Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

Clubb	**Clyde**	***Comment #:***
903 237-5815	**cnclubb@eastman.com**	518

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 1.0-5.0

Comment with Rationale and Proposal ***Attached Document*** ☐

Constant references to ISO 17025 makes this module an addendum to ISO 17025. The quality systems should be readable and understandable by laboratory personnel. It also concerns me that ISO makes the rules and removes control from laboratory and regulatory organizations. Some of the ISO language is bureaucratic and has minimal influence upon laboratory quality. The emphasis on ISO 17025 compliance has shifted attention from laboratory quality issues to a laundry list of requirements which dilutes the effectiveness of the standard.

Replace ISO 17025 references with new TNI language that is applicable to environmental laboratories and that makes this a readable, workable document. The standard should focus on environmental lab issues with clear, concise language easily understood by labs and auditors. At a minimum, replace ISO references with actual ISO text.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

It's our understanding that the entire module including ISO text will be available. The use of ISO text was indicated by NELAC stakeholders in 2002 and the TNI module is consistent with NELAC 2003.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Shepherd	**Michael**
512-335-0906	**mcshepherd@austin.rr.com**

Comment #: 499

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 1.1

Comment with Rationale and Proposal ***Attached Document*** ☐

1. Section 1.1: Grammar/construction error "This Standard contains detailed quality system requirements for consistent and uniform implementation by both the laboratories conducting testing and the evaluation of those laboratories by accreditation bodies."
I believe the text intends to describe "consistent and uniform implementation by the laboratories conducting testing and the consistent and uniform evaluation of those laboratories by accreditation bodies".

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jackson	**Kenneth**
518-485-5570	**jackson@wadsworth.org**

Comment #: 413

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 1.2

Comment with Rationale and Proposal ***Attached Document*** ☐

I do not understand the last sentence of the second paragraph. As written, it looks like a loophole to allow people to produce environmental data without being in compliance with the standard (i.e., without having an adequate QS!). Anyway, why tell anyone the standard does not apply? The standard should only tell people what does apply.

Remove the sentence

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Arms	**Stephen**
9047911502	**steve_arms@doh.state.fl.us**

Comment #: 468

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 1.2

Comment with Rationale and Proposal ***Attached Document*** ☐

In the second paragraph, "extent" better conveys the meaning than "degree." This is an accreditation standard and the Scope should reflect this. If there is a need to state when the Standard does not apply, which I question, then this should relate to accreditation.

Change "degree" to "extent" in 1.2. Add: "accreditation in accordance with or" before the word "compliance" in the second paragraph.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 578

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 1.2

Comment with Rationale and Proposal ***Attached Document*** ☐

The sentence, "When the use of the data does not require compliance with the Standard, this Standard does not apply," is not appropriate. The PA program does not require NELAP/TNI accreditation, most regulatory programs do not require NELAP/TNI accreditation, but we do require accreditation. This means, if a laboratory is accredited in PA and it has been granted NELAP/TNI accreditation, we expect that the samples will be analyzed in accordance with and meet the NELAP/TNI Standard. Any laboratory receiving a subcontracted sample may not know whether or not the samples must meet a specific requirement. The subcontracting laboratory may be choosing a NELAP/TNI laboratory because it is such.

This requirement should definitely be deleted. It is not practical and if a laboratory is NELAP/TNI accredited, all testing in the laboratory should be under the umbrella of the laboratory's Quality System.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 580

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 1.2

Comment with Rationale and Proposal ***Attached Document*** ☐

The third paragraph says that ABs "grant approval." This is not the appropriate term. ABs grant accreditation. The last sentence of the third paragraph says tha the laboratory operates the QS in accordance with applicable ISO/IEC 17025. This inaccurately implies that the laboratory meets the ISO requriements. This is not for TNI to assert.

Change the term to "accreditation". This sentence should be deleted.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 579

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 1.2

Comment with Rationale and Proposal ***Attached Document*** ☐

The sentence, "When the use of the data does not require compliance with the Standard, this Standard does not apply," is not appropriate. The PA program does not require NELAP/TNI accreditation, most regulatory programs do not require NELAP/TNI accreditation, but we do require accreditation. This means, if a laboratory is accredited in PA and it has been granted NELAP/TNI accreditation, we expect that the samples will be analyzed in accordance with and meet the NELAP/TNI Standard. Any laboratory receiving a subcontracted sample may not know whether or not the samples must meet a specific requirement. The subcontracting laboratory may be choosing a NELAP/TNI laboratory because it is such.

This requirement should definitely be deleted. It is not practical and if a laboratory is NELAP/TNI accredited, all testing in the laboratory should be under the umbrella of the laboratory's Quality System.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Tholen	**Dan**
231.929.1721	**tholen.dan@gmail.com**

Comment #: 218

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 1.2 Scope

Comment with Rationale and Proposal ***Attached Document*** ☐

The last paragraph states that this standard is complete, and that it is not a supplement to ISO 17025. Yet the language of 17025 is not included, and is only referenced. Therefore this is a supplement to ISO 17025. There cannot be any clauses of 17025 that are not included, or the statement that a lab that meets this also standard also meets 17025 is not correct.

The Scope (or Introduction) should clearly state that the requirements - and language - of 17025 are required, and this document has clearly identified where 17025 requirements are made more specific, or where requirements are additional.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Tholen	**Dan**
231.929.1721	**tholen.dan@gmail.com**

Comment #: 222

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3 terms and definitions

Comment with Rationale and Proposal ***Attached Document*** ☐

Environmental testing covers sufficiently broad technologies and methods that general language is preferred. VIM, ISO, or ASTM definitions should be used when they exist. If rewordings are used for exceptional circumstances, they should be careful for clarity and consistence with consensus definitions. Several definitions are inconsidtent with VIM/ISO (e.g, accuracy, bias, corrective action, limit of detection) and others are needlessly confusing (limit or quantitation, measurement uncertainty, analytical uncertainty).

Use VIM3, ISO 3534, or ASTM definitions where they exist.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 582

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Laboratory Control Samples are taken through the sample prep and exponsed to all analytical steps of the analysis. Matrix Spike definition: should be added before the sample prep (with the exception of TCLP extractions).

Include the term, "taken through all sample preparation and analytical steps of the procedure." Change the definition of matrix spike to say that the samples are spiked before sample prep, unless the method specifies otherwise.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Loewer	**Beth**
239-278-7070	**loewerbl@leegov.com**

Comment #: 310

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Calibration definition is overworked. Not the right place to define traceable reference materials.

Suggested definition: A set of operations that establish, under specified conditions, the relationship between the theoretical values of reference materials/standards and the values obtained. The values obtained in calibration of support equipment and test methods are established through the use of purchased or prepared traceable reference materials.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The intent of the propsed definition and the current definition are consistent. The committee would like to use standard definitions when possible.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Loewer	**Beth**
239-278-7070	**loewerbl@leegov.com**

Comment #: 313

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Re: Data reduction Sentence "Data reduction is irreversible...loss of detail." is not an accurate statement because not all data reductions are irreversible and result in loss of detail.
Delete this sentence.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Loewer	**Beth**
239-278-7070	**loewerbl@leegov.com**

Comment #: 314

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal	***Attached Document*** ☐
Re: Measurement uncertainty	This definition is useless to anyone.
Remove from standard.	Possible replacement definition: A statistical parameter that characterizes the dispersion of values that could be reasonably applied to a measured result.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Agreed, The QS Committee removed this definition and changed the analytical uncertainty definition to:
A subset of uncertainty that includes all laboratory activities performed as part of the analysis.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Loewer	**Beth**
239-278-7070	**loewerbl@leegov.com**

Comment #: 316

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal	*Attached Document* ☐
Manager or Technical Manager not defined.	Supervisor not used in this module.
Define Manager or Technical Manager.	Remove Supervisor definition.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Supervisor definition has been removed. Manager and Technical Manager are sufficiently addressed in section 4.1.7.3. and do not need definitions.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Grimes	**Terri**
727-582-2302	**Tgrimes@co.pinellas.fl.us**

Comment #: 332

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal	***Attached Document*** ☑
unnecessary or left out definitions	
See Attachment	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The definition for Field Blank has been removed.
Calibration: The intent of the propsed definition and the current definition are consistent. The committee would like to use standard definitions when possible.
Data Reduction changed to : The process of transforming the number of data items by arithmetic or statistical
calculations, standard curves, and concentration factors, and collating them into a more useful form. Removed last sentence
Manager or Technical Manager: Manager and Technical Manager are sufficiently addressed in section 4.1.7.3. and do not need definitions.
Measurement Uncertainty: The QS Committee removed this definition and changed the analytical uncertainty definition to:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600 x1032	**jaspard@epchc.org**

Comment #: 415

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

I assume that the purpose of the definitions section is to clarify the meaning of commonly used terms. I can't see where the definition of the term "measurment uncertainty" in any way clarifies its meaning! Please change it.

A parameter associated with the results of a measurement that characterizes the dispersion of the values that could reasonably be attributed the measurand.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The definition of measurement uncertainty is being removed because its not used in the module.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Barron	**Joe**
813-627-2600	**barron@epchc.org**

Comment #: 378

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Calibration definition needs to be simplified. Data Reduction is not always "irreversible" Manager definition needs to be added. Measurement Uncertainty is too complex. Test Method should not cover calculations.
Define calculated values as a process or technique.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The definition for Field Blank has been removed. Calibration: The intent of the propsed definition and the current definition are consistent. The committee would like to use standard definitions when possible. Data Reduction changed to : The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors, and collating them into a more useful form. Removed last sentence Manager or Technical Manager: Manager and Technical Manager are sufficiently addressed in section 4.1.7.3. and do not need definitions. Measurement Uncertainty: The QS Committee removed this definition and changed the analytical uncertainty definition to:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	289

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Supervisor: remove this definition as it is not used in this module

remove

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Supervisor definition has been removed.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 581

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

The term "Field of Accreditation" is used in section 4.1.7.3.b, this term should be included in the definitions section. Additionally, the term Field of Accreditation Matrix is used in the definition of Quality System Matrix. This should also be included in the definitions section.

include definition of Field of Accreditation and Field of Accreditation Matrix.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Add Field on Accreditation definition from Volume 2, module 2 and change
Quality System Matrix: These matrix definitions shall be used for purposes of batch and quality control requirements:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	288

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Measurement Uncertainty: This definition is so convoluted that I don't know how anyone could hope to understand it.

Suggested Wording: A statistical parameter that characterizes the dispersion of values that could reasonably be applied to a measured result.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The definition of measurement uncertainty is being removed because its not used in the module.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Junio	**Paul**
920-261-1660	**Paul.Junio@testamericainc.com**

Comment #: 341

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Preparation Batch definition - Preparation units (such as a Hot Block) are capable of preparing with the same process, personnel and lots of reagents larger quantities of samples than 20 at the same time. The limitation of preparation batches to 20 is an arbitrary figure for such equipment. I suggest that an exception be written into the definition allowing for greater numbers where such equipment is designed to hold more than 20 samples.

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 to 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 24 hours (unless an instrument is designed for continuous preparation of more than 20 samples, in which case the maximum batch size is the number of samples that can be placed in the instrument at one time).

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would introduce a concept that had not been subject to public review by being included in a related proposal as published in the Draft Interim Standard.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 261

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Matrix Spike Can this be written clearer?

A sample replicate that has a known mass of target analyte added to it, to determine the effect of the sample matrix on the target analyte.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A sample prepared by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Axelrod	**Steve**
(813) 264-3887 ext 111	**axelrods@hillsboroughcounty.org**

Comment #: 125

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Comments: Please consider revising the definition of analytical uncertainty to something more easily understood. eg., The portion or subset of measurement uncertainty that can be attributed to the lab activities associated with producing the measurement. Unfortunately, the definition of “Measurement Uncertainty” makes no sense to me and all the people I’ve asked to read it. How about a definition the average analyst can understand? The definition of technical manager has been deleted yet it continues to be used 23 times in this section; the definition of “Supervisor” has been added but not used.

Revise definition of analytical uncertainty. Keep a definition for technical manager.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The definition of measurement uncertainty is being removed because its not used in the module.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Applewhite	**John**
352 256 9332	**japplewhite@aplsciences.com**

Comment #: 148

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

3.1 Addtional Terms and Definitions The following terms need to be defined: INTEGRITY, QUALITY, UTILITY, and INFORMATION
Use the definitions published in the Federal Register at: http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf There is also an explanation of the reason the notice was published and why these definitions apply to all Federal Agencies

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

These terms are being used in their common meaning and therefore do not need definition.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 258

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Legal COC: It is not just the sample - bottles, sample aliquots, extracts, and digestates, etc. are all subject to custody documentation. Some programs start custody with sample bottles shipped to the field. Others require the data packages to be delivered under chain of custody. All are considered to be part of Legal COC.

Procedures to document the physical possession of all sample components involved in generation of the data.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Addressed by current definition.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 259

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

The LOD is (not may be) laboratory dependent.

A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	290

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Test Method: clarification is needed for calculations, which are not test methods.

Suggested Wording: "An adoption of a scientific technique for a specific measurement process as documented in a laboratory SOP or published by a recognized authority, not to include calculations such as TN=TKN+NOx"

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Test Method: Non Persausive - The current definition is retained.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 260

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Matrix Duplicate: "second replicate" is redundant.

A replicate of a sample of a given matrix, prepared and analyzed by the laboratory, to give an indication of precision or sample homogeneity.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gibson	**Diane**
8635347377	**dianegibson@polk-county.net**

Comment #: 287

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Manager or Technical Manager: mentioned > 30 times in this module, yet is not defined;

please add; and may want to just reference 4.1.7.3, here, for simplicity.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Manager or Technical Manager: Manager and Technical Manager are sufficiently addressed in section 4.1.7.3. and do not need definitions.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 262

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Matrix Spike Duplicate: second replicate is redundant

same as matrix duplicate

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 264

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Replicate: This definition doesn't fit with how the term is used (matrix duplicate or matrix spike duplicate).
A second aliquot of a sample that has the same apparent physical, chemical, and biological characteristics as the original.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

These terms are being used in their common meaning and therefore do not need definition. Removed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gibson	**Diane**
8635347377	**dianegibson@polk-county.net**

Comment #: 284

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal	*Attached Document* ☐
3.1 Additional Terms and Definitions:	Field Blank: remove this definition as it is not in this module
remove	

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gibson	**Diane**
8635347377	**dianegibson@polk-county.net**

Comment #: 285

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Calibration: This definition, while from an authoritative source (VIM), is convoluted. It needs to be simplified! Also, the last part of both 1) & 2) should not be defined here (re: Reference Stds traceable to SI and Reference Materials's CoAs, etc). This info, if really needed, should be in the Reference Material & Reference Standard definitions.

Suggested Wording: A set of operations that establish, under specified conditions, the relationship between the theoretical values of reference materials/standards and the values obtained. 1) In calibration of support equipment, the values obtained are established through the use of Reference Standards. 2) In calibration for test methods, the values obtained are established through the use of Reference Materials.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Calibration: The intent of the propsed definition and the current definition are consistent. The committee would like to use standard definitions when possible.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 263

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Preservation: this definition doesn't take into account all types of preservation.

Conditions under which a sample must be kept prior to analysis to maintain the chemical and/or biological integrity of the sample. This may include refrigeration, chemical additives, or protecting the sample from light.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Any conditions under which a sample must be kept in order to maintain chemical and/or biological integrity prior to analysis.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	286

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Data Reductions: Remove the last sentence which was added to the NELAC 2003 Standard definition: “Data reduction is irreversible and generally results in a reduced data set and an associated loss of detail.” It is an inaccurate statement in that not all data reductions are “irreversible” and do not necessarily result in a “loss of detail”.

remove

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Data Reduction changed to : The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors, and collating them into a more useful form. Removed last sentence

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Junio	**Paul**
920-261-1660	**Paul.Junio@testamericainc.com**

Comment #: 342

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1 Definitions

Comment with Rationale and Proposal ***Attached Document*** ☐

Use the definition of Proficiency Testing as found in V1M1 for consistency

Proficiency Testing (PT): A means to evaluate a laboratory's performance, under controlled conditions, relative to a given set of criteria, through analysis of unknown samples provided by an external source.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A means to evaluate a laboratory's performance, under controlled conditions, relative to a given set of criteria, through analysis of unknown samples provided by an external source.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Junio	**Paul**	***Comment #:***
920-261-1660	**Paul.Junio@testamericainc.com**	343

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1 Definitions

Comment with Rationale and Proposal ***Attached Document*** ☐

Use definition and acronym of Proficiency Testing Provider as found in V1M1 for consistency purposes
Proficiency Test Provider (PTP): A person or organization accredited by the TNI-approved Proficiency Testing Provider Accreditor to operate a TNI-compliant PT program.

Disposition Non-Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Delete this - not used in V1M2

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Junio	**Paul**	***Comment #:***
920-261-1660	**Paul.Junio@testamericainc.com**	344

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1 Definitions

Comment with Rationale and Proposal ***Attached Document*** ☐

Use the definition and acronym for Proficiency Test Sample as found in V1M1

Proficiency Testing Sample (PT Sample): A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Proficiency Testing Sample (PT Sample): A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within the specified acceptance criteria. Change This

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wasko	**Mike**
706-355-8821	**wasko.mike@epa.gov**

Comment #: 228

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 3.1, 5.2.7.1 and 5.3.9

Comment with Rationale and Proposal ***Attached Document*** ☐

I am opposed to the removal of all references to work cells from this module. Our laboratory has been successfully using the work cell concept in the organic extraction lab. It is unclear to me how the removal of work cells from the standard will impact our laboratory, and whether it will require the analysts to perform new DOCs as individual analysts rather than being able to use the work cell DOCs.

Return all references to the work cell in Section s 3.1, 5.2.7.1, 5.4.9 and any other section which previously contained references to the work cell

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Workcells are allowed if defined by the laboratory. See Technical Modules

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 265

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.1

Comment with Rationale and Proposal	***Attached Document*** ☐
lines of responsibility?	
lines of authority	

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 583

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.1

Comment with Rationale and Proposal ***Attached Document*** ☐

This section is already included in ISO 4.1.5.e.

delete the repeat.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 181

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Delete entire 4.1.7.1 : Laboratory documentation shall include a clear description of the lines of responsibility in the laboratory. Responsibilities and shall be proportioned such that adequate supervision is ensured. Rational: This is already covered in corresponding ISO sections 4.1.5.e, f and g. The TNI section 4.1.7.1 does not add anything different or require any different approach.
Delete 4.1.7.1

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-931-7404	**bfconnor@usgs.gov**

Comment #: 182

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Clause 4.1.7.2 is misaligned with the ISO corresponding section. The TNI additional requirements for Quality Managers do not belong orphaned at the end of ISO section 4.1.5. THe TNI additional requirements for Quality Managers belongs under the discussion of Quality Managers (4.1.5.i.1 in ISO)

TNI 4.1.7.2 should be placed as 4.1.5.i.1 so that it directly follows the ISO requirements for the quality manager.

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kenton	**Roger**
903-237-6882	**rogerk@eastman.com**

Comment #: 213

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.2

Comment with Rationale and Proposal ***Attached Document*** ☐

The 2003 NELAC Standard allows the quality manager to serve as teh technical director or deputy technical director when staffing is limited. The removal of this option could be an obstacle that discourages small labs from seeking NELAP accreditation.

Add a section h or alter to an earlier bullet. h) Where staffing is limited, the quality manager may also be the technical director or deputy technical director.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

h) Where staffing is limited, the quality manager may also be the technical manager.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Shepherd	**Michael**
512-335-0906	**mcshepherd@austin.rr.com**

Comment #: 500

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.2

Comment with Rationale and Proposal ***Attached Document*** ☐

The quality manager does not have to be a member of the staff but the technical manger does?

The Qaulity Manger must be a member if the Technical Staff.

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would introduce a concept that had not been subject to public review by being included in a related proposal as published in the Draft Interim Standard.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 183

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.2.d

Comment with Rationale and Proposal ***Attached Document*** ☐

Clause 4.1.7.2.d has two different requirements - (1) have training or experience, and (2) be knowledgable in lab quality system. One point is - Let's separate all requirements into single requirements, each with their own clause number. THis isn't the most aggregious of examples, but if we are going to make the standards clearer, we need to do this to all double clauses. I will bring up the others in separate comments. So this one would need to be separated, but beyond that... The second point - is that the second clause about being knowledgable should actually be deleted.

4.1.7.2.d) have documented training and/or experience in QA/QC procedures DELETE THIS PART --> 4.1.7.2.e) be knowledgeable in the laboratories quality system Comment: A requirement that the QM is "knowledgeable in the lab QS" is subjective and immeasureable. Are you sure you want to include it at all? Isn't the whole job description about the QManager being the lead in quality issues? I think this is stating the obvious, and

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

4.1.7.2.d) have documented training and/or experience in QA/QC procedures and the laboratory's quality system.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

therefore clutters up the standard. Besides, you couldn't get anybody to agree what knowledgeable means in any particular case. So take it out. Its omission won't change a thing.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

4.1.7.2.d) have documented training and/or experience in QA/QC procedures and the laboratory's quality system.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 584

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.2.d

Comment with Rationale and Proposal ***Attached Document*** ☐

This wording and requriement are different than the 2003 NELAC STandard, and not in a good way. While it is a requriement for the QM to be knowledgeable in the laboratory's quality system, they also need to be knowledgeable in the quality system requriements of the TNI Standard.

