Radiochemistry Expert Committee (REC)
Meeting Summary

June 28, 2017

1. Roll Call and Minutes:

Bob Shannon, Chair, called the meeting to order at 1:00 pm Eastern on June 28, 2017 by teleconference. Attendance is recorded in Attachment A – there were 7 members present. Associates: Jim Chambers, Brian Miller, Joe Pardue, and Carolyn Wong.

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

2. NEMC

The committee meeting in Washington, DC is planned for Tuesday, 8-8-17, at 1-3pm Eastern. Ilona will plan to set-up Webex if there is internet in the meeting room. Bob asked who will be in Washington, DC: Yoon, Bob, Ilona.

Ilona asked that Bob keep her in the loop if he does not think he needs two hours.

3. Assessment Checklist

Larry reviewed the version of the checklist distributed yesterday evening by email. Item 113 has been corrected, but otherwise the version is the same as that viewed by the committee in April.

Larry motioned that the Checklist distributed by email on 6/27/17 be approved. The motion was seconded by Tom and unanimously approved. (For – Bob, Yoon, Dave, Vas, Larry and Tom Against – 0 Abstain – 0.)

The next step is to send it to Ilona. Take from 6/27/17 email.

4. Small Laboratory Handbook

Dale Piechocki performed a review of the Handbook vs. the Standard and then Ilona went through and made editorial updates and started formatting the final document. She noted an issue with a missing reference to Attachment 5. Dave thinks the reference is at the beginning of the document where a radiation batch is defined. Ilona will re-number attachments as appropriate.

Bob preferred that the definitions be in a conceptual order, rather than alphabetical. Tom would prefer that it stay alphabetical. More committee members preferred conceptual and this change will be made.

Section 1.5.1 – Additional language was added to Keypoints 2, 3, and 4. There was agreement with the changes.

The SLH was reviewed and tweaked by the committee in Webex. Changes made to the document can be found in Attachment D.

Bob reviewed the document through Section 1.7.1.7 prior to the call and added his comments to the document.

Bob reviewed the Attachments too. There was a lot of information in the method validation example, and Bob simplified it and provided more calculation information.

Bob will finish his comments by tomorrow and distribute them with track changes turned on.

Bob asked that everyone continue to review the SLH and give comments to Bob by 7/14/17. He will have an updated document at the next meeting to hopefully finalize the document for a vote.

5. New Business

Carolyn noted that ASTM developed a method awhile back - Standard Test Method for Alpha and Beta Activity in Water by Liquid Scintillation Counting - D7283-17. It has been submitted to EPA and it will be approved for SDWA. Vas asked if a DRAFT is available – it is, but it must be purchased. They are only waiting for the Federal Register to be published showing EPA's approval.

6. New Business

The committee has been invited to provide feedback on the PTP Executive Committee's SOP on developing FoPT limits. Bob will be distributing this to committee members. It was originally written without thought that there are differences with Radiochemistry.

7. Action Items

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

8. Next Meeting and Close

The next meeting is scheduled for July 26, 2017 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 3:02pm Eastern.

Attachment A
Participants
Radiochemistry Expert Committee

Members	Affiliation		Contact Information	
			Phone	Email
Bob Shannon (Chair) (2019) **Present**	QRS, LLC Grand Marais, MN	Other	218-387-1100	BobShannon@boreal.org
Tom Semkow (Vice Chair) (2019) **Absent**	Wadsworth Center, NY State DOH Albany, NY	AB	518-474-6071	thomas.semkow@health.ny.gov
Sreenivas (Vas) Komanduri (2019) **Present**	State of NJ Department of Environmental Protection Trenton, NJ	AB	609-984-0855	Sreenivas.Komanduri@dep.state.nj.us
Marty Johnson (2019) **Present**	US Army Aviation and Missile Command Nuclear Counting Redstone Arsenal, AL	Lab	865-712-0275	Mjohnson@tSC-tn.com
Dave Fauth (2018) **Present**	Consultant Aiken, SC	Other	803-649-5268	dj1fauth@bellsouth.net
Keith McCroan (2018) **Absent**	US EPA ORIA NAREL, Montgomery AL	Lab	334-270-3418	mccroan.keith@epa.gov
Larry Penfold (2018) **Present**	Test America Laboratories, Inc; Arvada, CO	Lab	303-736-0119	larry.penfold@testamericainc.com
Ron Houck (2018*) **Absent**	PA DEP/Bureau of Laboratories	AB	717-346-8210	rhouck@pa.gov
Yoon Cha (2020) **Present**	Eurofins Eaton Analytical	Lab	213-703-5800	YoonCha@eurofinsUS.com
Candy Friday (2020) **Absent**	CdFriday Environmental, Inc.	Lab	713-822-1951	candy@fridayllc.com
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
75	Prepare copy of Standard annotated with summary document language.	Carolyn	On hold	
83	Send SLH to Ilona after final update from today so she can do editing and formatting.	Bob/Dave	6/10/17 6/28/17	7/5/2017
84	Ilona will send the SLH back to the QS committee for further review.	Ilona		

