The NELAC Institute (TNI) Quality Systems Expert Committee

Meeting Minutes

The Quality Systems Expert Committee of The NELAC Institute (TNI) met on February 1, 2011 during the Forum in Savannah, Georgia. The agenda is attached as Appendix A, the attendees are listed in Appendix B ("p(t)" means present via teleconference) and the Table of Comments are presented in Appendix C.

Silky Labie welcomed the attendees to the session. She noted that hard copies of the review materials are available, but are controlled due to the inclusion of ISO language. Attendees should return the materials at the end of the session.

Silky reviewed the mission statement for the expert committee and the agenda for the session.

Silky noted that only highlighted language proposed for revision was included in the recent electronic ballot. Comments to other sections will not be considered at this time. She explained a comment was received about not posting the committee voting results for moving the document to the working draft and voting draft stages, and those records have been made available on the TNI site.

Voting to accept the voting draft standard as the TNI standard required the expert committee members to vote electronically, but an insufficient number of votes were returned to pass the proposal. Silky noted this issue will be discussed with the Consensus Standard Development Executive Committee as to the appropriate action. Module by module voting results for the voting draft standards are summarized in the handout.

The expert committee began addressing the comments received on the voting draft standard. The committee will determine whether the comments are persuasive or not.

V1M2 Quality Systems General Requirements Comments

Section 5.4.4

The committee proposal was to put the ISO language for 5.4.4 Non-Standard Methods that was not included in the original TNI standard into the module. The comment raises concern about confusion with methods published in "Standard Methods for the Examination of Water and Wastewater" and the general term "standard methods" as used in the module. It was noted that a glossary term for "reference method" was added. The committee could provide some clarification in the standard with a note at each usage of the term. Similar language already is in section 1.4.

Robin/Eugene motioned to find the comment persuasive. All were in favor of the motion – ruled persuasive.

Sections 5.4.5.2 and 5.4.5.3

Three comments were received (one affirmative and two negative) related to notes being advisory in nature and the potential for inconsistent interpretation. It was proposed that the committee could add the ISO language from the Scope about notes. Stephanie noted that as an AB, her organization cannot enforce non-mandatory language. Paul added that putting in a note about notes creates a circular problem. Mike Miller noted that all the standards have notes, and this could impact across the standard

modules. TNI notes may be different than ISO notes. Paul asked whether notes could be converted to some sort of numbered system, rather than as a note. This was not done originally to preserve the ISO section numbering. Fred added that if the note is important, it should be incorporated, or otherwise deleted. Tamara suggested notes could be moved into an annex for guidance.

Robin/Gil motioned to find the comments persuasive. All were in favor of the motion – ruled persuasive.

Section 5.4.5 (comments to V1M3 section 1.5 Method Validation)
Comments related to the definition for "data integrity":
Data integrity is a process or condition, not a type of data. A term should not be defined by what it's not. The proposed definition was a combination of several existing definitions.

Robin /Stephanie motioned that data integrity comments are persuasive. All were in favor of the motion – ruled persuasive.

Comments on the definition for "parameter":
Comment about "parameter" being used in place of the analyte (substance being measured). "Parameter" is being used to describe conditions of use, not to refer to the analyte. Tamara noted that in general practice, all these terms are used interchangeably. The committee could clarify that it is not the measurement of the analyte of interest. Some ABs may define temperature as an analyte or use parameter as analyte in their LIMS system, so it may be confusing. The committee could use "oven temperature" as a better example than "temperature".

Gene/Robin motioned that comments 1 and 3 together are persuasive. All were in favor of the motion – ruled persuasive.
Gene/Gil motioned Comment 4 as non-persuasive. All were in favor of the motion – ruled non-persuasive.

Comment 5 – This comment brings in the question of method validation. The committee discussed incorporating the definition into the standard and deleting the sentence about validation. The required elements could be added to ViM2 section 5.4.5.4 and leave just the definition part. This will also address the circular reference. The committee will also consider matrix in the language since labs are frequently asked to test methods to matrices for which they were not intended. Matrix should be included when talking about method/analyte combinations.

Robin/Katie motioned to find the reference method comments persuasive. All were in favor of the motion – ruled persuasive.

V1M3 Quality Systems for Asbestos Testing Comments

Section 1.4 Method Selection

Comment 1 - The QC language could be referring to a non-standard method.
Dorothy/Gene motioned to find the comment non-persuasive. All were in favor of the motion – ruled non-persuasive.

Comment2 relating to reference method has been found persuasive by previous discussion. The expert committee will apply that action to all instances of this comment.

Section 1.5 Method Validation
Robin/Gene motioned that the comment is non-persuasive even though the text is potentially redundant. All were in favor of the motion – ruled non-persuasive.

V1M4 Quality Systems for Chemistry Testing

Section 1.3.1 Additional Terms and Definitions

Comment 1 – Definition for “physical parameter”. The comment suggests moving this definition to the Module 2 glossary rather than having it appear in the technical module. There was a question of whether a reference to Standard Methods is needed. The text is not a quote directly from Standard Methods, but the expert committee will confirm what content was used from Standard Methods.

Robin/Gene motioned to find this comment non-persuasive. All were in favor of the motion – ruled non-persuasive.

Comment 2 – this comment suggested the deletion of the term “physical parameter”, since “parameter” has been defined.
Robin/Gil motioned this comment as non-persuasive. All were in favor of the motion – ruled non-persuasive.

Comment 3 – This comment requests clarification that a physical parameter can also be an analyte.
Stephanie/Robin motioned this comment as persuasive. All were in favor of the motion – ruled persuasive.

Section 1.4 Method Selection
Comment 1 – This comment is similar to the previous comment regarding the redundancy of content.
Robin/Gene motioned that comments regarding redundancy for sections 1.4 and 1.5 be considered non-persuasive as previously decided. All were in favor of the motion – ruled non-persuasive.

Comment 2 – This comment may be referring to issues such as the method 624 guidance document on items that can’t be changed in an analytical method. The intent is not to hold the lab to just a reference method. If the lab is using a method being requested by client, they don’t have to be accredited for the method as it is outside the TNI accredited scope. In some states it may be required. The text specifically refers to situations where there is not QC included in the analytical method, and does not limit the use of the analytical method the lab chooses to use.
Tamara/Gene motioned the comment as non-persuasive. All were in favor of the motion – ruled non-persuasive.

Comment 3 was already addressed by previous discussion.

Section 1.5 2.1 Limit of Detection
Comment 1 – Editorial comment, does not need to be voted.

Comment 2 – This comment does not completely refer to text that is up for revision. The first part of the comment is tabled for future consideration. For the second part of the comment, the expert committee notes that the LOQ is set by the lab as the verification of sensitivity. The examples cited are not an exclusive list and does not necessarily include everything that might fall in the category.