Include, "and the requriements of the quality system as outlined in the TNI Standard."

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

4.1.7.2.d) have documented training and/or experience in QA/QC procedures and the laboratory's quality system.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 184

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.2.g

Comment with Rationale and Proposal ***Attached Document*** ☐

Split this out into two different lines since it asks for two different actions. Original: g) notify laboratory management of deficiencies in the quality system and monitor corrective action

g) notify laboratory management of deficiencies in the quality system h) monitor corrective action.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

g) notify laboratory management of deficiencies in the quality system
h) monitor all corrective actions.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Connor	**Brooke**	***Comment #:***
303-236-1877	**bfconnor@usgs.gov**	185

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.3

Comment with Rationale and Proposal ***Attached Document*** ☐

Clause 4.1.7.3 needs to be with its corresponding section in ISO. That would make this clause 4.1.5.h.1 instead of 4.1.7.3

4.1.5.h.1 The laboratory's technical manager(s), however named, and/or his/her designee(s) shall: a) be a full time member of the staff of an environmental laboratory who exercises actual day-to¬day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results. b) be experienced in the fields of accreditation for which the laboratory is seeking accreditation. c) Have duties that include: i. monitoring standards of performance in quality control and quality assurance, and ii. monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data. d) Not be the technical manager(s) of more than one accredited environmental laboratory without authorization from the Primary Accreditation Body. Circumstances to be considered in the decision to grant such authorization shall include: i.

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

the extent to which operating hours of the laboratories to be directed overlap, ii adequacy of supervision in each laboratory, and iii the availability of environmental laboratory services in the area served. e) If absent for a period of time exceeding fifteen consecutive calendar days shall designate another full-time staff member meeting the qualifications of the technical manager(s) to temporarily perform this function. If this absence exceeds sixty-five consecutive calendar days, the primary accreditation authority shall be notified in writing. f) Meet qualification requirements as specified in section 5.2.6.1.

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 585

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.3

Comment with Rationale and Proposal ***Attached Document*** ☐

item b) should state experience not experienced. item e) allows for a technical manager to be out for 65 days. this is way too long. Too many laboratories do not correctly evaluate the education and experience requriements of personnel. the ABs should not have to allow an unqualified person to be responsible for that long without be notified.

delete the d. Change the time to 30 calendar days. This is more reasonable.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Will be changed to 35 days

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 441

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.3 d) iii

Comment with Rationale and Proposal ***Attached Document*** ☐

I don't believe this should be an area reviewed by the standard. Either the lab is adequately supervised or not.

delete

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This is guidance to AB on granting approval.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 186

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.1.7.3.e

Comment with Rationale and Proposal ***Attached Document*** ☐

Separate comingled requirements into separate clauses.

Proposed change: e) If absent for a period of time exceeding fifteen consecutive calendar days shall designate another full-time staff member meeting the qualifications of the technical manager(s) to temporarily perform this function. f) If this absence exceeds sixty-five consecutive calendar days, the primary accreditation authority shall be notified in writing.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The committee feels that these are the similar requirements and therefore not comingled.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Sotomayor	**Alfredo**
608-266-9257	**Alfredo.Sotomayor@Wisconsin.go**

Comment #: 539

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.11.6

Comment with Rationale and Proposal ***Attached Document*** ☐

The material in this section would flow better and would be better understood if it were inserted after the last sentence of ISO 17025 4.11.3. If is desirable to maintain the material here as a block then it needs a header.

Insert material after the last sentence of ISO 4.11.3 or create subsection 4.11.6 as "Corrective action documentation procedures".

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 270

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.11.6 c)

Comment with Rationale and Proposal ***Attached Document*** ☐

Asking labs to predict circumstances that require cause analysis is difficult to do. Everything should require it - appropriate to the magnitude and risk of the problem.

Proceduers for performing cause analysis (4.11.2) appropriate to the magnitude and risk of the problem.

Disposition Non-Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 589

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.11.6.c

Comment with Rationale and Proposal ***Attached Document*** ☐

This section implies that cause analysis is not always required. This is in conflict with the ISO standard 4.11.2.

If this is the intent, is should be specified what particular instances "cause analysis" are not required. Otherwise, it is acceptable for a laboratory to say that cause analysis is never required, and this is unacceptable.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

4.11.7

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 248

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.12.3.f

Comment with Rationale and Proposal ***Attached Document*** ☐

Make this 4.13.1.5 Also put 4.13.3.b-e in with corresponding ISO sections. Currently they are all thrown on the end of "Control of Records" even though they match up with some of the current ISO subheadings.

4.13.3.a - make this a note under 4.13.1.1 (as previously commented) 4.13.3.b - make this 4.13.1.2.a 4.13.3.c - make this 4.13.1.2.b 4.13.3.d - make this 4.13.1.2.c 4.13.3.e - make this 4.13.1.5

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Arms	**Stephen**
7911502	**steve_arms@doh.state.fl.us**

Comment #: 469

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.13.3(f) and (c)

Comment with Rationale and Proposal ***Attached Document*** ☐

Items 4.13.3(f)xvi, xvii, xviii, and xix are not data-related and would be better placed under 4.13.3(c).

Move items 4.13.3(f)xvi, xvii, xviii, and xix to become 4.13.3(c)i, ii, iii, iv, and add the word "All" at the beginning of 4.13.3(c) and "including:" after "body"

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The section is not only for data but all records maintained by the laboratory.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 247

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.13.3.a

Comment with Rationale and Proposal ***Attached Document*** ☐

The existing standard is too subjective based on the requirement to be "readily understood". However, the text is useful in that it provides background.

Make the first sentence in 4.13.3.a a note under 4.13.1.1. Delete the second sentence. There is no such thing as unequivocal and accurate records because to err is human and this wording is too subjective. So the text would now read: "Laboratory facilities, equipment, analytical test methods, and related laboratory components, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts shall be recorded.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

"readily understood through the documentation"

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 249

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.13.3.f.ix

Comment with Rationale and Proposal ***Attached Document*** ☐

The protocols listed are not "records" they are procedures and will be documented in the SOP. Keep the list to just records, which includes the second half of your list only

delete: sample preparation, including cleanup, separation protocols keep: incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

these are sample preparation records.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 381

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.13.3.f.xiv

Comment with Rationale and Proposal ***Attached Document*** ☐

The term "protocol" is not in the glossary. Use common terms throughout. I suggest inserting "procedure" instead of protocol, if the meaning is correct in this usage.

xiv. quality control procedures and assessment;

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Protocol is defines as - A detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 382

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.13.3.f.xix

Comment with Rationale and Proposal ***Attached Document*** ☐

This is already covered in TNI 4.2.8.3

omit

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Not necessarily the same signatures.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 387

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.13.3.h

Comment with Rationale and Proposal ***Attached Document*** ☐

Delete this requirement. It goes way beyond the assurance of data of known and documented quality. If a client wants their data to last an eternity beyond the life of the laboratory, they can make arrangements to do so. But the lab shouldn't have a plan in case a client wants this provision - the lab can create an arrangement at the time.
Delete 4.13.3.h

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Been there all along - this has everything to do with records.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 590

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.14.5 and 4.

Comment with Rationale and Proposal ***Attached Document*** ☐

There is no required time-frame for internal audits and management reviews in ISO. the TNI standard does not include them either. THis is a problem, and not an auditable/assessable "requirement" from an AB standpoint.

Include a time-frame, specifically anually, for the internal audits and management reviews.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Include a statement that these are done annually in section 4.14.5 and somewhere in 4.15.3 Additional Requirements.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 446

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.14.5 c

Comment with Rationale and Proposal ***Attached Document*** ☐

Statement is vague- if it is about data integrity isn't it already in data integrity- if it implies a corrective action, it is already covered there.

delete

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Schrenkel	**Carol**	***Comment #:***
(610) 280-3013	**schrenkc@lionvillelab.com**	271

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.14.5 c)

Comment with Rationale and Proposal ***Attached Document*** ☐

This doesn't seem to fit here.

Move to 4.16

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 388

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.14.5.a

Comment with Rationale and Proposal ***Attached Document*** ☐

THis would be more simply stated that the laboratory must have a policy outlining the timeframe for client notification when the validity of results are in question. The current wording suggests that each client shall have a specific time frame in case of questionable data.

The laboratory shall have a policy outlining the date by which the client must be notified when the validity of their results are in question.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

must have a policy is the requirement

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 591

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.14.5.c

Comment with Rationale and Proposal	***Attached Document*** ☐
what are inappropriate actions? and do the reviews need to be documented?	
clarify the requirement and specify that the reviews need to be documented and retained.	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

deleted

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Sotomayor	**Alfredo**
608-266-9257	**Alfredo.Sotomayor@Wisconsin.go**

Comment #: 549

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.16

Comment with Rationale and Proposal ***Attached Document*** ☐

This section seems to have been hastily drafted or edited. The term surveillance has a specific meaning in ISO 17011 and should be avoided here. The first sentence is lacking a lead that places the "invetigations" in their proper context. If a general statement is made that unless otherwise specifiied in the standard, all records alluded to in the module must be retained for at least five years, the last sentence is unnecessary.

Change the header of 4.16 to "Data Integrity Investigations" or "Data Integrity Audits".

Rephrase item to: "All investigations resulting from data integrity issues shall be documeted and conducted in a confidential manner until they are completed. The results of these investigations shall be documented, including any disciplinary and corrective actions taken, as well as any notifcations made to clients receiving any affected data."

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 4.16

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 447

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.16

Comment with Rationale and Proposal ***Attached Document*** ☐

It doesn't make sense to have this seperate from the data integrity procedures in 4.2.8.1

Add to end of 4.2.8.1

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 4.16

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 414

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.16

Comment with Rationale and Proposal ***Attached Document*** ☐

Split out separate requirements into separate clauses for easy referral. The 3 sentences in 4.16 each represent a different requirement.

1. All investigations shall be documented and shall include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients. 2. Potential issues shall be handled in a confidential manner until such time as a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified.

3. All documentation of these investigations and actions taken shall be maintained for at least five years.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The committee does not see the need for this modification.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kenton	**Roger**
903-237-6882	**rogerk@eastman.com**

Comment #: 214

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.16

Comment with Rationale and Proposal ***Attached Document*** ☐

Disciplinary actions may require confidential handling even after a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified.

Potential issues shall be handled in a confidential manner (as appropriate).

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Sotomayor	**Alfredo**
608-266-9257	**Alfredo.Sotomayor@Wisconsin.go**

Comment #: 533

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8

Comment with Rationale and Proposal ***Attached Document*** ☐

The header "Quality System" for this item does not convey the content of the following subsections. Since the subsections of ISO 17025 4.2 do not contain headers, the subsection 4.2.8 should not either. The numbered itemized content in 4.2.1 proper should be converted to letters to follow the ISO format. The material in 4.2.8.1 (a) and (b) should become subsections 4.2.xx and 4.2.xx.
Reformat to comply with ISO 17025 style.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 4.2.8

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 187

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Separate different requirements into separate clauses. Don't reference readers away other sections to get more information about this subject, move all related subject material to the same location.

Proposed change: 4.2.8.1 The laboratory shall establish and maintain documented data integrity procedures. There are four required elements within a data integrity system. These are: 1) data integrity training, [insert related sections of 5.2.8 here] 2) signed data integrity documentation for all laboratory employees, 3) in-depth, periodic monitoring of data integrity, and [insert integrity surveillance, TNI section 4.16 here] 4) data integrity procedure documentation. [insert related sections of 5.2.8 here] 4.2.8.2 Management shall annually review data integrity procedures and update as needed.

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would introduce a concept that had not been subject to public review by being included in a related proposal as published in the Draft Interim Standard.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Applewhite	**John**
352 256 9332	**japplewhite@aplsciences.com**

Comment #: 149

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.1

Comment with Rationale and Proposal ***Attached Document*** ☐

4.2.8.1 This section initially refers to "data integrity procedures" and the next sentence refers to a "data integrity system."

Define "data integrity procedures" and "data integrity system." By define I am not referring to the practice of giving examples of what constitute these efforts since examples are not all inclusive and cannot be used by the lab to determined what is required to comply with the standard.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 4.2.8.1

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 442

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.2

Comment with Rationale and Proposal ***Attached Document*** ☐

I believe the standard should allow the lab to decide who will keep the quality manual current. Smaller labs need the flexibility in how they run their labs.
The quality manual shall be maintained current. under the responsibility of the quality manager or technical manager. (or delete who will do it)

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Quality manager is responsible, but not necessarily responsible for edits.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 188

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.2

Comment with Rationale and Proposal ***Attached Document*** ☐

This clause is about a Quality Manager requirement. Move it to the Quality Manager section - 4.1.5.i

Proposed change: Stick this within 4.1.5.i as a subsection.

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Connor	**Brooke**	***Comment #:***
303-236-1877	**bfconnor@usgs.gov**	189

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.3

Comment with Rationale and Proposal ***Attached Document*** ☐

This section lists requirements but does not group like subjects together. Also, doubled clauses need to be separated into single clauses.

Proposed change: 4.2.8.3 The quality manual shall contain: a) document title; b) laboratory's full name and address; c) name, address (if different from above), and telephone number of individual(s) responsible for the laboratory; i) identification of the laboratory's approved signatories; ii) the signed and dated concurrence (with appropriate titles), of all responsible parties including the quality manager(s), technical manager(s), and the agent who is in charge of all laboratory activities, such as the laboratory director or laboratory manager; d) name of the quality manager (however named); e) identification of all major organizational units which are to be covered by this quality manual f) the effective date of the version; MOVE the original 4.2.8.3.h to the first statement in 4.2.8.4 g) the laboratory's official quality policy statement, which shall include quality

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A checklist format could be developed if needed. The committee feels that there are multiple instances of mulitiple ideas throughout the modules and these changes were not imperative.

Last Name	*First Name*
Phone Number	*Email*

system objectives and management's commitment to quality and to ethical laboratory practices; and h) a table of contents i) applicable lists of references j) glossaries and

k) appendices.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A checklist format could be developed if needed. The committee feels that there are multiple instances of mulitiple ideas throughout the modules and these changes were not imperative.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 443

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.3 d

Comment with Rationale and Proposal	***Attached Document*** ☐
this is included in 4.2.8.3g	
delete	

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 586

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.3.i

Comment with Rationale and Proposal ***Attached Document*** ☐

The laboratory's quality policy statement should include its commitment to imlement and uphold the requriements of the TNI standard too.
Include this requirement.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 4.2.8.3

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 266

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.4

Comment with Rationale and Proposal ***Attached Document*** ☐

I think "or related quality documentation" should stay in. It is redundant considering the statement is "contain or reference", but too many people already read it as "contain" only. Taking the phrase out removes the emphasis on the fact that everything does not have to be in the quality manual.

leave "or related quality documentation" in.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Withdrawn

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 190

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.4

Comment with Rationale and Proposal ***Attached Document*** ☑

Split out clauses with double subjects. Rearrange clauses in sequence... Group similar requirements....

Proposed change is attached as a file....

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A checklist format could be developed if needed. The committee feels that there are multiple instances of mulitiple ideas throughout the modules and these changes were not imperative.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Sotomayor	**Alfredo**	***Comment #:***
608-266-9257	**Alfredo.Sotomayor@Wisconsin.go**	534

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.4 (f)

Comment with Rationale and Proposal ***Attached Document*** ☐

I am not sure what is meant by "measures of laboratory performance"n here. Many the elements in 4.2.8.4 could be considered measures of laboratory performance. If the term means something else, then it should be defined or clarified.

Delete 4.2.8.4(f)

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Deleted

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 444

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.4 f

Comment with Rationale and Proposal ***Attached Document*** ☐

measures of lab performance is vague and open to interpretation
delete

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Deleted

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 268

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.4 l)

Comment with Rationale and Proposal ***Attached Document*** ☐

rephrase
procedures for handling samples received

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 587

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.8.4.n

Comment with Rationale and Proposal	***Attached Document*** ☐
it should be laboratory's not laboratory	
change to the possessive tense.	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 191

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.9.1

Comment with Rationale and Proposal	***Attached Document*** ☑
4.2.9.1.a is a note, not a requirement. Move it up to 4.2.9.1. Rearrange for better flow as in attached document.	
Proposed change: see attached document.	

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 445

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.9.1 b

Comment with Rationale and Proposal ***Attached Document*** ☐

makes better sense to change to be to: and be
and be

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 198

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.9.2

Comment with Rationale and Proposal ***Attached Document*** ☐

There has been too much confusion over the 23 items bulleted as SOP requirements. We (the Small Lab Committee) believe that the 23 items should be subjects to cover or reference. There are many who believe the standard says that these are best as the Headers for 23 required sections in the SOP. Our suggestion is that the 23 items be covered in the SOP only.

Proposed change: From this: b) The SOP may be a copy of a published or referenced test method or may be written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced test method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each test method shall include or reference where applicable: To this: b) Subjects to be covered in test method SOPs include:

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See changes to 4.2.8.5 f

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Penfold	**Larry**
303-736-0119	**Larry.Penfold@testamericainc.co**

Comment #: 376

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.9.2,b),iii

Comment with Rationale and Proposal ***Attached Document*** ☐

Current Text: Each test method [SOP] shall include or reference….iii. detection limit Comment: a) Detection limits are not always required or used, whereas quantitation limits virtually always are. Therefore, quantitation limit is the more universally significant concentration to include or reference in the scoping section of an SOP. b) Detection limits are subject to change, whereas as quantitation limits tend to be more constant.

Each test method [SOP]shall include or reference...iii. quantitation limit

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

where applicable

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 588

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.2.9.2.b.iii

Comment with Rationale and Proposal ***Attached Document*** ☐

The detection limit is less important that the reporting limit. The RL triggers the qualifier on the report. The AB and the analyst should know what limit is being reported by the laboratory.

include "reporting limit"

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

limits of detection and quantitation

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 602

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.3.3.3

Comment with Rationale and Proposal ***Attached Document*** ☐

"as soon as practicable" This term should be defined in the TNI Standard

I suggest within one year.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Amendments need to follow a labs procedures/policy

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Riddick	**Wayne**
423-229-4034	**wriddick@eastman.com**

Comment #: 375

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.6

Comment with Rationale and Proposal ***Attached Document*** ☐

I have received comments from associates to the effect that some of the administrative requirements of the standard, in areas such as organization, purchasing, subcontracting, etc., take up resources without adding value. Many of these requirements are found in the ISO/EIC 17025 standard. One example is clause 4.6.2 of the ISO standard, which requires that RECORDS be kept of actions taken to check compliance of purchased supplies with specifications. I must agree with some of these comments from my associates.
Deletion of such requirements.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This decision was made by NELAC stakeholders in 2001, 2002 and 2003.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 267

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.8.2.4 j)

Comment with Rationale and Proposal ***Attached Document*** ☐

We may want to reconsider the phrasing on this. How many auditors would accept a simple list of accredited methods (e.g., 8260B, 8270C, etc). I think what they're looking for is a complete scope of accreditation - matrix-method/technology-analyte.
rephrase as appropriate

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Withdrawn

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 269

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 4.8.2.4 s)

Comment with Rationale and Proposal ***Attached Document*** ☐

This requirement should be as applicable. Some labs do not use electronic signatures.

add: , as applicable.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Bader	**Michael**
620-793-4170	**mbader@greatbendks.net**

Comment #: 529

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.1

Comment with Rationale and Proposal ***Attached Document*** ☐

ISO is hard to read and small labs may not care if they are ISO.
Drop ISO language or have a separate barebones module for small labs.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This decision was made by NELAC stakeholders in 2001, 2002 and 2003.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Hassani	**Farzaneh**
813-247-3451	**Farzaneh.Hassani@ci.tampa.fl.us**

Comment #: 383

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.10.10

Comment with Rationale and Proposal ***Attached Document*** ☐

The proposed standard has become confusing due to the proposed removal of the “or” at the end of 5.10.10.a. Does the proposed standard require 5.10.10.a and (5.10.10.b or 5.10.10.c)? Removing the “or” for 5.10.10.a and then adding an “or” at the end of 5.10.10.b appears to create an inconsistency between the conditions in a and b. As proposed, the standard narrowly eliminates the reporting exception for wastewater labs that provide data as in 5.10.10.b but do not directly prepare the regulatory reports.

