| 4        | V1M6<br>Section<br>Number(s)<br>for | Vada                     | Value O amount  | Biomarition                   | Oleman (December)  |
|----------|-------------------------------------|--------------------------|---|-------------------------------|--|
| 1        | 1.3.1                               | Vote<br>Affirmative      | Web link is incomplete:   | <b>Disposition</b> Persuasive | Change/Reasoning Make editorial change as requested.   |
| <u>'</u> | 1.5.1                               | with comment             | http://www.epa.gov/radiation/marlap/manual.html   | rersuasive                    | wake editorial charige as requested.   |
| 2        | 1.3.1                               | Affirmative with comment | Editorial: Several terms are included that are never used in the document. Consider deleting areic, massic, and volumic activity.   | Withdrawn                     | Robert Shannon withdrew comment 5/27/2015 on monthly teleconference.   |
| 3        | 1.3.1                               | Affirmative with comment | The definition for "Critical Value" (sic) includes a timeframe specification of 14 days in the last sentence. It is not clear whether it is meant as 14 business days or calendar days.  Recommended language for last sentence, after change:  "The maximum time between the start of processing of the first and last sample in an RMB is fourteen (14) calendar days."                                 | Persuasive                    | Make clarifying change to definition of the RMB as requested. This has also been passed to the Quality Systems Expert Committee which is considering the issue of calendar vs. business days for the quality systems module. |
| 4        | 1.3.2                               | Affirmative with comment | unneeded comma after Phosphorimetry)  | Persuasive                    | Make editorial change as requested   |
| 5        | 1.3.2                               | Affirmative with comment | The phrase of "corresponding sections of Module 4" is confusing and may not match the specific section numbers in Module 6. One interpretation of this anomaly could be to dismiss the requirements entirely.  Recommended language in second sentence, after change:  "The laboratory shall comply with the requirements of Module 4 in cases where technique-specific QA/QC is not defined in Module 6" | Persuasive                    | Make clarifying change as suggested.   |

| 6  | 1.3.2       | Affirmative with comment | There is a mismatch of pronouns and their antecedents in the last sentence of this clause.  Recommended corrections in the last sentence:  "The laboratory shall identify in its quality system how and when it is complying with the requirements and elements of Module 4 and Module 6, as applicable."   | Persuasive                  | Make editorial change as suggested.   |
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| 7  | 1.5.1 (c)   | Affirmative with comment | Editorial: "for whichis" should read "for whichare"   | Persuasive                  | Make editorial change as suggested.   |
| 8  | 1.5.1 (g)   | Affirmative with comment | Affirmative with comment: This section is meant to address initial validation. The language may be misinterpreted to mean that PTs should be analyzed more frequently than during the one-time validation of the method "analyze PTs whenever available" and "evaluate on an ongoing basis". This could be addressed by removing "whenever available" and "on an ongoing basis" | Persuasive  Non- persuasive | The phrase "on an ongoing basis" will be removed to ensure that the intent of the requirement to use PT materials during the initial demonstration of capability is not misinterpreted. This has no impact on the separate TNI requirement for the laboratory to perform ongoing PTs as a condition of maintaining accreditation for a specified test.  The phrase "leave as available" was intended to address the situation where external PT materials are not available and does not imply anything about the frequency of PTs. No change will be made to this. |
| 9  | 1.5.1 (g)   | Affirmative with comment | suggest changing source to ANSI since N42.22 is an ANSI Standard  | Non-<br>persuasive          | Stating ANSI is somewhat redundant. Since leaving this only underscores the source of the standard, there is no risk in leaving the reference to ANSI and no change will be made.   |
| 10 | 1.5.2.1 (c) | Affirmative with comment | eliminate all commas in the sentence none are needed  | Persuasive                  | Make editorial change as suggested.   |
| 11 | 1.5.3 (c)   | Affirmative with comment | eliminate comma   | Persuasive                  | Make editorial change as suggested.   |

| 12 | 1.5.4 (c)   | Affirmative with comment | , , ,   | Non-<br>persuasive | This is not a new requirement, rather it was contained in the 2012 standard. The process is intended to validate the calculated uncertainty reported with each result by comparing it to the standard deviation estimated during validation measurements. As the uncertainty is a key part of each result, demonstrating that the uncertainty calculated with each result reasonably reflects that obtained by actual measurement provides information that is crucial to the DOC. No change will be made. |
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| 13 | 1.6.2.2     | Affirmative with comment | This is an editorial suggestion with revised text.  It is the responsibility of the laboratory to document other approaches to initial DOC, if any, available and acceptable.   | Non-<br>persuasive | The requirement as currently written is clear and unambiguous. The intention of the proposed language would be to allow the laboratory to use alternate approaches to DOCs as long as these are adequately documented - which is exactly what the existing language would do. Since there would be no improvement, and since the language provided is somewhat ambiguous, no change will be made.  |
| 14 | 1.6.2.2 (a) | Affirmative with comment | suggestion to include new text as follows. Prepare four (4) Test Samples consistent with Section 1.7.2.3. The analyst shall also prepare four (4) blank samples of clean quality system matrix in which no target analytes or interferences are present at activities that will impact the results of a specific method. Samples need not be counted on different dates. However, if there are multiple instruments, the samples shall be distributed across the instruments. | Place on hold      | The current requirement is clear and adequate as written. The idea that multiple instruments be used if available is good but would introduce a concept that would need public review. Since the comment would change the proposed text to the point that the Committee would have to restudy the text of the standard, the topic will be put on hold for consideration in the next version of the standard.   |