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	

- Validation includes specification of the requirements and scope, determination of the characteristics of the methods, appropriate tests to prove that the requirements can be fulfilled by using the method and a statement on the validity.

Examples(s):

1 Both reference and non-reference methods must be supported with data on the method's detection capability, precision, bias, measurement of uncertainty, and selectivity. Such method validation data is required for each analyte/quality system matrix combination. Whenever a laboratory develops a method, or modified a method to meet different data quality objectives, the new method must be validated prior to use.

2 Use external performance testing (PT) samples to verify laboratory performance.

3 The use of non-TNI accredited PT providers is strictly for method validation purposes, and not for laboratory accreditation.

4 Attachment 2 for further discussion and examples pertaining to validation.

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1.5.2 Detection Capability

Detection capability refers to terms commonly used in radiochemistry such as Critical Value, Minimum Detectable Activity (MDA) or the Safe Drinking Water Act (SDWA) Detection Limit. See Attachment 1 for information on the key term, Minimum Detectable Activity. Methods and associated MDAs will vary as implemented from laboratory to laboratory. The Standard does not specify the procedure to use to determine the Detection Capability. It is left to the laboratory to select any method that they can defend as being technically sound as long as regulatory, method, contractual, or laboratory quality system requirements are met.

Key Points Are:

- The laboratory detection capability must be verified initially as part of the method validation study for each matrix.
- The laboratory detection capability must be re-verified when there is a change in the method or when there are substantial changes to the instruments used. If no changes have been made to the method or the type of instrumentation used, there is no need to re-verify the detection capability.

- The laboratory is required to document the procedure used to determine detection capability.
- The method needs to be appropriate and relevant for the intended use of the data recognizing that project-specific or client-specific requirements may be unique.
- If software is used to perform calculations for the validation of detection capability, it must be clearly identified. For example, the name, tracking, control, or revision numbers of commercially or laboratory developed software should be documented.

Discussion:

The Standard requires that the detection capability be initially determined for each analyte in each matrix. All steps of the analytical process must be included in the detection capability determination and confirmation. The procedure a laboratory uses to determine the detection capability of a method must comply with the specific requirement of Volume 1, Module 6, Sections 1.5.2.1 and 1.5.2.2.

Some regulatory programs, such as the SDWA compliance program, may prescribe acceptable approaches for detection capability determinations See Attachment 2 for more details on Detection Capability.

1.5.3 Evaluation of Precision and Bias

The laboratory needs to evaluate the precision and bias of a method for each analyte of concern and each quality system matrix. Precision and bias must be characterized across the range of activities that brackets those applicable in samples, including zero activity. This might be accomplished by analyzing test sources with activity ranging from zero (i.e., blank) to the highest activity the laboratory will process for a given type of sample.

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Key Points:

- The laboratory must establish the laboratory precision and bias for all measurements and all matrix types.
- The initial demonstration of capability (DOC) does not replace the method validation where the precision and bias are determined.
- Acceptance criteria for performance should be based on one of the following:
  - DQOs/MQOs
  - Applicable regulations (e.g., SDWA, CWA)
  - Published guidelines, such as MARLAP or FEM

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Example(s):

1 One approach might involve using LCS or other spiked samples at different activity levels to generate performance data for precision and bias across a range of activities.

2 A laboratory could also analyze replicate blanks and evaluate the results for absolute bias (i.e., bias at zero activity).

3 A laboratory could evaluate recent historical batch method blank, LCS, and duplicate results to generate data on bias and precision.

4 See Attachment 2 for further discussion and examples on evaluation of precision and bias.

1.5.4 Measurement Uncertainty

All radiochemical measurement results needs to be reported with an estimate of uncertainty expressed either as a standard deviation or a multiple thereof.