Dorothy/Gene motioned to find the comment non-persuasive. All were in favor of the motion – ruled non-persuasive.

Comment 3 – This comment was tabled for future consideration.

Comment 4 – The intent of defining “physical parameter” was to utilize this term in LOD requirements. Part 1 of the comment was found persuasive by a previous vote. Part 2 of the comment is tabled for future discussion.

Section 1.5.2.2. Limit of Quantitation (LOQ)

Comment 1 – Affirmative comment, no action taken.

Comment 2 – For part one, the committee confirmed the intent is correct. For part two, it was suggested to stop the sentence prior to “unless”. Also “residues” are cited in both examples so the committee agreed

to strike “residues” from the second part. The lab needs to determine the LOQ by some means, such as a spiked study, or using test conditions. It was agreed the section needs some additional wordsmithing. Does the wording mean the lab can’t use lowest standard from 5 point curve but must use the spiked sample?

Gene/Gil motioned to consider the comment as persuasive. All were in favor of the motion – ruled persuasive.

Comment 3 – This comment was already discussed and found persuasive by previous motion.

Comment 4 – This comment goes beyond the intent of the proposed changes – tabled for future consideration.

Comment 5 – This comment was already found persuasive by previous discussion.

Comment 6 – The committee considered whether the previous discussion on section 1.5.1.2.e already covers this issue and decided it is a different topic. There is no such thing as an LOQ study. LOQ just has to be greater than LOD. LOQ “study” implies statistics, etc.

Robin/Stephanie motioned to find the comment persuasive. All were in favor of the motion – ruled persuasive.

Comment 7 – This comment was already found persuasive based on previous discussion.

Comment 8 – Part one of this comment suggests get rid of the word “component” in both sections 1.5.2.1 and 1.5.2.2. Part two of the comment suggests using the term “available” versus “feasible”, which the committee believes is a different meaning.

Silky/Gil motioned to find part one of the comment persuasive and part two of the comment non-persuasive. All were in favor of the motion.

Comment 9 – This comment was tabled for future discussion.

V1M5 Quality systems for Microbiological Testing

Section 1.4 Method Selection

Similar comments that have been addressed for prior sections in the other modules.

Section 1.5 Method Validation

Comment 1 identifies a circular reference.
Robin/Stephanie motioned this comment to be found persuasive. All were in favor of the motion – ruled persuasive.

Affirmative comment will be addressed by the committee at a later date.

Comments 2 and 3 were both addressed by previous discussion.

Section 1.6.2.2 Buffered water
Comments 1 and 2 – Committee discussion involved whether this issue is dependent on the types of water used by the laboratory. There is a need to provide options to the lab.

Silky/Robin motioned to find this comment persuasive. All were in favor of the motion – ruled persuasive.

Section 1.7.3.1 Sterility Checks and Method Blanks

Comment 1 – Robin explained the reason for inclusion of this provision is to make sure that what grows is from the test sample, not from a non-sterile piece of equipment or supplies. The lab needs to confirm sterility before use. Roger Kenton suggested that labs have some flexibility to approach how to best do this, and proceed at lab's own risk. Some states require documentation of the sterility check. Media made in house should be tested per sterilization lot.

The Quality Systems session concluded at this point. Further review of comments for persuasiveness will start with this comment and continue with the rest of the modules.

Appendix A

Conference Call Agenda:		
The NELAC Institute Quality Systems Expert Committee		**February 1, 2011 1:30 pm EST** **3.5 Hour** **Face-to Face Meeting**
Old Business:		
Introductions, Announcements and Housekeeping	All	15 minutes
New Business:		
Voting Results on Revisions to V1M2-7	All	1;45 – 2:00
Discussion on Comments (Negative Vote comments addressed first)	all	2:00 – 4:45
Summary, Next Steps		4:45 – 5:00

Appendix B - Participants

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Appendix C – Summary of Comments

Total votes cast: 61

V1M2
Affirmative: 47
Affirmative with Comment: 3
Negative with Comment: 8
Abstain: 3

V1M3
Affirmative: 37
Affirmative with Comment: 1
Negative with Comment: 2
Abstain: 21

V1M4
Affirmative: 44
Affirmative with Comment: 1
Negative with Comment: 12
Abstain: 4

V1M5
Affirmative: 43
Affirmative with Comment: 3
Negative with Comment: 6
Abstain: 9

V1M6
Affirmative: 40
Affirmative with Comment: 0
Negative with Comment: 6
Abstain: 15

V1M7
Affirmative: 41
Affirmative with Comment: 1
Negative with Comment: 3
Abstain: 16

5.4.4 Non-Standard Methods *(ISO/IEC 17025:2005(E), Clause 5.4.4*)

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.

NOTE For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:

a) appropriate identification;

b) scope;

c) description of the type of item to be tested or calibrated;

d) parameters or quantities and ranges to be determined;

e) apparatus and equipment, including technical performance requirements;

f) reference standards and reference materials required;

g) environmental conditions required and any stabilization period needed;

h) description of the procedure, including

- *affixing of identification marks, handling, transporting, storing and preparation of items,*
- *checks to be made before the work is started,*
- *checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,*
- *the method of recording the observations and results,*
- *any safety measures to be observed;*

i) criteria and/or requirements for approval/rejection;

j) data to be recorded and method of analysis and presentation;

k) the uncertainty or the procedure for estimating uncertainty.			
jm	Negative with Comment	5.4.4	5.4.4 Non-Standard Methods 3.1 defines reference method as being the same as the ISO language for standard method. Even though it is defined, it still creates confusion. It would be reasonable to believe that some readers could confuse the term to apply only to the methods published in "Standard Methods for the Examination of Water and Wastewater". Recommendation: In the pure ISO language where the term standard method must be used, can we provide a note on the section that reference and standard method are equal? Or eliminate the term reference method altogethe
	5.4.5.2 *The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.* ***5.4.5.3*** *The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.*		
	Affirmative with Comment	5.4.5.3	In 5.4.5.3, I do not believe the Notes are informative or clear and are likely to set the stage for inconsistency during assessments. Note 1 introduces a new "Statement of Validity". This goes beyond the requirements of 4.1.7.2 and 4.14.2 and is not necessary. Note 2 is not appropriate for a minimum accreditation standard and is an ambiguous requirement prone to inconsistent assessment. Note 3 is unclear: the text of 5.4.5.3 does not include a minumum standard that the note appears to attempt to relax. The lack of clarity is likely to contribute to inconsistent assessments. All three notes should be removed. As a side issue, where in the published standard does it explain whether a note is required or suggested (I thiought they were only suggestions, but I cannot find that in the published standard)?
	Negative with Comment	5.4.5.2, .3	Sections 5.4.5.2 and 5.4.5.3 are written such that consistent interpretation of the Standard would be difficult (too many uses of the words "may" and "should" if this is to be a Standard). I cannot vote for affirmative for something that leads to inconsistent interpretation and subjective assessor applications of the Standard.
jm	Negative with Comment	5.4.5.2	5.4.5.2 Validation instructions. This is vague and gives opportunity for interpretation issues. Note 2 states "…..should be one of, or a combination of the following:" This gives a lot of latitude to those who won't do anything more than the minimum unless it is a requirement.
	5.4.5.4 See section 1.5. of each of the technical modules (Volume 1 modules 3 throught 7) for specific requirements. ~~Except when specified, an initial demonstration of capability (see 1.6 of the technical modules) is adequate to validate reference methods.~~ **V1M3 1.5 Method Validation** Refer to Volume 1 Module 2, Section 5.4.5.		

