The TNI Standard – Module 2

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INTRODUCTION

NELAC Standard (RIP) 2003
TNI Standard – 2009
TNI Standard – 2016

2003 NELAC Standard

- First National Standard
- Good, but room for improvement
- Not consensus driven
- One Big Document

2009 TNI Standard

- Consensus driven
- Volume and Module based

Module Structure

1.1 Introduction

1.2 Scope

1.3 Terms and Definitions

1.4 Method Selection

1.5 Method Validation

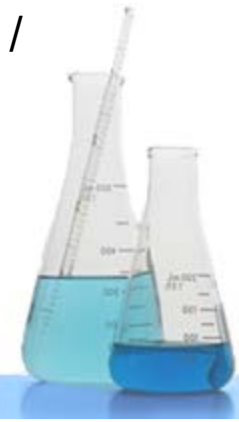
Validation of Methods, Limit of Detection and Limit of Quantitation, Evaluation of Precision and Bias, and Evaluation of Selectivity

1.6 Demonstration of Capability (DOC)

General, Initial DOC, and Ongoing DOC

1.7 Technical Requirements

Calibration, Quality Control for the specific Module, Data Acceptance / Rejection Criteria, Sample Handling



Additions / New Items

ISO/IEC 17025:2005 Structure

Placement of additional NELAC Requirements was made at the end of all ISO language, where we resumed the numbering from that point. KEY –*ISO language is presented in Italics*

Then / Now

- 2003 became 2009
- 2009 becomes 2016
  - Quality Systems Committee subdivided
  - Each Module becomes a Committee
  - No more Chemists writing Microbiology!

Clarification

Revisions to the 2009 TNI Standard were almost exclusively clarification

Chemistry Committee has done a great deal of work on LOD and Calibration – those are more than clarifications

Clarification

- Change ISO citation from ISO/IEC 17025:2005(E) to ISO/IEC 17025:2005

Clarification

- Any Notes were either eliminated or had the “NOTE” removed – this makes them requirements
- ISO Notes, also not enforceable, were reviewed to see if they needed to become requirements

Clarification

4.15 Management Reviews *(ISO/IEC 17025:2005, Clause 4.15)*

4.15.1 In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system …
NOTE 1: A typical period for conducting a management review is once every 12 months.

4.15.3 Management review shall be completed on an annual basis.

Clarification

- Definitions
  - *Analyte (revised, and was formerly Parameter)*
  - *Data Integrity (revised from body)*
  - *Parameter (deleted)*
  - *Physical parameter (added)*
  - *Reference Method (revised from body)*

Clarification

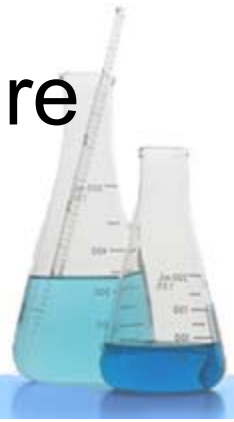
- **Parameter:** a measurable quantity, e.g. temperature, that determines the result of a scientific experiment and can be altered to vary the result
- **Analyte:** A substance, organism, physical parameter, property, or chemical constituent(s) for which an environmental sample is being analyzed.

Clarification

- **Data Integrity:** The condition that exists when data are sound, correct, and complete and accurately reflect activities and requirements.

Clarification

4.2.8.1 The laboratory shall establish and maintain a documented data integrity system. There are four (4) required elements within a data integrity system. These are 1) data integrity training, 2) signed data integrity documentation for all laboratory employees, 3) periodic in-depth data monitoring, and 4) data integrity procedure documentation.



Clarification

- **Physical Parameter:** a measurement of a physical characteristic or property of a sample as distinguished from the concentrations of chemical or biological components

Clarification

- **Reference Method**: (To be used to determine the extent of method validation in Modules 3-7) A reference method is a published method issued by an organization generally recognized as competent to do so. (When the ISO language 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 reference method of the same matrix and technology.