Key Points:

- The laboratory is required to document its procedure for estimating uncertainty in its quality system documentation.
- The reported results must also explicitly specify the total uncertainty. The results of the precision evaluation need to be compared to the uncertainty estimates as a check on the validity of the uncertainty evaluation procedure.
- The Standard's intent is that the laboratory will report total uncertainty unless they are specifically required to report counting uncertainty.
- Reports must specify the type of uncertainty reported (counting or total) and coverage (e.g., 95%, 1 sigma, or k=1).

Example(s):

1 Refer to Attachment 3 for a discussion of uncertainty calculation.

1.6 Demonstration of Capability

1.6.1 General

Key Points:

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- The laboratory analyst must have constant, close supervision until a satisfactory DOC has been completed.
- All DOCs need to be documented, retained and readily available at the laboratory.

1.6.2 Initial DOC

An initial DOC needs to be completed prior to using any method and at any time there is a change in instrument type, personnel, or method, and any time that a method has not been performed by the laboratory or analyst in a twelve month period. The DOC is not a method validation rather it demonstrates that the analyst is capable of running a validated method. Generally, the validation is more extensive and provides enough detail to simultaneously meet requirements for the initial DOC for the analyst performing it.

Key Points:

- Performance requirements are generally defined by method, regulation, contract, or accreditation requirements.
- A documented DOC is performed for each unique method and quality system matrix combination.
- Each analyst must perform a DOC before analyzing any samples.
- A new DOC is required whenever there is a change in method, instruments, or personnel.

Discussion:

- The laboratory needs to document each initial DOC in a manner such that the following information is readily available for each analyst:
  - Analyst(s)
  - Matrix
  - Analyte(s), class of analyte(s), or measured parameters
  - Identification of method(s) performed
  - Identification of laboratory-specific SOP used for analysis, including revision number
  - Date(s) of analysis
  - Summary of analyses

- If the method, regulation or contract does not specify an initial DOC, the following procedure would be one acceptable approach. It is the

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responsibility of the laboratory to document that other approaches to initial DOC meet applicable requirements.

1. Prepare 4 test samples consistent with Section 1.7.2.3 Positive Control and 4 method blanks using clean quality system matrix in which target analytes or interferences are not present at activities that will impact the evaluation of results of the specific method.
2. Analyze the samples according to the method.
3. Calculate the mean recovery and standard deviation of the spikes.
4. Compare the data to acceptance criteria specified in the method/regulation or contract.

- Where no external acceptance criteria exist, the laboratory needs to compare the data with criteria established in the laboratory quality system.
- When performing multi-elemental analysis by gamma spectrometry, the DOC need not involve every radionuclide. The standard specifically states the test sample needs to contain gamma-emitting radionuclides that represent the low, medium, and high energy range of the analyzed gamma-ray spectra.

1.6.3 Ongoing DOC

The laboratory needs to have a documented procedure describing ongoing DOC that includes procedures for how the laboratory will identify data associated with ongoing DOCs. The analyst(s) demonstrates on-going capability by routinely meeting the quality control requirements of the method, regulation or contract, or as established by this Standard and by the laboratory's quality system. If other approaches to ongoing DOC are used, it is the laboratory's responsibility to document that these approaches are adequate.

Key Points:

- Ongoing DOC is by method, analyst and matrix.
- Performance requirements must be defined by the method, regulation, contract or the Laboratory's quality system.
- Perhaps the easiest approach involves ongoing review of QC samples to identify trends with respect to performance requirements as described in 1.6.3.2.
- If the method has not been performed by the analyst in a 12-month period, an initial DOC needs to be performed.

1.7 Technical Requirements

1.7.1 Instrument Set-Up, Calibration, Performance Checks and Background Measurements

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The set-up, calibration, performance checks of instrumentation, and background determinations are all critical steps of an analytical process. If not done adequately, all subsequent analyses are suspect. Many reference methods, however, contain no or incomplete requirements. The laboratory may need to supplement the method to satisfy applicable program, regulatory, or contractual requirements, in addition to those specified in Module 6.

The structure of this section parallels the stages of the calibration life cycle

- Instrument set-up
- Initial calibration
- Calibration verification
- Instrument checks

The approach in the standard parallels that in ASTM D7282 – Standard Practice for Set-up, Calibration and Quality Control of Instruments Used for Radioactivity.

1.7.1.1 Initial Set-up of Instrumentation

Many of these requirements address procedures and documentation for set-up and configuration of instrumentation. They might be implicit in requirements for procedures and documents but they are routinely overlooked and impact the quality of results produced.

