**Module 6 Standard Update - Summary of Suggested Changes - Final (10/1/21)**

|  | **Original Text** | **Suggested Change** | **Justification** | **Comments** |
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| 1 | Page 3 - definition - Uncertainty, Counting: The component of Measurement Uncertainty attributable to the random nature of radioactive decay and radiation counting **(often estimated as the square root of observed counts)** (MARLAP3). Older references sometimes refer to this parameter as Error, Counting Error or Count Error (c.f., Total Uncertainty). | Add "Standard Uncertainty by means of" such that we have: "(often estimated as Standard Uncertainty by means of the square root of observed counts)" | Clarification, and to refer to other defined term (Standard Uncertainty). |  |
| 2 | 1.5.1.c - The laboratory shall perform validation for each method for which documented data are not available to demonstrate that the above requirements are met. For reference methods, published data, if available, may be used to satisfy these requirements. | To the end, add the sentence: "For existing methods, QC data produced at the laboratory may be used to comply with validation requirments." | Allows the laboratory to apply ongoing QC results to methods that have previosly existed at the laboratory and my not have had an specific validation performed. |  |
| 3 | 1.5.2.1 - Minimal Detectable Activity (MDA) | "Minimum Detectable Activity (MDA)" | "Minimal" to "Minimum" as correction and for consistency |  |
| 4 | 1.5.4.c - section is out of alignment | Fix formatting | Consistency and readability |  |
| 5 | 1.5.4.c.ii - A comparison of the experimentally-observed precision evaluation need not be performed for measurements that are required to be reported only with Counting Uncertainty per Section 1.5.4 a) ii). | Add to the end of the sentence: “except as required by program/project specific requirements or regulations”. | New EPA procedure in EPA 815-B-17-003 requires a chi-square test at DL, which is a kind of precision evaluation.  Use language similar as in other places this type of language is used. |  |
| 6 | 1.5.5.b | Fix Formatting | Font is too large - consistency. |  |
| 7 | 1.6.2.2.b - Where gamma-ray spectrometry is used to identify and quantify more than one analyte, **the Test Sample shall contain gamma-emitting radionuclides that represent th10e low (e.g., 241Am), medium (e.g., 137Cs), and high (e.g., 60Co) energy range of the analyzed gamma-ray spectra.** 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. | Edit the text as follows: "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." | To be consinstent 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.   This would also be consistent with ANSI N42-14 (above the knee and below the knee).   Not necessary to state what is not required. |  |
| 8 | 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. | Edit **bold text** to state: "…each containing activity consistent with method…" | clarification/wording |  |
| 9 | 1.7.1.2.a.ii, iii, and iv -  ii. after a repair when subsequent performance checks indicate a change in performance;   iii. after modification of system parameters that affect instrument response;  iv. when instrument performance checks exceed predetermined acceptance criteria (i.e., limit of a statistical or tolerance control chart or other QC parameters) indicating a change in instrument response since the initial calibration; | Combine ii, iii and iv into: "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." | All state essentially the same thing - combine into a single point. |  |
| 10 | 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 demonstratable reason to remove a point, and such removal must be approved by the Technical Manager or designee and documented." | Section 1.7.1.2 does not address potential for deleting/not using individual points from calibration curves.  In 1.7.1.2.e.ii - suggest to have approval be by Technical Manager or designee instead of 'or Supervisor' to cover all bases when supervisor not there |  |
| 11 | Section 1.7.1.3.a | Insert the following into section a):  "(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." | The Standard needs to describe what to do if an independent (second) source cannot be procured. This is not uncommon in Radiochemistry.  Note that the REC evaluated the definition of "independent source" in Section 1.7.1.3 and considered whether it is more appropriate for Module 2 (e.g. V1M2 1.7.1.1.n.) The REC communicated with the Quality Systems Committee, who suggested it should be placed in Module 6. |  |
| 12 | 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. | Add the following (to become 1.7.1.4.a.iii.a): a. If the instrument performance check source becomes compromised (e.g. dropped and becomes damaged), in lieu of performing a new initial calibration the laboratory may confirm that the check source was actually compromised and document the investigation showing this. The current calibration must then be verified using an independent standard (e.g. Calibration Verification). If the veracity of the calibration is substantiated, the laboratory may employ a new check source with newly generated limits. | 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 compromosed, the detector "shall" be recalibrated.  Use concept of verifying the current calibration with a LCS or other independent standard. Verify that the check source was actually compromised and document the investigation showing this. Employ a new check source with newly generated limits. |  |