Clarification

- 5.4.4 Non Standard Methods – added ISO Text
- 5.4.5 Validation of Methods – added ISO Text
  - 5.4.5.4 *(TNI additional requirements – revised for clarity)*

Clarification

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

When it is necessary to use methods not covered by standard methods … (t)he method developed shall have been validated appropriately before use. [bullet points a-k deleted for space considerations]

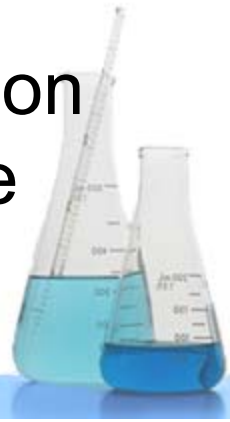
NOTE For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:

5.4.4.1 The note in 5.4.4 above, which includes a – k, shall be considered during the development of the method.

5.4.4.2 The laboratory shall ensure that once the method has been developed, a Standard Operating Procedure as outlined in 4.2.8.5 f shall be written.

Clarification

- **5.4.5.4** All methods used by the laboratory, whether non standard or standard (reference) methods shall be validated before use to ensure that the laboratory has the capability of using the method for its intended use. See section 1.5. of each of the technical modules (Volume 1 Modules 3 through 7) for specific validation requirements. Non-standard methods must comply with 5.4.5.1 – 5.4.5.3 above in addition to specific requirements in Section 1.5 of the technical modules.



Clarification

- The requirement for validation of methods is DIFFERENT for standard methods compared to non-standard methods

Clarification

5.8.5 a) The laboratory shall have a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates.

Clarification

Temperature measuring devices shall be calibrated or verified at least annually. Calibration or verification shall be performed using a recognized National Metrology Institute traceable reference, such as NIST, when available.

Clarification

i) If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable;

Clarification

ii) If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket the range of use.

Clarification

Keep in mind that the presentation of Section 5.5.13.1 was also changed to create a better flowing ‘thought process’, but there were no other changes made to requirements

Clarification

Modules 3-7

- 1.4 Method Selection – deleted majority of text and referred to Module 2
- 1.5 Method Validation – deleted majority of text and referred to Module 2
- 1.6.1 Added clarifying language to indicate that DOCs are related to individual competency.
- 1.6.3.1 Revised for clarity – *on-going DOC are meant to be continuous rather than singular events.*

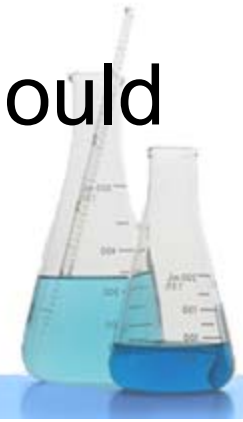
Isn't it Obvious?

Standard Interpretations

TNI has established an avenue for resolution of questions on interpretation of the 2009 TNI Standard. A consensus of three individuals shall determine who oversees the final disposition of the Standard Interpretation Request (SIR). Timelines are defined to ensure a timely response to the question. Publication of the consensus resolution is then made to the affected parties via email and on the TNI web site.

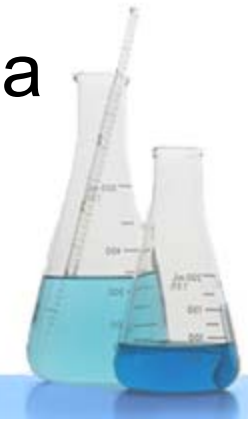
Standard Interpretations

Please remember that any disputes between a laboratory and their AB regarding accreditation are to be handled through the appropriate appeals process established by applicable state laws and regulations. Any SIR submission indicating that it originates with such a dispute will be rejected. Your question should be clearly stated and should meet the following criteria:



Standard Interpretations

1) contains only one question;
2) applies directly and clearly to a cited section of the Standard;
3) can be understood without supposition;
4) is compelling, that the language used in the Standard(s) section cited is not clear or might have more than one interpretation;
5) is not a “how to” question or a request for a method interpretation.



Standard Interpretations

Where possible, the question should be framed in a manner that solicits a “Yes” or “No” response. If the question identifies a conflict within the Standard between two or more sections of the Standard, interpretation will not provide a resolution. The conflict will be addressed through other avenues available within TNI.