	Negative with Comment	5.4.5.4	5.4.5.4 the references to Volume 1 modules 3 through 7 are circular as the sections noted refer back to 5.4.5.4.
	Analyte: The substance being measured in an analytical procedure**.** **Data Integrity:** Data that are sound, correct, and complete and accurately reflects activities and requirements. It is achieved by preventing accidental or deliberate but unauthorized insertion, modification or destruction of data. (TNI) **Parameter:** a measurable quantity, e.g. temperature, that determines the result of a scientific experiment and can be altered to vary the result **Reference Method**: A reference method is a method issued by an organization generally recognized as competent to do so. (When ISO refers to a standard method, that term is equivalent to reference method). When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology. Reference Methods do not require validation as outlined in 5.4.5 of this standard, but must follow the applicable technical requirements found in Section 1.5. of Modules 3-7.		
	Affirmative with Comment	Data Integrity	The definition for Data Integrity states: Data Integrity: Data that are sound..... Data Integrity is not Data. Perhaps it would be better to say "A process that results in data that are sound.....
	Negative with Comment	Data Integrity	Sec. 3.1: The definition describes "data" or "data that have integrity". The definition should say: "Data integrity" is "A process that produces data that are sound ...."
mf	Negative with Comment	Data Integrity	Data Integrity: 1) The definition is worded as though “Data Integrity” was a kind of data, whereas the term should actually describe a state or condition. Furthermore, data integrity does not require that data “accurately reflects…requirements.” Data integrity systems exist to ensure that data is handled properly – that when errors occur, they are dealt with in an open, ethical, and effective way. The definition goes on to state how to achieve data integrity. The means to achieve data integrity are provided elsewhere in the Standard, and should not be included, even in abbreviated form, in the definition of the term. Suggest alternate definition: “The condition that exists when data has not been inappropriately, accidentally, or maliciously modified, altered, or destroyed.
	Negative with Comment	Parameter	The definition of parameter is inconsistent with its use throughout the standard. Clarifying language that reflects the interpreation responses provided by the quality systems committee should be included in the standard to eliminate ambiguity.
	Affirmative with	Parameter	Please consider re-defining parameter. The definition of parameter should be "a measurable, chemical or physical, property of a sample or material that is quantifiable and repeatable."

	Comment		
	Negative with Comment	Parameter, Analyte	V1 M2 3.0 Terms and Definitions 3.1 Definitions of Analyte and Parameter – by adding these as separate items and defining them separately, the result to the other volumes is inconsistency. Two widely accepted definitions for analyte are: “A chemical substance that is the subject of a chemical analysis” or “A substance or chemical constituent that is undergoing analysis”. State agencies may or may not recognize both terms (analyte & parameter) in their existing programs. In addition, the term is inconsistent with the one given in V1M4 for Physical Parameter. Recommendation: Remove the reference to parameter or set them equal in a single definition. V1M2 – Analyte and parameter are both used. V1M3 – Analyte and parameter are used interchangeably (Corrected in the draft but switched to the term parameter) V1M4 - Analyte and parameter are used interchangeably (Corrected in the draft but added the term physical parameter) V1M5 – Parameter is used exclusively V1M6 - Analyte and parameter are used interchangeably (Corrected in the draft and kept the term analyte) V1M7 – Analyte and Parameter are both used.
sw	Negative with Comment	Parameter, Analyte,	V1M2 - Comment Although I agree in concept with the use of "parameter"/"analyte"/"organism", defining them here and using them in the modules creates a regulatory issue for us. We accredit laboratories by analyte-matrix-technology combinations. FoPTs are defined using analyte as well. We would not be able to enforce the standard if the committee uses terms other than "analyte" to indicate "the substance measured".
sw	Negative with Comment	Reference method	V1M2 - Comment The definition for reference method also creates an issue. The definition includes a requirement, rather than just defining 'reference method'. The last sentence contradicts instruction provided later in the standard. Do published reference methods require validation or not? The standard seems to say 'no' in the definition and 'yes' in the other modules.
jm	Negative with Comment	Reference method	3.1 Definition of Reference Method The last sentence states: “Reference Methods do not require validation as outlined in 5.4.5 of this standard, but must follow the applicable technical requirements found in Section 1.5. of Modules 3-7.” V1M3, V1M5, V1M6, V1M7 1.5 Supports the statement above, but each one refers back to V1M2 5.4.5, creating a circular reference. V1 M4 Chemical Testing 1.5.1(b) Requires method validation of reference methods Recommendation: 1. Remove the last statement in the definition or clarify the appropriate section in V1M4. 2. Revise the last sentence to clarify: While general validation of reference methods is not required per 5.4.5 of this standard, specific testing modules 3 –7 may list validation requirements in section 1.5, as discussed