Suggested wording: Leave the “or” at the end of 5.10.10.a and 5.10.10.b. Add 5.10.10.c.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Axelrod	**Steve**
813-264-3887 ext 111	**axelrods@hillsboroughcounty.org**

Comment #: 128

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.10.10 (a)

Comment with Rationale and Proposal ***Attached Document*** ☐

Comment: While it's probably not needed, deleting the "or" at the end of this phrase allows possible misinterpretation as an implied "and".

do not delete "or"

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Applewhite	**John**
352 256 9332	**japplewhite@aplsciences.com**

Comment #: 150

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.10.11

Comment with Rationale and Proposal ***Attached Document*** ☐

5.10.11 d) Clear identification of numerical results with values outside the working calibration range. Picky editorial comments. 1) Is a "working" calibration range different from a calibration range - is the intent to identify results that were obtained by dilution of the sample? The reported results after the dilution factor is applied are technically outside the calibration range. 2) Calibration range is not defined either. I know we all feel like we intuitively know what constitutes a calibration range. Best nail it down.

3) The word "clear" is superfluous. For instance, if the word "clear" is not included in the standard does this imply that "ambiguous" is allowed?

Damned if I know.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Removed the word working

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 454

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.10.11 b

Comment with Rationale and Proposal ***Attached Document*** ☐

Statement is vague. Not sure what it is implying.
clarify or delete

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

such as dry weight - see revision

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 600

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.10.11.b

Comment with Rationale and Proposal ***Attached Document*** ☐

This statement is not properly worded. As written it states that the results are received in the laboratory. I believe the intent is "as the samples are received." This may be an appropriate place to include an example, otherwise it doesn't make much sense.

"Basis on how the sample result have been calculated, i.e. dry or wet weight basis or the statistical package used to provide the data (Whole Effluent Toxicity). "

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Sotomayor	**Alfredo**
608-266-9257	**Alfredo.Sotomayor@Wisconsin.go**

Comment #: 554

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6 - 5.2.8

Comment with Rationale and Proposal ***Attached Document*** ☐

The addtional subsections added to 5.2 contain headers, but the original ISO 17025 subsections of 5.2 do not.

Remove the headers for the added language to ISO 17025 5.2.

Disposition Non-Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Clarification

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Meier	**Kari**	***Comment #:***
(502) 315 6316	**kari.l.meier@us.army.mil**	296

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

the requirements for technical management personnel itemizes verbiage for laboratories "engaged in" certain types of chemistry/biological testing. It is concevable that a technical manager may be over more than one of these areas such that the verbiage would be interpretive, ie. allow the choice to meet either the stricter of the guidance requirements (probably prefered), or choose to meet one of the other (and possibly the least stringent of the requirements). There is verbiage for educational exchange for experience, but no experience exchange for education (BS).
Make statement such that if a TM is over more than one area, must meet the highest educational requirement applicable for the subject areas, and meet the appropriate experience in each section (where again, post grad degree may substitute for year experience in the areas.) include statement for experience exchange for education (BS).

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A technical manager must be qualified

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 426

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

We are over-reaching our intentions here. I believe we have this standard because we wanted to make sure that labs are managed by knowledgable people. I don't think we meant to deny accreditation to a competent laboratory because a technical manager only completed 22 hours of chemistry instead of 24. What we meant (?) is that we are pretty sure someone with the college credentials listed will be competent. We don't mean that someone without the credentials will definitely be incompetent! We have to be careful about the flip side of our standards. If "college = competentence", then "no college = incompetence" is not a fact. I don't think you should specify in such detail who a laboratory can hire - no matter how high the position. There are those who graduate college and are still complete idiots, and those who didn't go to college who are the brightest, most capable individuals you've ever met. I think a regulation is never going to be able to judge a person's worth. This must be judged by people. Further, having this standard does not protect labs and their

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The QS committee met stiff resistance from the stakeholders when trying to substitute experience for education in 2006. This needs more comments and discussion from stakeholders during the next revision cycle.

Last Name	*First Name*
Phone Number	*Email*

customers from incompetence. Let's lighten up the standards by simplying stating the Technical Manager (please add to glossary) has xxxx job functions and has sufficient training, education, or experience to provide a working quality system. The QS is designed to let you know where failures occur and if it is with a Technical Manager, then you can deal with them at that time.

Delete 5.2.6.1.a, b, c, d, e, f through 5.2.6.2.c - All of it. The ISO requirements are sufficient.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The QS committee met stiff resistance from the stakeholders when trying to substitute experience for education in 2006. This needs more comments and discussion from stakeholders during the next revision cycle.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 440

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

I think we should reintroduce the 5 years of experience to substitute for college credit hours. Although college credit hour have merit, experience provides the real learning ground for what happens in each of the disciplines (chemistry, micro) in a lab setting. Also in a small lab, the whole lab is usually run by one person and this requirement can be hard to meet. That person could have a BS in chemistry and no microbiology education or vice versa. Most people that I interview usually have one discipline and not the other. Yet the educated person may have more knowledge than a wastewater plant operator with their certificate.

Five years of experience in the appropriate discipline shall be considered acceptable to meet the applicable college semester credit hours for the given technical manager position.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The QS committee met stiff resistance from the stakeholders when trying to substitute experience for education in 2006. This needs more comments and discussion from stakeholders during the next revision cycle.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
McCracken	**Kirstin**
802-923-1019	**Kirstin.McCracken@testamericain**

Comment #: 239

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.1 a)

Comment with Rationale and Proposal ***Attached Document*** ☐

The qualification for the technical manager to have 24 college semester credit hours in chemistry is restrictive and inconsistent with current trends in the qualifications of job applicants to the environmental laboratory. (In the experience of this laboratory) The number of job applicants to the environmental laboratory with chemistry degrees is negligible and those applicants that possess a bachelors degree in environmental, biological or physical sciences do not have the requisite 24 chemistry credit hours because that number of credit hours in chemisry is not required by their institution to confer the degree. As a result, the laboratory is finding it increasingly difficult to meet this qualification requirement. The responsibilities and tasks of the technical manager as defined in clause 4.1.7.3 are generally learned on the job and they are performed by a section supervisor who is designated a "technical manager" for the purpose of accreditation. The performance standards for QA/QC are well-defined, instrument technology and data processing systems are superior, and the

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The QS committee met stiff resistance from the stakeholders when trying to substitute experience for education in 2006. This needs more comments and discussion from stakeholders during the next revision cycle.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

validty of test resuls checked against established reference methods and quality system requirements. I do not believe that 24 hours in college chemistry is necessary to sucessfully perform these tasks and I would like to see a provision in this clause that allows for a work experience to substitute or replace the requisite for 24 college semester credit hours in chemistry.

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

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The QS committee met stiff resistance from the stakeholders when trying to substitute experience for education in 2006. This needs more comments and discussion from stakeholders during the next revision cycle.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Haynes	**RaeAnn**
503-229-5983	**haynes.raeann@deq.state.or.us**

Comment #: 238

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.1 b)

Comment with Rationale and Proposal ***Attached Document*** ☐

The technical manager of an inorganic section is often responsible for over sight of ion chromatography (and flow injection analysis). This analytical techniques require as much understanding as other chromatography and a two year degree is not sufficient. 5.2.6.2 Technical Manager Qualification Exceptions already allow waste treatment facilities to run basis inorganic tests with an associates degree.

Shall be a person with at least a bachelor's degree.....

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Existing NELAC Language was used here.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Arms	**Stephen**
9047911502	**steve_arms@doh.state.fl.us**

Comment #: 470

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.1(c), 5.6.2(a) and (b)

Comment with Rationale and Proposal ***Attached Document*** ☐

POSSIBLE DUPLICATE - CONNECTION LOST DURING SUBMISSION The changes proposed in these sections impose additional requirements for experience of the managers of small laboratories, when many already consider the current requirements onerous. This conflicts with efforts in TNI to encourage increased participation from these laboratories and the organizations that represent them. The committee must seriously consider the impact these changes will have on these efforts. Also problematic is the fact that the previous requirements have been adequate and in place for many years. Changing them will put labs newly accredited to this Standard at a disadvantage and will cause labs now accredited even more difficulty when recruiting new managers. (If it were allowed to break out sections for voting, I would have voted NO.)

Eliminate the additional experience requirements in 5.2.6.1(c), 5.6.2(a) and (b).

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The QS committee met stiff resistance from the stakeholders when trying to substitute experience for education in 2006. This needs more comments and discussion from stakeholders during the next revision cycle.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
71-346-8212	**aaalger@state.pa.us**

Comment #: 592

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.1.c

Comment with Rationale and Proposal	***Attached Document*** ☐
Why didn't we include e.coli in the list of parameters?	
inlcude e.coli.	

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Bader	**Michael**	***Comment #:***
620-793-4170	**mbader@greatbendks.net**	535

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Treatment plants may not require operators certificates or afford to hire a person with a bachelors degree to run the lab. In treatment plants where staffing is limited one person may be needed to do everything. Contracting analysis out may cause violations in holding times if shipped or increased man hours if driven to a contract lab. (look at maps of larger states and see how far it is from a remote town to the closest contract lab) LOVED THE EXPERIENCE PART!!!!!!

Allow more leeway, for example 5 years experience equals 5 hours chemistry. ABC (American Board of Certification) based lab certificate worth 5 hours chemistry.

http://www.abccert.org/about.html

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The QS committee met stiff resistance from the stakeholders when trying to substitute experience for education in 2006. This needs more comments and discussion from stakeholders during the next revision cycle.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Sotomayor	**Alfredo**
608-266-9257	**Alfredo.Sotomayor@Wisconsin.go**

Comment #: 557

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.2 (a), (b)

Comment with Rationale and Proposal ***Attached Document*** ☐

In the spirit of inclusion, the experience requirements for the technical managers of drinking water, sewage treatment, and industrial wate treatment facilities that do not meet the educational requirements of other managers could be both one year. Alternatively, the years of experience could be a function of the type of tests undertaken at each of these facilities, much in the same way that the educational requirements for technical managers are predicated on the type of testing performed at their respective laboratories. For example, I do not think I would be detrimental to allow an operator with one year of experience to qualify as the technical manager of a facility that only analyzes biochemical oxygen demand (BOD) and total suspended solids (TSS) samples.

Change experience requirements for for the technical managers of drinking water, sewage treatment,and industrial wate treatment facilities that do not meet the educational requirements of other managers to one year, or make the number of years commensurate witht

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The QS committee met stiff resistance from the stakeholders when trying to substitute experience for education in 2006. This needs more comments and discussion from stakeholders during the next revision cycle.

the complexity of the analyses performed at these facilities.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The QS committee met stiff resistance from the stakeholders when trying to substitute experience for education in 2006. This needs more comments and discussion from stakeholders during the next revision cycle.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 272

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.2 c) i)

Comment with Rationale and Proposal ***Attached Document*** ☐

clarification

...on the date the laboratory applies for accreditation and/or becomes subject to accreditation under this Standard, and must have...

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Broderick	**James**
518-573-7548	**jdb10@health.state.ny.us**

Comment #: 394

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.6.2.c.iii

Comment with Rationale and Proposal ***Attached Document*** ☐

The purpose of grandfathering is to promote inclusion of labs by reducing the potential for problems with Lab management credentials. This clause does not protect existing labs, allowing for easier adoption of standards: it protects lab directors as individuals. I see no benefit for the protection of individuals that wouldn't meet the more general requirements. In no other way does NELAP give protection to individiuals who are no longer under the employment of a lab.

Remove clause.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A grandfather clause is needed for qualified individuals that understand NELAC requirements.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 273

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.7

Comment with Rationale and Proposal ***Attached Document*** ☐

this is covered in ISO 17025 5.2.5

delete

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 541

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.8

Comment with Rationale and Proposal ***Attached Document*** ☐

Split this paragraph into separate requirements (training upon orientation and annual refreshers). Make the part about "Managers upholding the spirit..." a Note, or delete it, because it is completely subjective and immeasurable. Make the part about emphasis of proper written narration a Note, or delete it, because it is not a standard, it is information. A standard would be, "A required element of Data Integrity training is proper written narration". Perhaps you can add it to the list as f). The last paragraph adds suggestions. This is not a standard. Make it a note.

Data integrity training shall be provided as a formal part of new employee orientation.

Data integrity training shall be provided on an annual basis for all employees. The topics covered in such training shall be documented in writing (such as an agenda) and provided to all trainees. All data integrity training shall have a signature attendance sheet or other form

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Partly - Eliminated last sentence

Last Name	*First Name*
Phone Number	*Email*

of documentation that demonstrates all staff have participated and understand their obligations related to data integrity. Note 1: Employees are required to understand that any infractions of the laboratory data integrity procedures shall result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution. Note 2: Managers acknowledge their support of these procedures by 1) upholding the spirit and intent of the organization's data integrity procedures and 2) effectively implementing the specific requirements of the procedures.

At a minimum, the following data integrity topics and activities shall be included:

a) organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues, and record keeping; b) training, including discussion regarding all data integrity procedures;

c) data integrity training documentation; d) in-depth data monitoring and data integrity procedure documentation; and e) specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards. f) the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient. Note 3: The data integrity procedures may also include written ethics agreements, examples of improper practices, examples of improper chromatographic manipulations, requirements for external ethics program training, and any

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Partly - Eliminated last sentence

Last Name	*First Name*
Phone Number	*Email*

external resources available to employees.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Partly - Eliminated last sentence

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Shepherd	**Michael**
512-335-0906	**mcshepherd@austin.rr.com**

Comment #: 501

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.8

Comment with Rationale and Proposal ***Attached Document*** ☐

"Data integrity training requires emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient." This sentence at the beginning of the second paragraph suggests that proper narration is the main focus of data integrity training. It is not, it is simply one of many issues that should be addressed.
The topic should be listed along with the other bulleted/lettered items below the paragraph.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Narrative is important in conveying the need for Data Integrity.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 593

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.2.8

Comment with Rationale and Proposal ***Attached Document*** ☐

the last sentence is not something that can effectively be evaluated by an AB. How do you determine if the managers have upheld "the spirit and intent of the organization's data integrity procedures"?
change the wording to make it enforceable or delete it.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 594

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.3.6

Comment with Rationale and Proposal ***Attached Document*** ☐

This section repeats the requirements of ISO 5.3.2.
delete the repeat.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 544

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.3.7

Comment with Rationale and Proposal ***Attached Document*** ☐

A standard does not need to judge whether workspaces MIGHT impact the quality of the data. The data quality will speak for itself. Delete 5.3.7 completely. I believe this goes overboard for NELAC to get involved in tidiness (I don't mean cleanliness, I mean tidiness - the analytical blanks will tell you about cleanliness).

Delete 5.3.7

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Shepherd	**Michael**
512-335-0906	**mcshepherd@austin.rr.com**

Comment #: 502

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.4.6

Comment with Rationale and Proposal ***Attached Document*** ☐

5.4.6 Estimation of Analytical Uncertainty Clause 5.4.6 of the ISO/IEC 17025:2005(E) concerning calibration testing does not apply. The following requirements replace replaces the ISO/IEC Clause.: Environmental testing laboratories shall have a procedure(s) for estimating analytical uncertainty. Quality control measurement data may be used to determine analytical uncertainty. This requirement does NOT apply to the VAST MAJORITY of environmental laboratories. Rarely, IF EVER, are they required (or are even able) to estimate uncertainty in any meaningful way. Requiring a laboratory to have a procedure for estimating uncertainty when they are never required to do so by their clients (or the Accrediting Authority), is nonsensical and does nothing to add to the quality of the data.

If this requirement must remain in the standard, it should be revised to state “Environmental testing laboratories shall have a procedure(s) for estimating analytical uncertainty if required by client, contract, or program”.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

A procedure is required.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Murphy	**Mark**
2549689570	**murphy@tarleton.edu**

Comment #: 209

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.4.8

Comment with Rationale and Proposal	***Attached Document*** ☐
typo- Extra period in the paragraph	
remove extra period	

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 274

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.4.8

Comment with Rationale and Proposal ***Attached Document*** ☐

This section isn't applicable anymore. Since each individual has to have a DOC prior to running the method, it's a filing excercise to consider one of the DOC's the "method" DOC. What does it demonstrate when eg, Joe Smith, who left the company 10 years ago, did the DOC prior to implementation of the method. The method hasn't changed any, everyone who's performed it since has their own DOC, and the records are only kept for 5 yrs, so they're no longer available.

delete this section

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 546

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.4.8

Comment with Rationale and Proposal ***Attached Document*** ☐

This doesn't state anything different than what ISO already states in 5.4

delete 5.4.8

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Reininger	**Rodney**
(217) 698-0642	**rreininger@tmilab.com**

Comment #: 553

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.4.8 and 5.8.9 a) ii)

Comment with Rationale and Proposal ***Attached Document*** ☐

Remove second period from first sentence in each of these paragraphs.

Remove second period from first sentence in each of these paragraphs.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gerald	**Dechant**
970-434-4875	**gldechant@aol.com**

Comment #: 98

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.5.13.1

Comment with Rationale and Proposal ***Attached Document*** ☐

In section d) there is a daily check requirement for balances, ovens, refrigerators, water baths, and freezers. These items are generally not used for all analyses and none of this equipment is known to have a high failure rate. In section e) there is a quarterly requirement to check volumetric dispensing devices. These devices are used in all analytical techniques, are used for both calibration and sample preparation, are commonly used multiple times in the preparation process, and many have a known relatively high failure rate. It does not seem logical to apply the most stringent requirements to the equipment with the lowest failure rate and the least stringent requirements to the equipment with the highest failure rate. In addition, using a quarterly check requirement does not allow for a reasonable corrective action. If a volumetric dispensing device fails the quarterly check what does the laboratory do about the potentially effected sample data from the last quarters worth of work using that device?

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Details are necessary in this section.

Comments with TNIQS Response

Last Name	***First Name***
Phone Number	***Email***

drop section e and put all equipment with a daily check requirement

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Details are necessary in this section.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 279

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.5.7.1

Comment with Rationale and Proposal ***Attached Document*** ☐

clarify

The laboratory shall implement procedures to verify and document field preservation of samples.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

5.8.7.1

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
7147-346-8212	**aaalger@state.pa.us**

Comment #: 595

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.6.1 and 5.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

These requirements are calibration lab requirements.

they should not be inlcuded in the standard for envrionmental laboratories.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See beginning of 5.6

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 448

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

5.6.2.1 is for calibration labs

Should either disclaim 5.6.2.1 for claibration labs or just reference 5.6.2.2

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 5.6

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 449

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.6.4.1 a & b

Comment with Rationale and Proposal ***Attached Document*** ☐

The ISO 5.6.3.1 and 5.6.3.2 already refer to SI units. This should make it so either SI or national units are acceptable

SI units or national units

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

ISO Language cannot be changed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 597

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.6.4.2

Comment with Rationale and Proposal ***Attached Document*** ☐

It does not make sense that items c) and d) do not include "reagents". for traceability of measurements, the reagent preparation records should be required in the same fashion as standards and reference materials. By adding reagents to items c) and d) you can delete item f).

Include "reagents" in c) and d) and delete f).

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

fixed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 551

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.6.4.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Omit redundancy and clarify b and f. b) ...an expiration date..shall be recorded on the container...If an expiration date is not provided by the manufacturer...it is not required. f) All containers of prepared reagents shall bear an expiration data. A preparation date shall be recorded. Huh???? It's not required but it is required?? THe preparation date shall be recorded where? And why is that requirement buried in back of a thought about expiration dates????

b) Original containers of purchased materials shall have the expiration date recorded on the label unless unknown. f) Prepared reagents shall have the preparation date recorded in a log or on the label. g) Prepared reagents shall have the expiration date written on the label.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

see changes to d

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 596

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.6.4.2

Comment with Rationale and Proposal ***Attached Document*** ☐

This is a major change from the current standard. All containers should be required to have an expiration date.

inlcude, "When the manufacturer does not provide an expiration date, the laboratory shall assign an expiration date. the laboratory-assigned expiration date shall be no more than 10 years from the date of receipt."

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Withdrawn

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Axelrod	**Steve**
813-264-3887 ext 111	**axelrods@hillsboroughcounty.org**

Comment #: 126

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.6.4.2 (b)

Comment with Rationale and Proposal ***Attached Document*** ☐

"For original containers…If an expiration date is not provided by the manufacturer or vendor it is not required." Comment: If a portion of the contents is transferred to another container, is an expiration date required on its label? Maybe this can be clarified.
Clarify the need for expiration dates on containers whose contents do not have an expiration date stipulated by the vendor or method.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The only exception is for original containers

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 450

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.6.4.2 b

Comment with Rationale and Proposal ***Attached Document*** ☐

I believe this is an exemption to having an expiration date in a) and so should be part of a)

above

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

see a and new f

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Schrenkel	**Carol**	***Comment #:***
(610) 280-3013	**schrenkc@lionvillelab.com**	275

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.6.4.2 f)

Comment with Rationale and Proposal ***Attached Document*** ☐

Specify where the prep date is recorded, or it could be on the bottle, and thrown out.

A preparation date shall be recorded in the preparation logs.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Ziomek	**betsy**	***Comment #:***
804-698-4181	**esziomek@deq.virginia.gov**	207

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.6.4.2.a & b.

Comment with Rationale and Proposal ***Attached Document*** ☐

a. & b. contradict one another concerning use of an expriation date. 'a' states it must be on the container while 'b' states if it is the originial container and the manufacturer doesn't provide an expiration date, then it isn't required.

