## Radiochemistry Expert Committee (REC) Meeting Summary August 7 and 8, 2014

#### 1. Roll Call and Minutes:

Bob Shannon, Chair, called the meeting to order at 9am ET on August 7, 2014 and at 8am on August 8, 2014 in Washington, DC. Attendance is recorded in Attachment A – there were 9 members present on Thursday the 7<sup>th</sup> and 7 members present on Friday the 8<sup>th</sup>. The meeting on Thursday was all day and the meeting on Friday concluded at 3pm EST. Associate members: Thursday - Joe Pardue, Brian Miller, Reed Jeffrey, Ariana Mankerian, Bill Ray, Yoon Cha. Friday – Ariana Mankerian, Brian Miller.

Larry's email motion on May 30 to approve the May 28, 2014 minutes was seconded by Vas and approved unanimously.

Associate members need to let Bob and Ilona know they own a copy of ISO 17025 so they can be included in distributions of the draft working standard updates.

2. Review of Comments

Bob and Ilona received the comments sent after the Webinar late June. Ilona pasted them into a spreadsheet for the committee to use to document their review, comments and status.

Attachment D summarizes the results of the discussion held in reviewing the comments. Bob asked for confirmation on each decision as to whether these initial comments on the standard were Persuasive or Non-Persuasive. A simple tally was taken on who agreed, disagreed or preferred to abstain.

Bob thanked everyone for their participation and hard work. The committee was able to address the majority of the comments. There are still several issues that will require further discussion before the WDS can be modified. The goal will be complete the update by mid-September.

## 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 August 27, 2014 at 1 pm by teleconference.

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

The meeting was adjourned 4:58 pm ET on August 7, 2014 (Motion: Marty Second: Larry. Unanimously approved) and reconvened on August 8, 2014 at 8am EST.

A quorum was held on August 8, 2014 until 12:04 pm on August 8, 2014. A motion was made by Larry to adjourn the formal meeting and seconded by Nile. The motion was unanimously approved. The meeting continued informally after lunch until 3pm EST with Bob, Tom, Carolyn, Marty and interested attendees.

#### 7. Informal Discussion (No Quorum) on Batches - 1 pm ET

It was determined that a "QC Batch" concept may not provide as much advantage as Bob had originally hoped.

The committee should state more clearly that preparation batches must be prepared together, at the same time, using the same processes and people, but that once preparation is complete, they need not be analyzed together and can be counted on one or more properly calibrated instruments.

On redefining the preparation batch to address the 24-hour window. It is important to recognize that TNI/NELAC has been through extensive controversy on this issue since it applies equally to certain stable chemical tests. Ilona underscored that NELAC has clearly stated that small laboratories are not entitled to relaxed QC requirements. In other words, if there are labs (large or small) who can meet a requirement, we will not likely be able to argue that it is not possible for a laboratory to meet QC requirements. This applies most directly to trying to expand the 24 hour window on starting preparation batches. There are indeed numerous labs who successfully run larger batches of Sr-89/90, for example, thus making the argument that this is not feasible could result in the committee losing credibility in TNI and with the ABs.

There is more hope for making changes for analytical batches since there is no 24 hour requirement there, and we can very clearly argue that the instrument is under control (by virtue of instrument checks, and as evidenced by batch QC samples). For analytical batches, we discussed clarifying that like analytical parameters, as opposed to the nominal quality systems matrix, should be used to group samples. We discussed emphasizing that positive controls can be higher activity and analyzed with a short count (e.g., 5 minutes) which will significantly minimize the effort required to perform analytical batch QC.

We did not, however, come to any final conclusions, rather, lacking a quorum, we reserved this for the next meeting.

Tom noted the following additional comments in an email to Bob on 8/18.

As far as the batch is concerned, I concluded from the discussion at the end of Washington meeting that to address several comments on the batch:

1. Preparation batch will be left unchanged in this version.

2. Analytical batch should be renamed to something like "radiation measurements batch (RMB) for non-destructive analysis" not to confuse it with the NELAC's analytical batch concept.

3. It needs to be discussed how different geometries and matrices could be combined into an RMB, based on a discussion of what could go wrong with the RMB. Possible errors are from switching of the samples while filling of the containers, errors in container positioning on the detector, as well as errors from data analysis such as incorrect efficiency file selection, incorrect density correction file selection, or incorrect analysis sequence selection. The scope, availability, and perishability of LCS and MB, as well as their natural radioactivity content, should be considered in their selection.

Attachment A
Participants
Radiochemistry Expert Committee

Members			Con	tact Information
P – Present	Affiliation		Phone	Empil
A - Absent			FIIONE	
Bob Shannon	QRS, LLC			
(Chair)	Grand Maraia MNI	Other	218-387-1100	BobShannon@boreal.org
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I om Semkow		۸D	E10 171 CO71	tmc1E@boolth.ctato.pv.uc
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Sroonivas (Vas)	State of NI Department of			
Komanduri	Environmental Protection			Sreenivas Komanduri@dep
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Marty Connoon	Command Nuclear Counting	Lab	865-712-0275	Mjohnson@tSC-tn.com
Th – P Fri - P	Redstone Arsonal Al			
Dava Fauth	Consultant			
Dave Faulti	consultant	Other	803-649-5268	di1fauth@hellsouth.net
Th – P Fri - A	Aiken, SC	Other	000 040 0200	<u>ajiladin@belisodin.net</u>
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Keith McCroan	US EPA ORIA NAREL,	Lah	224 270 2440	mannan kaith Gana any
Th _ A Fri - A	Montgomery Al	Lab	334-270-3418	mccroan.keitn@epa.gov
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Richard Sheibley		Other		
	Sheibley Consulting, LLC	(Former AB)	651-485-1875	RHSHEIB111@yahoo.com
Th-P Fri-A		(1 0		
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Administrator)	The NELAC Institute	n/a	828-712-9242	institute.org
Present				