			in section 5.4.5.4. The addition of 5.4.5.4 also points the reader to section 1.5 of the technical modules for specific requirements. Additional Comment on the proposed definition: A reference method is a validated method that is promulgated by state or federal regulation or is required/issued by a recognized organization. The addition of analytes to a reference method and modifications to a reference method is covered by sections 5.4.3, 5.4.4 and 5.4.5 of ISO 17025. In the standard, modification of a method through the addition of an analyte contradicts 5.4.5.2 which states that methods used outside their scope or amplifications and modifications to methods require validation
	Negative with Comment	Parameter, Analyte, Reference method	V1M2 - Comment 3.1 Analyte: Delete definition – word is used in this volume as it is commonly defined in readily available dictionaries. Parameter: Delete definition – word is used in this volume as it is commonly defined in readily available dictionaries. Should the definition be retained the following comments are provided: This definition does not include all appropriate definitions for how this term is used in this chapter. For example, operating parameters are included in the instrument section. The appropriate definition for this use would be a limiting factor or a fact or circumstance that restricts how something is done or what can be done. The definition is also not compatible with the definition of Physical Parameter given in V1M4. Reference method. Delete definition and add a definition for standard method as it is used throughout the ISO standard. Change terminology in the TNI text to be consistent by using the term standard method. Comments on definition proposed: A reference method is a validated method that is issued by a competent organization or a promulgated method required by state or federal regulation. Addition of analytes to a reference method and modifications or enhancements to a reference method is covered by sections 5.4.3, 5.4.4 and 5.4.5 of ISO 17025. Calling the modification of a method by means of adding an analyte contradicts 5.4.5.2 which states that methods used outside their scope or amplifications and modifications to methods require validation.
mf	Negative with Comment	Reference method	Reference Method: 1) Regarding the language "…the analyte/method combination is recognized as a reference method…" Analytes are substances (as also defined in the VDS), and methods are techniques/procedures. A reference method, as defined in the Standard, is a method issued by an organization generally recognized as competent to do so. A new "analyte/method combination" is not issued by such an organization; by its nature, it is a new use or modification of a reference method that was not vetted by the organization which published the reference method in the first place. Designating new "analyte/method combinations" as reference methods only dilutes the imprimatur of reference methods and the bodies that publish them. Suggest altering the language to make it clear that, while new analytes may be analyzed using an established reference method, a new combination is not a new reference method by itself, but a modification

			of a reference method. The example regarding method 624, being retained in V1M4 section 1.4, makes this clear, but the “reference method” definition only muddies the waters. 2) Regarding the language “…the analyte/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology.” This phrase can be interpreted to mean that two new analyte/method combinations, neither “reference methods” by themselves, can justify each other by virtue of there being at least two analyte/method combinations of the same matrix and technology. Suggest adding the term “established” to clarify: “…the analyte/method combination is recognized as a reference method if it can be analyzed by another similar established reference method of the same matrix and technology.” 3) Regarding the language “Reference Methods do not require validation as outlined in 5.4.5 of this standard, but must follow the applicable technical requirements found in Section 1.5 of Modules 3-7.” The Terms and Definitions section of the Standard is not the appropriate place to define requirements or applicability. Any exceptions to 5.4.5, for example, should be incorporated into 5.4.5 itself. We should not rely on the user of the Standard to refer to the Terms and Definitions section to learn of exceptions to requirements stipulated in 5.4.5 or elsewhere.
	Negative with Comment	Reference Method	Many of the draft standards hinge on a clear definnition of "reference method." The definition in 3.1 is not clear. "When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology." This is too broad to be enforceable and does not specify who will make the determination of what constitutes a reference method. ABs cannot routinely determine when the first sentence above is true. The second sentence above is very unclear.

	1.4 Method Selection Volume 1 Module 2, Sections 5.4.2, 5.4.3 and 5.4.4. The inclusion of the analyte in the method shall meet all required calibration requirements of the method and the quality control requirements of the method to which the analyte is being added. If no QC exists in the method, the laboratory shall adhere to the requirements outlined in a similar reference method (when available). A method that meets these requirements shall be identified in such a way so that there is no confusion that the method has been modified.		
	Affirmative with Comment	1.4	1.4 Delete this section. It seems as though most of the text is redundant with V1M2 sections 5.4.2 and 5.4.3 and ISO 17025 5.4.4. All required quality control should be listed in section 1.7 V1M3.
rs	Negative with Comment	1.4	1.4: Delete section as most of the text is redundant with V1M2 sections 5.4.2 and 5.4.3 and ISO 17025 5.4.4. All required quality control should be contained in section 1.7 V1M3.
	Negative with Comment	Reference Method	See V1M2 comment Many of the draft standards hinge on a clear definnition of "reference method." The definition in 3.1 is not clear. "When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology." This is too broad to be enforceable and does not specify who will make the determination of what constitutes a reference method. ABs cannot routinely determine when the first sentence above is true. The second sentence above is very unclear.

rs	**1.5** a)	**Method Validation** to Volume 1 Module 2, Section 5.4.5. For all methods (e.g. reference), laboratories shall participate in proficiency testing programs. The results of these analyses shall be used to evaluate the ability of the laboratory to produce acceptable data.		
		Negative with Comment	1.5	1.5 Delete section as it presents a redundant requirement given in the V1M1 and elsewhere

	Negative with Comment	Reference Method	See V1M2 comment Many of the draft standards hinge on a clear definnition of "reference method." The definition in 3.1 is not clear. "When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology." This is too broad to be enforceable and does not specify who will make the determination of what constitutes a reference method. ABs cannot routinely determine when the first sentence above is true. The second sentence above is very unclear.
1.3.1 Additional Terms and Definitions **Physical Parameter:** a measurement of a physical characteristic or property of a sample as distinguished from the concentrations of chemical or biological components. (Standard Methods, TNI).			
rs	Negative with Comment	1.3.1	1.3.1 Physical parameter: Delete definition from this section. If a definition is required add to V1M1 definition as the term can be used in more than one module. Term is currently used in V1M7 where examples of physical parameters are provided. It is unclear to what “Standard Methods” refers.
jm	Negative with Comment	1.3.1	1.3.1 Definition for Physical Parameter. V1M2 defined the term parameter. Delete the addition of this definition. In addition, this definition is inconsistent with the definition given in V1M2
sw	Negative with Comment	1.3.1	Remove 1.3.1. definition of 'physical parameter'. Is this considered an analyte? If so, include it in the analyte definition in Module 2. If not, the standard is not enforceable by ABs. We can only accredit for 'analytes' per the standard.
1.4 Method Selection Refer to Volume 1 Module 2 Sections 5.4.2, 5.4.3 and 5.4.4. The inclusion of the analyte in the method shall meet all required calibration requirements and the quality control requirements of the method to which the analyte is being added. If no QC exists in the method, the laboratory shall adhere to the requirements outlined in a similar reference method (when available). For example, when adding acetone to Method 624, the calibration and QC requirements shall follow Method 624. A method that meets these requirements shall be identified in such a way so that there is no confusion that the method has been modified.			
rs	Negative with Comment	1.4	1.4: Delete section as most of the text is redundant with V1M2 sections 5.4.2 and 5.4.3 and ISO 17025 5.4.4. [NOTE: ISO 17025 section 5.4.4 needs to be added V1M2.] All required quality control should be contained in section 1.7 V1M3.

	Negative with Comment	1.4	I believe the changes in 1.4 deviate from the intent of ISO 17025 (5.4.2 first sentence). The proposed changes remove communication and approval by the client and instead replace with an overly limited "similar reference method". This requirement prevents inclusion of other EPA publications, state publications, direct communication with the regulator, or as previously stated, the client. These restrictions could place laboratories in position where they would have to choose between conflicting requirements.
	Negative with Comment	1.4 and 1.6.2.2	Sections 1.4 and 1.6.2.2: In each instance where "parameter" has been crossed out and replaced by "analyte", it should say "parameter or analyte" or "parameter/analyte". Crossing out "parameter" is totally inconsistent with the addition of "physical parameter" in Sec. 1.3.1.