If the intent was that the expiration date doesn't have to be on the original container unless the manufacturer provides it, then state that it doesn't have to be on the container.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

fixed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 276

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.7.4

Comment with Rationale and Proposal ***Attached Document*** ☐

Switch a) and b). "this documentation" looks like it's referring to the deviations. Even if there aren't any deviations, the date/time should be recorded.

a) Documentation shall include the date and time of sampling b) Any deviations....

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gibson	**Diane**
8635347377	**dianegibson@polk-county.net**

Comment #: 291

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8

Comment with Rationale and Proposal ***Attached Document*** ☐

5.8.5.c) "The laboratory ID code shall be placed on the sample container as a durable label." is too restrictive. Allow for indelible ink to hand-write Lab IDs.

Suggested wording: "The laboratory ID code shall be placed on the sample container as a durable label or written on the sample container with indelible ink."

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Barron	**Joe**
813-627-2600	**barron@epchc.org**

Comment #: 379

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8

Comment with Rationale and Proposal ***Attached Document*** ☐

Requiring sample containers to have a durable label is too restrictive.

Sample ID shall be placed on the sample container as a durable label or with indelibile ink.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Loewer	**Beth**
239-278-7070	**loewerbl@leegov.com**

Comment #: 318

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8

Comment with Rationale and Proposal ***Attached Document*** ☐

Re: Handling Samples & Test Items 5.8.5 c) Durable label section too restrictive.
Include the use of indelible ink on sample container for times when durable labels cannot be printed.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Grimes	**Terri**
727-582-2302	**Tgrimes@co.pinellas.fl.us**

Comment #: 333

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.1

Comment with Rationale and Proposal ***Attached Document*** ☑

5.8.1 Handling Samples and Test Items (ISO/IEC 17025:2005(E), Clause 5.8)

5.8.5.c) “The laboratory ID code shall be placed on the sample container as a durable label.” is too restrictive. Allow for indelible ink to hand-write Lab IDs, especially when computers or label printers are down.

“The laboratory ID code shall be placed on the sample container as a durable label or written on the sample container with indelible ink.”

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Schrenkel	**Carol**	***Comment #:***
(610) 280-3013	**schrenkc@lionvillelab.com**	277

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.5

Comment with Rationale and Proposal ***Attached Document*** ☐

Delete "while the laboratory may not have control of field sampling activities". I believe most labs do not have control of the field sampling activities, but the documentation is essential whether they do or not.

The following documentation is essential...

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Steve	**Axelrod**	***Comment #:***
(813) 264-3887 ext 111	**axelrods@hillsboroughcounty.org**	127

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.5 (e)

Comment with Rationale and Proposal ***Attached Document*** ☐

In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the laboratory ID code may be the same as the field ID code.

There's no reason that an ID code assigned in the field can not be used as the lab ID code as long as there's a convention for creating the field ID code that ensures that each will be a unique number.
Proposed Change "In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, or the field ID code is a unique identifier, the laboratory ID code may be the same as the field ID code

---

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The same code can be used but it must be unique.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 598

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.5.b

Comment with Rationale and Proposal ***Attached Document*** ☐

change "sample" back to "container" this is consistent with the current requirement, and allows traceability back to the original container to assure that the correct preservation/sample container was sampled for the analysis.

change "sample" back to "container"

Disposition Non-Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 5.8.5 a

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
ziomek	**Betsy**
804-698-4181	**esziomek@deq.virginia.gov**

Comment #: 233

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.5.b

Comment with Rationale and Proposal ***Attached Document*** ☐

As the standard now reads, only the sample needs to have a unique field code. This means that multiple containers with different preservations will all have the same field code if they are taken at the same sampling site. Because the preservations are performed in the field, as a regulator, I want to be able to track the sample results to a specific container not to the sampling location.

Re-insert the word 'container'.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 5.8.5 a

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600 x1032	**jaspard@epchc.org**

Comment #: 417

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.5.c

Comment with Rationale and Proposal ***Attached Document*** ☐

Don't restrict the placement of laboratory ID codes to labels only. Allow them to be written directly onto bottles with indelible ink.

The laboratory ID code shall be placed on the sample container. It may be placed as a durable label, or written directly onto the container with indelible ink.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 278

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.6

Comment with Rationale and Proposal ***Attached Document*** ☐

rephrase to be clearer and not repetitive

The laboratory shall have a written sample acceptance policy that includes the following areas of concern. Data from any samples that do not meet the following criteria shall be flagged in an unambiguous manner...

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
COnnor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 555

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.7.1

Comment with Rationale and Proposal ***Attached Document*** ☐

It sounds like you have to have an SOP on "HOW" to write down the preservation used on a sample. Wouldn't it be easier to just let them "document preservation" and let them do it however they need, so long as it is documented. This will not affect data quality because no matter what logbook or spreadsheet, which column or row it goes in, who maintains and checks it, who copies it....the actual record will be the important piece, not the placeholder.

The laboratory shall document preservation at the time of receipt.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 451

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.7.1

Comment with Rationale and Proposal ***Attached Document*** ☐

not specific

The laboratory shall implement procedures to verify and document field preservation of samples.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 280

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.7.2 b)ii

Comment with Rationale and Proposal ***Attached Document*** ☐

"flagged" gives the impression that the laboratory has a LIMS system capable of adding flags to the data. The data can be qualified in the case narrative.

Leave "qualified" instead of "flagged"

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 452

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.7.2 b)ii

Comment with Rationale and Proposal ***Attached Document*** ☐

use qualified instead of flagged. It sounds better and people are used to the term.

above

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Schrenkel	**Carol**	***Comment #:***
(610) 280-3013	**schrenkc@lionvillelab.com**	281

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.8

Comment with Rationale and Proposal	***Attached Document*** ☐
consistancy	
change "must" to "shall"	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Shepherd	**Michael**
512-335-0906	**mcshepherd@austin.rr.com**

Comment #: 503

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.8

Comment with Rationale and Proposal ***Attached Document*** ☐

Legal chain of custody procedures are used for evidentiary or legal purposes. If a client specifies that a sample is to be used for evidentiary purposes, then a laboratory shall have a written SOP for how that laboratory must carry out legal chain of custody. The standards should be clear that the laboratory should be able to refuse to accept samples requiring evidentiary custody procedures.

The standards should be clear that the laboratory should be able to refuse to accept samples requiring evidentiary custody procedures.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Contract review allows this.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Ziomek	**Betsy**
804-698-4181	**esziomek@deq.virginia.gov**

Comment #: 234

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.9.1.i

Comment with Rationale and Proposal ***Attached Document*** ☐

Because 40 CFR Part 136 has increased the preservation temperature to 6 degrees C, allowing the temperature to be +/- 2 degrees would mean that the sample is no longer compliant with regulation.
Add "unless regulatory or method specific criteria exist."

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 599

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.8.9.ii

Comment with Rationale and Proposal ***Attached Document*** ☐

put the previous wording back. "other potentially contaminating sources" is very important.

put the old wording back in .

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

withdrawn

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Shepherd	**Michael**
512-335-0906	**mcshepherd@austin.rr.com**

Comment #: 504

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.9.3

Comment with Rationale and Proposal ***Attached Document*** ☐

The laboratory shall ensure that the essential standards outlined in Technical Modules or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent, the QC in the mandated method or regulations is to be followed. An approved Quality Assurance Project Plan or other client directed set of specifications for quality control criteria must be able to "trump" the "whichever are more stringent" clause. Otherwise, the standards are directing project Data Quality and Measurement Quality Objectives that are the domain of the project and client. (Note that this same principle is effectively what allows different report formats in Section 5.10.10. or Volume 1 Module 4 Section 1.7.3.3.1.b for the allowance of variance in matrix spike frequency as part of the contract review process).

In the absence of a superceding approved Quality Assurance Project Plan, rhe laboratory shall ensure that the essential standards outlined in Technical Modules or mandated methods or

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Contract review allows this.

Last Name	*First Name*
Phone Number	*Email*

regulations (whichever are more stringent) are incorporated into their method manuals.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Contract review allows this.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 453

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.9.3 a

Comment with Rationale and Proposal ***Attached Document*** ☐

This whole section could be eliminated. They are either covered in section 5.9 or in the seperate modules.
delete section

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Provides clarity

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 282

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.9.3 a)i

Comment with Rationale and Proposal ***Attached Document*** ☐

positive and negative controls should be included in the definitions if they're going to be used here.

Don't delete positive and negative controls from the definitions.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

If definitions are included in the body the committee feeld that thay need not be defined in terms and definitions.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
McAninch	**Thomas**
903-757-4269	**mcaninch@cablelynx.com**

Comment #: 144

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.9.3 and 1.5.2 (V1M4)

Comment with Rationale and Proposal ***Attached Document*** ☐

The comment is applicable to the section on the LOD (V1M4, 1.5.2) The standard provides an exception for performing a LOD study if the lab does not report outside its calibration range. However, many labs are trapped into performing needless exercises because the method requires an LOD and/or a LCR and assessors are requiring labs to follow the most restrictive requirements. If a lab does not report outside its calibration range, any exercise to evaluate the region above or below the calibration range has no value for the lab.

Reporting requirements are data user specified requirments. As I indicated in a similar comment for this section, the specifications of the data user should be the ultimate authority and the one with whom the lab must comply.

5.9.3 (2nd paragraph) The quality control protocols specified by the laboratory's SOP shall be followed. The laboratory shall ensure that the essential quality control standards required

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See scope and contract review

by the data user are implemented. In the absence of data user specifications, the most restrictive requirements of the method, standard, or regulation shall be implemented.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See scope and contract review

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Schrenkel	**Carol**	***Comment #:***
(610) 280-3013	**schrenkc@lionvillelab.com**	283

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.9.3 c)

Comment with Rationale and Proposal ***Attached Document*** ☐

The lab should have to comply with the requirements of the data user rather than the most stringent requirements. A laboratory should not have to put the effort into meeting the most stringent requirements when that's not what the data user needs.

rephrase

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See scope and contract review

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Arms	**Stephen**
9047911502	**steve_arms@doh.state.fl.us**

Comment #: 471

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.9.3(c)

Comment with Rationale and Proposal ***Attached Document*** ☐

The second paragraph is better placed in 4.9.2.

Move the second paragraph of 5.9.3(c) to become 4.9.2(c).

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Add Clarity

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
McAninch	**Thomas**
903-757-4269	**mcaninch@cablelynx.com**

Comment #: 142

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.9.3.c

Comment with Rationale and Proposal ***Attached Document*** ☐

This comment may apply to other Standard citations. The data user should be the ultimate authority in establishing data quality. If a data user established data qualioty indicators that are less restrictive than a method, the data user quality specification should prevail, not the most restrictive. Many labs in Texas that are involved in the TCEQ Clean Rivers Program have to comply with method requiremetns that are most restrictive than the CRP Program. The labs have to qualify data because they do not meet method requirements. However, the CRP does not accept qualified data, yet the data meets CRP quality specs.

The standard should be clear that the data user establishes teh data quality requirements. In the absence of data user specs, teh most restrictive is to be used.

5.9.3.c The laboratory shall ensure that the essential standards outlined in data user quality specifications are incorporated into their methods manuals. In the absence of data

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See scope and contract review

Comments with TNIQS Response

Last Name	***First Name***
Phone Number	***Email***

user quality specifications, the laboratory shall ensure that the essential standards outlined in the Technical modules or mandated methods or regulations (whichever are more stringent) are incorporated into their methods manuals. When it is not which is more stringent, the QC in the mandated method or regualtion is to be followed.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See scope and contract review

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kenton	**Roger**
903-237-6882	**rogerk@eastman.com**

Comment #: 215

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section 5.9.3.c

Comment with Rationale and Proposal ***Attached Document*** ☐

Laboratories should not be forced to follow requirements that are more stringent than Project Data Quality Objectives (when present).

The quality control protocols specified by the laboratory's SOP (see Section 4.2.9) shall be followed. The laboratory shall ensure that the essential standards outlined in Project Data Quality Objectives (DQOs) or Technical Modules or mandated methods or regulations are incorporated into their method manuals. When present, Project DQOs are to be followed. When it is not apparent which QC requirements should be followed, the QC in the mandated method or regulations is to be followed.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See scope and contract review

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wasko	**Mike**
706-355-8821	**wasko.mike@epa.gov**

Comment #: 229

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section all

Comment with Rationale and Proposal ***Attached Document*** ☐

Throughout this module, ISO 17025 clauses are referenced rather than reproducing the actual text of the relevant ISO 17025 clause. While I am aware of copyright issues relating to the use of the ISO standard, the TNI standard, as written is very cumbersome to read and understand. (There are also references to ISO 17011 and 1700 in this module). The Draft TNI standard is a step backward from the present NELAC standard.
Incorporate actual text of ISO standards into the TNI standard in a single stand-alone module.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

ISO version will be available

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 439

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section all

Comment with Rationale and Proposal ***Attached Document*** ☐

I think more small labs would like a standard that is not based on ISO. Many of the ISO requirements that are extra paperwork trails can be really hard to keep track of.

get rid of ISO

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This decision was made by NELAC stakeholders in 2001, 2002 and 2003.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Connor	**Brooke**
303-236-1877	**bfconnor@usgs.gov**

Comment #: 556

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section all

Comment with Rationale and Proposal ***Attached Document*** ☐

Just a closing note... Thank you to the committee(s) for the tremendous amount of work and rework given to this standard. I know that you are trying to listen to many varied opinions, most of which probably conflict. We honestly do try to make the standards better for all by making suggestions and we certainly hope we don't get on your nerves too much!! Keep up the good work!

No change!

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Thank You

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Sotomayor	**Alfredo**
608-266-9257	**Alfredo.Sotomayor@Wisconsin.go**

Comment #: 525

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Entire Module

Comment with Rationale and Proposal ***Attached Document*** ☐

The module does not track very well with ISO 17025. The lack of concordance is structural as well as conceptual and is pervasive throughout the entire module. For example, the module's 4.1.7.2 contains material that should have been inserted after ISO 17025 4.1.5 (j), since that is where ISO discusses the duties and resposibilities of the quality manager. When one reads the module's 4.1.7.2, many of the items described already have counterpats in ISO 17025 Clause 4.1. The reader is not sure which item takes precedence or the exact hierarachy of applicablity. There are many sections where the additional language added to the ISO 17025 core results in redundancies, unecessary verbiage, and excessive prescription. Sadly, this module betrays a desire to include as much as possible of the last NELAC standard without regard to relevance or potential conflicts with ISO 17025.

Re-evaluate the necessity of including any additional language to the ISO 17025 core rigorously. The review should consider whether ISO covers the material already and whether

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

the addtional language clarifies or truly augments ISO's. When added language is in conflict with an ISO 17025 item, the need for its inclusion must be conslusively justified and the corrresponding ISO clause must be declared "not applicable."

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Sotomayor	**Alfredo**	***Comment #:***
608-266-9257	**Alfredo.Sotomayor@Wisconsin.go**	537

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Entire Module

Comment with Rationale and Proposal ***Attached Document*** ☐

ISO 17025 uses the term "customer" while the added language uses the term "client". If there is a reason why "client" cannot be replaced with "customer" then a definition for client needs to be included in section 3.0.
Replace "client" with "custormer" or define "client".

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

These terms are interchangable.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kenton	**Roger**
903-237-6882	**rogerk@eastman.com**

Comment #: 223

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Entire Standard

Comment with Rationale and Proposal ***Attached Document*** ☐

The standard as written is not a stand alone document. Citations to the ISO 17025 Standard in the draft makes it more difficult to read the TNI Standard. The Committee should considering dropping many of the lower value adding items (e.g., requirement for having a procedure on purchasing items, signature log, etc.) and focusing on items that make a more significant impact on data quality. I am looking for a TNI Standard for Environmental Laboratories and not necessarily an ISO 17025 Standard.

Re-drafting of the standard without the large quantity of ISO 17025 citations. This could mean inclusion of ISO 17025 language or the actual generation of a new (not ISO) Quality Systems standard for use by Environmental Laboratories.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This decision was made by NELAC stakeholders in 2001, 2002 and 2003.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Mertens	**Sharon**
414-277-6384	**smertens@mmsd.com**

Comment #: 536

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section general

Comment with Rationale and Proposal ***Attached Document*** ☐

General comments: As noted in previous conversations, the format of this module is inconsistent with other interim standards. Additions, clarifications and notes should be incorporated with the ISO language rather than separated into “ISO and additional” in each subsection as is currently presented. There are many inconsistencies, as well as redundancies, between the ISO requirement and the “additional” requirements within the individual sections. The following are terms that are covered in the ISO language and are similar or the same. These should not be called out as different. This will cause inconsistencies with the other modules and is confusing for the user. If the committee needs to, a note of clarification can be added to the ISO definition rather than creating a new one: Accreditation; Accuracy; Audit; Bias; Certified Reference Material; Measurement System; Measurement Uncertainty; Precision; Procedure; Reference Material; Reference Standard; Sampling; Verification The terms “preservation” and “matrix” as defined in this

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

adds clarity

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

module are inconsistent with the definitions presented in the FSMO modules. Those in the FSMO modules appear more complete – the committee should look at these. Section 4.1.4 Note 2: It is unclear to me what is meant by a third-party laboratory (as it appears that this is called out as a choice in this standard.) If this is actually germane to the standard, this needs to be defined. Likewise, references to laboratories performing calibration are confusing and inconsistent. The committee should decide whether these standards apply to calibration labs and either include the requirements or take them out. In section 4, various parts of the standard include calibration (e.g. "testing or calibration activities" in 4.1.4). Some clauses in section 5 include calibration; others specifically state that these are not applicable (e.g. 5.4) but then include the references in the text. If these are to remain, the terms "testing laboratory" and "calibration laboratory" need to be defined. It is unclear to me the difference between Document Control (4.3) and Control of Records (4.13). I think that the term "control" was added in error in section 4.13.

Words that are defined in common language (i.e. dictionary) with no other special meaning should not be included in the terms and definitions sections. Examples include "shall", "must" "may" or any others from Random House or Webster's, the dictionaries listed in section 3.2. All sections should be formatted so that additional requirements and ISO requirements are consistently in the same sections and not redundant or conflicting.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

adds clarity

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schantz	**Leonard**
585-428-7378	**lgs@cityofrochester.gov**

Comment #: 138

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section general

Comment with Rationale and Proposal ***Attached Document*** ☐

Drop verbatim ISO requirements. Most labs could care less about international recognition. The ISO language adds a lot of resource-consuming requirements that add little or no value to a labs operation. We need a standard that focuses on the issues that significantly impact data quality.

We need to delete requirements for administrative procedures that relate to how a lab runs its business and client interaction. Some of the issues that can be reduced or eliminated include organization, purchasing, contracting, subcontracting, preventive action, management reviews, and reporting. I think some state folks are starting to see this and are open to another option. SIMPLIFY, an attorney should not be needed to interpert.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This decision was made by NELAC stakeholders in 2001, 2002 and 2003.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Ziomek	**Betsy**	***Comment #:***
804-698-4181	**esziomek@deq.virginia.gov**	204

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Glossary

Comment with Rationale and Proposal ***Attached Document*** ☐

Matrix Duplicate: The definition indicates that a duplicate is a second replicate of a sample prepared in the lab and analyzed. "Replicate" is defined in the Standard as a sub-sample of the same sample. 'Duplicate' using the definitions above is simply a split sample. I believe that the intent was that the duplicate be a second sample collected from the same sampling location at the same time the original sample is collected. Using a split sample evaluates the homogeneity of an aliquot of a given sample, while a duplicate using my definition evaluates the homogeneity of the entire sample.

Duplicate: a second sample collected from the same sampling location at the same time the original sample is collected.

Disposition Persuasive

CommitteeComments

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

fixed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 601

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section ISO 4.1.6

Comment with Rationale and Proposal ***Attached Document*** ☐

how do you propose we evaluate this requirement?

explanation in the TNI Standard

Disposition Persuasive

CommitteeComments

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This is not the committees job. We did edite the section for clarity.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Sotomayor	**Alfredo**
608-266-9257	**Alfredo.Sotomayor@Wisconsin.go**

Comment #: 527

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Mesurement Uncertainty

Comment with Rationale and Proposal ***Attached Document*** ☐

This text contains non-substantive material that complicates the definition. The definition proper is contained in the first sentence. The rest of the text should be included, if at all, in notes to the definition after simplification.

Inlcude the material after the first sentence in notes, following the ISO format.