| 15 | 1.6.2.2 (d)                 | Affirmative with comment | The intent of this statement is to calculate the mean recovery of the spike and the mean of the blank. Insert "mean of the" between "the" and "blank. "Using all of the results, calculate the mean recovery of the spiked samples and the 'mean of the' blank results"   | Persuasive         | Make editorial change as suggested.   |
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| 16 | 1.6.3.1                     | Affirmative with comment | suggestion for minor text revision It is the responsibility of the laboratory to document other approaches for ongoing DOC, if any available and acceptable.  | Non-<br>persuasive | The requirement as currently written is clear and unambiguous. The intention of the proposed language would be to allow the laboratory to use alternate approaches to DOCs as long as these are adequately documented - which is exactly what the existing language would do. Since there would be no improvement, and since the language provided is somewhat ambiguous, no change will be made. |
| 17 | 1.6.3.2 (a)                 | Affirmative with comment | new text added.  Acceptable performance of blank(s) and sample(s) that have known, accepted values, single blind to the analyst; Replace with  a) Acceptable performance of blank(s) and sample(s) that have known, accepted values, single blind to the analyst, including Proficiency Testing Sample(s) from an approved PT Provider. | Non-<br>persuasive | PT samples are by definition samples that have known, accepted values. Since this concept is already allowed under the current language, there is no need or benefit to making a change here.   |
| 18 | 1.7.1.1 (a)                 | Affirmative with comment | Editorial: set-up should not have a hyphen.   | Persuasive         | Make editorial change as suggested.   |
|    | 1.7.1.2 (b) (v)<br>and (vi) | with<br>comment          | Editorial: the final sentence in v) is redundant with vi) and should be deleted.  | Persuasive         | Make editorial change as suggested.   |
|    |                             | with<br>comment          | The statement "quench-crosstalk calibration of liquid scintillation detectors" is in both "v" and "vi" of Section 1.7.1.2 b). This appears to be redundant and unnecessary. We need to pick one location.   | Persuasive         | Make editorial change as suggested.   |
| 21 | 1.7.1.3 (a) (i)             | Affirmative with comment | Insert the word "of" between "set " and "calibration". "performing a second set of calibration measurements to be compared to the initial calibration;"   | Persuasive         | Make editorial change as suggested.   |

| 22 | 1.7.1.4 (b) (i)  | Affirmative with comment | Replace text, Detection efficiency, energy calibration, and peak resolution, with  The activity of the radionuclides present in the calibration standard, the detection efficiency, energy calibration and photo peak resolution (full width at half maximum).   | Place on hold | The current requirement is clear as written. The proposed "activity check" is another name for "efficiency checks". While there may be merit to finding a more universal description for this term, it will involve making numerous changes to text throughout this section that would need public review. Since the comment would change the proposed text to the point that the Committee would have to restudy the text of the standard; the topic will be put on hold for consideration in the next version of the standard. |
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| 23 | 1.7.1.4 (c) (ii) | Affirmative with comment | The sentence in this section includes a timeframe specification of 7 days. It is not clear whether it is meant as 7 business days or calendar days.  Recommended language, after change:  " as long as the period between the checks does not exceed seven (7) calendar days, and checks are done"   | Persuasive    | Similar to comment on 1.3.1 above, will make clarifying change as requested. This also has been passed to the Quality Systems Expert Committee which is considering the issue of calendar vs. business days for the quality systems module.  |
| 24 | 1.7.1.5          | Affirmative with comment | Subtraction Background Measurements Replace 'lost data' with unacceptable data because there is no lost data. The note currently reads,  Note: The frequency of subtraction background measurements may be increased from the above requirements when there is a low tolerance for lost data due to failure of a subtraction background measurement.  Replace with:  Note: The frequency of subtraction background measurements may be increased from the above requirements when there is a low tolerance for unacceptable data due to failure of a subtraction background measurement. | Persuasive    | Make editorial change as suggested.  |

