-003 requires a chi-square test at DL, which is a kind of precision evaluation.	No additional comments
10	1.5.5.b	Fix Formatting	Font is too larger - consistency	No additional comments

	Original Text	Suggested Change	Justification	Comments
11	<p>1.6.3.2.c - At least four (4) consecutive spiked samples (e.g., batch laboratory control samples) each with levels of precision and accuracy consistent with those specified in the method scope; and four (4) consecutive blank samples, each with activity consistent method performance specified in the method scope (e.g., generally activity less than Critical Value). The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing Laboratory Control Samples (LCS) and four (4) consecutive blank samples for each method for each analyst each year. The laboratory shall specify acceptable limits for precision and accuracy prior to analysis.</p>	<p>"...each containing activity consistent with method..."</p>	<p>clarification/wording</p>	<p>No additional comments</p>

	Original Text	Suggested Change	Justification	Comments
12	<p>1.7.1.7 - The laboratory shall have written procedures that address cases where radiation detectors have been contaminated, as determined by the subtraction background measurements, short-term background checks, or method blanks (Section 1.7.2.3). Detectors may not be brought back into service until corrective actions are completed.</p>	"Section 1.7.2.2"	Typo/mis-reference	No additional comments

	Original Text	Suggested Change	Justification	Comments
13	<p>1.7.2.3.d - The laboratory shall spike the LCS at a level such that the uncertainty of the analytical result is less than one-third (1/3) of the acceptance criteria. For example, if it is required that the LCS result be within +/- 30% of the known value, the laboratory shall spike the LCS at a level such that the uncertainty of the analytical result is less than or equal to 10%. <u>When practical, the LCS should be spiked at a level comparable to the action level if known; or that of routine samples if the activities are expected to exceed ten (10) times the Decision Level (Critical Value).</u></p>	<p>"When practical, the LCS should be spiked at a level comparable to the action level if known; or at approximately ten (10) times the MDA; or that of routine samples if the activities are expected to exceed ten (10) times the MDA."</p>	<p>Concern is that this may not give enough direction at what level to spike when activity is below 10x the Decision Level and that the decision level (critical value) isn't really a well-defined measurable quantity. As we ordinarily define and use it, it's just a statistic that can vary with each measurement. The MDC is the a priori concept, whose value we can estimate. Also, TNI 2009 uses a value of "at least 10 times the MDA". Other guidance (e.g. QSM) uses 5-20x the MDA.</p>	<p>Is there a need for a laboratory to measure accuracy at a low level on a defined frequency? Or, should we leave this as a project-specific need (in SOW)?</p> <p>10/28: Leave language as proposed.</p>

	Original Text	Suggested Change	Justification	Comments
14	<p>1.7.2.3.e - When available, the standard used to prepare the LCS shall meet the requirements for reference standards provided in Section 1.7.2.6.c. The final prepared LCS need not be traceable to a national standard organization. The LCS shall include all of the radionuclide(s) being determined with the following exceptions:</p>	<p>"The final prepared LCS needs to have the activity and its uncertainty known; however, it need not be strictly traceable to a national standard organization."</p>	<p>While requirements for standards/documentation are outlined elsewhere, this may provide clarity and avoid confusion.</p>	<p>Go with this language.</p>
15	<p>1.7.2.4.a.iii - The radionuclides spiked shall be as specified by the mandated method, regulation or as determined as part of the contract review process. At minimum, they will be consistent with those specified for the LCS in Sections <u>1.7.2.3.e</u> and <u>1.7.2.3.f.</u></p>	<p>"1.7.2.3.d and 1.7.2.3.e"</p>	<p>Correction necessary - reference to incorrect section(s).</p>	<p>reference correct section(s)</p>

	Original Text	Suggested Change	Justification	Comments
16	1.7.2.4.a.viii - When available, the standard used to prepare the MS shall meet the requirements for reference standard provided in Section 1.7.2.6.c. The final prepared MS need not be traceable to a national standards organization.	"The final prepared MS needs to have the activity and its uncertainty known; however, it need not be strictly traceable to a national standard organization."	While requirements for standards/documentation are outlined elsewhere, this may provide clarity and avoid confusion.	Go with this language.
17	1.5.1.c - The laboratory shall perform validation for each method for which documented data are not available to demonstrate that the above requirements are met. For reference methods, published data, if available, may be used to satisfy these requirements.	To the end, add the sentence: "For existing methods, QC data produced at the laboratory may be used to comply with validation requirements."	Allows the laboratory to apply ongoing QC results to methods that have previously existed at the laboratory and may not have had a specific validation performed.	Go with this language.