Disposition Persuasive

CommitteeComments

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

deleted

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Moore	**Marlene**
302 354 1717	**mmoore@advancedsys.com**

Comment #: 437

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section none

Comment with Rationale and Proposal ***Attached Document*** ☐

For all volumes voted no - The process for review of comments does not allow interchange on the standards. Many comments presented for review were not adequately resolved with the parties before development of this standard. Discussion on the standard is inadequate for vote for such an important standard to the industry. There remains in this standard inconsistencies, missing information and inadequcies to the standard that are not resolved and will continue to cause problems during the assessment of these volume 1 and 2

Involve the party providing comment in the decision that the comment is not being accepted by the committee and allow input on the floor of TNI for people to propose changes. It might be best to do this over the internet and use a "chat" type function so everyon feels like they are being heard and not ignored.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

No action is required by this committee.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Reininger	**Rodney**
(217) 698-0642	**rreininger@tmilab.com**

Comment #: 548

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Preface

Comment with Rationale and Proposal ***Attached Document*** ☐

Change ISOI/IEC to ISO/IEC, in the last paragraph, third sentence, as I believe it is probably a typographical error.
Change ISOI/IEC to ISO/IEC.

Disposition Persuasive

CommitteeComments

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Evans	**James**
614-644-4222	**james.evans@epa.state.oh.us**

Comment #: 511

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Quality Manual Section and records retention

Comment with Rationale and Proposal ***Attached Document*** ☐

For clarity and addressing drinking water records retention.

Quality Manual Section: Recommend that labs. maintain and provide appropriate sampling instructions for their clients. Records retention: Drinking water chemistry records need to be retained ten years as required by 40 CFR 141.33 - Microbiological data 5 years. Data for lead and copper 12 years (40 CFR 141.91)

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This is a data user specific requirement.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Sotomayor	**Alfredo**	***Comment #:***
6	**Alfredo.Sotomayor@Wisconsin.go**	528

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Raw data definition

Comment with Rationale and Proposal ***Attached Document*** ☐

This definition perpetuates the common error of confusing an entity with its evidence, or the information with the medium use to documen it. Raw data is actually the unreduced response provided by an analytical instrument or support equipment, or the first unadulterated observation of a system condition. Raw data is captured in documents such as the one's mentioned in the second sentence. The documents themselves are not the raw data but are evidence of it.

Redefine to " the unreduced response provided by an analytical instrument or support equipment an unadulterated observation of a system condition". Provide examples of acceptable documentation of raw data by converting the material after the first sentence of the definition into a note following the ISO format.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

No comment by the committee. The definition is acceptable.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Sotomayor	**Alfredo**	***Comment #:***
608-266-9257	**Alfredo.Sotomayor@Wisconsin.go**	531

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Raw data definition

Comment with Rationale and Proposal ***Attached Document*** ☐

Note: I submitted by accident an unedited version of this comment. Please disregard the former and consider this one. This definition perpetuates the common error of confusing an entity with its evidence, or the information with the medium use to documen it. Raw data is actually the unreduced response provided by an analytical instrument or support equipment, or the first unadulterated observation of a system condition. Raw data is captured in documents such as the one's mentioned in the second sentence. The documents themselves are not the raw data but are evidence of it.

Redefine to " the unreduced response provided by an analytical instrument or support equipment, or an unadulterated observation of a system condition". Provide examples of acceptable documentation of raw data by converting the material after the first sentence of the definition into a note following the ISO format.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

No comment by the committee. The definition is acceptable.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 27

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 1.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.2: Part of paragraph 2 now reads, “When the use of the data does not require compliance with the standards, these standards do not apply.” This sentence is uncomfortably ambiguous. The Committee suggests the following revision: “Compliance with these Standards may be required by law, regulation, contract, or project data quality objectives.” (Uniformity of Standards Committee)

Section 1.2: Part of paragraph 2 now reads, “When the use of the data does not require compliance with the standards, these standards do not apply.” This sentence is uncomfortably ambiguous. The Committee suggests the following revision: “Compliance with these Standards may be required by law, regulation, contract, or project data quality objectives.”

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 28

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 1.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.2: Part of paragraph 2 now reads, “If the requirements of this document are met, the laboratory shall operate a quality system in accordance with applicable ISO/IEC 17025.” The word “shall” adds a requirement, but the sentence appears to be a note or observation. As a suggestion, the Committee recommends the use of the word “will” in place of “shall.” (Uniformity of Standards Committee)

Section 1.2: Part of paragraph 2 now reads, “If the requirements of this document are met, the laboratory shall operate a quality system in accordance with applicable ISO/IEC 17025.” The word “shall” adds a requirement, but the sentence appears to be a note or observation. As a suggestion, the Committee recommends the use of the word “will” in place of “shall.”

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

Reininger	**Rodney**	***Comment #:***
(217) 698-0642	**rreininger@tmilab.com**	550

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 3.0 Definitions

Comment with Rationale and Proposal ***Attached Document*** ☐

The definition for data reduction included the phrase "a reduced data set". This phrase seems a bit circular in nature.

The phrase "a reduced data set" should be removed.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Reininger	**Rodney**
(217) 698-0642	**rreininger@tmilab.com**

Comment #: 552

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 3.0 Definitions

Comment with Rationale and Proposal ***Attached Document*** ☐

The definition for "Performance Testing Provider" is similar, but not identical between Volume 1, Module 1 and Volume 1, Module 2. The definitions should be the same for the same term for all Modules in all Volumes to avoid any type of descrepancy from existing.

Change all Modules within all Volumes to have identical definitions for the same term.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 29

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 3.1: The Committee recommends that definitions be added for “analyte” and/or “target analyte.” (Uniformity of Standards Committee)
Section 3.1: The Committee recommends that definitions be added for “analyte” and/or “target analyte.” (Quality Systems Committee is more qualified to provide definition than the Uniformity of Standards Committee, but remember the terms "analyte" and "target analyte" are used in the modules, so definitions may be needed)

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The terms are commonly used. No definitions were supplied ith this comment.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Kircher	**Carl**	***Comment #:***
904-791-1574	**carl_kircher@doh.state.fl.us**	31

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

The terms “preservation” and “matrix” as defined in this module are inconsistent with the definitions presented in the FSMO modules. Those definitions in the FSMO modules appear more complete; the relevant expert committee should look at these. The Committee questions whether a definition for “Requirement” is needed. (Uniformity of Standards Committee)

The terms “preservation” and “matrix” as defined in this module are inconsistent with the definitions presented in the FSMO modules. Those definitions in the FSMO modules appear more complete; the relevant expert committee should look at these. The Committee questions whether a definition for “Requirement” is needed.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The terms are commonly used. No definitions were supplied ith this comment.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kenton	**Roger**
903-237-6882	**rogerk@eastman.com**

Comment #: 212

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Many of the definitions appear to contain notes that were used during the generation of the draft document. These notes may need deleting.
Delete unneeded notes from the following items. Accreditation . . . (Note: Compare ISO 17011:2004(E) #3.1) Accuracy . . . (Note: Compare VIM draft 3rd #A2 and VIM 2nd #3.5) Assessment . . . (Note: Compare ISO 17011:2004(E) #3.7) Audit . . . (Note: Compare ISO 17000 #4.4) Bias . . . (Note: Compare VIM draft 3rd #A14 and VIM 2nd #5.25) Calibration . . . (VIM: 6.11) Measurement Uncertainty . . . (Note: Compare VIM draft 3rd #2.11)

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Notes are removed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 82

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 3.1: The following definitions could not be found in this Module or any of the subsequent technical modules. These definitions should be deleted: Proficiency Testing, Proficiency Testing Provider.

Section 3.1: The following definitions could not be found in this Module or any of the subsequent technical modules. These definitions should be deleted: Proficiency Testing, Proficiency Testing Provider.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 30

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 3.1 throughout

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 3.1: In this section of "Additional Terms and Definitions," this Committee notes that the following definitions may differ from terms defined in ISO. The relevant expert committee should consider adding a cross reference, perhaps as "(Defined differently at ISO 17011 clause xx)": "Accreditation"—note/compare ISO 17011#3.1 "Accuracy"—note/compare VIM draft 3rd #A2 and VIM 2nd #3.5 "Assessment"—note/compare ISO 17011 #3.7 "Audit"—note/compare ISO 17000 #4.4. Sentence 2 circularly defines an audit as an audit. "Bias"—note/compare VIM draft 3rd #A14 and VIM 2nd #5.25. This definition depends on the undefined term "true value." "Blank" and subsidiaries—compare FSMO V1 #3.3. "Method Blank"—the final clause "and in which no target …" appears redundant. "Field Blank"—note/compare FSMO V1 #3.3. A field blank also detects contamination introduced during laboratory procedures. The definition is correct only if comparable lab blanks also are

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Notes are removed

Last Name	*First Name*
Phone Number	*Email*

available. “Calibration Standard”—Redundant with “reference standard.” Inconsistent with “Standard” as defined in this clause 3.1. The use of “Standard” as a reference material is used frequently throughout the document. See VIM draft 3rd #5 heading. “Chain of Custody Form”—Suggest adding cross reference to “Legal Chain of Custody Protocols.” The first sentence is an adequate definition. The second sentence combines several ideas addressed in various clauses of FMSO V1. Suggest adding a reference to FSMO V1 # 5.7.4, #5.7.5, the clauses cited there, and #5.8 Note 4. “Corrective Action”—is defined in detail by the requirements of clause 4.11. Suggest replacing this definition with “See requirements of #4.11” or adding that idea to the existing text. “Demonstration of Capability”—Suggest revision to “…generate analytical results of acceptable accuracy …” “Finding”—Conflicts with FSMO V2 #3.25 which recognizes both positive and negative findings during an assessment. “Laboratory Control Sample”—Choose one term and use it consistently in the document. Suggest deleting either word from “… verified known …” as the pair is redundant. “Matrix”—Suggest using the more complete statement at FSMO V1 #3.8 and FSMO V2 #3.27. The three “matrix ___” definitions are inconsistent with either the existing or suggested definitions of “matrix.” “Matrix Duplicate”—is unclear. It appears to refer to a laboratory subsample taken from an environmental sample that is expected to contain the target analyte. “Matrix Spike”—includes undefined term “matrix sample.” Choose one term and use it consistently in the document. “Matrix Spike Duplicate”—Choose one term and use it consistently in the document. “Measurement Uncertainty”—is essentially the definition in VIM draft 3rd #2.11 but expressed in classical statistical terms. Suggest adding a cross reference. Suggest

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Notes are removed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

the Committee decide whether this Standard will treat metrological uncertainty using the classical approach or the uncertainty approach (VIM draft 3rd Foreword), state in the introduction which approach was chosen, and use it consistently throughout.

"Standard"—appears to be closely parallel to ISO language, although I can't locate the source. This definition conflicts with multiple uses of the term throughout the document as a reference material. The following additional definitions are terms that are covered in the ISO language and are similar or the same. These definitions should not be called out as different because their listing may cause inconsistencies with the other modules and confusion for the user. If the relevant expert committee needs to, a note of clarification can be added to the ISO definition rather than creating a new one: Certified Reference Material; Measurement System; Precision; Procedure; Reference Material; Reference Standard; Sampling; Verification (Uniformity of Standards Committee)

Section 3.1: In this section of "Additional Terms and Definitions," this Committee notes that the following definitions may differ from terms defined in ISO. The relevant expert committee should consider adding a cross reference, perhaps as "(Defined differently at ISO 17011 clause xx)": "Accreditation"—note/compare ISO 17011#3.1 "Accuracy"—note/compare VIM draft 3rd #A2 and VIM 2nd #3.5 "Assessment"—note/compare ISO 17011 #3.7 "Audit"—note/compare ISO 17000 #4.4. Sentence 2 circularly defines an audit as an audit. "Bias"—note/compare VIM draft 3rd #A14 and VIM 2nd #5.25. This definition depends on the undefined term "true value." "Blank" and subsidiaries—compare FSMO V1 #3.3. "Method Blank"—the

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Notes are removed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

final clause “and in which no target …” appears redundant. “Field Blank”—note/compare FSMO V1 #3.3. A field blank also detects contamination introduced during laboratory procedures. The definition is correct only if comparable lab blanks also are available.

“Calibration Standard”—Redundant with “reference standard.” Inconsistent with “Standard” as defined in this clause 3.1. The use of “Standard” as a reference material is used frequently throughout the document. See VIM draft 3rd #5 heading. “Chain of Custody Form”—Suggest adding cross reference to “Legal Chain of Custody Protocols.” The first sentence is an adequate definition. The second sentence combines several ideas addressed in various clauses of FMSO V1. Suggest adding a reference to FSMO V1 # 5.7.4, #5.7.5, the clauses cited there, and #5.8 Note 4. “Corrective Action”—is defined in detail by the requirements of clause 4.11. Suggest replacing this definition with “See requirements of #4.11” or adding that idea to the existing text. “Demonstration of Capability”—Suggest revision to “…generate analytical results of acceptable accuracy …” “Finding”—Conflicts with FSMO V2 #3.25 which recognizes both positive and negative findings during an assessment. “Laboratory Control Sample”—Choose one term and use it consistently in the document. Suggest deleting either word from “… verified known …” as the pair is redundant.

“Matrix”—Suggest using the more complete statement at FSMO V1 #3.8 and FSMO V2 #3.27. The three “matrix ___” definitions are inconsistent with either the existing or suggested definitions of “matrix.” “Matrix Duplicate”—is unclear. It appears to refer to a laboratory subsample taken from an environmental sample that is expected to contain the

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Notes are removed

Last Name	*First Name*
Phone Number	*Email*

target analyte. “Matrix Spike”—includes undefined term “matrix sample.” Choose one term and use it consistently in the document. “Matrix Spike Duplicate”—Choose one term and use it consistently in the document. “Measurement Uncertainty”—is essentially the definition in VIM draft 3rd #2.11 but expressed in classical statistical terms. Suggest adding a cross reference. Suggest the Committee decide whether this Standard will treat metrological uncertainty using the classical approach or the uncertainty approach (VIM draft 3rd Foreword), state in the introduction which approach was chosen, and use it consistently throughout. “Standard”—appears to be closely parallel to ISO language, although I can’t locate the source. This definition conflicts with multiple uses of the term throughout the document as a reference material. The following additional definitions are terms that are covered in the ISO language and are similar or the same. These definitions should not be called out as different because their listing may cause inconsistencies with the other modules and confusion for the user. If the relevant expert committee needs to, a note of clarification can be added to the ISO definition rather than creating a new one: Certified Reference Material; Measurement System; Precision; Procedure; Reference Material; Reference Standard; Sampling; Verification

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Notes are removed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 32

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 3.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 3.2: In this section, the Committee recommends that all acronyms be listed out in full at first usage (e.g., VIM). The Committee also suggests that the relevant expert committee consider listing the technical modules here, since the text references the “technical modules” even though they are not fully identified anywhere. (Uniformity of Standards Committee)

Section 3.2: In this section, the Committee recommends that all acronyms be listed out in full at first usage (e.g., VIM). The Committee also suggests that the relevant expert committee consider listing the technical modules here, since the text references the “technical modules” even though they are not fully identified anywhere.

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would introduce a concept that had not been subject to public review by being included in a related proposal as published in the Draft Interim Standard.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 33

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 4.1.3.3

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 4.1.3.3: As an editorial recommendation, the word “and” should be deleted at the end of subsections xv. and xvii.

Section 4.1.3.3: As an editorial recommendation, the word “and” should be deleted at the end of subsections xv. and xvii.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 34

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 4.1.4 NOTE 2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 4.1.4 Note 2: The Committee notes that the reference to a third-party laboratory may be unclear (as it appears that this is called out as a choice in this standard.) If this concept is actually germane to the standard, then the term “third-party laboratory” needs to be defined.

(Uniformity of Standards Committee)

Section 4.1.4 Note 2: The Committee notes that the reference to a third-party laboratory may be unclear (as it appears that this is called out as a choice in this standard.) If this concept is actually germane to the standard, then the term “third-party laboratory” needs to be defined.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

ISO language

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 83

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 4.1.7.3(b)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 4.1.7.3(b): This section contains the term “fields of accreditation.” This term needs to be defined, preferably the same as the definition given in Volume 1, Module 1.

Section 4.1.7.3(b): This section contains the term “fields of accreditation.” This term needs to be defined, preferably the same as the definition given in Volume 1, Module 1.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 36

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 4.11.6

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 4.11.6: This section is entirely redundant with the ISO requirements in 4.11.1 – 4.11.5 and in 4.9. The Committee suggests that it is impossible to have a policy and procedure that laboratory staff can implement if it is not documented. The Committee recommends deleting this clause (Section 4.11.6). (Uniformity of Standards Committee)

Section 4.11.6: This section is entirely redundant with the ISO requirements in 4.11.1 – 4.11.5 and in 4.9. The Committee suggests that it is impossible to have a policy and procedure that laboratory staff can implement if it is not documented. The Committee recommends deleting this clause (Section 4.11.6).

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 84

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 4.2.8.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 4.2.8.1: There needs to be a link or connection between the terms “data integrity procedures” and “data integrity system,” so that the requirements on the laboratories can be clearly delineated.

Section 4.2.8.1: There needs to be a link or connection between the terms “data integrity procedures” and “data integrity system,” so that the requirements on the laboratories can be clearly delineated.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 85

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 5.3.7(f)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 5.3.7(f): The term “prep” may not be a real word. The following language is recommended: “laboratory sample preparation and analytical testing areas.”

Section 5.3.7(f): The term “prep” may not be a real word. The following language is recommended: “laboratory sample preparation and analytical testing areas.”

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

section deleted

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 38

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 5.5.12

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 5.5.12: The Committee questions whether the Note after this section is really needed. If the ISO clauses are listed, it is assumed they apply unless otherwise specified. (Uniformity of Standards Committee)

Section 5.5.12: The Committee questions whether the Note after this section is really needed. If the ISO clauses are listed, it is assumed they apply unless otherwise specified.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The committee feels this adds clarity.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 39

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 5.5.13.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 5.5.13.1: The last clause after the semicolon does not appear to make sense. The Committee wonders whether the clause is actually out of order. (Uniformity of Standards Committee)

Section 5.5.13.1: The last clause after the semicolon does not appear to make sense. The Committee wonders whether the clause is actually out of order.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 40

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 5.8.6

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 5.8.6: The first sentence should be reworded as "…under which samples are accepted." The requirement is that the lab has an acceptance policy, not that the sample is accepted

Section 5.8.6: The first sentence should be reworded as "…under which samples are accepted." The requirement is that the lab has an acceptance policy, not that the sample is accepted

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 41

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 5.8.7.2(b)(ii)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 5.8.7.2(b)(ii): The Committee suggests saying “appropriately ‘flagged’” for consistency with Section 5.8.6. (Uniformity of Standards Committee)

Section 5.8.7.2(b)(ii): The Committee suggests saying “appropriately ‘flagged’” for consistency with Section 5.8.6.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The entire module has been changed to "qualified".

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 42

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 5.8.8

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 5.8.8: The second sentence should be reworded as "…specifies that a sample is to be used for evidentiary purposes…" The requirement is that the lab have a SOP for legal chain of custody.

Section 5.8.8: The second sentence should be reworded as "…specifies that a sample is to be used for evidentiary purposes…" The requirement is that the lab have a SOP for legal chain of custody.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 86

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 5.9.3(a)(vii)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 5.9.3(a)(vii): Since definitions appear for Accuracy, Precision, and Sensitivity, the term “Selectivity” should also be defined. The following is suggested language: “Selectivity – The ability to analyze and determine a specific analyte or test species from another component that may be a potential interferent or that may behave similarly as the target analyte or species within the measurement system.”

Section 5.9.3(a)(vii): Since definitions appear for Accuracy, Precision, and Sensitivity, the term “Selectivity” should also be defined. The following is suggested language: “Selectivity – The ability to analyze and determine a specific analyte or test species from another component that may be a potential interferent or that may behave similarly as the target analyte or species within the measurement system.”

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 43

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Section 5.9.3(c)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 5.9.3(c): The second paragraph should be revised to read, "The quality control protocols specified by the laboratory's SOP (see section 4.2.9) shall…" As is, the sentence appears to reference a section 4.2.9 in the lab's SOP, not section 4.2.9 in the TNI standard.