## Attachment B

## Action Items – REC

	Action Item	Who	Target Completion	Actual Completion
48	Send updated copy of WDS for Ilona to review and format for WDS vote next week.	Bob Ilona	5/27/14	Complete
49	Review and update comment response form and send to Ilona for inclusion in minutes.	Bob	8-15-14	8-17-14
50	Address open comment on 1.7.2.1k), 1.7.3, 1.7.3.1, and 1.7.3.2	Richard	8/26	
51	Address open comments on 1.7.3.4, and 1.7.3.5	Tom	8/26	8/18
52	Brian Miller follow up on ISO Guide 34 question	Bob	8/27	8/11
53	Provide new suggestions on batching	Larry, Tom, Vas	9/15	

	Item	Meeting	Comments
		Reference	
1	Update charter in October 2014	n/a	
2	Issue of noting modifications to methods.	1/16/13	
3	Look at batching when QC is looked at.	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	

### Attachment C – Back Burner / Reminders

	Radiochemistry Expert Committee				
Document No./Title: STD	-2-ELV1M6-RadC-WDS-5-30-14				
Commenter (Who): 1 – Carl C. Kircher 2 – Lynn Bradley 3 – Bob Shannon 4 – Dale Piechocki 5 – Abdul Bari	6 – Richard Sheibley 7 – George Miller 8 – Ron Houck 9 – Thomas L. Rucker 10 – Tom Semkow	Contact: <u>Carl.Kircher@flhealth.</u> <u>lynn.bradley@nelac-ir</u> <u>Rhsheib111@yahoo.c</u> <u>rhouck@pa.gov</u>	<u>.gov</u> <u>istitute.org</u> :om		
Who Section/ Clause no.	Comments	Comment Resolution. Committee vote, P=persuasive, NP=Non	Persuasive		

# Comments from 8/7-8/8 with corrections from 8/27 conference call. – Note that corrections from Sheibley and from working group on batching are pending and will be addressed in future meeting minutes.

10.	Line 11	Remove "activities".	P – Passed 9-0-0	Y
7.	1.3.1	We suggest that: (DPM) be added after disintegrations per minute.	Editorial	Y
6.	1.3.1	Conflict in time frames between the definitions. Analytical batch is defined as samples analyzed together for a time period up to 14 days. Preparation batch includes "analyzed together" and limits the time frame to 24 hours. Change time frames for both definitions to twenty four (24) hours or change definition of preparation batch by eliminating "analyzed together".	While this language This definition may be confusing. Added clarifying language to 1.7.2.1 c) and a note after 1.7.2.1 f). Following discussion on 8/27 call, Marty moved to delete the new text in c) but to keep the note after f). Tom seconded. Motion passed 6-0-0.	Y
6.	1.3.2	Wording is confusing. This chapter does not address the requirements for ICP-MS or other traditional chemistry detection methods. It would be extremely impossible to determine conformance to V1M6 if a laboratory using ICP-MS chose to comply with this module instead of V1M4. Use current language. Procedures for determination of radioactive isotopes by mass spectrometry (e.g. ICP-MS or TIMS) or optical (e.g. KPA) techniques are outside the scope of this document.	It was moved that the comment is non-persuasive - passed 7-1-0. In order to minimize the risk of confusion, however, the 2nd sentence of proposed language was amended to "laboratory shall comply" "The laboratory shall comply with corresponding sections of Module 4 in cases where technique-specific QA/QC is not defined by Module 6 (e.g. Mass Spectrometry [ICP-MS, TIMS] or Kinetic Phosphorimetry), or by the respective reference method (e.g., calibrations, calibration verifications, determinations of detection statistics, or method-specific quality controls)." Longer term: the committee will work to include MS experts in the process. At the current time	Y

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Who	Section/ Clause no.	Comments	Comment Resolution. Committee vote, P=persuasive, NP=Non	Persuasive	
6.	1.5.1 b)	This is a list of items to be determined and precision and bias are separate entities. "by demonstrating the method's detection capability, precision, bias, measurement uncertainty, and selectivity	Editorial change: Add comma after precision. and delete "and" after precision.	Y	
10.	Line 140 [1.5.1 e)]	Replace "fit" with "suitable".	Editorial change: Make change as proposed	Y	
10.	Line 146 [1.5.1 f)]	Replace "produce" with "deliver".	Voted non-persuasive. Persons moving and seconding not recorded. The committee supported the motion 8-0-0. (Note that a vote would not formally be required for this)	n/a	
6.	1.5.1 f)	Use "i.e" which implies an all inclusive list. As written, this could exclude an ISO/IEC Guide 34 accredited reference material provider who does not meet any of the other criteria. Change i.e to e.g and add ISO/IEC Guide 34 accredited reference material provider	Nile moved to change to "(i.e., a national metrology institute, accredited TNI PT or ISO 17043 provider, or from an ANSI N42.22 or ISO/IEC Guide 34 compliant commercial vendor)." Larry seconded: Motion passed 8-0-0.	Y	
		Note that Vas joined the meeting			
4.	1.5.2	Under Validation of Methods- Indicates that either MDA or DL calculations are acceptable. Are both MDA or DL acceptable for SDWA compliance samples? If not make it clearer.	Tom moved to vote this comment non-persuasive since the text is accurate as written. Nile seconded: The motion passed 9-0-0.	n/a	
9.	1.5.3	There should be a tie to MQOs here.	Nile moved to vote this non-persuasive since, although we agree with stressing MQOs, the term is more restrictive than the intent and does not add value to the current language. Dave seconded. The motion passed 9-0-0. Note: Bob will review to make sure that similar language is	n/a	