	Original Text	Suggested Change	Justification	Comments
18	<p>1.7.1.2.a.ii, iii, and iv -</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>"after a repair, modification of system parameters, or other event (possibly unknown) when subsequent performance checks exceed predetermined acceptance criteria (i.e., limit of a statistical or tolerance control chart or other QC parameters) indicating a change in performance since the initial calibration."</p>	<p>All state essentially the same thing - combine into a single point.</p>	<p>Combining is fine.</p>

	Original Text	Suggested Change	Justification	Comments
19	<p>1.7.2.2.b.i The laboratory shall prepare the MB using materials that are free of analytes of interest at levels that will interfere with the evaluation of the results. If an analyte-free matrix is not available, the laboratory shall use a surrogate matrix to simulate the quality system matrix.</p>	<p>Add sentence to end of this section something like: "For a RMB, the MB should be handled along with other samples during sample management (e.g. aliquotting, handling/transporting) when there is significant potential for contamination."</p>	<p>While 1.7.2.2 requires analysis of MB for a radiation measurement batch (RMB), it does not describe how this MB would be handled for the RMB.</p>	<p>Use proposed wording.</p>

	Original Text	Suggested Change	Justification	Comments
20	1.7.1.2.e - no text related to this (new inclusion)	<p>Insert as section 1.7.1.2.e.ii - "Except in technically justifiable instances (e.g. prepared standard is dropped, physically marred, inconsistent distribution on the planchet, etc), it is NOT acceptable to remove points from a calibration curve to meet established criteria. There must be some demonstratable reason to remove a point, and such removal must be approved by the a Supervisor or Technical Manager or designee and documented." In 1.7.1.2.e.11 - suggest to have approval be by Technical Manager or designee instead of 'or Supervisor' to cover all bases when supervisor not there</p>	<p>Section 1.7.1.2 does not address potential for deleting/not using individual points from calibration curves.</p>	<p>Use wording as modified.</p>

	Original Text	Suggested Change	Justification	Comments
21	1.7.3.4 - no text related to this (new inclusion)	Insert as section 1.7.3.4.d - "Sample-specific QC requirements (e.g. FWHM, centroid (energy), quench value or mass within calibration range, etc) shall be defined in the laboratory SOPs and/or client requirements and evaluated to ensure that samples meet method quality objectives (MQOs).	Section 1.7.3.4 does not address sample-specific QC requirements (e.g. FWHM, quench, mass within range, etc)	Use wording as is.

	Original Text	Suggested Change	Justification	Comments
22	Section 1.7.2.6.c - all	The Committee should evaluate the concern, and if determined to be needed provide updated language in relation to requirements for standards.	<p>Consider updating requirements for standards. ISO requirements for standards are vague and make no distinction in requirements for reference materials used for calibration and QC/PT standards. One might consider uncertainty as a criterion although how does one evaluate the uncertainty of the material.</p> <p>Right now, ISO providers are not required to intercompare . One might say that study performance will show problems (i.e., compare grand mean to true values) but that is putting the cart is before the horse. Round robin/consensus studies with labs of untested capability provide little in the way of confidence. Many people feel that the approach in ANSI N42.22, which requires providers to participate in a Measurements Assurance Program (MAP) where the RM provider intercompares with an NMI, is the minimum that should be requires for calibration. Is this possibly a Module 2 issue?</p>	<p>Bob to look at</p> <p>Committee agrees that Bob's language is fine. 12/23/2020. See 12/23/20 minutes for Bob's suggested language.</p>

	Original Text	Suggested Change	Justification	Comments
23	Whole document	The Committee should evaluate the concern, and if determined to be needed provide updated language in the introduction section and move any requirements into numbered sections.	The original intent to the introductory language in each section was to frame the requirements that follow - not to establish requirements. The original intent was to number all requirements to facilitate writing findings. Review all sections. Add any clarifying language needed to intro and move requirements to numbered sections.	8/26 Greg and Carl volunteered to take a look at it. 9/23 Greg had some suggestions, gone over and in Standard document.
24	Section 1.6	The Committee should evaluate section 1.6 in relation to Module 2 and consider removing items already contained in Module 2. While not critical, a conflict between Module 2 and Module 6 might be avoided if one or the other were to change.	Consider removing DOC requirements that are already addressed in Module 2. Include only the differences specific to radchem.	9/23 Sherry to take a look at - need to provide her with Module 2. Leave everything is as-is, not much in module 2. 12/23/20

	Original Text	Suggested Change	Justification	Comments
25	Section 1.7.1.3	<p>The Committee should evaluate the definition of "independent source" in Section 1.7.1.3 and consider if this is more appropriate for Module 2 (e.g. V1M2 1.7.1.1.n.) Something to the effect of the following might be used: "All initial calibrations are verified with a standard obtained from a second source and traceable to a national standard, when available (or vendor certified different lot if a second source is not available). For unique situations where no other source or lot is available, a standard made by a different analyst at a different time or a different preparation would be considered a second source. This verification occurs immediately after the calibration curve has been analyzed, and before the analysis of any samples."</p>	<p>Define independent source – what if there is only one source - can procure two sources and handle differently?</p>	<p>9/23 Go with this language. Terry will check with QC group regarding inclusion in Module 2. 10/28: QC group passed on this – we will include it in Module 6.</p>

	Original Text	Suggested Change	Justification	Comments
26	Another suggestion on same section 1.7.1.3 is to add that labs have supporting records to demonstrate good faith effort to find second source and still did not find one			9/23 ABs will typically go on their own to see if they can locate. So, this requirement is not necessary to include.
27	Need to go through document references and ensure they point to current revisions and/or reference numbers/titles.			9/23 Need to get a volunteer. Terry to put out specific email with request. Update: Sherry volunteered to do this. 12/23 Use updates provided by Chrystal and Candy. Combine.