Section 5.9.3(c): The second paragraph should be revised to read, "The quality control protocols specified by the laboratory's SOP (see section 4.2.9) shall…" As is, the sentence appears to reference a section 4.2.9 in the lab's SOP, not section 4.2.9 in the TNI standard.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Kircher	**Carl**	***Comment #:***
904-791-1574	**carl_kircher@doh.state.fl.us**	35

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Sections 4 and 5

Comment with Rationale and Proposal ***Attached Document*** ☐

Sections 4 and 5: Likewise, the Committee notes that references to laboratories performing calibration are confusing and inconsistent. Perhaps the Consensus Standard Development Board needs to decide whether these standards apply to calibration labs and either include the requirements or take them out. In section 4, various parts of the standard include calibration (e.g. “testing or calibration activities” in Section 4.1.4). Some clauses in Section 5 include calibration; others specifically state that these are not applicable (e.g. Section 5.4) but then include the references in the text. If these references are to remain as stated, then this Committee recommends that the terms “testing laboratory” and “calibration laboratory” be defined. (Uniformity of Standards Committee)

Sections 4 and 5: Likewise, the Committee notes that references to laboratories performing calibration are confusing and inconsistent. Perhaps the Consensus Standard Development Board needs to decide whether these standards apply to calibration labs and either include the

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

no action required by this committee

Last Name	*First Name*
Phone Number	*Email*

requirements or take them out. In section 4, various parts of the standard include calibration (e.g. “testing or calibration activities” in Section 4.1.4). Some clauses in Section 5 include calibration; others specifically state that these are not applicable (e.g. Section 5.4) but then include the references in the text. If these references are to remain as stated, then this Committee recommends that the terms “testing laboratory” and “calibration laboratory” be defined.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

no action required by this committee

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 37

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Sections 4.3 & 4.13

Comment with Rationale and Proposal ***Attached Document*** ☐

Sections 4.3 and 4.13: The Committee notes that the differences between "Document Control" (4.3) and "Control of Records" (4.13) may be unclear. It is possible that the term "control" was added in error in Section 4.13, and the relevant expert committee should review to see if this is the case. (Uniformity of Standards Committee)

Sections 4.3 and 4.13: The Committee notes that the differences between "Document Control" (4.3) and "Control of Records" (4.13) may be unclear. It is possible that the term "control" was added in error in Section 4.13, and the relevant expert committee should review to see if this is the case.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This is ISO language

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Howell	**David**
813.247.3451 ext.206	**david.howell@ci.tampa.fl.us**

Comment #: 358

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section see attached file

Comment with Rationale and Proposal	*Attached Document* ☑
See attached file	
See attached file	

Disposition Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Some comments are persuasive. You must look at applicable sections in the revised interim standard.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 44

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section The Whole Module

Comment with Rationale and Proposal ***Attached Document*** ☐

General comments: The Committee reports that the format of this module is inconsistent with other interim standards. Additions, clarifications, and notes should be incorporated with the ISO language, rather than separated into "ISO and additional" in each subsection as is currently presented. There are many inconsistencies, as well as redundancies, between the ISO requirement and the "additional" requirements within the individual sections. The relevant expert committee should consider that words defined in common language (i.e. dictionary) with no other special meaning should not be included in the terms and definitions sections. Examples include "shall," "must," "may," or any others from Random House or Webster's, the dictionaries listed in Section 3.2. This Committee also recommends that the relevant expert committee review this entire Module to ensure that there is consistency in using the reference to "this Standard" versus "this document." The Committee also strongly recommends that the entire Volume 1 be reviewed to ensure consistent use of the term "shall"

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Last Name	*First Name*
Phone Number	*Email*

and the term “must.” (Uniformity of Standards Committee)

General comments: The Committee reports that the format of this module is inconsistent with other interim standards. Additions, clarifications, and notes should be incorporated with the ISO language, rather than separated into “ISO and additional” in each subsection as is currently presented. There are many inconsistencies, as well as redundancies, between the ISO requirement and the “additional” requirements within the individual sections. The relevant expert committee should consider that words defined in common language (i.e. dictionary) with no other special meaning should not be included in the terms and definitions sections. Examples include “shall,” “must,” “may,” or any others from Random House or Webster’s, the dictionaries listed in Section 3.2. This Committee also recommends that the relevant expert committee review this entire Module to ensure that there is consistency in using the reference to “this Standard” versus “this document.” The Committee also strongly recommends that the entire Volume 1 be reviewed to ensure consistent use of the term “shall” and the term “must.”

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would propose something that could not be handled properly within the time frame for processing the changes.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Roach	**Kathleen**
727-582-2302	**kroach@pinellascounty.org**

Comment #: 242

Item/Volume and Module

Item 2 VOLUME 1: LABORATORY REQUIREMENTS Module 2 - Quality Systems: General Requirements

Section Volume 1, Module 2

Comment with Rationale and Proposal ***Attached Document*** ☑

All comments and proposed changes are listed in the section below:

Volume 1, Module 2, Quality Systems, General Requirements: 3.0: Terms and Definitions: Manager (however named) : This is mentioned numerous times in the standard and needs to have a definition. In the last version there was confusion between the written definition of manager and supervisor and it did not match the verbiage used in the body of the standard, but this time around it looks like you kept the supervisor definition and removed the manager definition and then in the body of the standard you removed all references to supervisor and left in (or added) manager. Measurement of Uncertainty: We read this definition, en mass, and had a collective response of 'Huh?'. You have got to simplify this definition. This is a requirement that many of us have had a problem figuring out how to comply with, and this definition n is not helping. 5.10 Reporting the Results 5.10.10 Clarification of this section is needed and here's our confusion; in the

Disposition Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Some comments are persuasive. You must look at applicable sections in the revised interim standard.

Comments with TNIQS Response

Last Name	***First Name***
Phone Number	***Email***

second paragraph, the last sentence says: “However, formal reports detailing the information are not required if: and then you list a, b and c. The confusion is that on a) you deleted the word “or”, so does this mean you must meet “a” AND “b” OR then meet c, or does this mean one of the following must apply: a or b or c? 5.10.11.b. says, in it’s entirety : “If the results are reported on a basis other than as received”. As a stand alone requirement, it is not apparently clear what this requirement is asking. It’s only when you read the deleted portion that the requirement makes sense. We suggested keeping in an example (ie reporting dry weight vs wet weight).

Disposition Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Some comments are persuasive. You must look at applicable sections in the revised interim standard.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

Arms	**Stephen**	***Comment #:***
9047911502	**steve_arms@doh.state.fl.us**	477

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section 1.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

For clarity and because the Standard has and will be interpreted in this way, language to relate DOC by parameter to accreditation is needed.

Reword the first paragraph of 1.6.1: Prior to acceptance and institution of any method for data reporting and/or accreditation of specific analytes, satisfactory demonstration of method capability is required for each analyte (see Section 1.6.2).

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Asbestos is accredited by method not parameter.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Haynes	**RaeAnn**
503-229-5983	**haynes.raeann@deq.state.or.us**

Comment #: 240

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section 1.7.4.3

Comment with Rationale and Proposal ***Attached Document*** ☐

Other Quality Control MEasures Polarized Light Microscopy Friable Materials. 1/100 samples could be a sample from a round robin study in place of a limited number of reference or standard samples with well known answers.

1.7.4.3 a) ....one out of one-hundred samples shall be a standard or reference or round robin sample that has been submitted to determine the analysts' precision and accuracy.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Round robins are not defined and currently not approved as a PT program.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 608

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section All

Comment with Rationale and Proposal ***Attached Document*** ☐

This section includes multiple "should"s is it really the intent to make the majority of the items in this standard recommendations?

re-evaluate and make sure requriements are denoted with "shall" and/or "must"

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 87

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Section 1.7.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1: The acronym SRM first appears without any prior definition in this module or in Module 2 definitions. The term “Standard Reference Material (SRM)” should be defined in Section 1.3.1 or else spelled out in this section.

Section 1.7.1: The acronym SRM first appears without any prior definition in this module or in Module 2 definitions. The term “Standard Reference Material (SRM)” should be defined in Section 1.3.1 or else spelled out in this section.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 88

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Section 1.7.1.1.1(e)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.1.1(e): The acronym EDXA first appears without any prior definition in this module or in Module 2 definitions. The term “Energy Dispersive X-ray Analysis (EDXA)” should be defined in Section 1.3.1 or else spelled out in this section.

Section 1.7.1.1.1(e): The acronym EDXA first appears without any prior definition in this module or in Module 2 definitions. The term “Energy Dispersive X-ray Analysis (EDXA)” should be defined in Section 1.3.1 or else spelled out in this section.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 89

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Section 1.7.1.2.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.2.2: The acronym HSE/NPL first appears without any prior definition in this module or in Module 2 definitions. The term for “HSE/NPL” should be defined in Section 1.3.1 or else spelled out in this section.

Section 1.7.1.2.2: The acronym HSE/NPL first appears without any prior definition in this module or in Module 2 definitions. The term for “HSE/NPL” should be defined in Section 1.3.1 or else spelled out in this section.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This is a accepted designation for asbestos labs.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 90

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Section 1.7.2.1.1(a)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.2.1.1(a): The acronym MFL first appears without any prior definition in this module or in Module 2 definitions. The term “Million Fibers per Liter (MFL)” should be defined in Section 1.3.1 or else spelled out in this section.

Section 1.7.2.1.1(a): The acronym MFL first appears without any prior definition in this module or in Module 2 definitions. The term “Million Fibers per Liter (MFL)” should be defined in Section 1.3.1 or else spelled out in this section.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Common reporting units

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 91

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Section 1.7.2.1.3(a)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.2.1.3(a): The acronym ACM first appears without any prior definition in this module or in Module 2 definitions. The term for “ACM” should be defined in Section 1.3.1 or else spelled out in this section.

Section 1.7.2.1.3(a): The acronym ACM first appears without any prior definition in this module or in Module 2 definitions. The term for “ACM” should be defined in Section 1.3.1 or else spelled out in this section.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 92

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Section 1.7.4.1(a)(i)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.4.1(a)(i): The reference “NISTIR 5351” first appears without any prior appearance in this module or in Module 2 references. The complete reference for NISTIR 5351 should be added to Section 1.3 or else spelled out in this section.

Section 1.7.4.1(a)(i): The reference “NISTIR 5351” first appears without any prior appearance in this module or in Module 2 references. The complete reference for NISTIR 5351 should be added to Section 1.3 or else spelled out in this section.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Commonly used term for asbestos.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 93

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Section 1.7.6.1(b)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.6.1(b): The acronyms EPA and ANSI first appear without any prior definitions in this module or in Module 2 definitions. The terms “Environmental Protection Agency (EPA)” and “American National Standards Institute (ANSI)” should be defined in Section 1.3.1 or else spelled out in this section.

Section 1.7.6.1(b): The acronyms EPA and ANSI first appear without any prior definitions in this module or in Module 2 definitions. The terms “Environmental Protection Agency (EPA)” and “American National Standards Institute (ANSI)” should be defined in Section 1.3.1 or else spelled out in this section.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Commonly used

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Kircher	**Carl**	***Comment #:***
904-791-1574	**carl_kircher@doh.state.fl.us**	94

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Section 1.7.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.6.2: The acronym NIOSH first appears without any prior definition in this module or in Module 2 definitions. The term “National Institute for Occupational Safety and Health (NIOSH)” should be defined in Section 1.3.1 or else spelled out in this section.

Section 1.7.6.2: The acronym NIOSH first appears without any prior definition in this module or in Module 2 definitions. The term “National Institute for Occupational Safety and Health (NIOSH)” should be defined in Section 1.3.1 or else spelled out in this section.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Commonly used

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 95

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Section 1.7.7.1.2(a)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.7.1.2(a): The acronym AHERA first appears without any prior definition in this module or in Module 2 definitions. The term for “AHERA” should be defined in Section 1.3.1 or else spelled out in this section.

Section 1.7.7.1.2(a): The acronym AHERA first appears without any prior definition in this module or in Module 2 definitions. The term for “AHERA” should be defined in Section 1.3.1 or else spelled out in this section.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 49

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Sections 1.6.1 & 1.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.6.1 and 1.6.2: The last 2 paragraphs in Section 1.6.1 and the paragraphs under Section 1.6.2 are duplicative. The relevant expert committee should consider whether these requirements can be consolidated in one section. This comment also applies to Sections 1.6.1 and 1.6.2 in other technical modules in Volume 1.

Section 1.6.1 and 1.6.2: The last 2 paragraphs in Section 1.6.1 and the paragraphs under Section 1.6.2 are duplicative. The relevant expert committee should consider whether these requirements can be consolidated in one section. This comment also applies to Sections 1.6.1 and 1.6.2 in other technical modules in Volume 1.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 96

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section the whole Module

Comment with Rationale and Proposal ***Attached Document*** ☐

General: Various sections of this module use the terms “Friable Materials,” “Nonfriable Materials,” and “Bulk Samples” with regards to different types of Asbestos. These different types should be described in the text or else added to Section 1.3 as definitions.

General: Various sections of this module use the terms “Friable Materials,” “Nonfriable Materials,” and “Bulk Samples” with regards to different types of Asbestos. These different types should be described in the text or else added to Section 1.3 as definitions.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Commonly used

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Broderick	**James**
518-573-7548	**jdb10@health.state.ny.us**

Comment #: 395

Item/Volume and Module

Item 3 VOLUME 1: LABORATORY REQUIREMENTS Module 3 - Asbestos Testing

Section Title

Comment with Rationale and Proposal ***Attached Document*** ☐

The title should be "Fibers Testing", not "Asbestos Testing". PCM analysis cannot detect asbestos.

The title should be "Fibers Testing", not "Asbestos Testing".

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Fibers is more than asbestos.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 603

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.0

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.1 and 1.2 are missing some words.
include "the" in the second sentence of 1.1 between "in" and "general" Include "also" in the second sentence in 1.2 between "shall" and "be"

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Shepherd	**Michael**
512-335-0906	**mcshepherd@austin.rr.com**

Comment #: 505

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.1

Comment with Rationale and Proposal ***Attached Document*** ☐

1. General Comment: The standard needs to indicate that activities irrelevant to the testing procedures performed at the specific laboratory are not required. For example: If a lab is not required to report outside its calibration range by its client, quality assurance project plan, or the data user, a requirement in a method or the standard to determine/document/verify an LOD or a Linear Calibration Range (above and beyond establishing the calibration curve) should be interpreted as irrelevant, and not more stringent. If a lab does not report outside its calibration range, what happens above or below the calibration range is of no interest to or has no impact on the lab. With respect to an LCR determination, regardless of whether or not an LCR is performed, the standard requires qualification of data outside of its calibration range.

1. General Comment: The standard needs to indicate that activities irrelevant to the testing procedures performed at the specific laboratory are not required. For example: If a lab is

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Contract Review Process

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

not required to report outside its calibration range by its client, quality assurance project plan, or the data user, a requirement in a method or the standard to determine/document/verify an LOD or a Linear Calibration Range (above and beyond establishing the calibration curve) should be interpreted as irrelevant, and not more stringent. If a lab does not report outside its calibration range, what happens above or below the calibration range is of no interest to or has no impact on the lab. With respect to an LCR determination, regardless of whether or not an LCR is performed, the standard requires qualification of data outside of its calibration range.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Contract Review Process

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 478

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.4

Comment with Rationale and Proposal ***Attached Document*** ☐

For non-standard methods, being able to analyze by a similar standard method is not sufficient. The need to produce the same results.

If there is not a regulatory requirement for the parameter/method combination, the combination is recognized as a standard method if the analyte/matrix can be analyzed by a similar technology with similar results.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 479

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.4

Comment with Rationale and Proposal ***Attached Document*** ☐

Reality is that even analytes in the methods don't meet all required calibration requirements. This is a critical issue that MUST be resolved for all QC criteria (ICAL, ICV, CCV, LCS, MS/MSD, etc) on all analytes. e.g.: There are 129 Appendix IX Semivolatile Compounds. Most can be determined by SW846 Method 8270C with expectations that QC will pass criteria. There's a small subset that have lower expectations – these may fall outside criteria more frequently due to e.g., chromatographic behavior. Last are the analytes considered "poor performers". This group (maybe about ½ dozen) doesn't pass criteria on most occasions.

To be a National Standard, TNI should define a set of analytes (the FoPTs?), with defined criteria (LOD, LOQ, control limits, %RSD for ICAL and %D for ICV, CCV). ALL ABs should then accredit accordingly (the labs must meet minimum specified criteria). There must be a consensus among ABs on the analytes – even if it is to document where they agree

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Out of control of this committee.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

to accredit differently, and that they will recognize accreditation from another AB (e.g., state A accredits o-xylene and m/p-xylene; state B accredits total xylenes. State B has to recognize the accreditation even though they don't match exactly). The analytes not accredited may still be analyzed, but the lack of accreditation for these may be a key to getting clients to understand that there is a reason - they are not accredited because performance data is poor or not available. (buyer beware) Looking at the current list of FoPTs: can criteria realistically be set for all of these analytes? If the answer is yes, what are the expectations? (i.e., lab's LOQ<=PTRL. LOD must support it). If no, how can they be accredited? How are the labs expected to provide all information? The process is already in place to add analytes – the experimental FoPTs. The TNI Board can use the information gathered from the studies to decide if there is sufficient evidence that analytes can be reliably quantitated. If so, add it to the accredited list. If not, the analyte continues to not be accredited until technology is such that PT studies demonstrate acceptable results. (AND... the control limits used for the PT study can be used as "default" until the lab develops their own). If a laboratory comes up with a proprietary process for analysis, and demonstrates on the PT that data are acceptable, then those analytes should be added to the list, and it's up to other labs to figure out how they're going to do it to be accredited.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Out of control of this committee.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 462

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.4 first paragraph 2nd half , paragraph 2

Comment with Rationale and Proposal ***Attached Document*** ☐

If there is not a regulatory requirement for the parameter, method combination....- Does not make sense.

clarify or delete

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
miller	**michael**
609-633-2804	**michael.w.miller@dep.state.nj.us**

Comment #: 208

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.4 Method Selection

Comment with Rationale and Proposal	***Attached Document*** ☐
I have attached because I get kick out of the system by the time I finish typing	
I have attached	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gibson	**Diane**
8635347377	**dianegibson@polk-county.net**

Comment #: 294

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5

Comment with Rationale and Proposal ***Attached Document*** ☐

1.5.2.2 Limit of Quantitation 1.5.2.2.e) "The LOQ shall be verified annually for each quality system matrix, method, and analyte, but need not be re-verified for each instrument if the LOD was performed on that instrument." The current, 2003 NELAC Standard, allows for re-evaluation or verification annually. See Chapter 5, Appendix D.1.2.2.b). The way this sounds as written doesn't seem to allow for that.

Suggested wording: "The LOQ shall be verified annually for each quality system matrix, method, and analyte, but need not be re-verified for each instrument if the LOD was determined or verified on that instrument."

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 480

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5

Comment with Rationale and Proposal ***Attached Document*** ☐

If validation is as extensive as necessary, than 1.5.2 etc. cannot be minimum requirements, e.g., add analytes to standard methods (one time client request) may not need full validation.

Sections 1.5.2, 1.5.3, and 1.5.4 give the requirements for test method validation unless otherwise specified by the data user.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	292

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5

Comment with Rationale and Proposal ***Attached Document*** ☐

1.5.2 Limit of Detection and Limit of Quantitation "Validation" (1.5.2.1 last sentence before a)), "confirm" (1.5.2.1.a)), and "verified/verification" (1.5.2.1.b, f))…are these all the same thing? If yes, then is it possible to choose one word to use throughout?
see above

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	293

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5

Comment with Rationale and Proposal ***Attached Document*** ☐

1.5.2 Limit of Detection and Limit of Quantitation "Performed" (1.5.2.1.b)), "determined" (1.5.2.1,1.5.2.1.a), d), e))…are these the same thing? If yes, then is it possible to choose one word to use throughout?
see above

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Loewer	**Beth**
239-278-7070	**loewerbl@leegov.com**

Comment #: 320

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5

Comment with Rationale and Proposal ***Attached Document*** ☐

Re: Method validation 1.5.2 Limits of detection and quantitation. Determined, validated, verified and performed seem to be used interchangeably throughout this section. Do they all mean the same thing?
Be consistent with word usage.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Roach	**Kathleen**
727-582-2302	**kroach@pinellascounty.org**

Comment #: 243

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5 Method Validation

Comment with Rationale and Proposal ***Attached Document*** ☐

see below for comment and changes for section 1.5

1.5 Method Validation 1.5.2.2 Limit of Quantitation (LOQ) Keep your terms consistent in this entire section. We are assuming the intent is to determine what the LOQ is and then confirm (or verify or validate it). Please don't interchange your words. Does confirm mean the same thing as verify and is this the same as to validate? See example below:

1.5.2.2.e) We find the wording in this sentence confusing. "The LOQ must be confirmed annually for each quality system matrix, method and analyte, but need not be re-verified for each instrument if the LOD was performed on that instrument." - Assuming that performed means determined, and confirmed means verified, this reads that if I performed an LOD study on the instrument, then I don't need to annually re-confirm the LOQ? I'm not sure that's the intent. 1.5.3a Please do no require this "alternate procedure" to be "documented in the

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	***First Name***
Phone Number	***Email***

Quality Manual". Please change this to "referenced in the Quality Manual". Many labs, like ours, have a separate procedure for their "Method Validation Procedure" and it's not part of the quality manual, but reference within.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600 x1032	**jaspard@epchc.org**

Comment #: 419

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Do the words "validation," "confirm," and "verified" all have the same meaning here? Do the words "performed" and "determined" all have the same meaning here? Please be consistent with your terms.
Use only one of the terms throughout.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Grimes	**Terri**
727-582-2302	**Tgrimes@co.pinellas.fl.us**

Comment #: 334

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2

Comment with Rationale and Proposal ***Attached Document*** ☑

1.5.2.1a,b,f and 1.5.2.1a,b,d,e: Inconsistent verbiage which creates confusion. 1.5.2.2.e): And, add back (from the 2003 Std) the "verification" of the LOD annually.
See attachment.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 481

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2

Comment with Rationale and Proposal ***Attached Document*** ☐

There is a contradiction - all procedures do not have to be documented. If these specifically do, then say so.