|    |                  | Affirmative with comment | The language here could possibly lead to misinterpretation: "shall be specific to each detector and method" does not preclude using one subtraction background for multiple methods as long as the subtraction background adequately reflects the background count rate of samples being counted as evidenced by evaluation of method blank control charts. Would adding a note help here?  The note under ii) could be moved to after iii) |                    | The intent was to ensure that the background used appropriately reflected that of the source being counted as opposed to preventing one subtraction background that reflects the background for multiple methods from being used for more than one method. Make editorial change to clarify as follows: "a) The subtraction background shall be specific to each detector and appropriate to the method." |
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| 26 | 1.7.1.5 (c) (ii) | with comment             | The minimum frequency for proportional counter backgrounds seems too low.   | Non-<br>persuasive | Keith McCroan was on the call and mentioned that he did not expect any change to be made.  No change will be made.  |
| 27 | 1.7.1.6          | Affirmative with comment | Editorial: Change "electronics noise, as well as monitor each detector for" to "electronics noise, and to monitor each detector for"  Note after a)i) – Editorial: Change: "sample, or at predetermined frequency." To "sample, or at a predetermined frequency."   | Persuasive         | Persuasive, non-controversial - Make editorial change as requested  |
| 28 | 1.7.1.6 (a)      | Affirmative with comment | Replace lost data with unacceptable data in the 'note' of this section.   | Persuasive         | Make editorial change as suggested.   |
|    | 1.7.1.6 (b) (ii) | with<br>comment          | specification of 7 days. It is not clear whether it is meant as 7 business days or calendar days.  Recommended language, after change:  " as long as the period between the checks does not exceed seven (7) calendar days, and checks are done"  | Persuasive         | Similar to comment on 1.3.1 above, will make clarifying change as requested. This also has been passed to the Quality Systems Expert Committee which is considering the issue of calendar vs. business days for the quality systems module.   |
|    | ,                | Affirmative with comment | sentence: "If it is not apparent which Standard is more stringent". This would be improved by deleting the word "Standard", or replacing it with the word "requirement"   | Persuasive         | Make editorial change as suggested.   |
| 31 | 1.7.2.1 (c)      | Affirmative with comment | Editorial: remove comma after "performed,"  | Persuasive         | Make editorial change as suggested.   |

| 32 | 1.7.2.1 (c) (iii)      | Affirmative with comment | The sentence in this section includes a timeframe specification of 14 days. It is not clear whether it is meant as 14 business days or calendar days.  Recommended language, after change:  "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" | Persuasive | Similar to comment on 1.3.1 above, will make clarifying change as requested. This also has been passed to the Quality Systems Expert Committee which is considering the issue of calendar vs. business days for the quality systems module.  |
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| 33 | 1.7.2.1 (g)<br>and (i) | Affirmative with comment | Editorial: would it make sense to move i) to before g)?  | Persuasive | Make editorial change as suggested.  |
| 34 | 1.7.2.3 (b) (i)        | Affirmative with comment | Editorial: hyphenate "analyte-free"  | Persuasive | Make editorial change as suggested.  |
|    | 1.7.2.3 (d)            | Affirmative with comment | A comma needs to be added in the second sentence for clarity.  Recommended language in the second sentence, after change is made:  "For example, if it is required that the LCS"   |            | Make editorial change as suggested.  |
| 36 | 1.7.2.4 (c) (iii)      | Affirmative with comment | Clarify sentence. "The chemical yield (Tracer or Carrier) does not make sense. The tracer or carrier are used to monitor the chemical yield. The chemical yield is not something that is added. Suggested wording – The Tracer or Carrier shall be added   | Persuasive | This sentence is awkward. Although the terms chemical yield tracer and chemical yield carrier are commonly used, the parentheses make this confusing. The sentence will be rewritten to ensure clarity: "iii) The Tracer or Carrier used to monitor chemical yield shall be added to the sample prior to performing any processes that affect the analyte of interest (e.g., chemical digestion, dissolution, ashing, separation, etc.) unless otherwise specified by the method." |

| 37 | 1.7.2.4 (c) (iii) | Affirmative with comment | Insert the word "indicator" or "monitor" after "yield". Alternately delete the parenthesis "The chemical yield (Tracer or Carrier) 'indicator' shall be added to the sample" or "The chemical yield Tracer or Carrier shall be added to the sample"                                | Persuasive | This sentence is awkward. Although the terms chemical yield tracer and chemical yield carrier are commonly used, the parentheses make this confusing. The sentence will be rewritten to ensure clarity: "iii) The Tracer or Carrier used to monitor chemical yield shall be added to the sample prior to performing any processes that   |
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|    |                   |                          |  |            | affect the analyte of interest (e.g., chemical digestion, dissolution, ashing, separation, etc.) unless otherwise specified by the method."  |
| 38 | 1.7.2.6 (c) (i)   | Affirmative with comment | What is meant by "an ANSI N42.22 reference material provider? This needs clarification.  | Persuasive | Since ANSI uses the N42.22 defined term "manufacturer" instead of "provider" provider will be changed to manufacturer. Richard Sheibley also pointed out that the term "reference material provider" is used to refer to laboratories being accredited for the ISO standards. These clarifying editorial changes will be made here and in 1.5.1.(g) where the same language is used. |
| 39 | 1.7.2.6 (c) (i)   | Affirmative with comment | I do not believe "National Metrology Institute" needs to be capitalized.   | Persuasive | Make editorial change as suggested.  |
| 40 | 1.7.3.3 (b) (i)   | Affirmative with comment | A comma needs to be added in the sentence for clarity.  Recommended language in the sentence, after change is made:  "For those methods that employ radioactive Tracers or stable Carriers as chemical yield monitors in each sample, results shall be expressed as percent yield" | Persuasive | Make editorial change as suggested.  |