Section: V1M2, Section 4.1.7.2 and 5.2.6.1 (a)

At present, our laboratory has a NELAC Lab (Lead) Technical Director who fulfils the NELAC requirements as per referenced sections above. We also have three other Technical Directors whose responsibilities are either for environmental analysis of representative organic analytes or inorganic analytes for which our lab maintains NELAC accreditation. Our laboratory is in process of management change where current NELAC Lab Technical Director will be reassigned to other duties and no longer will have responsibility over the NELAC accredited lab. The annual renewals of the NELAC accreditations with our primary and secondary Accrediting Bodies require a "Certificate of Compliance" to be signed by a Lab Key Staff, often listing a Lead Technical Director as the one who needs to sign this document. The Lead Technical Director is also listed on each NELAC certification we maintain.
Although the NELAC standard allows for more than one Technical Director, do we must have a Lead Technical Manager/Director who fulfils above requirements for both inorganic and organic environmental analysis. At this time only our Lead Technical Director fulfils the requirements

TNI RESPONSE

There is no requirement for a "lead technical director". The standard requires that the individual (or individuals) who are identified as technical directors meet the applicable credentials for the areas over which he/she has oversight.

Section: V1M2, 5.4.2

5.4.2 includes the following statement: "The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so."
In general, it seems that most certification authorities certify for the method, but not the version, allowing any version that is still valid to be run, which seems to violate/contradict this statement.
Does this statement mean that all previous valid method versions are NOT to be used and that the lab MUST update to the newest version of a standard? For example, if the lab runs EPA 8270C which is still valid, must the lab update to 8270D if it can? In other words, does running 8270C (when 8270D is the latest version) become a violation of the standard?

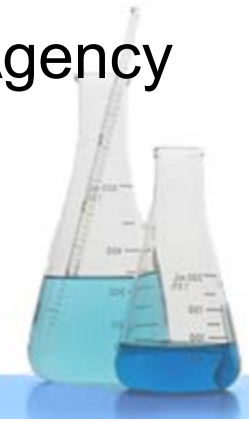
TNI RESPONSE

The term "Standard", as defined by ISO, is as follows:
"Standard: document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.
NOTE - Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits."

TNI RESPONSE

"Standard" refers to the source document or publication that mandates the "approved test method." For laboratories, this use of the term "standard" in V1M2 Section 5.4.2 is a reference to the most current publication(s) that define or require certain methods/actions based on program or regulatory need, such as:

- International (global documents),
- Regional (i.e., requirements specific to State, local, EPA Region, etc.), or
- National (i.e., requirements by Federal Regulation/Agency via the Code of Federal Regulations (CFR).



TNI RESPONSE

Additional analytical requirements can be listed in/by reputable technical organizations (i.e., AOAC, AIHA, etc.), scientific texts/journals and manufacturers (i.e., instrument specific, process requirements, etc.). Analytical methods ("test methods" in the ISO language) used by the environmental laboratory industry are driven by regulations where governing programs exist. The "standard" that mandates the required methods for EPA programs is the US CFR Title 40 (40 CFR.) Where programs are federally regulated, laboratories shall use the most current CFR to determine method requirements by specific program. Methods found in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" (SW-846) are to be used "as published" by the EPA and do not go through a formal promulgation process. Individual state and program requirements may exist that mandate one version of a method over another, such as Method 8270D vs 8720C, therefore requirements by project, accreditation body, and state/local/regional agency must be considered.

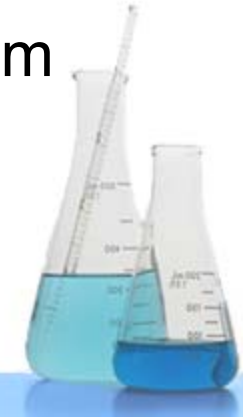
Section: V1M2, Section 5.6.4.2

This section requires the lab to retain records of the standard or reagent manufacturer's Certificates of Analysis. One of our largest standard manufacturers recently stopped automatically sending hard copies of the C of A with the material, stating that it can be accessed electronically from their website. The manufacturer says an advatange of this, among other things, is "immidiate accessibility for audits".

My question is if hard copy of the C of A onsite at the lab is stictly required, or if access to the electronic copy "on-demand" is sufficient.

TNI RESPONSE

The laboratory must maintain copies of the Certificates of Analysis (CoAs), whether in hard copy or electronic format, in accordance with the lab's records and document control procedures and as required by the TNI Standard. The laboratory must maintain and control all records used to document lab activities, including CoAs, and all records must be made available to the accreditation body. The laboratory must retain all records (hard copy or electronic) for a minimum of five years (V1M2, section 4.13.3), and labs must incorporate procedures to maintain CoA from manufacturers that do not have the same retention schedule for electronic CoAs.