Procedures used for determining limits of detection and quantitation shall be documented.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Barron	**Joe**
813-627-2600	**barron@epchc.org**

Comment #: 380

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Need to use consistant terms throughout or define specific terms such as validation vs. confirm vs. verify and performed vs. determined. LOQ verification should be allowed if LOD was determined on an instrument.
Use minimal terminolgy and define those terms. add "or verified" to LOQ rule.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schantz	**LEonard**
585-428-7378	**lgs@cityofrochester.gov**

Comment #: 139

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2 & general

Comment with Rationale and Proposal ***Attached Document*** ☐

The standard needs to indicate that irrelevant activities are not required of labs. If a lab is not required to report outside its calibration range by its client or the data user, a requirement in a method or teh standard to perform a LOD or a LCR should be interpreted as irrelevant, not more stringent. If a lab does not report outside its calibration range, what happens above or below the calibration range is of no interest to or has no impact on the lab. They should not have to do it.

Simplify, you will never get support from organizations like AWWA unless the the requirements are streamlined.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 482

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1

Comment with Rationale and Proposal ***Attached Document*** ☐

An LOD is not required for a test method... (2nd sentence, 2nd paragraph) 1st sentence of 1.5.2.1 already says that.
delete

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 483

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1

Comment with Rationale and Proposal	***Attached Document*** ☐
LODs shall be determined by the protocol... I don't know of any mandated test methods or regulations that have protocols for determining "LODs".	
If a mandated test method or applicable regulation includes protocols for determining detection limits, these must be followed. The lab shall then document how LODs were derived from the determinations.	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 461

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1 a

Comment with Rationale and Proposal ***Attached Document*** ☐

confusing adding sample

quality system matrix

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 484

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1 a)

Comment with Rationale and Proposal	***Attached Document*** ☐
delete "when required" It's covered in e)	
delete	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 485

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1 c)

Comment with Rationale and Proposal ***Attached Document*** ☐

redundant

delete "or when test results are not required to be reported to the LOD..." through the end of the sentence.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 486

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1 d)

Comment with Rationale and Proposal	*Attached Document* ☐
language	
neither target analytes nor interferences or interferences	where there are no target analytes or

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Junio	**Paul**
920-261-1660	**Paul.Junio@testamericainc.com**

Comment #: 345

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1 d)

Comment with Rationale and Proposal ***Attached Document*** ☐

Delete the parenthetical (see definition of matrix), as pointers like this could be placed everywhere in the Standard.

The LOD shall be initially determined for the compounds of interest in each test method in a quality system matrix in which there are not target analytes nor interferences at a concentration that would impact the results or the LOD shall be determined in the quality system matrix of interest.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 487

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1 e)

Comment with Rationale and Proposal ***Attached Document*** ☐

Clipping the column changes the sensitivity of the analysis. Where do you draw the line (it's too open to interpretation)?

Suggest wording similar to SW846 8000C: "9.4.10 There are various types of instrument maintenance that require recalibration. However, they do not automatically require the initial demonstration of capability be repeated. They are listed in Sec. 9.2.5.2. Only major changes in instrumentation or procedure should require this to be repeated. Some examples which would require a new IDC are using a different type of detector (ECD to ELCD); using a different mode on the detector (SIM to Full Scan); changing the extraction apparatus or solvent; changing derivatization agents; using a different column phase; changing carrier gas (H2 to He); changing HPLC solvents; or changing chromatograph to detector interfaces (Thermospray to Particle Beam). Changing temperature conditions of the analysis will require recalibration but not a new IDC. New analysts along with changes in procedures and

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Good Idea but this standard is more than SW846.

instruments require a new IDC to be performed.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Good Idea but this standard is more than SW846.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Junio	**Paul**	***Comment #:***
920-261-1660	**Paul.Junio@testamericainc.com**	348

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1 f)

Comment with Rationale and Proposal ***Attached Document*** ☐

Delete “quality system” from this requirement. Since this would be accomplished in a sample matrix free from the analytes of interest, there will likely be no difference between an aqueous matrix LOD verification and drinking water matrix LOD verification.

The LOD, if required, shall be verified annually for each matrix, method and analyte.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Withdrawn

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 488

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1 f)

Comment with Rationale and Proposal ***Attached Document*** ☐

"…verified annually for each quality system matrix, method, and analyte."
… each quality system matrix, method, and analyte accredited under this Standard. There should also be some discussions re: PCB's (1016/1260 mix should be sufficient), and extraction/digestion methods.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

We believe it already is sufficient

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Penfold	**Larry**
303-736-0119	**Larry.Penfold@testamericainc.co**

Comment #: 377

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.1, b)

Comment with Rationale and Proposal ***Attached Document*** ☐

Current Text: The validity of the LOD shall be verified by identification of the analytie(s) in a QC sample in each quality system matrix containing 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. Comment: Reference to acceptance criteria is needed, and the detection criteria should be the same for LOD verification as it is for identification of analytes in samples.

Proposed Addition (italics): The validity of the LOD shall be verified by identification of the analyte(s) in a QC sample in each quality system matrix containing 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. A LOD verification shall be acceptable if the laboratory can reliably

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Last Name	*First Name*
Phone Number	*Email*

detect and identify by routine method or procedure specified criteria.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Applewhite	**John**
352 256 9332	**japplewhite@aplsciences.com**

Comment #: 146

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.2

Comment with Rationale and Proposal ***Attached Document*** ☐

The LOQ is not meaningful since the LLOQ (Lower Limit Of Quantitation) Section 1.7.1.1 (f) is the lowest concentration for which quantitative data are to be reported.

1.5.2.2 (a) Determination and verification of the LOQ is optional unless required by the client. 1.5.2.2 (e) If a LOQ is reported it shall be verified annually for each quality matrix....

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

Ward	**Gary**	***Comment #:***
360-501-3371	**gward@caslab.com**	498

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.2

Comment with Rationale and Proposal ***Attached Document*** ☐

If LOQ is set at the lower ICAL standard, there are no laboratory generated limits for this source. LOQ is verified if ICAL passes method requirements with good peak shape and signal to noise @ the LOQ.

LOQ study is not required if LOQ is at or above the lowest ICAL standard.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

LOQ is not related to calibration standards

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Shepherd	**Michael**
512-335-0906	**mcshepherd@austin.rr.com**

Comment #: 506

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.2

Comment with Rationale and Proposal ***Attached Document*** ☐

1.5.2.2 Limit of Quantitation (LOQ) a) All sample-processing and analysis steps of the analytical method shall be included in the determination of the LOQ. c) The validity of the LOQ shall be confirmed 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 test method acceptance criteria or client data quality objectives for accuracy. This single analysis is not required if the bias and precision of the measurement system is evaluated at the LOQ. Subsection c is redundant with Subsection a. If the LOQ is determined with the inclusion all of the sample processing steps, and if the LOQ determination meets corresponding performance or recovery criteria, then resulting value is de facto confirmed by that process.

Remove redundant requirements.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Axelrod	**Steve**
813-264-3887 ext 111	**axelrods@hillsboroughcounty.org**

Comment #: 129

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.2 (e)

Comment with Rationale and Proposal ***Attached Document*** ☐

The LOQ shall be verified annually for each quality system matrix, method and analyte, but need not be re-verified for each instrument if the LOD was performed on that instrument. The word "performed" is not consistent with the rest of this section. Replace it with "determined or verified".

The LOQ shall be verified annually for each quality system matrix, method and analyte, but need not be re-verified for each instrument if the LOD was determined or verified on that instrument.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Haynes	**RaeAnn**
503-229-5983	**haynes.raeann@deq.state.or.us**

Comment #: 250

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.2 d)

Comment with Rationale and Proposal ***Attached Document*** ☐

A circular argument can become a distraction since the LOQ requires that it must be above the LOD. I can see that the words 'any determined' were added perhaps to allow for instances where LOD's are not necessary. I propose the use of more obvious wording to prevent misunderstandings between users of the standard.

When an LOD is established by the laboratory the LOQ must be above the LOD.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Junio	**Paul**
920-261-1660	**Paul.Junio@testamericainc.com**

Comment #: 347

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.2 e)

Comment with Rationale and Proposal ***Attached Document*** ☐

Delete “quality system” from this requirement. Since this would be accomplished in a sample matrix free from the analytes of interest, there will likely be no difference between an aqueous matrix LOQ verification and drinking water matrix LOQ verification.

The LOQ shall be verified annually for each matrix, method and analyte, but need not be re-verified for each instrument if the LOD was performed on that instrument.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

quality system is in to limit the types of matrices. For example, each soil is different?

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kenton	**Roger**
903-237-6882	**rogerk@eastman.com**

Comment #: 211

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.5.2.2.e)

Comment with Rationale and Proposal ***Attached Document*** ☐

Is the LOD requirement an annual or one time requirement? LOQ verification should not be required if LOD verification is performed on an instrument. The proposed change below appears to be consistent with Section D.1.2.2.b of Appendix D of Chapter 5 from the 2003 NELAC Standard.

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

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Roach	**Kathleen**
727-582-2302	**kroach@pinellascounty.org**

Comment #: 244

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6

Comment with Rationale and Proposal ***Attached Document*** ☐

This entire section could use a little reorganization, because the info listed in 1.6.2 contains both General DOC information and Initial DOC information. We suggest breaking this section into 3 Parts:

1.6.1 General DOC Information
1.6.2 Initial Demonstration of Capability
1.6.3 Continuing (or On-going) Demonstration of Capability

1.6.2: Move the various verbiage in this section “Demonstration of Capability” and put it in the corresponding section listed above. The first paragraph/sentence belongs in the General Information and the second sentence belongs in the Initial DOC section, and third sentence belongs under General Information.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	***First Name***
Phone Number	***Email***

We do not like the added/underlined statement in section 1.6.2, and recommend it's deletion or change the wording:
"A demonstration of capability shall be conducted prior to using any test method and at any time there is a change in instrument type, personnel or test method or anytime that a method has not been performed by the laboratory or analyst in a twelve month period."

This gets dicey with auditors and staff in complying with a twelve month period, some labs are set up annually, some per fiscal year and others every 365 days. But what happens if a continuing DOC is done at day 366? We give employees a slight grace period which is defined in our quality manual. Suggested wording:
. . ..anytime that a method has not been performed by the laboratory or analyst annually, as defined in the quality manual, or not to exceed 13 months.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Grimes	**Terri**
727-582-2302	**Tgrimes@co.pinellas.fl.us**

Comment #: 335

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6

Comment with Rationale and Proposal ***Attached Document*** ☑

1.6.1, 1.6.2: Remove repetitive language and remove mis-placed verbiage.
See attachment.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	295

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6

Comment with Rationale and Proposal ***Attached Document*** ☐

1.6 Demonstration of Capability 1.6.1 General This section is OK, but is somewhat repeated in 1.6.2 1.6.2 DOC This entire section is repetitive and should be moved/removed. The first paragraph is very similar to the last paragraph in section 1.6.2. Why not just incorporate this paragraph there? The second paragraph is repetitive of 1.6.2.1.a); you just need to add the "…retained & available at the lab" to 1.6.2.1.a). Also, the "12-month period" is too stringent. Many labs have built in a small buffer for this. For example, "…DOCs must be done every year, plus or minus one month...". This adheres to the intent, but allows a little flexibility for labs. Also, the twelve month criteria belongs with the "On-going" DOC, not with the "Initial" DOC. It makes better sense to just remove it from this section.

Suggested wording: 1.6 Demonstration of Capability 1.6.1 General Prior to acceptance and institution of any method for data reporting, satisfactory demonstration of

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Last Name	*First Name*
Phone Number	*Email*

method capability is required (see Section 1.6.2). Thereafter, ongoing demonstration of method capability (section 1.6.3), as per the quality control requirements in Section 1.7.3 (such as laboratory control samples), is required. In cases where a laboratory analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for accreditation and there have been no significant changes in instrument type, personnel or method, the continuing demonstration of method performance and the analyst's documentation of continued proficiency shall be acceptable. The laboratory shall have records on file to demonstrate that a demonstration of capability is not required. 1.6.2 Initial Demonstration of Capability (DOC) A demonstration of capability (DOC) shall be conducted prior to using any test method and at any time there is a change in instrument type, personnel or test method. All initial demonstrations shall be documented as listed in 1.6.2.1. All data applicable to the demonstration shall be retained and available at the laboratory. 1.6.2.1 Initial Demonstration of Capability Documentation a) The laboratory shall document each initial demonstration of capability in a manner such that the following information is readily available for each affected employee: i. analyst(s) involved in preparation and/or analysis; ii. matrix; iii. analyte(s), class of analyte(s), or measured analyte(s); iv. identification of test method(s) performed; v. identification of laboratory-specific SOP used for analysis, including revision number; vi. date(s) of analysis; and vii. summary of analyses, including information outlined in 1.6.2.2.d.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Loewer	**Beth**
239-278-7070	**loewerbl@leegov.com**

Comment #: 322

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6

Comment with Rationale and Proposal ***Attached Document*** ☐

Re: Demonstration of Capability 1.6.2 Twelve-month period is too restrictive and does not give labs some necessary latitude and flexibililty. Using annually instead would not hurt the intent of this criteria.

Change 12 month period to annually. Put this requirement with on-going DOC, not with initial DOC. In 1.6.2.1 a) iii Change "measured parameter(s)" to measured analyte(s) to be consistent with "analytes" and "class of analytes."

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The committee feels that annually is not appropriate. Can Jan 2007 and Dec 2008 qualify as annual.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 490

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

"… method that has been in use by the laboratory for at least one year prior to applying for accreditation…"
…accreditation to this Standard…

Disposition Non-Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Does not add clarity.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 489

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

clarification

... any method where the data will be reported...

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Arms	**Stephen**
9047911502	**steve_arms@doh.state.fl.us**

Comment #: 474

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

POSSIBLE DUPLICATE For clarity and because the Standard has and will be interpreted in this way, language to relate DOC by parameter to accreditation is needed.
Reword the first paragraph of 1.6.1: Prior to acceptance and institution of any method for data reporting and/or accreditation of specific analytes, satisfactory demonstration of method capability is required for each analyte (see Section 1.6.2).

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 1.6.2.2 h

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Arms	**Stephen**
9047911502	**steve_arms@doh.state.fl.us**

Comment #: 472

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

For clarity and because the Standard has and will be interpreted in this way, language to relate DOC by parameter to accreditation is needed.

Reword the first paragraph of 1.6.1: Prior to acceptance and institution of any method for data reporting and/or accreditation of specific analytes, satisfactory demonstration of method capability is required for each analyte (see Section 1.6.2).

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

see 1.6.2.2h

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Wasko	**Mike**	***Comment #:***
706-355-8821	**wasko.mike@epa.gov**	230

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

I am opposes to the addition of a requiement for an analyst to perfom a new DOC if the method has not been performed by the analyst in the last 12 months. Most EPA methods contain a requirement for an Initial Demonstration of Proficiency, which is essentially the same as a DOC. EPA methods, however, do not include this time requirement. Once an analyst has demonstrated a basic level of proficiency, competence is demonstrated in every batch through all the associated QC such as instrument calibration checks, second source checks, method blanks, LCSs, matrix QC, etc. Whether it has been 12 days or 12 months since an analyst has performed the method, all batch QC must be performed and documented, and thus analyst proficiency is demonstrated at a known and documented quality.

remove the prhrase "or any time that a method has not been performed by the laboratory or analyst in a twelve-month period." from Section 1.6.2

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The committee feels that initial DOC needs to be completed after a one year period has elapsed.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 491

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.2.1

Comment with Rationale and Proposal ***Attached Document*** ☐

"laboratory-specific SOP used for analysis, including revision number" The DOC can be traced to the SOP revision number by the dates (revision of SOP in effect and date of DOC). Including the revision number on the DOC is opening it to interpretation and not giving any additional information. Is a new revision number a change in the method, and therefore requires a new DOC? Laboratory SOPs can be revised in many ways without changing the method.
Delete "including revision number".

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

withdrawn

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Junio	**Paul**
920-261-1660	**Paul.Junio@testamericainc.com**

Comment #: 349

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.2.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Delete “For chemistry”, since that is the only concern of this Module.

If the method or regulation does not specify a DOC, the following procedure is acceptable.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Zielke	**Theresa**
574-472-5515	**theresa.j.zielke@us.ul.com**

Comment #: 519

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.2.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Are labs still going to be held to analyzing a DOC with a second source if the method only requires the DOC to be analyzed using the same standard as the calibration?

If the method specifies a procedure for the DOC, the method criteria shall be followed.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 492

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.2.2

Comment with Rationale and Proposal ***Attached Document*** ☐

It is not clear whether the DOC has to be taken through all steps or not. For instrument analysts, second source standards would be sufficient. Also, for instrument analysts, a DOC is not matrix dependant. They receive an extract – it doesn't matter to them whether it was initially water or soil. The analysis procedures are the same either way. After the analyst calculates ng/µL of a target analyte, the LIMS system does the rest.

reword

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 493

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.2.2 e)

Comment with Rationale and Proposal ***Attached Document*** ☐

For a significant number of analytes, acceptance criteria is not available. How can a lab develop criteria if they first have to pass the DOC? Using 70-130% as a default is unrealistic - analytes that can meet that criteria already have that criteria set.

Use the control limits from the PT studies as a default until in house limits can be developed.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This is allowed.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wasko	**Mike**
706-355-8821	**wasko.mike@epa.gov**

Comment #: 231

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.3

Comment with Rationale and Proposal ***Attached Document*** ☐

I propose removing all references to Ongoing Demonstration of Capability. Every time that an analyst prepares and analyzes a batch of samples there is ample QC to demonstrate and document the analyst's proficiency. While I appreciate the increased flexibility in the Draft TNI standard versus the present NELAC standard, I believe Ongoing Demonstrations of Capability are burdensome paperwork requirements that return little to no value in ensuring the quality of the data. As I previously stated, batch QC is more than adequate to demonstrate analyst capability.

Remove all references to Ongoing Demonstrations of Capability in Section 1.6.3 and any other location in the Draft TNI standards.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The committee has added clarity to these sections in all technical modules.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 604

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.3.2

Comment with Rationale and Proposal	***Attached Document*** ☐
the section is missing some letters	
in item a), test should be plural it should be "tests" at the end of the paragraph. In item c), LCS should be plural it should be "LCSs"	

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Junio	**Paul**
920-261-1660	**Paul.Junio@testamericainc.com**

Comment #: 350

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.3.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Delete “For chemistry”, since that is the only concern of this Module.

This ongoing demonstration may be one of the following:

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Flowers	**June**
407.339.5984 x212	**june@flowerslabs.com**

Comment #: 123

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.6.3.2d)

Comment with Rationale and Proposal ***Attached Document*** ☐

There is no mention of analyte, only test method. Item d provides a logical means of the lab defining their ongoing DOC. As long as the method is being performed at least once a year, that means that primary and secondary standards are in house. An acceptable calibration curve or QC spike sample containing each accredited analyte is adequate DOC.

Add "analyte" to the header, i.e., "For chemistry analytes, this ongoing demonstration may be one of the following"

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 1.6.2.2 h

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gibson	**Diane**
8635347377	**dianegibson@polk-county.net**

Comment #: 297

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.2.c).ii. "if the time period for calibration of the most previous calibration verification has expired" Should "previous" really be "recent"?
see above

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Loewer	**Beth**
239-278-7070	**loewerbl@leegov.com**

Comment #: 325

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

Re: Technical Requirements Allow for reference to test method SOP describing the grade of reagents used, in addition to certificates of purity. This would be just as reliable as manufacturers' documentation. Data associated with spikes and duplicates not clearly stated.

1.7.2 c) ii Change most "previous" to most recent. 1.7.3.5 a) Change "Documentation of purity shall be available." to Documentation of purity shall be available, which may include certificates of purity/analysis or may be a clear reference in the test method SOP describing the reagent grade(s) used. 1.7.4.3 a) Clarify last sentence. Should be "data corresponding to the spiked sample." b) Same thing. Should be "data corresponding to the duplicate sample."

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

allows this for 1.7.3.5a
changed for 1.7.2.c
1.7.4.3 changed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Grimes	**Terri**
727-582-2302	**Tgrimes@co.pinellas.fl.us**

Comment #: 336

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7

Comment with Rationale and Proposal	***Attached Document*** ☑
1.7.2.2c)ii: editorial change be allowed. See attachment. 1.7.3.5.a): SOP documentation of reagent grades used should 1.7.4.3.a) & b): clarify that only the failed MS & MSD need to be coded since it is a sample specific, not batch, control. See attachment.	
See Attachment.	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	298

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.3.5.a) "Documentation of purity shall be available." While this is preferable to "…shall be retained.", it shouldn't be necessary at all…as long as a lab clearly documents that only "Analytical Reagent Grade or better" is used in their SOPs. Analytical Reagent Grade is a universally accepted designation that a high quality chemical is produced specifically for laboratory use. Documenting the grade in the SOP provides a "documented reference" as to what the lab is using, should anyone need to see such a reference in writing. CoAs have become fairly meaningless since manufacturer's make and/or ship the wrong items more and more these days.