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			consistent throughout the standard.			
4.	1.5.4 (a) (i) Section 1.5.4.a.i	Last sentence can be removed. All other radiochemical measurements shall be reported with an estimate of the total uncertainty. I think the paragraph could be written shorter and clearer. Reverse the logics by stating that "for all radiochemical measurements the reported uncertainty shall be total	Vas moved to change to: "All radiochemical measurement results shall be reported with an estimate of the total uncertainty of the measured result. For purposes of compliance with the Safe Drinking Water Act, or to comply with specific requirements established by method, regulation, or contract, or as established in the laboratory's quality management plan (if there are no established mandatory criteria), laboratories may report the counting uncertainty, in lieu of the total uncertainty. " Richard seconded. The motion passed 9-0-0 See resolution of previous comment (1.5.4.(a)i))	Y		
4.	1.5.4 (c)	uncertainty, except". Last sentence, remove the word "statistically".	Richard moved the comment to be non-persuasive. Without "statistically" the meaning of this requirement is unclear. This places the onus on the lab to demonstrate that their estimate of uncertainty is reasonable without tying their hands as to how. Marty seconded; The motion passed 8-0-1.	Y		
1.	1.5.5, 1.6.2, and 1.6.3	As worded in these Standards, my questions from a laboratory perspective is "What do I need to do to get certified for Iodine- 131, Technicium-99, and any other specific radioisotopes?" And from a laboratory assessor perspective, my questions are "How to I apply the Selectivity requirements and demonstration of capability requirements to assess the laboratory for Iodine-	Commenter was present at the meeting and withdrew the comment.	n/a		

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no.	5			
	131, Technicium-99, and any other radionuclides that the laboratory wants on its accreditation scope?" I have considerable angst over the possibility that a laboratory can be accredited for an analyte and never have the actual radionuclide analyte in its possession at the laboratory facility. If, as an Accreditation Body I ONLY offer accreditation for "Actinides" or "Gamma Emitters" as analyte classes (and do NOT offer accreditation for specific radionuclides in these methods), then I am A-Okay with all your radiochemistry Module 6 proposed standards as you have presented them. However, if the accreditation needs to be for specific analytes, then I insist that the laboratory have all accredited radioisotopes in its possession with whatever Certificates of Analysis are possible for these analytes. Each isotope would need to be present in order to verify absence of interferences or overlaps (selectivity) and evaluations of precision and bias (demonstrations of capability). For ongoing QC with day-to-day client samples in the later sections, I think I am okay with your recommendations to just evaluate low-, medium-, and high- energy analytes spanning the Gamma or Alpha spectrum, ONCE capability and selectivity are established on an initial or ongoing basis. If the argument is made that the laboratory should not get accredited for such radioisotopes in the first place since they will not be present in client samples for any long-enough-to-be- of-concern length of time.			

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10.	Line 278 [1.6.1 a)]	Replace "performs any activity" with "is".	Marty moved to change to "who performs any activity involved with preparation and/or analysis of"to "activity" to "who prepares and/or analyzes" Nile seconded. The motion passed 9-0-0.	Y	
10.	1.6.2.2. b	Is inconsistent with Section 1.7.2.3.f.iii. Only two energy ranges are required.	Carolyn moved to amend this section as by replacing "The analyte(s) shall be diluted in a volume of clean quality system matrix (a sample in which no target analytes or interferences are present at activities that will impact the results of a specific method) sufficient to prepare four (4) aliquots at a laboratory specified activity. with "Prepare four (4) aliquots consistent with section 1.7.2.3 Positive Control – Method Performance." and to delete b) Richard seconded. Motion passed 9-0-0	Y	
10.	Line 337 [1.6.2.2. d)]	What is logarithmic value?	Carolyn moved to delete "such as for presence/absence and logarithmic values." Nile seconded. Passed 9-0-0	Y	
4.	1.6.3.2	B and C look the same maybe they can be combined.	Larry moved to declare non-persuasive since the concepts are different. Tom seconded. Motion passed 9-0-0	n/a	
2.	?	I have a non-specific comment, and that's please to follow the requirements of the Calibration Standard (now at Interim Standard phase but may be revised again) and do what you can to ensure that confusion between its requirements and those of the rad module will be minimized.	Richard moved that this comment be deemed non- persuasive since it is not relevant to the scope of this module. Nile seconded. The motion passed 9-0-0	Y	
	1.6.3.2 a)	" acceptable performance of blank and samples single blind to the analyst." We suggest samples be changed to sample(s) if for	Make editorial change: " acceptable performance of blank(s) and sample(s) single	Y	