1.5.2.1 Limit of Detection (LOD)

If the laboratory is not reporting a value below the Limit of Quantitation, a Limit of Detection study is not required, unless specified by the method.

An LOD study is not required for physical parameters, for any component for which spiking solutions are not available or for any test that does not use a calibration curve (e.g., residues, specific conductance, chlorophyll, titrimetric determinations,etc.).

The laboratory shall utilize a method that provides an LOD that is appropriate and relevant for the intended use of the data. If a mandated method or regulation includes procedures for determining detection limits, these shall be followed. The laboratory shall document how LODs were derived from the determinations. If the protocol for determining the LOD is not specified, the selection of the procedure shall reflect instrument limitations and the intended application of the method.

All sample-processing and analysis steps of the analytical method shall be included in the determination or validation of the LOD.

a) When required, the laboratory shall determine or verify the LOD for the method for each target analyte of concern in the quality system matrices.

b) The validity of the LOD shall be verified by detection (a value above zero) of the analyte(s) in a QC sample in each quality system matrix. This QC sample shall contain the analyte at no more than 3X the LOD for single analyte tests and 4X the LOD for multiple analyte tests. This verification shall be performed on every instrument that is to be used for analysis of samples and reporting of data. The validity of the LOD shall be verified as part of the LOD determination process. This verification shall be done prior to the use of the LOD for the sample analysis.

c) The LOD shall be initially determined for the analytes of interest in each method in a quality system matrix in which there are neither target analytes nor interferences at a concentration that would impact the results or the LOD shall be performed in the quality system matrix of interest.

	d) An LOD shall be performed each time there is a change in the method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis. e) The LOD, if required, shall be verified annually for each quality system matrix, technology, and analyte.		
rs	Negative with Comment	1.5.2.1	1.5.2.1 The use of “etc” at the end of the list is not appropriate when the list is preceded with “e.g.” which means “for example”.
jm	Negative with Comment	1.5.2.1	.5.2.1 Limit of Detection (LOD) Statement: "If the laboratory is not reporting a value below the Limit of Quantitation, a Limit of Detection study is not required, unless specified by the method." The term MDL is not defined in V1M2, even though it is the reference in most EPA publications. Since the term Limit of Detection is so different from majority of the methods, which actually reference MDL, will anyone be required to do this? If LOD is a replacement for MDL, then a definition should be given to relate the two procedures. Second paragraph: An LOD study is not required for physical parameters, for any component for which spiking solutions are not available or for any test that does not use a calibration curve (e.g., residues, specific conductance, chlorophyll, titrimetric determinations,etc.). Comment: While the items listed in parentheses are only examples, not all of them would be completely exempt. An LOD may not be appropriate but there are certain sensitivity requirements based on the equipment being used. The statement should either be more specific or should caution that while an LOD is not required, verification of sensitivity may be required.
gb	Negative with Comment	1.5.2.1	*Note: No change proposed* 1.5.2.1 Limit of Detection (LOD) The 3-4 X rule (QC sample shall contain the analyte at no more than 3X the LOD for single analyte tests and 4X the LOD for multiple analyte tests) vs. 10 X rule for LOD is not practical for many analyte lists that contain wide variety of diverse analytes - this will cause problems with Herbicides and Pesticides, volatiles, semi-volatiles and some metals. Additionally, it may be very difficult to find a quality system matrix with no significant interferences. A more defined procedure for LOD/LOQ determination in a quality system matrix should be provided to make it an equal playing field and not so subjective. We already do PCB MDL's on oils, water, swipes, soils, ASE soils, low level soils etc. Since this is for 9 Aroclors already adding all the replicates for more MDL's is an incredible burden. It would have very severe, negative and time consuming consequences for all metals LOD studies. For most methods we prep 3 or 4 levels at the same time and run them all to see which level will both have good enough recovery (50-150%) even though the level may be 10-100x lower than our reporting limit, and also have a good "factor" (1-10 currently). We shoot for a factor of 3-6, not much different than the proposed factor of 4. However, for metals with any trace level of contamination, if we use a level low enough to get the recovery right, the factor is 5-10 quite often. A quick check of our 2010 ICP MDL study shows that only 9 of the 30 metals had a factor between 1 and 4; the other 21 were 4-10. Some of those 21 may have been fine with a factor 1-4 using other data already available, but it appears that we'd have a 50% greater failure rate using this new criteria. And that is for the best-defined instrument we have, with the most constant LODs year to year. The

			smaller the acceptance window, the more runs we have to do, and as mentioned many metals (B, Zn, Ct), there is background contamination that make a lower factor impossible. And for extremely sensitive metals like Be, since the LOD calculates to maybe 50 ppt, we'd have to run an LOD study at 0.20 ppb or less, which might not be possible.
sw	Negative with Comment	1.5.2.1	1.5.2.1. LOD definition uses 'physical parameter' which should be changed to 'analyte'. The text gives some examples but not an exhaustive list. The list should be removed and placed in guidance/training for assessors and labs so that the list can be easily expanded to address inconsistent application. 1.5.2.1. remove outdated terms 'mandated method' and replace with 'reference method' now that it is defined.

1.5.2.2 Limit of Quantitation (LOQ)

A determination of an LOQ is not required for physical parameters, for any component for which spiking solutions are not available or for any test that does not use a calibration curve (e.g., residues, specific conductance, chlorophyll, titrimetric determinations,etc.) unless the method or regulation requires reporting to a specific level or restricts reporting values below a certain level (e.g., BOD and residues).

The laboratory shall determine the LOQ by a study using spiked samples. If spiking samples is not an option, the laboratory shall determine an appropriate LOQ by using test conditions or instrument restrictions (e.g., sample volume, accuracy of balance, method QC requirements) as the basis

a) All sample-processing and analysis steps of the analytical method shall be included in the determination of the LOQ.

b) The validity of the LOQ shall be verified by successful analysis of a QC sample containing the analytes of concern in each quality system matrix at 1 to 2 times the claimed LOQ. A successful analysis is one where the recovery of each analyte is within the laboratory established method acceptance criteria or client data quality objectives for accuracy.

c) When an LOD is determined or verified by the laboratory, the LOQ shall be above the LOD.

d) The LOQ shall be verified annually for each quality system matrix, technology, and analyte. However, the annual LOQ verification is not required if the LOD was determined or verified annually on that instrument.