Key Points:

- The laboratory needs to maintain the required radiation measurement systems for each method it performs.
- The laboratory needs to maintain records documenting radiation measurement system configuration and values for hardware- and software-related operational parameters .
- The laboratory must ensure the continued integrity of system configuration and perform corrective actions to determine and ameliorate any potential impact if any changes are made or identified.

1.7.1.2 Initial Calibration

This section specifies the essential elements for initial calibration of radiation measurement systems. Although standards of varying activity are not needed to calibrate radiometric techniques, multiple points may be needed to correlate parameters other than activity. Here are six common examples:

1 channel-energy calibration of alpha or gamma spectrometers;

2 energy-efficiency calibration of gamma spectrometers;

3 mass-efficiency (mass-attenuation) calibration of gas-flow proportional or x-ray detectors;

4 quench-efficiency calibration of liquid scintillation detectors;

5 mass-crosstalk calibration of gas-flow proportional detectors; and

6 quench-crosstalk calibration of liquid scintillation detectors.

This section reiterates the need for physical calibration of instruments against traceable reference materials but opens the door for applying mathematical or statistical corrections based on mathematical techniques such as Monte Carlo simulations.

Key Points:

- The laboratory needs to establish and document in written procedures and in records the details of the initial calibration including, at a minimum:
  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 uncertainty of the calibration parameter and a minimum number of counts collected (e.g., 1% or 10,000 counts); and
  7 all calculations.

- The laboratory needs to document the criteria for conditions that initiate (re)calibration in its SOPs.
- The laboratory needs to quantitate sample results only from the initial instrument calibrations unless otherwise allowed by regulation, method or contract.

Example(s):

1 Mathematical Corrections to Calibration:
The laboratory has performed a calibration of a Marinelli beaker geometry for Ge gamma spectrometer using a physical source containing a mixed gamma reference standard (Sections 1.7.1.2c) and 1.7.2.6c)). The calibration source consisted of an acidic solution of density 1.015 g cm^3. In order to use

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a mathematical technique (i.e., Monte Carlo simulation) to correct efficiencies determined using the water equivalent standard for counting vegetation across a specified range of density, the laboratory must validate the corrections prior to use.

Two LCS samples are prepared by spiking and homogenizing two vegetation matrices (Section 1.7.2.3) with densities of 0.5 and 0.9 g cm^3 and transferring them to Marinelli beakers that match the mixed gamma calibration standard ensuring that they are filled to the same height as the standard. Density and coincidence (cascade)-summing corrections are calculated for these two samples using a Monte Carlo program (Section 1.7.1.2d)). Calculations performed used nominal Ge detector parameters (i.e., detector characterization) provided by the manufacturer, Marinelli beaker dimensions measured by the laboratory, and the elemental compositions of the aqueous calibration standard and a typical or representative vegetation sample. The LCS samples are quantified, the calculated corrections are applied, and the results verified by comparing to the known values. Since the LCSs bracket the range of densities 0.5-0.9, this established the range sample densities to which the corrections are applicable.

Comment: The nominal detector parameters as well as average vegetation composition are acceptable when the corrected values agree with the known values across the range over which corrections will be made because the calculated corrections are not very dependent on uncertainties in these quantities. For analyzing real vegetation samples, the corrections can be calculated between 0.5 and 0.9 g/ cm^3 in steps of 0.05 and applied based bulk density calculated based on the mass of sample needed to fill the container to the proper volume. From these values, the corrections are interpolated for a given sample density in the range. This is much faster and nearly as accurate as calculating the corrections for every sample.

1.7.1.3 Calibration Verification

This section of the Standard establishes requirements for verification of initial calibrations prior to use for analyzing samples. Requirements for calibration verification were poorly differentiated from and frequently confused with instrument performance checks. Calibration verifications verify the integrity of initial method-specific calibrations relative to established criteria that is based on measurement of independently produced calibration verification sources.

Key Points:

- Initial instrument verifications must be performed prior to use of an initial calibration for analysis of samples

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Example(s):

1. Change of Operational Parameter: Laboratory establishes an initial conversion gain of 4096 channels for a full energy range of 2 MeV for a Ge gamma spectrometer (Section 1.7.1.1b)). The gamma *energy* calibration is then performed using an $^{125}Sb/^{154,155}Eu$ mixed gamma source (Section 1.7.1.2b) i)). The initial efficiency calibration (Section 1.7.1.2b) ii)) is performed using a reference mixed gamma standard (Sections 1.7.1.2c) and 1.7.2.6c)). The calibration is verified (Section 1.7.1.3) and instrument performance checks were performed as scheduled (Section 1.7.1.4).