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		example, the intent is to allow an acceptable single blind PT sample and blank to count as on-going DOC.	blind to the analyst."			
	1.7.1	While we agree with the concept in this section we are concerned that when the EPA Certification Manual is not interpreted correctly, this standard, for drinking water radiochemistry, will be changed, as there is no procedure or decision making process to determine what standard is more stringent when imposed regulations take precedence. For example drinking water MDL studies have been required, at least at our lab, by the EPA contract auditor for at least two audit cycles even though the federal register, 40 CFR 141.25(c), is quite clear about how the Detection Limit (DL) is to be determined as detailed in section 1.3.1 and section 1.5.2.2.	No action necessary or appropriate. This is clearly not within the scope of this module rather it is an issue of interpretation of regulatory, contractual requirements which with labs must comply if the requirements are deemed acceptable during the evaluation of contracts and tenders.	n/a		
3.	1.7.1.6 a) i)	In order to provide a minimum threshold for data quality, would it not make sense to define a minimum frequency for short-term background? Since there is no requirement to perform at some minimum frequency, the lab could theoretically not detect a problem associated with short-lived activity such as radon that could be impacting sample results until there was enough method blank data to trigger an investigate. See also next comment.	Commenter was present at meeting and withdrew the comment.	n/a		
3.	1.7.1.6 b) i)	Does 1.7.1.6 b) i) imply a minimum short-term background check frequency of 7 days? Does this requirement run counter to not specifying a frequency in 1.7.1.6 a)?	Commenter was present at meeting and withdrew the comment.	n/a		
4.	1.7.1.1	Would be helpful to include examples of measurement system configuration parameters that they are referring to.	Marty moved that this be deemed non-persuasive since it adds unnecessary specificity to the requirement and could limit the effectiveness of the language.	n/a		

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			Nile seconded. The motion passed 9-0-0	
6.	1.7.1.2 b) i-iv	Are the items listed examples where multi-point calibration curves are required or examples where varying activity need not be performed or both? Clarify the language to be more specific.	Richard moved to change the sentence to: "Multiple-point calibration curves correlating other parameters (e.g., mass-efficiency, or channel energy) are required for some methods, for example:" Larry seconded. The motion passed 9-0-0	Y
6.	1.7.1.2 c) and d)	Section "c" requires standards have the same physical characteristics as the samples. Section "d" allows the use of empirical techniques and computation modeling techniques in which the sample may not match the physical characteristics of the calibration standard. Clarify the language in "c" by referring to "d" as an allowable exception.	Nile moved that c) be amended as follows: "to which the calibration will be applied, except as noted in section 1.7.1.2 d)." Vas seconded. The motion passed 9-0-0	Y
6.	1.7.1.2 e) i and ii	As written, calibration protocols must be the "method SOP". The procedure for calibration of instruments should not be limited to the method SOP. For line 501 change "method SOPs" to "written procedure"	Larry moved to search rest of the module and change "method SOPs" to "written procedures" throughout. Marty seconded. The motion passed 8-0-1 (TS abstained since he finds the issue to be non-pertinent.)	Y (three instances changed)
9.	1.7.1.2 e) i) 7)	There should be a tie here to MQOs.	Marty moved to add to section 1.2 as follows: "Additional quality assurance and quality control Requirements (e.g., Measurement Quality Objectives (MQOs))". This reference to MQOs will apply to the entire document and address concerns raised throughout by Tom Rucker below. Carolyn seconded. The motion passed 9-0-0.	Y
9.	1.7.1.3 b)	There should be a tie to MQOs here.	See response to 1.7.1.2 e) i) 7) above.	Y
9.	1.7.1.4 a) iv)	There should be a tie to MQOs here.	See response to 1.7.1.2 e) i) 7) above.	Y

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9.	1.7.1.4 a) vi)	The use of control charts does not meet the objectives stated in the introductory paragraph or in this sentence. The use of tolerance charts is necessary. There should also be a tie of the tolerance limits to MQOs.	Nile moved to modify text in 1.7.1.4 a) vi) to: "If a performance check result exceeds established limits, instrument performance may have changed since the initial calibration." Dave seconded. The motion passed 9-0-0. See also response to 1.7.1.2 e) i) 7) above about MQOs.	Y	
6.	1.7.1.4 a) vi	Section does not contain a requirement. By using "may have" and "should", no requirements are imposed on laboratories.	Richard moved to convert "If a performance check result exceeds control limits, instrument performance may have changed since the initial calibration. The laboratory should verify that the change is not attributable to normal statistical variability of the check measurement prior to taking corrective action." in vi) to a note after vii). Tom seconded. The motion passed 9-0-0	Y	
9.	1.7.1.5 c) ii) 4)	You are specifying everything else. Why not specify something for this? (quarterly or annually)	Tom moved that this be deemed non-persuasive. The timing is addressed by the subtraction frequency and the requirements to control backgrounds. Dave seconded. The motion passed 9-0-0	Y	
9.	1.7.1.6 a) i)	Since these checks are a monitor on the applicability of the background determination, the use of control charts does not meet the objectives and the use of tolerance charts are necessary. The tolerance limits should be tied to MQOs.	See response to 1.7.1.2 e) i) 7) above about MQOs.	Y	
9.	1.7.1.6 a) iii)	There should be a tie to MQOs here.	See response to 1.7.1.2 e) i) 7) above about MQOs.	Y	
5.	1.7.2	Isotopic gamma analyses: The new guidelines for quality controls as mentioned in 1.7.2 of WDS-TNI Standard-V1M6- Radiochemistry-5-30-14.pdf. are fine for water samples.	Persuasive. We are working on this.	pending	

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	Our lab routinely receives samples throughout the year that include: Potable and non-potable water, bucket, milk, vegetation (fruits, vegetables, and grass), various ??xxxxxxxxx types of fish (e.g. bottom feeder, top feeder), charcoal, air filter, urine, soil, and sediment. In order to accommodate all these, the geometries used are 10 mL, 50 mL, 125 mL, 250 mL, 500 mL, and 1400 mL, single and composite of 13 filters. The efficiency calibrations are performed using NIST traceable standards and mixed- gamma standards in aqueous solutions, and density corrections are applied if needed during data reduction. The quality control samples used are aqueous solutions except for filter paper. The samples received from FDA, FERN, or during emergency exercises include: water, vegetation, grass, fruits, juices, chicken, turkey, beef, soil, sediment, filter paper. We have received shipments from FDA that included: (1) Fat free milk, skim milk, 1% milk, 2% milk and whole milk (2) Lettuce, ground beef, chicken breast, chicken thighs, chicken wings, pork sausage, and pork lion (3) Pork with vinegar, smoked turkey, turkey sausage, chicken breast, smoked beef, beef patties, and oven roasted pork Given the above information, in short it will be almost impractical/impossible to follow the new guidelines for quality controls as mentioned in 1.7.2 of WDS-TNI Standard-V1M6- Radiochemistry-5-30-14.pdf. except for water.			