Section: V1M2, Section 5.6.4.2

My question is about documentation and traceability of consumables. Are environmental labs required to maintain records (i.e., Certificate of Analysis, storage, date of receipt, etc.) for such consumables as carrier gasses used for Mass Spec or Spec type instrumentation?

TNI RESPONSE

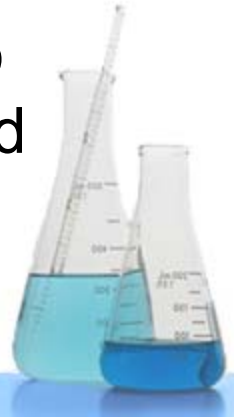
V1M2 5.6.4.2 requires documentation for "standards, reagents, reference materials, and media". Carrier gasses are not referenced within this section. However, a carrier gas is a laboratory consumable material that affects the quality of tests, and is subject to the policy and procedure requirements described in V1M2 4.6.

Section: V1M2, Section 5.6.4.2 (d)

Assuming that we have a working definition for reagents, does the word "prepared" in 5.6.4.2(d) refer only to standards or all three (standards, reference materials and reagents)? Assuming the latter, see the discussion below for the actual question).

Section: V1M2, Section 5.6.4.2 (d)

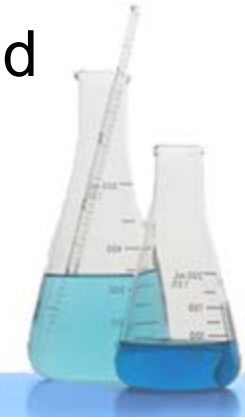
Prepared reagents are readily defined as reagents that are prepared in the lab by modifying (diluting, mixing, etc.) one or more precursor reagents or standards. However there is some ambiguity concerning the term "container". Suppose I make 200 mL of a reagent stock used in an analysis that is stored in a lab refrigerator. Every time we perform a run, a small amount of this reagent is poured into a second container, a removable, plastic reagent well that is part of our discrete analyzer's autosampler. At the end of the day, this reagent is not completely used up, and to minimize waste, we cap the removable plastic well and store it in the refrigerator overnight. It is refilled the following day for the next day's analysis.



Section: V1M2, Section 5.6.4.2 (d)

Since the reagent stock was prepared only once, it would be assigned a single, unique serial number. The mere act of pouring some of this reagent into a second container should not (logically) require one to generate a second serial number.

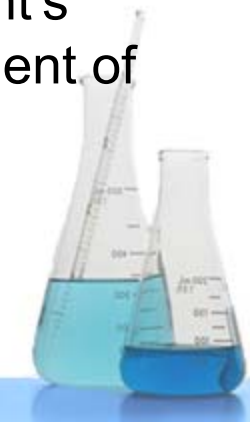
To summarize the question, is only one unique serial number needed for each contiguous preparation, regardless of the number of containers in which the reagent might be stored? i.e., Is this description of unique identifiers for prepared reagents consistent with the meaning and intent of 5.6.4.2 (d)?



TNI RESPONSE

The use of the reagent at analysis requires that all data necessary for the historical reconstruction of the data be available (see 4.13.3 f). Somewhere with the analytical batch, reference must be made to the unique serial number of this reagent. A new serial number need not be created due to the act of pouring the reagent from one container to another. The unique serial number is created at a point in time when the reagent, standard or material is made in the lab. If no changes are made, then a new number need not be created.

The act of removing the container from its specific location on the instrument requires that the container be labeled with the reagent's unique identifier in order to comply with the traceability requirement of 5.6.4.2 c.



Section: V1M2, Section 5.4.2

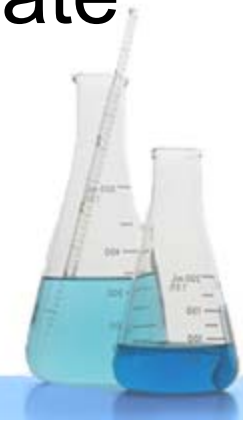
I am not sure what section, but my question refers to a statement that was made in reference to ‘everyone must use the most recent version of Standard Methods’. For clarification, I wanted to know if this is for the most recently EPA approved version of Standard Methods? Currently some EPA approved methods go as far back to the 18th ed. of Standard Methods.