   A specific project for measurement of fresh fission products requires readjusting the conversion gain to 16384 channels for the same energy range (Section 1.7.1.1.c)). The laboratory recalibrates the energy using Sb/Eu source (Section 1.7.1.2b)i)). Subsequent performance checks do not indicate any change in efficiency or resolution.

   Comment: A new energy calibration must be performed but efficiency re-calibration is not necessary because the instrument performance checks verify that the efficiency has not changed.

2. Performance Check Failure: An analyst performs a daily instrument check on a solid-state scintillation detector (Section 1.7.1.4b)v)) and it shows no counts. The analyst recognizes that the high voltage was off. He turns it on and the repeated performance check passes (Section 1.7.1.4a)vi)).

   Comment: In this case, the zero counts do not enter the database, so the analyst follows laboratory SOP (Section 1.7.1.4a)vii)) which do not require informing supervisor or writing a corrective action.

3. Performance Check Failure: An analyst performs an instrument check on a semiconductor gamma detector (Section 1.7.1.4b) i) 1). The performance check falls outside 95% tolerance (Section 1.7.1.4a) vi)). The analyst repeats the measurement (Note to Section 1.7.1.4) and it falls outside the tolerance again. The analyst informs the supervisor as required by the laboratory's SOP (Section 1.7.1.4a) vii)). The supervisor subsequently determins that the check source has been measured in the wrong position. The source is repositioned and subsequent performance check passes.

   Comment: Since the out of tolerance results that enter the QC database are due to a known procedural non-compliance, The data should not be used to evaluate past or future control or tolerance. The record should not be deleted or obliterated, however. Instead, the laboratory may choose to flag the datapoint in the database as invalid ensuring that the rationale is

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documented (e.g., by entering a dated record in the detector mainentance logbook). There may or may not be need for a written corrective action depending on how the laboratory's SOP/quality system addresses this case.

4. Performance Check Deviates From Expected Value: After initial calibration of a liquid scintillation counter for tritium analysis, the laboratory performs recalibrations on an annual basis (Section 1.7.1.2). Performance check is performed using a factory sealed tritium check source (Section 1.7.1.4a)iii)). The performance check results are plotted on a tolerance chart (Section 1.7.1.4a)vi)) and includes accounting for radioactive decay of tritium (Section 1.7.1.4a)v)). In between recalibrations, the supervisor observes a steadily increasing deviation from the fitted exponential curve up to 0.5%, in spite of satisfying statistical tolerance chart.

   Comment: The supervisor determines that this discrepancy is caused by ageing of the optical system in the liquid scintillation counter. However, since this deviation is much smaller than the uncertainty required for the laboratory reported results (e.g., 5% or more), supervisor may decide that it is not necessary to replace the detector system or initiate out of schedule recalibration. The next recalibration will accommodate this aging of the counter. The supervisor should document the occurrence, for example, in the detector maintenance logbook.

5. Exception to Minimum Frequency of Performance Check: An analyst performs the daily performance check procedure for a gas proportional counter with an automatice sample changer on Friday (Section 1.7.1.4b)iii)) and then initiates counting a batch of 20 samples which will run until Sunday morning after which another batch of 20 samples will start counting. The analyst prepares a daily performance check procedure to be counted automatically and immediately after the sample procedure on Sunday, skipping Saturday.

   Comment: Skipping Saturday is allowed according to Section 1.7.1.4c)ii). If a second batch of samples were not being counted following the first, measuring the closing performance check on Monday (the next working day) instead of Sunday would also be acceptable.

1.7.1.5 Subtraction Background Measurements

Subtraction background measurements are performed to assess and correct for contributions due to cosmic radiation, naturally-occurring radioactivity, electronic noise, impurities in the detector, shielding, and source mounting material, or other sources that are not affected by the analytical processes.

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Even a small amount of bias in background measurements may be significant when results are close to background since it can influence decisions about whether the measurement indicates the presence of analyte of not.

Numerous counting configurations may be used to determine subtraction background, depending on the detector and the method, including: counting an empty detector; counting an empty container or blank Test Source in a detector; or counting a container filled with a surrogate matrix material free of measureable levels of radioactivity.

Discussion: The frequency of subtraction background measurements may be increased from the requirements listed below when there is low tolerance for lost data due to failure of a subtraction background measurement.