| 13 | 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. | Change "Day of use." to "Prior to use." | "Day of use" 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. |  |
| 14 | 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. | Edit **bold text** to state: "Section 1.7.2.2" | Typo/mis-reference |  |
| 15 | 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. | Add sentence to end of this section: "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." | 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. |  |
| 16 | 1.7.2.3.d - The laboratory shall spike the LCS at a level such that the uncertainty of the analytical result is less than one-third (1/3) of the acceptance criteria. For example, if it is required that the LCS result be within +/- 30% of the known value, the laboratory shall spike the LCS at a level such that the uncertainty of the analytical result is less than or equal to 10%. **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).** | Edit **bold text** to state: "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." | 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. |  |
| 17 | 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: | Edit **bold text** to state: "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." | While requirements for standards/documentation are outlined elsewhere, this may provide clarity and avoid confusion. |  |
| 18 | 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 **1.7.2.3.e and 1.7.2.3.f.** | Edit **bold text** to state: "1.7.2.3.d and 1.7.2.3.e" | Correction necessary - reference to incorrect section(s). |  |
| 19 | 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.** | Edit **bold text** to state: "The final prepared MS needs to have the activity and its uncertainty known; however, it need not be strictly traceable to a national standard organization." | While requirements for standards/documentation are outlined elsewhere, this may provide clarity and avoid confusion. |  |
| 20 | Section 1.7.2.6.c - sections i. - iv. | Sections i. - ii. replaced with the following:  i. Radionuclide standards shall be fit for purpose; they shall be of appropriate chemical and physical form and stability, and be traceable to an NMI, with levels of uncertainty, purity that exceed those required to meet measurement quality objectives.  ii. Reference standards used for instrument calibration shall be obtained from a national metrology institute (NMI), e.g. NIST in the USA or NPL in Great Britain, or from suppliers of NMI reference standards. Alternatively, reference standards may be obtained from reference material providers that conform to ANSI N42.227 or other standards or programs that require intercomparison with an NMI similar to that specified in ANSI N42.22. iii. Reference materials used for quality control purposes may be obtained from providers described in 1.7.2.6 c) i. above or from providers that are accredited to ISO Guides 17034:20166 or 17043:20105. iv. Reference standards shall be accompanied with a certificate of calibration that meets the requirements of either ISO Guide 31:2000 , or ANSI N42.227, Section 8, Certificates, and shall include at least the following information: manufacturer, radionuclides calibrated, identification number, calibration method, activities or emission rates with associated uncertainties and the confidence limits, standard quantity, activity reference time (date or time as appropriate to the half-life of the 21radionuclide), physical and/or chemical description of the source, and radionuclide impurities. | ISO requirements for standards are vague and make no distinction in requirements for reference materials used for calibration and QC/PT standards. Standards used for calibrations need to meet a higher standard than reference materials for QC purposes. Need to delineate this. |  |
| 21 | 1.7.3.4 - no text related to this (new inclusion) | Insert as section 1.7.3.4.d - "Sample-specific QC requirements (e.g. FWHM, centroid (energy), quench value or mass within calibration range, etc) shall be defined in the laboratory SOPs and/or client requirements and evaluated to ensure that samples meet method quality objectives (MQOs). | Section 1.7.3.4 does not address sample-specific QC requirements (e.g. FWHM, quench, mass within range, etc) |  |
| 22 | Whole document | Create "a)" in sections 1.5.3, 1.7.1, 1.7.2.4 for language that is not introductory, but rather a requirement. | 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. Clarifying language needed was added to intro and moved requirements to numbered sections. |  |
| 23 | Whole document | Several references updated: "ISO Guide 170433:2010" updated to "ISO/IEC 17043:2010" "ISO Guide 34:2009(E)" updated to "ISO 17034:2016" "ISO Guide 31:2000" updated to "ISO Guide 31:2015" | References updated to ensure they point to current revisions and/or reference numbers/titles. |  |
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