

Original Text	Suggested Change	Justification
<p>1.7.1.5.c.ii.e - The subtraction background measurement shall be accomplished in one of the following ways: e. Solid-state scintillation detectors (e.g., zinc sulfide) used for non-spectrometric measurements: Day of use.</p>	<p>Possibly change "Day of use." to "Before each use"</p>	<p>This could result in long counts (e.g. 24 hours) for which a background could not be counted the same day as the sample and therefore might not technically meet the requirement.</p>
<p>1.6.2.2.b - Where gamma-ray spectrometry is used to identify and quantify more than one analyte, <u>the Test Sample shall contain gamma-emitting radionuclides that represent the low (e.g., 241Am), medium (e.g., 137Cs), and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra.</u> As indicated by these examples, the nuclides need not exactly bracket the calibrated energy range or the range over which nuclides are identified and quantified.</p>	<p>"the Test Sample shall contain gamma-emitting radionuclides that, at a minimum, represent the low (e.g., 241Am) and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra. Commonly a medium energy radionuclide is also included in the LCS (e.g., 137Cs)."</p>	<p>To be consistent with 1.7.2.3.e.iii - the LCS shall contain gamma-emitting radionuclides that, at a minimum, represent the low (e.g., 241Am) and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra. Commonly a medium energy radionuclide is also included in the LCS (e.g., 137Cs). As indicated by these examples, the nuclides need not exactly bracket the calibration energy range or the range over which radionuclides are identified and quantified.</p> <p>This would also be consistent with ANSI N42-14 (above the knee and below the knee).</p>
<p>Section 1.7.1.4.a.iii - The laboratory shall prepare, handle, seal and/or encapsulate check sources to prevent damage, loss of activity and contamination.</p>	<p>The Committee should evaluate the concern, and if determined to be needed develop a requirement in regard to a compromised check source.</p>	<p>No guidance is provided as to what to do if the instrument performance check source is compromised. ANSI N42.23 seems to state that if the instrument performance check is compromised, the detector "shall" be recalibrated.</p>

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<p>Page 3 - definition - Uncertainty, Counting: The component of Measurement Uncertainty attributable to the random nature of radioactive decay and radiation counting <u>(often estimated as the square root of observed counts)</u> (MARLAP3). Older references sometimes refer to this parameter as Error, Counting Error or Count Error (c.f., Total Uncertainty).</p>	<p>"(often estimated as Standard Uncertainty by means of the square root)"</p>	<p>Clarification, and to refer to other defined term (Standard Uncertainty).</p>
<p>1.5.2.1 - Minimal Detectable Activity (MDA)</p>	<p>"Minimum Detectable Activity (MDA)"</p>	<p>"Minimal" to "Minimum" as correction and for consistency</p>
<p>1.5.4.c - section is out of alignment</p>	<p>Fix formatting</p>	<p>Consistency and readability</p>
<p>1.5.4.c.ii - A comparison of the experimentally-observed precision evaluation need not be performed for measurements that are required to be reported only with Counting Uncertainty per Section 1.5.4 a) ii).</p>	<p>Add something like "except as required by program/project specific requirements or regulations". Use language similar as in other places this type of language is used.</p>	<p>New EPA procedure in EPA 815-B-17-003 requires a chi-square test at DL, which is a kind of precision evaluation.</p>
<p>1.5.5.b</p>	<p>Fix Formatting</p>	<p>Font is too big- need consistency.</p>