Key Points:

- The laboratory needs to maintain written procedures for performing and evaluating subtraction background measurements.
- Background counting time must be at least as long as the associated sample counting time and be representative of the background count rate.
- The subtraction background measurement needs to be accomplished in one of the following ways:
  - Paired measurements in which the subtraction background measurement is counted before or after the Test Source measurement or batch of Test Source measurements.
  - Measurements performed at a fixed frequency, in which Test Sources may be measured between successive background subtraction measurements. In this case, the laboratory needs to perform background subtraction measurements at the following minimum frequencies:
    - Gamma-ray spectrometry systems: Monthly.
    - Alpha-particle spectrometry systems: Monthly.
    - Gas-proportional and semiconductor alpha/beta detectors: Quarterly.
    - 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) used for non-spectrometric measurements.
  - Day of use.

1.7.1.6 Short-Term Background Checks

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Short-term background checks performed between subtraction background measurements are quality control measures used to verify the integrity of subtraction background measurements, check for possible detector contamination, electronics noise and to monitor each detector for trends and deviations from Poisson statistics. These background checks may be shorter in duration, yet more frequent than the subtraction background measurements, and therefore they may not always effectively identify every discrepancy that could compromise Test Source measurements (e.g., low-level contamination).

Key Points:

- The laboratory needs to maintain written procedures for performing and evaluating short-term background checks.
- When short-term background has changed since the previous determination such that significant background bias is imparted to intervening Test Source measurements, the laboratory should take action to determine if the instrument is contaminated, and if previous sample results have been compromised. If any results have been compromised, the laboratory should take action to ameliorate or qualify affected results.
- If subtraction background measurements are performed with sufficient frequency for a given method or detector type, such that they ensure background integrity and are capable of identifying detector contamination in a manner that is timely enough to identify potentially impacted results, these subtraction background measurements may be substituted for short-term background checks, in which case the short-term background checks are not required.
- For liquid scintillation detectors, the laboratory needs to check short-term unquenched backgrounds each day of use. Unquenched backgrounds are sealed background vials such as those supplied by instrument manufacturers. Although unquenched backgrounds do not match the geometry or the levels of quench observed in real samples and should never be used for subtraction, if a change is detected, all sample counts since the last background check are suspect and would normally need to be recounted.

1.7.1.7 Contamination Monitoring

The laboratory must maintain 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. Detectors may not be brought back into service until corrective actions are completed.

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- If monitoring of instrumentation indicates contamination, the laboratory should refer to guidance from the instrument vendor for cleaning and decontamination to minimize the risk of damaging the instrumentation. To the extent possible, it is recommended that routine measures for decontamination be formalized in the laboratory's SOP.
- It is recommended that levels of contamination be confirmed by performing a background for subtraction prior to routine cleaning. An additional background measurement may not be needed if a detector is known to be contaminated.
- Contaminated detectors may not be brought back into service until corrective actions are completed, including determination of whether sample results have been impacted.

1.7.2 Quality Control for Radiochemistry

The essential elements of quality control are the quality control tests and/or samples that must be utilized to properly document the quality and defensibility of the data being generated. These elements consist of positive and negative controls, detection capability, data reduction, quality of standards and reagents, selectivity, and constant and consistent test conditions. Negative controls are method blanks (laboratory reagent blank) and positive controls are laboratory control samples (laboratory fortified blank), while sample specific controls consists of matrix spikes and matrix spike duplicates, matrix duplicates, and surrogate spikes.

1.7.2.1 General

It is important to recognize that many radiochemistry laboratories rely on *non-mandated* methods (e.g., laboratory-developed or modified methods). They frequently develop or modify (and validate) methods to address analytical needs. Since QC requirements are often not specified by a source external to the laboratory (e.g., regulation or contract) it may be incumbent on laboratories to establish additional QC. When applicable, external requirements are more stringent than the Standard, the more stringent requirements must be met. This provides flexibility while helping to ensure that the laboratory has a defensible basis for their QC requirements. It also allows assessors to ask about the basis for specific requirements, and to point to MARLAP or other standards to explain the rationale for QC measures they select to use.