	Affirmative with Comment	1.5.2.2	The added comment at the end of 1.5.2.2 regarding BOD and residues muddies the preceding comments. The Standard is not clear whether these analytes don't require an LOQ (as it appears at the start of 1.5.2.2), or do require an LOQ (as it appears at the end of 1.5.2.2). For increased clarity, I would re-order the items under 1.5.2.1 in the order of a, c, d, e, b. I would re-order the items under 1.5.2.2 in the order of a, d, b, c. This might add additional clarity to the requirements
rs	Negative with Comment	1.5.2.2	1.5.2.2 The 1st added sentence requires an LOQ determination if a method or regulation requires reporting to a specific level or restricts reporting values below a certain level. Is this what was intended? The 2nd

			added sentence contradicts the 1st sentence by providing instructions and guidance on how to determine an LOQ for a physical parameter by means of test conditions or instrument restrictions.
jm	Negative with Comment	1.5.2.2	1.5.2.2 The second sentence contradicts the first sentence by providing instruction for determining and LOQ for a physical parameter, where the first sentence requires an LOQ if a method/regulation requires reporting to a specific level or restricts reporting values below a certain level.
gb	Negative with Comment	1.5.2.2	1.5.2.2 Limit of Quantitation (LOQ) The reality in most laboratories is the frequent requirement to report results down to the LOD; therefore for most labs the LOD will always be a required study. Determination in the quality system matrices needs to be better defined -- waste waters and ground waters are not all equal and soils, sediments, oils, swipes, etc. are not all equal either. Right now, most labs determine LOD's in reagent water and in a blank soil or sand matrix and maybe a blank oil matrix for certain tests. This wording would be interpreted very broadly and create an undue burden. There is a stated consideration of variable Data Quality objectives (DQO's), however this would have to be repeated (since the stated LOQ will need to be different for the stated precision and accuracy acceptable) possibly multiple times for different clients quality objectives. Our lab has done extensive LOQ validations for the State of Texas and it is quite specific and time consuming; to require multiple versions of this (potentially) would be prohibitive, particularly given that most clients will not pay for this analytical work. I realize that quality should not look only at cost, but the requirement has to be both practical and provide a significant improvement to data quality.
	Negative with Comment	1.5.2.2	It is not clear on the new requirements listed in section 1.5.2.2 discussing the LOQ and how assessors will be looking at this. Initially it says that it's not required to do LOQ determinations and validations specifically for BOD and Residues and then the next paragraph it specifically says we do. The verbiage is confusing, and we are not sure what the thought process was behind this requirement.
	Negative with Comment	1.5.2.2	Section 1.5.2.2, p. 2 - "The laboratory shall determine the LOQ by a study using spiked samples." It should not be necessary for the lab to do an LOQ study using spiked samples if the lab has already done an LOD study. This requirement is adding an additional process which will create undue burden. If the intention of the committee is to require an LOQ study in those cases where an LOD is not required (para. 1, 1.5.2.1), the language should be cleaned up to clarify.
	Negative with Comment	1.5.2.2	V1M4 Section 1.5.2.2: Specifically the words: "The laboratory shall determine the LOQ by a study using spiked samples." I am opposed to this change to the standard for two reasons: 1- The use of a spiked sample study to establish a Limit of Quantitation is a new concept that is not present in any current methodology that I am aware of. 2- If this new requirement is established, there is no guidance available on how to perform the study and establish an LOQ. That is, I would have no idea how to fulfill this requirement. The requirement of a study using spiked samples to determine a Limit of Quantitation is a new concept not found in any environmental methods that I am aware of. Presently, the EPA methods and programs that I am familiar with use a spiked sample study to determine LODs (however named) and LOQs (however named) are established as either a multiple of the LOD, or as equivalent to the lowest calibration standard.

			For example: (a) SW846 Chapter One (Office of Solid Waste) defines an MDL through the use of a spiked sample study. Then and Estimated Quantitation Limit is chosen at 5 to 10 times the MDL. (b) EPA Method 1631E (Office of Water) defines and MDL through the spiked sample study procedure found in 40CFR Part 136 Appendix B. Then, the Minimum Level is established as the lowest calibration standard. (c) Standard Methods 1030C establishes MDLs through a spiked sample study, and then establishes a Practical Quantitation Limit at approximately five times the MDL. In none of these examples is the LOQ established through the used of a spiked sample study. Furthermore, while there is well established methodology to perform LOD studies through spiked sample studies, I am not aware of any methods or guidance that specify how to perform a spiked sample study to establish an LOQ. Therefore, because this seems to be a new concept that is currently not required by any current methods, and there is no guidance on how to perform the study, I am opposed to this new requirement. Finally, the current standard requires the verification of the LOQ through a spiked sample taken through the entire analytical process. This required procedure is adequate to verify/validate the LOQ.
	Negative with Comment	1.5.2.2	Second new paragraph under 1.5.2.2 (LOQ). I disagree with requiring LOQ determination "by a study using spiked samples". LOQ should be determined however the lab sees fit (usually lower calibration level in conjunction with default sample preparation/handling steps). The LOQ verification establishes whether the LOQ is valid; why require a "study on spiked samples" to determine the LOQ?
	Negative with Comment	1.5.2.1 and 1.5.2.2	1.5.2.1 (Limit of Detection) and 1.5.2.2 (Limit of Quantitation) Regarding an LOD study or LOQ determination "…is not required… for any component for which spiking solutions are not available…" Is "component" equivalent to "physical parameter" and/or "analyte?" The term is used liberally throughout the module, but is not defined. Since verbiage such as "parameter" and "compound" is being replaced with "analyte" throughout the Standard, the persistence of "component" is incongruous. Secondly, how is availability determined, and who makes that determination? If the intent is to provide an exception for those physical parameters or analytes for which spiking solutions are not feasible, suggest replacing the term "available" with "feasible" to clarify that point.
jm	Negative with Comment	1.5.3 b ii)	*Note: No change proposed* 1.5.3 b) ii) – No change to this section in the working draft. In the approved version, there is a reference to EPA's ATP process: "A validation protocol, such as the Tier I, Tier II, and Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) approval process." Recommendation: Reference the actual EPA document by title and document ID number. "Protocol for EPA Approval of Alternate Test Procedures for Organic and Inorganic Analytes in Wastewater

			and Drinking Water” - March 1999, EPA 821-B-98-002

1.4 Method Selection

Refer to Volume 1, Module 2 Sections 5.4.2, 5.4.3 and 5.4.4.

rs	Negative with Comment	1.4	1.4 Inappropriate reference. Refers to V1M2 Section 5.4.4 which indicates the section is not applicable.
jm	Negative with Comment	1.4	1.4 Inappropriate reference. Refers to V1M2 Section 5.4.4 which indicates the section is not applicable.
	Negative with Comment	Reference Method	See V1M2 comment Many of the draft standards hinge on a clear definnition of "reference method." The definition in 3.1 is not clear. "When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology." This is too broad to be enforceable and does not specify who will make the determination of what constitutes a reference method. ABs cannot routinely determine when the first sentence above is true. The second sentence above is very unclear.