Section: V1M2, Section 5.4.2

5.4.2 Selection of Methods (ISO/IEC 17025:2005(E), Clause 5.4.2)
The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. ***The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so.*** *When necessary, the standard shall be supplemented with additional details to ensure consistent application.... ....The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.*

TNI RESPONSE

The key is the **bolded** phrase from 5.4.2. The latest edition of a method must be used unless it is not appropriate or possible to do so. Therefore, if a method from an earlier edition of a published document (such as Standard Methods) is mandated for use by a regulatory agency, then it is not appropriate to use the most recent method.



Section: V1M2, 5.2.6.1 (a) and (b)

With respect to the wording about experience, paragraph A, sentence number one states ".....and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation." Paragraph b sentence 2 states.... " In addition, such a person shall have at least two (2) years of experience performing such analysis".

Section: V1M2, 5.2.6.1 (a) and (b)

Question #1 : What is the difference between "..experience in the environmental analysis of..." , as stated in paragraph a and "...experience performing such analysis", as stated in paragraph b.

Section: V1M2, 5.2.6.1 (a) and (b)

Question #2 : relating to the interpretation of "representative organic and inorganic analytes".... to what degree does methodology/technology coming in to play. Can the word "representative" be better defined?

Section: V1M2, 5.2.6.1 (a) and (b)

We do not find anywhere in the document that requires experience in multiple technologies. For example, if the director has experience with Analyte A using an automated inorganic method (such as segmented flow) and experience with Analyte B using a conventional wet inorganic method (such as titration) but the lab runs analyte A wet and analyte B automated, would this person have the requisite experience in that area?

TNI RESPONSE

Question 1 - There is no difference in the meaning of the wording of the two paragraphs. Each refers to two years' experience in the analysis of samples. (not oversight/management of sample analysis).

TNI RESPONSE

Question 2 - Representative - exemplifying a group or kind; typical: a representative selection of analytical methods. A Technical Director must have experience in the typical methods/technologies used by the laboratory.

Standard Interpretation Requests

Section: V1M2, 5.5.13.1.b

This section requires support equipment to be calibrated or verified annually with references "bracketing the range of use". The 2003 NELAC standard had comparable language requiring calibration or verification "over the entire range of use". Under the 2003 standard, an exception was permitted allowing the use of a single point calibration for narrow range use thermometers, such as those used for sample storage (>0-6C), BOD (20+/-1C) and micro incubators (35+/-0.5C and 44.5+/-0.2C), drying ovens (103C-105C), etc. However, the same exception has not been extended to the 2009 TNI standard requirement. As a result, labs are being cited for not performing bracketing checks for these thermometers.

Section: V1M2, 5.5.13.1.b

Although the AB for the state where this issue developed allows the use of a temperature at or below and at or above the boundary of the range of use, the requirement still requires the lab to take the equipment out of normal use and re-adjust the settings multiple times. The process provides data that is probably less reliable than a single point check and requires significantly more time to perform. For example, a single point check in the range of 44.3-44.5 C for a fecal incubator would seem to be better data than a check around 40C and a second around 50C

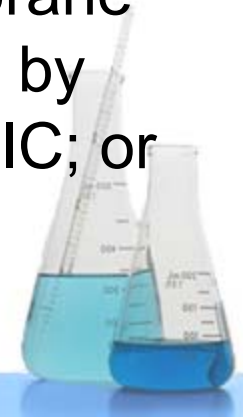
Section: V1M2, 5.5.13.1.b

The use of a single point calibration/verification check for narrow use range thermometers has worked well under the 2003 NELAC standard. I would like to propose that TNI extend the single-point exception used under the 2003 NELAC standard for narrow range use thermometers to the 2009 TNI standard.

Section: V1M2, 5.2.6.1

The 2009 TNI Standard states that a technical manager must have a minimum of 1 or 2 years of experience in the environmental analysis of representative analytes depending on the educational degree.

Question #1: What is "representative analytes"? Is this analyte by analyte? Such as, benzene, lead, nitrate, total coliform. Or by type of analyte? Such as, aromatic hydrocarbons, metals, non-metals, micro? Or is is more technology based? Such as, GC-MS, ICP, ISE, membrane filtration? Or something else? Does analysis of nitrate by electrode count as experience to supervise nitrate by IC; or phosphate by UV-VIS count toward supervision of phosphate by ICP?



Section: V1M2, 5.2.6.1

The 2009 TNI Standard states that a technical manager must have a minimum of 1 or 2 years of experience in the environmental analysis of representative analytes depending on the educational degree.