Key Points:

- The Laboratory needs to follow a documented QC program that monitors and assesses the performance of the laboratory's analytical systems. At a minimum, the QC program needs to incorporate requirements imposed by regulation, methods, and the TNI standard.
- The laboratory needs to process batch and sample-specific quality control samples to obtain empirical evidence that demonstrates their analytical system is in control.
- The laboratory needs to employ either a sample Preparation Batch or a Radiation Measurement Batch (RMB) to determine the grouping of samples and assignment of batch QC.
- A sample Preparation Batch needs to be initiated where sample testing is performed that involves physical or chemical processing which affects the outcome of the test. Samples and associated QC assigned to a Preparation Batch needs to be prepared together using the same processes, personnel, and lot(s) of reagents.
- Where testing is performed that does not involve physical or chemical processing which affects the outcome of the test (e.g., non-destructive gamma spectrometry, alpha/beta counting of air filters, or swipes on gas proportional detectors), an RMB may be initiated in lieu of a Preparation Batch. The samples and associated QC in the RMB needs to share similar physical and chemical parameters, and analytical configurations (e.g., analytes, geometry, calibration, and background correction).
- Samples may be added to the RMB for fourteen (14) calendar days from the start of the first sample count, or until twenty (20) environmental samples have been counted, whichever occurs first.
- The laboratory may combine 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).
- The laboratory procedures must document how method validation was performed, and records must document any corrections (e.g., for efficiency, density, cascade summing, and background) applied to physical calibrations.
- The laboratory QC program needs to document the frequency required for quality controls.
- The laboratory needs to process all batch QC samples together with and under the same conditions as the associated samples, and needs to use the same processes and procedures for preparation, analysis, data reduction and reporting of results.

Discussion: Although samples in a Preparation Batch must be prepared together, they need not be analyzed concurrently on a single detector, rather they may be analyzed on different detectors as long as the

detectors are calibrated for the technique in question and instrument quality controls indicate that the systems are in control. See also Attachment 4. Radiation Measurements Batch.

- The laboratory must ensure that is does not systematically or preferentially use specific detectors, equipment or glassware for the analysis of QC samples. This does not mean that laboratories should not identify and dedicate detectors, equipment, or glassware to minimize the risk of cross-contamination of samples or equipment. In general, this would be considered a good contamination control practice as long as the criteria for segregation apply equally to QC samples and samples.
- The laboratory's QC program needs to 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.
- The laboratory needs to assess the results of the QC samples against acceptance criteria documented in the QC program. Where there are no established criteria in regulations, the method, or contract, the laboratory needs to develop its acceptance criteria consistent with guidelines in MARLAP[3] or other consensus standards, or other criteria such as statistical control charts developed by the laboratory.
- The laboratory needs to track and trend the results of batch QC samples using statistical or tolerance control charts.
- The laboratory needs to 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. The laboratory needs to consider samples associated with a failed QC parameter as suspect and needs to, wherever possible, reprocess such samples. Where reprocessing is not possible, the laboratory needs to report results with appropriate data qualifiers. The laboratory needs to note the occurrence of a failed QC sample and any associated actions in the laboratory report.

Example(s):

1 All samples must be processed in a QC batch of which there are two types: Preparation batches and Radiation Measurements Batches.

a) Most samples will be processed in preparation batches. Preparation batches apply to samples that undergo physical or chemical processing that affects results. Examples of analyses requiring preparation batches are: gross alpha/gross beta in water (evaporation); tritium in water (distillation and mixing with cocktail); or total strontium in air filters (chemical separation.

bias, Measurement Uncertainty, and selectivity using the procedures specified in Sections 1.5.2 through 1.5.5.

Evaluating bias and precision are critical elements of method validation. While there are many approaches that could be taken, a relatively straight-forward one is presented here. By analyzing seven replicates in the quality systems matrix, spiked at different activity levels, the laboratory can produce representative data that forms the basis for the evaluation of bias and precision. Thus, bias and precision are characterized across a range of activities the laboratory expects to see in samples. The range should ideally include the activity at which important decisions will be made (e.g., whether contamination is present above a specified limit). The standard specifically mentions that the range should include zero activity since, generally, all results are reported as measured in association with their measurement uncertainty even if they are negative or zero.

In our example, the laboratory could perform replicate analysis to evaluate bias and precision for the coprecipitation method. The laboratory would analyze seven replicates at the MCL for gross alpha in drinking water (15 pCi/ L) as well as seven replicates at each of two concentration levels, one above and one below the action level. They also would analyze seven replicate blanks to evaluate absolute bias at background. Bias and precision can be evaluated at all levels.