1.5 Method Validation

a. Refer to Volume 1, Module 2 section 5.4.5.
b. The laboratory shall validate reference methods via the procedures outlined in 1.6.
c. For all methods, except reference methods, the validation must include the minimum requirements for method validation are given in Sections 1.5.1, 1.5.2 and 1.5.3.
d. Laboratories shall participate in a proficiency test program when available. The results of these analyses shall be used to evaluate the ability of the laboratory to produce acceptable data.
e. The laboratory shall maintain documentation of the validation procedure for as long as the method is in use and for at least five (5) years past the date of last use.

1.5.1 through 1.5.3 NO CHANGE			
rs	Negative with Comment	1.5	1.5.a includes a circular reference. This section refers to V1M2 section 5.4.5 which in section 5.4.5.4 refers to this section. 1.5.b contradicts the newly provided definition for “Reference method” which indicates validation is not required for reference methods. 1.5.c contains an awkward sentence structure. “the validation method must include the minimum requirements for method validation are given in Sections 1.5.1, 1.5.2 and 1.5.3.” 1.5.d is a redundant requirement which is contained elsewhere in Volume 1.
	Affirmative with Comment	1.5	Section 1.5.d could be removed. Proficiency testing is not really a part of validating a method, and PT requirements are covered in other areas of the Standard.
jm	Negative with Comment	1.5	1.5(a) Includes a circular reference. This section refers to V1M2 section 5.4.5 which in section 5.4.5.4 refers to this section. 1.5(b) Contradicts the new definition for “Reference method” which indicates validation is not required for reference methods. 1.5(c) Difficult to understand the meaning. “the validation method must include the minimum requirements for method validation are given in Sections 1.5.1, 1.5.2 and 1.5.3.” Recommendation: “the validation procedure must include the minimum requirements for method validation as given in Sections
	Negative with Comment	1.5	1.5 remove items b.(contradicts Module 2 proposed definition of reference method) c. (already required in item a.) and d.(already required for initial and renewal applicants to program through the requirements in the PT module). Recommend moving item e. to Module 2 General Requirements (section 4.13.3.) where other requirements for maintaining records reside.
1.6.2.2 If the method or regulation does not specify an initial DOC, the following procedure is acceptable. It is the responsibility of the laboratory to document that other approaches to initial DOC are adequate. a) The target organism(s) shall be diluted in a volume of clean quality system matrix (a sample in which no target organisms or interferences are present at concentrations that will impact the results of a specific method). This diluent matrix shall be sterile buffered water and/or sterile peptone water unless specified by the manufacturer. Prepare at least four (4) aliquots at the concentration specified, or if unspecified, to the countable range for plate methods or working range for most probable number (MPN) type methods. b) through f) NO CHANGE			
rs	Negative with Comment	1.6.2.2.a	1.6.2.2.a is not internally consistent. One part requires dilution of the target organism in a quality system matrix and in another part requires dilution in a sterile buffered water, etc

jm	Negative with Comment	1.6.2.2.a	1.6.2.2.a Contradictory statement: One part requires dilution of the target organism in a quality system matrix and in another part requires dilution in a sterile buffered water, etc.
1.7.3.1 Sterility Checks and Method Blanks a) NO CHANGE b) Sterility Checks i) Through v) NO CHANGE vi) Any other materials or supplies (whether sterilized in the lab or purchased as sterilized) which are required to be sterile prior to use in testing must be checked once per purchased or prepared lot using a nonselective growth media.			
rs	Negative with Comment	1.7.3.1 b vi	1.7.3.1.b.vi could add significant cost to some laboratories with minimal benefit. What is the perceived benefit for a wastewater treatment facility testing internally generated samples?
	Negative with Comment	Section 1.7.3.1 b)vi)	Section 1.7.3.1 b)vi) The addition of this statement will allow inspectors too much leeway with personal interpretation. Currently the info in 1.7.3.1.a) and b) both discuss the treatment of funnels. Under 'Method Blanks' a)ii requires "… insert a method blank after every ten samples or sanitize filtration units by UV light after each sample filtration" , under 'Sterility Checks' b)ii requires "For laboratory sterilized funnels, a sterility check shall be performed on one funnel per sterilization batch." These two statements alone confuse the issue of how UV-sterilized funnels are to be treated. Our interpretation of the second statement is that they are referring to AUTOCLAVED batches of sterilized funnels. The addition b) vi muddies this water further and allows inspectors to interpret the new standard to mean any type of sterilization is considered a "sterilization batch" and could require us to check one funnel from each cabinet prior to use using nonselective growth media; but how would we even go about doing that? We already check the UV output of the lights on a routine basis and do not get growth on blanks, but that additional statement leaves a lot up in the air. Under the language in the 2003 NELAC Standard, we UV sterilize after every funnel usage and our inspector has us running 2 method blanks for every sample, one before and one. We believe this is an incorrect interpretation, but the 2009 standard, as written, is still unclear. 1.7.3.1 b. ii, does not spell out if sterility check is done by the analysis of method blanks or using non-selective growth media (we are ASSUMING that means using blanks, but then again we did not think we needed to run 2 method blanks for every sample), but adding vi does not clarify this requirement. Can you provide any background as to why this was added? Was there a specific concern that the committee is trying to address?
	Negative	??	This section needs to be clarified A LOT. General, blanket requirements such as this do not achieve the

	with Comment		intended purpose, but create MAJOR issues between labs and assessors. If the items to be checked cannot be listed as in i-v, then it must be removed or labs will be running sterility checks on counter tops. 1.7.3.1.b.vi Any other materials or supplies (whether sterilized in the lab or purchased as sterilized) which are required to be sterile prior to use in testing must be checked once per purchased or prepared lot using a nonselective growth media.
1.7.5 Sample Handling a) NO CHANGE b) Microbiological samples from known chlorinated sources (such as wastewater effluent), unknown sources where chlorine usage is suspected (such a new client or a new source) and all potable water supplies (including source water) shall be checked for absence of chlorine residual. Laboratories that receive samples from potable water supplies (including source water) that have a demonstrated history of acceptable preservation may check a sample from each client at a frequency of once per month if: i) through iv) NO CHANGE			
rs	Negative with Comment	1.7.5 b	1.7.5.b changing source to client is not appropriate. A client may be an individual or a firm that submits samples to a laboratory. The client may submit samples from more than one public water source or supply. Limited testing for residual chlorine should be based upon individual public water supplies or sources
	Affirmative with Comment	1.7.5 b	1.7.5 b It appears that source water should never be chlorinated, if it TRULY is source water. It's a shame that we have to be concerned with the lowest common denominator in these cases, but I support the requirement to verify the lack of chlorine in these samples.
	Affirmative with Comment	1.7.5 b	I assume that the change in 1.7.5 - change "sources" to "supplies" implies that residual chlorine needs to be checked only if sample testing is directly applicable to a drinking water source. That is, surface water testing for routine water quality monitoring of a body of water that is also a water supply (such as Lake Michigan) wouldn't fall under this requirement. Right?
jm	Negative with Comment	1.7.5 b	1.7.5.b Source and client sound equal. Remove “such a new client or new source” and clarify to say “unfamiliar source”. If you choose not to clarify the statement, then fix the typo in “such a new client or new source” and add the word “as” after such