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		I hope the members of the Radiochemistry Expert Committee will look into it again.		
9.	1.7.2.1 a)	There should be a tie to MQOs here.	See response to 1.7.1.2 e) i) 7) above about MQOs.	Y
9.	1.7.2.1 e)	Frequencies are specified in the paragraphs below for each type of control.	Persuasive. Carolyn proposes to change as follows: "The laboratory's quality control program shall document the frequency required for quality controls. Minimum quality control requirements are specified below."	Y
6.	1.7.2.1 g)	Additional clarification needed. Temporal position in an analytical batch is not specified so a laboratory could analyze all quality control samples at the beginning of an analytical or preparation batch. Add clarifying language to require the laboratory to distribute QC samples throughout the batch.	Commenter was present at the meeting and withdrew the comment.	n/a
9.	1.7.2.1 h)	There should be a tie to MQOs here.	See response to 1.7.1.2 e) i) 7) above about MQOs.	Y
9.	1.7.2.1 i) and j)	Acceptance criteria should be tied to MQOs. The use of acceptance criteria requires the use of tolerance charts. The terminology here (tolerance control) is ambiguous and the term control should be eliminated.	See response to 1.7.1.2 e) i) 7) above about MQOs.	Y
10.	Line 482 [1.7.1.2. d)iii)]	Replace "1.5.4.c and 1.5.4.d" with "Section 1.5.4".	Persuasive	Y
6.	1.7.2.1 k), 1.7.3, 1.7.3.1, and 1.7.3.2	Potential conflict. Section 1.7.2.1.k requires the laboratory to take specific actions in the case of a failed quality control sample. Ensure final language in the later sections, lines 1067-1129, is consistent with the requirements in Section 1.7.2.1.k.	Richard will check these sections and propose potential fixes as appropriate.	pending

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10.	Analytic al batch, lines 64, 65, 745- 747	Requiring all samples and LCS to have similar characteristics in the analytical batch for non-destructive gamma spectrometry is too stringent. This requirement improves throughput only if all incoming samples are the same. For a typical state laboratory monitoring nuclear facilities, a variety of samples arrive at any time. Therefore, state labs can only: i) analyze each sample individually with its own set of QCs – a considerable overburden, or ii) delay samples until sufficient number of alike samples are batched into a preparation batch. The proposed requirement creates busy work as well as delays radiation protection of the population and, therefore, is not acceptable to state labs. Proposed change: i) remove these statements and let the labs develop and defend their own QC procedures, or ii) adopt Tom Semkow's proposal by allowing varied samples in the analytical batch with randomly selected LCS, which is based on sound principles and practice of modern non-destructive gamma spectrometry.	Revisit this after batching concept is fleshed out.	pending		
6.	1.3.1 1.7.2.1 d) ii 1.7.2.1 f) 1.7.2.1	The time period for an analytical batch is too long. Potential impact on reported results may be significant. The laboratory is required to assure the test instruments consistently operate within the specification required of the application for which the equipment is used. The laboratory shall process all batch quality control samples together with, and under the same	Revisit this after batching concept is fleshed out.	pending		

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	k) .7.2.7 a)	conditions as, the associated samples. In order to meet all of these criteria, the laboratory must be able to demonstrate that over a 14 day period, the instrument continues to operate consistently and the operating conditions have not changed in a way that could potentially affect the data. In order to achieve this, I would anticipate the laboratory would be required to analyze quality control samples, blanks, LCS, efficiency checks, etc throughout the entire time period for the analysis batch. The results for the entire batch should not be reported to clients until the entire batch is completed. Conversely, if results have been sent to clients, the laboratory would need to initiate the appropriate corrective actions, including client notifications. There are significant negative potential impacts on clients who would receive corrected results 14 days after receiving an initial result. This could impact drinking water supplies, remediation or cleanup, worker safety, disposal of potentially radioactive waste material, etc. Reduce the time frame to 5 days. Include a requirement that no results may be reported until the analytical batch is complete. Include requirements for distribution of quality control samples throughout the analysis batch. Include requirement for analysis of quality control samples at		