EVALUATION OF SPIKED SAMPLES FOR RELATIVE BIAS:

In general, relative method bias is determined by calculating the arithmetic mean recovery of the seven replicates at each activity level using the formula:

$$Relative\ Bias\ (\%) = \left(\frac{\overline{X}}{\mu} - 1\right) \times 100$$

Where,

$\overline{X}$ is the mean recovery of the seven replicates, and

μ = true value for the test sample

The output of this equation yields values for relative bias at three concentrations. The target value for relative bias is 0%. It is strongly recommended that laboratories test their relative bias results to determine whether bias is actually detected "bias" or not. If bias is not detected, there is no need to take action. They can state whether or not bias was detected in their documentation/reports, and if it was, the magnitude of the bias.

Describing tests for relative bias go beyond the scope of this document, one approach that has been used is discussed in detail in Section 5.6.2 of *Method Validation Guide for Qualifying Methods Used by Radiological Laboratories Participating in Incident Response Activities*, (EPA 402-R-09-006).

Many laboratories incorporate the results of the bias and precision testing into their Quality System documents. Bias and precision are quantitative performance criteria that can be incorporated into scope and applicability statements of SOPs or method capability tables in quality manuals. Laboratories can also use them to evaluate and present method performance to clients and data users and during the evaluation of contracts and tenders prior to accepting work.

When external acceptance criteria are established, the laboratory should be cautious about assessing the acceptability of fbias and precision results by comparing to an acceptance range, say for laboratory control samples, since this may give a skewed and misleading picture of method capability. Consider, for example, that if a QC acceptance range for LCS states that measured results much fall within 25% of the true value, and a relative bias of -24% is measured, nearly half of all results will fall outside the acceptable range. If the calculated bias falls within the specified range, it will be acceptable. These criteria are most commonly found in the industry and stringent for the method validation.

C) Measurement Uncertainty:

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Similar to above, there are different ways that one could demonstrate that the experimentally observed standard deviation (σ) is not statistically greater than the maximum combined uncertainty of the measurement results. The simplest test is compare the largest uncertainty value for a group of 7 validation samples at a given concentration to the standard deviation of those values. If the largest value is greater than the standard deviation, , the criterion is met.

D) Selectivity:

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Selectivity refers to the degree to which the method can quantify the target analyte in the presence of other analytes, matrices, or other potentially interfering materials. For the gross alpha technique being a screening technique, the selectivity is achieved by the radiochemical separation that isolates the analytes of interest in the medium. Additionally, when counting samples with a gas flow proprotional counter (that is capable of distinguishing alpha emsision and beta emissions on the basis of the energy deposition in the sensitive volume of the detector), the selecivity is enhanced substantially. And, the cross talk correction by the counting system further enhances selectivity of the method. Therefore, the selectivity of the method is adequate and acceptable.

Attachment 4:

Selectivity

A definition for selectivity can be found in the TNI Standard V1M2, Quality Systems. Laboratories are required to evaluate selectivity of a method per, TNI Standard V1M6 1.5.5. It is important, therefore, to put into proper perspective and describe various aspects of selectivity to meet the selectivity requirements.

In broad terms, selectivity refers to the ability of an analytical method to identify and quantify a specific analyte in the presence of other potential interfering analytes or components that behave similarly as analyte, during an analysis.
(Note: Selectivity is the accepted terminology that used to be understood as 'specificity' of a test method in the past. Both these terms may have been used interchangeably).

Very often, the matrix plays a significant part in the evaluation of selectivity of given a method. For this reason, quality control samples such as matrix blanks, matrix spikes and matrix duplicates are included in a sample batch for quantitative evaluation of selectivity. If there are no significant interferences from the matrix, the QC data will look good. As an example, a near 100 % recovery of the matrix spike and better than 10% RPD for duplicates ~~are~~ generally indicates the absence of matrix interferences.

Example 1: The example below is for illustration purpose only. The example shows two matrices, one, a relatively 'clean' matrix and one, not so 'clean', side by side to 'drive home' the point.

The laboratory analyzed one drinking water sample and one ground water sample in a batch for a customer. Following is a summary of the results.

	Drinking water	*Ground water*
Analyte of interest	*Ra-226*	*Ra-226*
Method Used	*EPA 903.0*	*EPA 903.0*
Method Blank	*-0.11 pCi/L*	*0.00 pCi/L*
LCS Recovery	*95%*	*93%*
Matrix Spike	*94%*	*66%*
Sample Duplicate, RPD	*8%*	*22%*
Sample Result	*1.5 pCi/L*	*2.8 pCi/L*

As can be seen from the data of the above, ground water sample exhibits matrix effects in the analysis of Ra-226.

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