			1.3 NO CHANGE
	Negative with Comment	1.3	*Note: No change proposed* 1.3 Refers to V1M2 section 5.4.4, which implies the section is not applicable.
1.4 Method Selection Refer to Volume 1 Module 2 sections 5.4.2, 5.4.3 and 5.4.4.			
rs	Negative with Comment	1.4	Inappropriate reference. Refers to V1M2 Section 5.4.4 which indicates the section is not applicable.
	Negative with Comment	Reference Method	See V1M2 comment Many of the draft standards hinge on a clear definnition of "reference method." The definition in 3.1 is not clear. "When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology." This is too broad to be enforceable and does not specify who will make the determination of what constitutes a reference method. ABs cannot routinely determine when the first sentence above is true. The second sentence above is very unclear.
1.5 Method Validation 1.5.1 Validation of Methods a) Refer to Volume 1, Module 2 section 5.4.5**.** The laboratory shall validate reference methods via the procedures specified in Sections 1.5.2.1 and 1.5.3. For reference methods, the procedures outlined in 1.6 can satisfy the requirements of 1.5.2. For all other methods, except reference methods, the validation must include the minimum requirements for method validation are given in Sections 1.5.2, 1.5.3 1.5.4 and 1.5.5.			
	Negative	1.5	1.5(a) Refers to V1M2 section 5.4.5 where section 5.4.5.4 refers to this section.

	with Comment		1.5(b) Contradicts the new definition for “Reference method” which indicates validation is not required for reference methods. 1.5(c) Difficult to understand the instruction. “the validation method must include the minimum requirements for method validation are given in Sections 1.5.1, 1.5.2 and 1.5.3.” Recommendation: “the validation procedure must include the minimum requirements for method validation as given in Sections
	Negative with Comment	1.5	1.5.a includes a circular reference. This section refers to V1M2 section 5.4.5 which in section 5.4.5.4 refers to this section. 1.5.b contradicts the newly provided definition for “Reference method” which indicates validation is not required for reference methods. 1.5.c contains an awkward sentence structure. “the validation method must include the minimum requirements for method validation are given in Sections 1.5.1, 1.5.2 and 1.5.3.” 1.5.d is a redundant requirement which is contained elsewhere in Volume 1
	Negative with Comment	1.5	1.5 remove item b. (contradicts Module 2 proposed definition of reference method). The laboratory should document demonstration of capability

1.7 Technical Requirements

1.7.1 Instrument Calibration

a) Through b) NO CHANGE

c) Background Measurement

Background measurements shall be made on a regular basis and monitored using control charts or tolerance charts to ensure that a laboratory maintains its capability to meet required measurement quality objectives. (This background measurement is not the short term check for contamination that is addressed in 1.7.1 d). These values must be subtracted from the total measured activity in the determination of the sample activity.

i) For gamma-ray spectroscopy systems, background measurements shall be performed on at least a monthly basis.

ii) For alpha-particle spectroscopy systems, background measurements shall be performed on at least a monthly basis.

iii) For gas-proportional counters background measurements shall be performed on at least a weekly basis.

iv) For scintillation counters, background measurements shall be performed each day of use.

	d) Instrument Contamination Monitoring The laboratory shall have a written procedure for monitoring radiation measurement instrumentation for radioactive contamination. The procedure shall indicate the frequency of the monitoring and shall indicate criteria, which initiates corrective action.		
	Negative with Comment	1.7	I dissent on the long background couting requirement being proposed to be performed on/at least weekly for gas proportional counters (GPC). There is no reason that gas proportional counters need weekly background measurements when gamma spectrometry and alpha spectrometry only need monthly background measurements. Most laboratories usually have a counting room where all the radiation equipment is located. Ambient backgrounds do not change substantially for both alpha and beta contributions even from month to month. Therefore, I recommend long background measurements for GPC on/at least monthly. In fact, ANSI N42.25-97 Standard "Calibration and Usage for GPC" recommends quarterly measurements for long background for GPC. Weekly measurments is undue burden on laboratories which is unnecessary.
	Negative with Comment	1.7	We are not convinced that 1.7.1 c iii is a good technical change. (poor science according to our radiochemical consultant)

1.4 Method Selection Refer to Volume 1, Module 2 Sections 5.4.2, 5.4.3 and 5.4.**4.**			
	Negative with Comment	1.4	1.4 Inappropriate reference. Refers to V1M2 Section 5.4.4 which indicates the section is not applicable.
	Negative with Comment	1.4	1.4 Refers to V1M2 section 5.4.4, which implies the section is not applicable.
	Negative with Comment	Reference Method	See V1M2 comment Many of the draft standards hinge on a clear definnition of "reference method." The definition in 3.1 is not clear. "When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology." This is too broad to be enforceable and does not specify who will make the determination of what constitutes a reference method. ABs cannot routinely determine when the first sentence above is true. The second sentence above is very unclear.
1.5 Method Validation Refer to Volume 1 Module 2 Section 5.4.5. No additional requirements for method validation are needed.			
	Affirmative with Comment	1.5	1.5 This is the statement that should be replicated in the other modules. If subcommittees of technical experts were used to draft the separate modules, the committee should assure that the language is consistent between modules before proposing the final version.
	Negative with Comment	1.5	1.5 includes a circular reference. This section refers to V1M2 section 5.4.5 which in section 5.4.5.4 refers to this section.
	Negative with Comment	1.5	1.5(a) Refers to V1M2 section 5.4.5 where section 5.4.5.4 refers to this section
1.7.1 Quality Control			

	The laboratory shall have quality control procedures for monitoring the validity of environmental tests undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following: a) regular use of certified reference materials and/or internal quality control using secondary reference materials; b) participation in inter-laboratory comparison or proficiency-testing program; c) replicate tests using the same or different methods; d) retesting of retained samples; and e) correlation of results for different characteristics of a sample (for example, total phosphate should be greater than or equal to orthophosphate).		
	Negative with Comment	1.7.1	*Note: No change proposed* 1.7.1 is not needed as it replicates V1M2 section 5.9.1 which contains the ISO 17025 language