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		the beginning and end of the batch, which must meet established limits or the entire batch reanalyzed or the data be reported with appropriate qualifiers. Add reference to the requirements in V1M6 Section 1.7.1.5 and 1.7.1.6.b.ii			
10.	Line 776, 777 [1.7.2.1. j)]	Replace "; and" with ", as well as".	Persuasive. Break sentence after long-term trends and make last phrase into its own sentence.	Y	
4.	1.7.2.2 (c) I	Define CSU.	Added definitions. Note also that uncertainty is actually defined in 1.5.4.a). Pointed 1.7.2.2.c) i) back to 1.5.4.a) (where uncertainty is defined) to minimize any confusion.	Y	
7.	1.7.2.2 c) i)	Please spell out the term CSU: combined standard uncertainty if not defined in the standards already.	Persuasive: Replace all references to CSU with total uncertainty. The changes Bob made in the standard were reviewed on the 8/27 call. Dave moved to make those changes as proposed. Vas seconded. Motion passes 6-0-0.	Y	
7.	1.7.2.2 d)	We suggest replacing the word shall with the word may or should in this sentence or rewording such that: 'Corrective actions should be considered if' These changes might accommodate situations such as when analyte-free matrix is not available and there is not a suitable surrogate available. Suitable qualifier or case narrative should be considered unless those are considered corrective action by the committee.	Marty moved that this been deemed non-persuasive – corrective action is not optional if a method blank is outside limits. The corrective action would include some investigation and would result in some action which might include qualifying data in the case narrative. Nile seconded. The motion passed 9-0-0	n/a	
4.	1.7.2.2 (d) and (f)	Is this section necessary? Consider deleting.	Nile moved that this be deemed non-persuasive. The committee has reconsidered these sections and determined that they are necessary.	n/a	

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			Larry seconded. The motion passed 9-0-0	
9.	1.7.2.2 f)	Because of day to day variability of backgrounds for liquid scintillation counters, batch blanks are often subtracted rather than historical averages. This requirement does not allow that practice and therefore may not be necessary or preferred for that case.	Nile moved to deem this non-persuasive. The language is acceptable as written. This section is about instrument calibration and not background subtraction. That notwithstanding, it is not acceptable to subtract a "batch blank" from samples (or QC samples) in the associated batch. An independent reagent blank, however, may be subtracted. Note also that 1.7.2.2.f) does allow subtraction of average activity of historical batch blanks but not that of a blank run with the samples. A comment has been added pointing to 1.7.2.2.f) Marty seconded. The motion passed 9-0-0	Y
4.	1.7.2.3 (b) I	What is quality system matrix? Is DW samples the same as reagent water?	No action needed. This is defined by TNI standard module 2.	n/a
		Marty moved to adjourn – seconded by <u>unknown</u> Meeting adjourned at 4:58. Meeting resumed at 8 AM Friday with quorum of 7 members.		
4.	1.7.2.3 (e)	The final prepared LCS need not be traceable to NIST. Why not?	Nile moved to find persuasive - the last sentence is not needed - it will be deleted. The requirements are specified in 1.7.2.6.c). Larry seconded. The motion passed 6-0-0. <i>Note: The reference in 1.7.2.3.e) was updated to 1.7.2.6.c).</i>	Y
10.	Line 877, 878, 948 [1.7.2.3. e),	Replace highlighted text with "Section 1.7.2.6.c".	Larry moved that this be deemed persuasive and that the references in 1.7.2.3.e) and in 1.7.2.4.a) viii) be changed to 1.7.2.6.c Nile seconded. The motion passed 7-0-0	Y

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	1.7.2.4.a )viii)]				
9.	1.7.2.3 g)	There should be a tie to MQOs here.	See response to 1.7.1.2 e) i) 7) above about MQOs.	Y	
4.	1.7.2.4 (a) vi	The activity of the matrix spike shall be greater than 5 times the MDA. EPA Cert Manual requires spiking less than the MDA.	Larry moved that this be deemed non-persuasive. The stated requirements do not agree with the certification manual which states that the MS concentration will be 10 times the expected levels in the samples. The draft standard is consistent with these requirements. Marty seconded. The motion passed 7-0-0.	n/a	
9.	1.7.2.4 a) viii)	There should be a tie to MQOs here.	See response to 1.7.1.2 e) i) 7) above about MQOs.	Y	
7.	1.7.2.4 b) i)	We suggest that for gamma environmental work and /or alpha/beta counting of air filters or swipes, that a replicate analysis be encouraged. For gamma environmental work and air filters/swipes we often do not have a second aliquant to prepare but do run a replicate (on a different detector if multiple detectors are used for a batch).	Nile moved that this be deemed non-persuasive since we are using the term "duplicate" and "replicate" as synonyms. This requirement is already addressed in 1.7.2.4.b)iii). Vas seconded. Motion passed 6-0-0 (Marty stepped out)	n/a	
NE W	1.7.2.4.a )viii)	The last sentence to this section needs to be stricken. This is already addressed in section 1.7.6.2.c)	Carolyn moved that this sentence be stricken since it is addressed in section 1.7.2.6.c. Nile seconded. The motion passed 7-0-0.	Y	
10.	Line 970, 971 [1.7.2.4. b)iii)]	Delete the last sentence since it is already covered in Section 1.7.2.1.g.	Commenter was present at the meeting and withdrew comment.	n/a	
4.	1.7.2.4	The MD shall consist of a second measurement of one sample.	Carolyn moved that this be deemed non-persuasive because	n/a	