Question #2: What constitutes a year of experience? How is the amount of experience determined? Is it a minimum number of samples per day/week/month/year? Is it a frequency of analysis over a period of time? What happens if the individual analyzes 100% of the samples over a two year period, but the total number of samples analyzed during those 2 years is only 2? Is this still 2 years of experience or only 2 days of experience?

Section: V1M2, 5.2.6.1

Any technical manager of an accredited environmental laboratory engaged in chemical analysis shall be a person with a bachelor's degree in the chemical, environmental, biological sciences, physical sciences or engineering, with at least twenty-four (24) college semester credit hours in chemistry and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience

Does the technical manager described in this section need to have a degree (associates, bachelors, masters, or doctoral) or "years of college" from an accredited institution? Or can the degree or "years of college" be from any institution, accredited or not?

Section: V1M2, 5.8.5.a

Do labs have to uniquely identify sample containers when received at the lab?

The 2009 standard states: "The laboratory shall have a documented system for uniquely identifying samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates."

Section: V1M2, 5.8.5.a

The 2003 standard stated the same but also added: "The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample."

Since the 2009 standard dropped the wording above in the third paragraph, some are interpreting this to mean the labs do not need to uniquely identify sample containers anymore. However, since the 2009 standard does still include sample containers in the last sentence of the second paragraph, above, some are interpreting that sample containers must be uniquely identified

Section: V1M2, 5.5.13.1

This section requires verification of volumes of volumetric dispensing devices (except Class A Glassware) if quantitative results are dependant on their accuracy. Historically, this section has been interpreted to include disposable pipettes and plastic tubes used for measuring sample volumes or final volumes after digestion. Section 5.5.13.1.d [editor's note – this is actually 5.5.13.1 e] appears to require quarterly checks of these devices. Quarterly checks seem excessive when the items are one use items. Once per lot number seems more reasonable and would be similar to receiving a certificate from the manufacturer about the accuracy of a particular lot number.

Since these are disposable, one use items. would verification of the volume once per lot number be acceptable?

Section: V1M2, 5.2.6.1.c

Please clarify 16 hours of microbiology and biology. Is it 16 hours combined total of microbiology and biology? Is it 16 hour of microbiology and 16 hours of biology 32 hours total?

What Does the Future Hold?

The Parking Lot

- Do individual sample containers need to be uniquely identified? See V1M2 Section 5.8.5 a)
- There are requirements of labs that are found in Volume 1 that are not detailed in Volume 2. Those requirements, although ISO 17011 language, must be included in Volume 2. See V2M1 Section 8
- Can on-going demonstration of capability be accomplished using a known sample that has no analyte present? See V1M4 Section 1.6.3.2

The Parking Lot

- There are detailed requirements for the Technical Manager, yet none for the Quality Manager. Should there be requirements for the qualification of a person as the Quality Manager? See V1M2 Section 5.2.6.1
- The requirements for a Technical Director for microbiological testing has explicit tests listed that don't consider newer tests. How can those requirements be corrected to anticipate newer technology and analytical requirements? See V1M2 Section 5.2.6.1 c)

The Parking Lot

- Does the current definition of Preparation Batch indirectly require that a preparation batch be analyzed together? See the use of ‘and/or analyzed’ in the definition of batch, followed by the preparation batch definition referring to ‘meeting the above mentioned criteria’. See V1M2 Section 3.1. A possible edit follows:

The Parking Lot

- **Batch:** Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one (1) to twenty (20) environmental samples of the same quality systems matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four (24) hours.

- **Batch, Preparation:** A preparation batch is composed of one (1) to twenty (20) environmental samples of the same quality systems matrix that are prepared together with the same process and personnel, using the same lot(s) of reagents, with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four (24) hours. *Note:* Preparation batches are only applicable for tests that require physical or chemical preparation that affects the outcome of the test.

The Parking Lot

- Throughout the Standard, terms used to reference time, such as “Annual”, should be reviewed in each case where used such that each case is addressed for its meaning (i.e., every 11-13 months, each calendar year, something else). Keep in mind that a laboratory may use fiscal year rather than calendar year in its policies and this shouldn’t be disallowed by any changes made if that definition of annual is acceptable.

The Parking Lot

- Define reagent, such that there is clarity on what is a reagent as opposed to an item of support. This relates to pH papers, for example.
- Class A plasticware; Teflon materials; other non-glass labware

Options?

Thank You

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