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<p>1.6.3.2.c - At least four (4) consecutive spiked samples (e.g., batch laboratory control samples) each with levels of precision and accuracy consistent with those specified in the method scope; and four (4) consecutive blank samples, each with activity consistent method performance specified in the method scope (e.g., generally activity less than Critical Value). The laboratory shall tabulate or be able to readily retrieve four (4) consecutive passing Laboratory Control Samples (LCS) and four (4) consecutive blank samples for each method for each analyst each year. The laboratory shall specify acceptable limits for precision and accuracy prior to analysis.</p>	<p>"...each containing activity consistent with method..."</p>	<p>clarification/wording</p>
<p>1.7.1.7 - The laboratory shall have written procedures that address cases where radiation detectors have been contaminated, as determined by the subtraction background measurements, short-term background checks, or method blanks (Section 1.7.2.3). Detectors may not be brought back into service until corrective actions are completed.</p>	<p>"Section 1.7.2.2"</p>	<p>Typo/mis-reference</p>

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<p>1.+B15:D157.2.3.d - The laboratory shall spike the LCS at a level such that the uncertainty of the analytical result is less than one-third (1/3) of the acceptance criteria. For example, if it is required that the LCS result be within +/- 30% of the known value, the laboratory shall spike the LCS at a level such that the uncertainty of the analytical result is less than or equal to 10%. When practical, the LCS should be spiked at a level comparable to the action level if known; or that of routine samples if the activities are expected to exceed ten (10) times the Decision Level (Critical Value).</p>	<p>"When practical, the LCS should be spiked at a level comparable to the action level if known; or at approximately ten (10) times the MDA; or that of routine samples if the activities are expected to exceed ten (10) times the MDA."</p>	<p>Concern is that this may not give enough direction at what level to spike when activity is below 10x the Decision Level and that the decision level (critical value) isn't really a well-defined measurable quantity. As we ordinarily define and use it, it's just a statistic that can vary with each measurement. The MDC is the a priori concept, whose value we can estimate. Also, TNI 2009 uses a value of "at least 10 times the MDA". Other guidance (e.g. QSM) uses 5-20x the MDA.</p>
<p>1.7.2.3.e - When available, the standard used to prepare the LCS shall meet the requirements for reference standards provided in Section 1.7.2.6.c. The final prepared LCS need not be traceable to a national standard organization.The LCS shall include all of the radionuclide(s) being determined with the following exceptions:</p>	<p>"The final prepared LCS needs to have the activity and its uncertainty known; however, it need not be strictly traceable to a national standard organization."</p>	<p>While requirements for standards/documentation are outlined elsewhere, this may provide clarity and avoid confusion.</p>

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<p>1.7.2.4.a.iii - The radionuclides spiked shall be as specified by the mandated method, regulation or as determined as part of the contract review process. At minimum, they will be consistent with those specified for the LCS in Sections <u>1.7.2.3.e and 1.7.2.3.f.</u></p>	<p>"1.7.2.3.d and 1.7.2.3.e"</p>	<p>Correction necessary - reference to incorrect section(s).</p>
<p>1.7.2.4.a.viii - When available, the standard used to prepare the MS shall meet the requirements for reference standard provided in Section 1.7.2.6.c. The final prepared MS need not be traceable to a national standards organization.</p>	<p>"The final prepared MS needs to have the activity and its uncertainty known; however, it need not be strictly traceable to a national standard organization."</p>	<p>While requirements for standards/documentation are outlined elsewhere, this may provide clarity and avoid confusion.</p>
<p>1.5.1.c - The laboratory shall perform validation for each method for which documented data are not available to demonstrate that the above requirements are met. For reference methods, published data, if available, may be used to satisfy these requirements.</p>	<p>To the end, add the sentence: "For existing methods, QC data produced at the laboratory may be used to comply with validation requirements."</p>	<p>Allows the laboratory to apply ongoing QC results to methods that have previously existed at the laboratory and may not have had an specific validation performed.</p>