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	(b) iii	(Sounds like you do not need a separate aliquot for the MSD, simply count the same sample twice. Section I above requires the MSD be a separate aliquot.	it is adequately defined in the draft standard. Marty seconded. The motion passed 7-0-0. Note: This language is going to be reworked while updating the QC batch concept.	
9.	1.7.2.4 b) iii)	There should be a tie to MQOs here.	See response to 1.7.1.2 e) i) 7) above about MQOs.	Y
9.	1.7.2.4 b) v)	There is no mention of methods of calculating performance criteria for duplicates in this section such as % difference and difference-error ratio (DER). The use of DERs takes into consideration low-level activity cases. Addition of calculational methods is recommended.	Nile moved that this be deemed non-persuasive since it is defined in 1.7.3.3.i). Larry seconded. The motion passed 7-0-0.	n/a
4.	1.7.2.4 (c) i	Need clarification. Can the carrier yield be recorded and saved electronically or must it be printed with the data-packet?	Clarification: There is no requirement of how the information should be reported, just that it must be reported.	n/a
10.	Line 994 [1.7.2.4. c)iv)]	Delete "specific".	Editorial – will delete first "specific"	Y
10.	Line 1007 [1.7.2.5. b)]	Replace "levels (MDA or Critical Level" with "capabilities (Critical Value, MDA, or DL".	Editorial . Change to: b) Detection capability (e.g., MDA or Critical Level, as appropriate) shall be calculated as described in Section 1.5.2.	Y
10.	Line 1017 [1.7.2.6. a)]	Delete last sentence.	Tom moved that this be deemed persuasive. Carolyn seconded. The motion passed 6-0-0 (Marty stepped out)	Y
6.	1.7.2.6 c) i and	Correction of terminology to be more consistent with ISO/IEC terminology. Language used is not consistent with generally	Nile moved to update the language of this section as follows to correct terminology and maintain consistency with	Y

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	ii	used language in ISO/IEC and other authoritative references. c.i) "Reference standards shall be obtained from a National Metrology Institute (e.g. NIST) or from suppliers of NMI reference standards. Alternatively, reference standards may be obtained from an ISO/IEC Guide 34 accredited reference material provider." c.ii) "Reference standards shall be accompanied with a certificate of analysis meeting the requirements of either ISO/IEC Guide 31 or ANSI N42.44 – 1955 Section 8, Certificates. Certificates shall include –add existing languate.	<ul> <li>ISO/IEC terminology.</li> <li>"c. i) "Reference standards shall be obtained from a Metrology Institute (e.g. NIST) or from suppliers of reference standards. Alternatively, reference standards be obtained from an ISO/IEC Guide 34 accredited rematerial provider."</li> <li>c.ii) "Reference standards shall be accompanied wit certificate of analysis meeting the requirements of ISO/IEC Guide 31 or ANSI N42.22 – 1995 Section 8, Certificates.</li> <li>Marty seconded. The motion passed – 7-0-0.</li> <li>Tom moved that the standard language will be upd using the language distributed to the committee metabolic committee committee metabolic committee metabolic committee committee committee committee metabolic committee committee</li></ul>	a National NMI dards may eference ith a either ated embers.		
10.	Line 1030 [1.7.2.6) c)ii)]	Insert "standard quantity".	Tom moved to deem persuasive. Nile seconded. The motion passed 7-0-0.	Y		
6.	1.7.2.6 c) iii	If the supplier of the reference material is either an NMI or an ISO/IEC Guide 34 accredited provider, the laboratory should be able to have confidence in the COA. The lab may perform checks but this should not be required. Delete requirement to check reference standards in this section.	Nile moved that this be deemed non-persuasive. Pr with reference standards are not infrequent and ca found by verifying prior to use. Marty seconded. The motion passed 7-0-0.	oblems n only be n/a		
6.	1.7.2.6 c) iv	The section implies the laboratory is required to verify reference materials which have not been obtained from either	Nile moved that the language be updated as follow "If there is no known provider of a particular standa	s: Y ard (e.g.,		

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		NIST or an accredited provider. Rewrite section and include requirement: "The laboratory shall verify the activity of reference standards have not been obtained from either an NMI or an ISO/IEC Guide 34 accredited provider." This section may need to be split into subsections for clarity.	non-routine radionuclide or non-standard matrix) that is traceable to the International System of Units (SI), the laboratory may have no alternative but to use a standard with less rigorously established traceability. In this event, the laboratory shall obtain from the provider the minimum information described in Section 1.7.2.6.c.ii. The laboratory shall verify the activity of such standards prior to use and document the verification. If the laboratory's verification indicates a significant deviation from the original information from the provider, the standard should not be used <b>unless the discrepancy can</b> <b>be resolved</b> . If the standard is used for analysis of sample unknowns, the source and any other known limitations of the standard shall be disclosed in the final report. Larry seconded. The motion passed 7-0-0 On the 8/27 teleconference, Larry moved to make the change as proposed. Tom seconded. The motion passed 6-0- 0.	
10.	Line 1052 [1.7.2.7. a)]	Append ", according to Section 1.7.1.".	Editorial – change will be made.	Y
6.	1.7.2.7 c)	It is unclear what is meant by "shall address." The next sentence appears to provide a specific requirement. Delete sentence with "shall address".	Carolyn moved that this is persuasive. Nile seconded. The motion passed 6-0-0	Y
10.	Line	Change "replicates" to "duplicates".	Tom moved that this is persuasive.	Y

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	1109 [1.7.3.3 a) i)]		Vas seconded. The motion passed 6-0-0	
10.	Line 1121 [1.7.3.3 b) i)]	Insert "," after "sample".	Editorial	Y
10.	Line 1124 [1.7.3.3 b) ii)]	Change "uncertainty" to "variability".	Nile moved that the text be amended as follows: "For alpha spectrometry, evaluation of tracer acceptability shall include evaluation of chemical yield (e.g., uncertainty, variability) and peak resolution." Marty seconded. The motion passed 7-0-0	Y
10.	Line 1135 [1.7.3.4 a)]	Replace "free of" with "evaluated for".	Nile moved that the text be amended as follows: "Instrument raw data from energy spectral analysis shall be evaluated to ensure that the target radionuclides are quantified consistent with laboratory procedures and applicable MQOs" Vas seconded and the motion passed 7-0-0.	Y
7.	1.7.3.5 b)	We suggest replacing the word shall with the word may in this sentence. Another suggestion or way to word this might be 'Results which are calculated below the detection limit or MDA may be reported as a less than value at DL/MDA or at a reporting level as established by laboratory'. Many of our 'customers' are the general public and request testing of drinking water and radon in air. We find using a reporting level is more effective and efficient to explain radioactivity results to them. For example: less than 1.50 pCi/L	Nile moved that this is non-persuasive since Part f of this section allows project or client specified reporting requirements to take precedence over the requirements of this standard. Larry seconded and the motion passed 7-0-0.	n/a

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		(our DL), for a gross alpha result is better understood by general public than - $0.25 \pm 2.51$ pCi/L. We realize that many labs do not report data in this way especially when the customer is a knowledgeable interpreter of radiochemistry data.							
10.	Section 1.7.3.5. b	<ul> <li>This statement has a theoretical value but is impractical in many situations such as:</li> <li>i) at many institutions, regulatory or legal reporting requirements unrelated to TNI differ from the above, for instance by not allowing negative results or not reporting below MRL.</li> <li>ii) in a library-driven gamma identification a variety of statistical and non-statistical censoring is performed by the software.</li> <li>Otherwise, one would end up with tens or hundreds of false positives that needed to be reported for every sample.</li> <li>iii) this statement is inconsistent with the Critical Value of Section 1.3.1.</li> <li>Proposed change:</li> <li>i) remove the statement, or</li> <li>ii) modify the statement by allowing censoring in many cases.</li> </ul>	Section 1.7.3.4 will be reviewed to address evaluation prior to reporting under 1.7.3.5. Tom will take the lead. The text was reviewed by Tom and the committee on the 8/27 call. Vas moved to update the text as edited on the call. Larry seconds. The motion passed 6-0-0.	Y					
10.	Line 1157 [1.7.3.5 d)]	Replace "1.6.5" with "1.5.4".	Agreed. Editorial	Y					
7.	1.7.3.5 e)	The term activity reference date is not defined in the standard and is not clear to us. Is this the sample collection date to be	Nile moved that this is persuasive and that we should add a definition for activity reference date.	Y					

Radiochemistry Expert Committee									
Document No./Title: STD-2-ELV1M6-RadC-WDS-5-30-14									
Commenter (Wi 1 – Carl C. Kircl 2 – Lynn Bradle 3 – Bob Shanno 4 – Dale Piecho 5 – Abdul Bari	b): er 6 – Richard Sheibley 7 – George Miller 8 – Ron Houck ki 9 – Thomas L. Rucker 10 – Tom Semkow		Contact: <u>Carl.Kircher@flhealth.gov</u> <u>lynn.bradley@nelac-institute.org</u> <u>Rhsheib111@yahoo.com</u> <u>rhouck@pa.gov</u>						
Who Section/ Clause no.	Comments	Comment Resolution. Committee vo	te, P=persuasive, NP=Non	Persuasive					
	included on the report?General: Consider changing the requirement for Proficiency testing in radiochemistry areas (at least drinking water) from 2 times a year to once. This would result in significant cost savings to laboratories, reduced radioactive waste disposal, preparation and analysis time. There are enough LCSs to show ongoing demonstration of capability of staff and instruments' performance, and the current drinking water provider does not match drinking water matrix for PT samples.My comments are for Gamma Spectrometry only and are regarding the following:(1) Efficiency calibration of each matrix type (2) Separate LCS for each matrix type in a batch	Marty seconded. The motion passed On the general comment: Proficiency scope of module 6 and will not be ad This was previously addressed.	– 7-0-0 y testing is outside the Idressed						
5. ?	<ul> <li>(3) Matrix spike for each matrix type in a batch</li> <li>In your email you have clarified that requirement to perform matrix spikes for gamma spectrometry has been eliminated. Thanks.</li> <li>If one has to have a LCS for each matrix type in a batch, one will face the same problems as it would have been for matrix spike for each matrix type. Can water sample be used to prepare LCS in a batch containing different matrix type?</li> <li>It will be impractical/impossible to prepare of efficiency</li> </ul>			n/a					

Radiochemistry Expert Committee									
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Commenter (Who 1 – Carl C. Kirche 2 – Lynn Bradley 3 – Bob Shannon 4 – Dale Piechocl 5 – Abdul Bari		<ul> <li>b):</li> <li>a):</li> <li>b):</li> <li>c):</li> <lic):< li=""> <li>c):</li> <lic):< li=""> <li>c):</li> <li>c):</li> <li>c):</li> <lic):< li=""> <lic):< li=""></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></lic):<></ul>		Contact: <u>Carl.Kircher@flhealth.gov</u> <u>lynn.bradley@nelac-institute.org</u> <u>Rhsheib111@yahoo.com</u> <u>rhouck@pa.gov</u>					
Who	Section/ Clause no.	Comments	Comment Resolution. Committee vo	te, P=persuasive, NP=Non	Persuasive				
		calibration for each matrix type given the different types of matrices our laboratory receives (mentioned in my email dated 7/18/2014).							
8.	?	I'm not sure if this changes anything, but there is one exception to the statement below that the LOQ is not defined for radiochemistry that comes to mind. That is uranium by KPA (i.e., ASTM D5174). In this case, an actual calibration curve based on concentration is constructed and the results are determined from that curve. In this case, I would expect the laboratory to indicate an LOQ on the report sent to the customer and flag any result that is below that LOQ. The same could also be said about uranium by EPA 200.8 (ICP-MS). Would laboratories be evaluated based on Module 4 (Chemistry) in these cases, or would they be evaluated based on Module 6?	Yes.		n/a				

Completed: 12:04pm ET 8-8-14