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<p>1.7.1.2.a.ii, iii, and iv -</p> <p>ii. after a repair when subsequent performance checks indicate a change in performance;</p> <p>iii. after modification of system parameters that affect instrument response;</p> <p>iv. when instrument performance checks exceed predetermined acceptance criteria (i.e., limit of a statistical or tolerance control chart or other QC parameters) indicating a change in instrument response since the initial calibration;</p>	<p>"after a repair, modification of system parameters, or other event (possibly unknown) when subsequent performance checks exceed predetermined acceptance criteria (i.e., limit of a statistical or tolerance control chart or other QC parameters) indicating a change in performance since the initial calibration."</p>	<p>All state essentially the same thing - combine into a single point.</p>
<p>1.7.2.2.b.i The laboratory shall prepare the MB using materials that are free of analytes of interest at levels that will interfere with the evaluation of the results. If an analyte-free matrix is not available, the laboratory shall use a surrogate matrix to simulate the quality system matrix.</p>	<p>Add sentence to end of this section something like: "For a RMB, the MB should be handled along with other samples during sample management (e.g. aliquotting, handling/transporting) when there is significant potential for contamination."</p>	<p>While 1.7.2.2 requires analysis of MB for a radiation measurement batch (RMB), it does not describe how this MB would be handled for the RMB.</p>

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1.7.1.2.e - no text related to this (new inclusion)	Insert as section 1.7.1.2.e.ii - "Except in technically justifiable instances (e.g. prepared standard is dropped, physically marred, inconsistent distribution on the planchet, etc), it is NOT acceptable to remove points from a calibration curve to meet established criteria. There must be some demonstrable reason to remove a point, and such removal must be approved by a Supervisor or Technical Manager and documented."	Section 1.7.1.2 does not address potential for deleting/not using individual points from calibration curves.
1.7.3.4 - no text related to this (new inclusion)	Insert as section 1.7.3.4.d - "Sample-specific QC requirements (e.g. FWHM, centroid (energy), quench value or mass within calibration range, etc) shall be defined in the laboratory SOPs and/or client requirements and evaluated to ensure that samples meet method quality objectives (MQOs).	Section 1.7.3.4 does not address sample-specific QC requirements (e.g. FWHM, quench, mass within range, etc)

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Section 1.7.2.6.c - all	The Committee should evaluate the concern, and if determined to be needed provide updated language in relation to requirements for standards.	<p>Consider updating requirements for standards. ISO requirements for standards are vague and make no distinction in requirements for reference materials used for calibration and QC/PT standards. One might consider uncertainty as a criterion although how does one evaluate the uncertainty of the material.</p> <p>Right now, ISO providers are not required to intercompare . One might say that study performance will show problems (i.e., compare grand mean to true values) but that is putting the cart is before the horse. Round robin/consensus studies with labs of untested capability provide little in the way of confidence. Many people feel that the approach in ANSI N42.22, which requires providers to participate in a Measurements Assurance Program (MAP) where the RM provider intercompares with an NMI, is the minimum that should be requires for calibration. Is this possibly a Module 2 issue?</p>
Whole document	The Committee should evaluate the concern, and if determined to be needed provide updated language in the introduction section and move any requirments into numbered sections.	The original intent to the introductory language in each section was to frame the requirements that follow - not to establish requirements. The original intent was to number all requirements to facilitate writing findings. Review all sections. Add any clarifying language needed to intro and move requirements to numbered sections.

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Section 1.6	The Committee should evaluate section 1.6 in relation to Module 2 and consider removing items already contained in Module 2. While not critical, a conflict between Module 2 and Module 6 might be avoided if one or the other were to change.	Consider removing DOC requirements that are already addressed in Module 2. Include only the differences specific to radchem.
Section 1.7.1.3	The Committee should evaluate the definition of "independent source" in Section 1.7.1.3 and consider if this is more appropriate for Module 2 (e.g. V1M2 1.7.1.1.n.) Something to the effect of the following might be used: "All initial calibrations are verified with a standard obtained from a second source and traceable to a national standard, when available (or vendor certified different lot if a second source is not available). For unique situations where no other source or lot is available, a standard made by a different analyst at a different time or a different preparation would be considered a second source. This verification occurs immediately after the calibration curve has been analyzed, and before the analysis of any samples."	Define independent source – what if there is only one source - can procure two sources and handle differently?