Suggested Wording: "Documentation of purity shall be available, which may include certificates of purity/analysis or may be a clear reference in the test method SOP describing the reagent grade(s) used"

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This is allowed

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gibson	**Diane**
8635347377	**dianegibson@polk-county.net**

Comment #: 299

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.4.3.a) & b) Sample Specific Controls: Last sentence needs clarification: "For matrix spike results outside established criteria, corrective action shall be documented or the data reported with appropriate data qualifying codes."

Suggested Wording: a) "For matrix spike results outside established criteria, corrective action shall be documented or the data for the corresponding spiked sample reported with appropriate data qualifying codes." b) "For matrix spike results outside established criteria, corrective action shall be documented or the data for the corresponding duplicate sample reported with appropriate data qualifying codes."

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Roach	**Kathleen**
727-582-2302	**kroach@pinellascounty.org**

Comment #: 245

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7 Technical Requirements

Comment with Rationale and Proposal ***Attached Document*** ☐

See below for several comments within this section, along with proposed changes

1.7 Technical Requirements 1.7.2.b) Chlordane is also a multi-component analyte and should be included in this listing. 1.7.2.e). The last sentence of this paragraph states "Data associated with an unacceptable calibration verification may be fully useable under the following special conditions" and then it goes into detail as to what those conditions are - but this needs further clarification: for example, under these conditions, does this "usable data" need to be coded? 1.7.4.3.a and b. Look to the last sentence of last paragraph - "For ….results outside established criteria, corrective actions shall be documented or the data reported with appropriate data qualifying codes. These should read AND the data reported with appropriate qualifier codes. This reads like I just need to to document corrective actions only, and then I don't have to qualify anything. 1.7.5 Sample Handling: This entire section belongs in section 5.8 of the General Requirements, in the Sample Acceptance

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Last Name	*First Name*
Phone Number	*Email*

requirements. This section is also listed in the Microbiological Testing Module, and for the most part, it's the same information, so if you are going to keep it in this module instead of section 5.8 then these two sections should contain consistent verbiage and format.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 494

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.1.1

Comment with Rationale and Proposal ***Attached Document*** ☐

The most stringent standards are not always necessary, and should depend on the needs of the data user.

If more stringent standards or requirements are included in a mandated test method or by regulation, or if a data user has specific requirements, the laboratory shall demonstrate such requirements are met.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Contract Review

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Haynes	**RaeAnn**
503-229-5983	**haynes.raeann@deq.state.or.us**

Comment #: 251

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.1.1 d)

Comment with Rationale and Proposal ***Attached Document*** ☐

When a different lot is allowed without qualification then a significant bias in laboratory results can become a problem when a laboratory never goes outside a specific QC supplier.

all initial instrument calibrations shall...from a second manufacturer or from a different lot when a second manufacturer is unavailable.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The committee feels that even from different vendors the raw material might be the same. Different lots are independentlt prepared and validated.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schrenkel	**Carol**
(610) 280-3013	**schrenkc@lionvillelab.com**

Comment #: 495

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.1.1 h)

Comment with Rationale and Proposal	***Attached Document*** ☐
redundant - already stated in f) and g)	
delete the first sentence	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Haynes	**RaeAnn**
503-229-5983	**haynes.raeann@deq.state.or.us**

Comment #: 252

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.1.1 h)

Comment with Rationale and Proposal ***Attached Document*** ☐

Here the standard requires that the lowest calibration point be above the limit of detection with the only qualification being ICP and ICP single point technology. This is direct contrast with the previous stnadrd that does not require the laboratory to establish an LOD if they only report to their lowest standard.

.....The lowest calibration standard shall be above the limit of detection or have been established as the limit of detection per section 1.5.2.2).

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Haynes	**RaeAnn**
503-229-5983	**haynes.raeann@deq.state.or.us**

Comment #: 253

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.1.1 j)

Comment with Rationale and Proposal ***Attached Document*** ☐

Laboratories will write procedures that only require 2 calibration points one of which is zero.

The laboratory must have.....number of points (3 as a minimum) for establishing the intial calibration.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Shepherd	**Michael**
512-335-0906	**mcshepherd@austin.rr.com**

Comment #: 507

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.1.1.g

Comment with Rationale and Proposal ***Attached Document*** ☐

Here (and elsewhere) the standard uses the term “case” to refer to a set of samples. In this context “case” is a term specific to the Contract Laboratory Program and is not generally applicable and is confusing to laboratories not familiar with CLP.

Recommended alternate language: “report narrative”.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 605

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.1.1.h.ii

Comment with Rationale and Proposal ***Attached Document*** ☐

missing a word

"A zero and single point calibration standard..."

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 606

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.2.e

Comment with Rationale and Proposal ***Attached Document*** ☐

The change in the last sentence is not correct. By deleting "an" before "unacceptable" you make the requriement for "calibration verification" to be plural. However, if you make "calibration verification" plural, you imply that you need to fail two CCVs.

Inlcude "an", change the wording back to what it was.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 460

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.3

Comment with Rationale and Proposal ***Attached Document*** ☐

This monitoring shall be planned and reviewed- This is just a paperwork trail- The only thing important is having the procedure

delete sentence

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Junio	**Paul**
920-261-1660	**Paul.Junio@testamericainc.com**

Comment #: 351

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.3

Comment with Rationale and Proposal ***Attached Document*** ☐

Delete “For chemistry”, since that is the only concern of this Module.
Quality Control

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Alger	**Aaren**
717-346-8212	**aaalger@state.pa.us**

Comment #: 607

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

The numbering is not consistent. In this section letter designations are used, but in the next section 1.7.3.2, are numbered.

number the paragraphs under 1.7.3.1

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Junio	**Paul**
920-261-1660	**Paul.Junio@testamericainc.com**

Comment #: 353

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.3.2.3

Comment with Rationale and Proposal ***Attached Document*** ☐

Delete “and verified”. How is this spiking level to be verified if it is already known?

The LCS is a quality system matrix, known to be free of analytes of interest, spiked with known concentrations of analytes.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Steve	**Axelrod**
(813) 264-3887 ext 111	**axelrods@hillsboroughcounty.org**

Comment #: 130

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.3.3.1 (b) and 1.7.3.3.2 (b)

Comment with Rationale and Proposal ***Attached Document*** ☐

The frequency of the analysis of matrix spikes are as specified by the test method, or may be determined as part of the contract review process.

The frequency of the analysis of matrix spikes are as specified by the test method or the Standard Operating Procedure, and may be determined as part of the contract review process.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This is already stated that when a test method is more stringent it must be followed.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Ziomek	**Betsy**	***Comment #:***
804-698-4181	**esziomek@deq.virginia.gov**	235

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.3.3.2.a

Comment with Rationale and Proposal ***Attached Document*** ☐

A duplicate should be a second sample that is collected at the same location and time as the sample. It should not be a sub-sample from the same sample container. [A possible exception would be a timed composite sample. Taking two samples from the compositing jug would demonstrate homegenity.]

Re-word the definition of 'Matrix Duplicate".

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Your description is a field duplicate.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 459

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.3.3.3 a)

Comment with Rationale and Proposal ***Attached Document*** ☐

add back the organic chromatography test methods so labs will know if this applies to them.

above

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Method 300.1 for anions has suggogates

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600 x1032	**jaspard@epchc.org**

Comment #: 425

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.3.5.a

Comment with Rationale and Proposal ***Attached Document*** ☐

It shouldn't be necessary to provide documentation of purity so long as the lab clearly documents that it uses only reagents that are Analytical Reagent Grade or better.

Documentation of purity shall be available, either as certificates of purity, or as references in laboratory Quality documentation, that specify the reagent grades that are used.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Documentation is required.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 458

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.3.6

Comment with Rationale and Proposal ***Attached Document*** ☐

Selectivity is not defined at all and this appears to be a vague statement open to interpretation.

delete section

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Defined in Module 2

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Applewhite	**John**
352 256 9332	**japplewhite@aplsciences.com**

Comment #: 147

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.3.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.3.7 a) This statement is vague. It appears that the intent is that the instrument should not be operated outside of its design specifications.
1.7.3.7 a) Instruments shall not be operated outside of their design specifications.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

1.7.3.7 is deleted

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 457

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.4

Comment with Rationale and Proposal ***Attached Document*** ☐

I prefer having the acceptance rejectance criteria in 1.7.3 under the corresponding headings. It makes it easier to find.

put 17.4 sections in 17.3

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This format was approved in Chicago in 2006.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
McAninch	**Thomas**
903-757-4269	**mcaninch@cablelynx.com**

Comment #: 232

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.4.2.a

Comment with Rationale and Proposal ***Attached Document*** ☐

Cases i and ii under 1.7.4.2.a should be deleted. With these two provisions, the standard is venturing into the area of data usability. The authority to address data usability belongs to the data user, not the standard. I strongly support the data usability concept. However, the data user is the appropriate entity to establish requirements.

The 3rd paragraph of 1.7.4.2.a should end with the 2nd sentence. Delete all text starting with "This includes any allowable marginal exceedences as described in b) below."

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Current NELAC requirements.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Shepherd	**Michael**
512-335-0906	**mcshepherd@austin.rr.com**

Comment #: 508

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.4.2.a.ii

Comment with Rationale and Proposal ***Attached Document*** ☐

ii. when the acceptance criteria for the positive control are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level with data qualifying codes. Otherwise the samples affected by the unacceptable positive control shall be reprocessed and reanalyzed. This provision precludes reporting data with qualifiers for samples for failed a LCS (low). Samples aliquots may not be available for reprocessing or reanalysis, yet the data may still be usable depending upon the intended use of the data. The standards can not presume to know whether the data are usable.

ii. when the acceptance criteria for the positive control are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level with data qualifying codes. Otherwise the samples affected by the unacceptable positive control shall be reprocessed and reanalyzed. If samples can not be reprocessed or reanalyzed or if allowed by project data use requirements, data may be reported with appropriate qualifiers.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Barron	**Joe**
813-627-2600	**barron@epchc.org**

Comment #: 385

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.4.3

Comment with Rationale and Proposal ***Attached Document*** ☐

Qualifying codes should only be applied to the corresponding sample for failed matrix spikes and matrix duplicates. Wording implies all data would need to be qualified.
Add "for the corresponding sample" to the definition in 4.7.4.3 a) & b).

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Steve	**Axelrod**
(813) 264-3887 ext 111	**axelrods@hillsboroughcounty.org**

Comment #: 131

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.4.3 (a)

Comment with Rationale and Proposal ***Attached Document*** ☐

Change For matrix spike results outside established criteria, corrective action shall be documented or the data reported with the appropriate data qualifying codes.

"the data" could be misinterpreted to mean all the associated sample results.
Proposed Change For matrix spike results outside established criteria, corrective action shall be documented or the data for the corresponding spiked sample reported with the appropriate data qualifying codes.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600 x1032	**jaspard@epchc.org**

Comment #: 427

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.4.3.a & b

Comment with Rationale and Proposal ***Attached Document*** ☐

The last sentence needs clarification: "For matrix spike results outside established criteria, corrective action shall be documented or the data reported with appropriate data qualifying codes."

a) "For matrix spike results outside established criteria, correctivea ction shall be documented or the data for the corresponding spike sampel reported with the appropriate data qualifying codes." b) " For matrix spike results outside established criteria, corrective action shall be documented or the data for the corresponding duplicate sample reported with appropriate data qualifying codes."

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 455

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.5 a)ii 2nd sentence, 1.7.5 a)iii

Comment with Rationale and Proposal ***Attached Document*** ☐

This criteria makes the lab refrigerate a sample that the lab will run that day and it needs to be brought to room temperature. It should really require that the sampler puts the sample in the fridge if that lab can't recieve it directly

Thermal preservation is not required in the field if the laboratory receives the sample or the field sampler refrigerates the sample within 15 minutes of collection.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Ziomek	**Betsy**	***Comment #:***
804-698-4181	**esziomek@deq.virginia.gov**	236

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 1.7.5.a

Comment with Rationale and Proposal ***Attached Document*** ☐

Temperature preservation in 40 CFR Part 136 has been increased to 6 degrees C. Anything above 6 degrees C is a violation.
Add 'Unless regulatory or method specific criteria exist.'

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Hassani	**Farzaneh**
813-247-3451	**Farzaneh.Hassani@ci.tampa.fl.us**

Comment #: 384

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 16.2

Comment with Rationale and Proposal ***Attached Document*** ☑

1.6.2 Add "Initial" to heading to be consistent with 1.6.3 "Ongoing….." 1.6.2 Change proposed standard. The twelve month period is unnecessarily restrictive. Suggest change in wording from "in a twelve month period" to "on an annual basis as defined in the laboratory's Quality Manual". This part of the standard would appear to be more appropriately associated with the Ongoing DOC standards. 1.7.3.3.1.b) Proposed standard limits the frequency of the analysis of matrix spikes to "test method or may be determined as part of the contract review process". This change is unnecessarily restrictive. The current standard includes matrix spike frequency based on a "systematic planning process (e.g. Data Quality Objectives)" which should continue to be appropriately available and not eliminated. 1.7.4.3.a) & b) Last sentence in both a) and b) needs clarification:

Suggested wording: For a) "For matrix spike results outside established criteria, corrective action shall be documented or the data associated with the specific sample spiked shall be

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Last Name	*First Name*
Phone Number	*Email*

reported with appropriate data qualifying codes." For b) "For matrix duplicates results outside established criteria, corrective action shall be documented or the data associated with the specific sample duplicated shall be reported with appropriate data qualifying codes."

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Ziomek	**Betsy**	***Comment #:***
804-698-4181	**esziomek@deq.virginia.gov**	205

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 4.13.1.h

Comment with Rationale and Proposal ***Attached Document*** ☐

The wording indicates that records must adhere to regulatory and state legal requirements only in the case of bankruptcy. If the lab goes out of business, they must only follow the clients requests/instructions.
Omit "in case of bankruptcy" from the sentence.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
ziomek	**betsy**
804698-4181	**esziomek@deq.virginia.gov**

Comment #: 206

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section 4.16

Comment with Rationale and Proposal ***Attached Document*** ☐

What are we telling the lab that their internal audit SHALL be confidential? That isn't our call.
Change 'Shall' to 'Should'

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Mertens	**Sharon**
414-277-6384	**smertens@mmsd.com**

Comment #: 538

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section General, 1.5.1, 1.6, 1.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

General comments: As noted in previous conversations, the format of this module is inconsistent with other interim standards. Additions, clarifications and notes should be incorporated with the ISO language rather than separated into “ISO and additional” in each subsection as is currently presented. There are many inconsistencies, as well as redundancies, between the ISO requirement and the “additional” requirements within the individual sections. The following are terms that are covered in the ISO language and are similar or the same. These should not be called out as different. This will cause inconsistencies with the other modules and is confusing for the user. If the committee needs to, a note of clarification can be added to the ISO definition rather than creating a new one: Accreditation; Accuracy; Audit; Bias; Certified Reference Material; Measurement System; Measurement Uncertainty; Precision; Procedure; Reference Material; Reference Standard; Sampling; Verification The terms “preservation” and “matrix” as defined in this

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Add clarity to the standard.

Last Name	*First Name*
Phone Number	*Email*

module are inconsistent with the definitions presented in the FSMO modules. Those in the FSMO modules appear more complete – the committee should look at these. Section 1.5.1 – The definition for validation should be moved this section to to terms and definitions. Section 1.6 – Terms demonstration of capability; demonstration of method capability and demonstration of method performance should be clarified if they are meant to be different; or made consistent if they are meant to be the same thing. Section 1.6.2 Change title to “Demonstration of Capability (DOC)” to be consistent with convention in previous sections (e.g. 1.5.2)

Words that are defined in common language (i.e. dictionary) with no other special meaning should not be included in the terms and definitions sections. Examples include “shall”, “must” “may” or any others from Random House or Webster’s, the dictionaries listed in section 3.2.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Add clarity to the standard.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Belleau	**Devin**
315-764-4763	**devin.belleau@alcoa.com**

Comment #: 124

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section NA

Comment with Rationale and Proposal ***Attached Document*** ☐

As a captured laboratory, I would like to see more references to the application of this and future standards to account for the differences in how information/data is gathered, used, and reported within a "captured" laboratory environment. Most of these references, with the exception of the reporting sections, do not specifically address the needs of the "captured" laboratory community.

See comments above

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Should be no difference

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 45

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section Section 1.5.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.5.1: The definition for “validation” should be moved from this section to terms and definitions.

Section 1.5.1: The definition for “validation” should be moved from this section to terms and definitions.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This is defined where it is used and does not require definition.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 47

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section Section 1.5.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.6.2: The title of this section should be changed to “Demonstration of Capability (DOC)” to be consistent with convention in previous sections (e.g. Section 1.5.2).

Section 1.6.2: The title of this section should be changed to “Demonstration of Capability (DOC)” to be consistent with convention in previous sections (e.g. Section 1.5.2).

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 46

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section Section 1.6

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.6: The terms “demonstration of capability,” “demonstration of method capability,” and “demonstration of method performance” should be clarified if they are meant to be different; or made consistent if they are meant to be the same thing.

Section 1.6: The terms “demonstration of capability,” “demonstration of method capability,” and “demonstration of method performance” should be clarified if they are meant to be different; or made consistent if they are meant to be the same thing.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Kircher	**Carl**	***Comment #:***
904-791-1574	**carl_kircher@doh.state.fl.us**	97

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section Sections 1.5 & 1.6

Comment with Rationale and Proposal ***Attached Document*** ☐

Sections 1.5 and 1.6: Throughout these sections, this module makes use of the term "instrument." Module 2 uses "equipment." The relevant expert committee should review all uses of the terms "instrument" and "equipment" to ensure consistent uses and to contrast use of one term versus another. At first glance, in Module 4 the term "instrument" can be changed to "equipment" as they appear to mean the same thing.

Sections 1.5 and 1.6: Throughout these sections, this module makes use of the term "instrument." Module 2 uses "equipment." The relevant expert committee should review all uses of the terms "instrument" and "equipment" to ensure consistent uses and to contrast use of one term versus another. At first glance, in Module 4 the term "instrument" can be changed to "equipment" as they appear to mean the same thing.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Sometimes they are different sometime they are not. We cleaned as much as possible.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 48

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section Sections 1.6.1 & 1.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.6.1 and 1.6.2: The last 2 paragraphs in Section 1.6.1 and the paragraphs under Section 1.6.2 are duplicative. The relevant expert committee should consider whether these requirements can be consolidated in one section. This comment also applies to Sections 1.6.1 and 1.6.2 in other technical modules in Volume 1.

Section 1.6.1 and 1.6.2: The last 2 paragraphs in Section 1.6.1 and the paragraphs under Section 1.6.2 are duplicative. The relevant expert committee should consider whether these requirements can be consolidated in one section. This comment also applies to Sections 1.6.1 and 1.6.2 in other technical modules in Volume 1.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Howell	**David**
813.247.3451 ext.206	**david.howell@ci.tampa.fl.us**

Comment #: 359

Item/Volume and Module

Item 4 VOLUME 1: LABORATORY REQUIREMENTS Module 4 - Chemical Testing

Section see attached file

Comment with Rationale and Proposal	***Attached Document*** ☑
See attached file	
See attached file	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Potter	**Michele**
(609)292-3950	**michele.potter@dep.state.nj.us**

Comment #: 157

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section 1.5

Comment with Rationale and Proposal ***Attached Document*** ☐

Minimum Quantifiable Activity (MQA) is not considered a useful concept for radiochemistry. Unlike method detection limits for Organic and Inorganic analyses, MQA for radiochemistry does not serve any purpose. In addition, there is ambiguity in the document since section 1.5.2.1.b states that the standard does not require an MQA to be performed.
If an MQA is not required it should be eliminated by removing the reference to MQA.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

deleted

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
potter	**michele**
(609) 292-3950	**michele.potter@dep.state.nj.us**

Comment #: 158

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section 1.5.2.3

Comment with Rationale and Proposal ***Attached Document*** ☐

SDWA detection limits: These are actually the Required Detection Limits (RDL) under the federal Safe Drinking Water regulations. There are no SDWA deteciton limits separately.

Need to revise terminology to be consistent with federal regulations throughout the document.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
potter	**michele**
(609) 292-3950	**michele.potter@dep.state.nj.us**

Comment #: 159

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section 1.5.4

Comment with Rationale and Proposal ***Attached Document*** ☐

Combined standard uncertainty: combined standard uncertainty is not accurately documented in the module.

must elaborate on the requirements for combined standard uncertainty.

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would introduce a concept that had not been subject to public review by being included in a related proposal as published in the Draft Interim Standard.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
potter	**michele**
(609) 292-3950	**michele.potter@dep.state.nj.us**

Comment #: 160

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section 1.5.5

Comment with Rationale and Proposal ***Attached Document*** ☐

Evaluation of selectivity: Selectivity is not entirely clear in the document, particularly what laboratories are expected to do for selectivity.

It can be removed and will have no effect on the module. However, if you want to retain, more information is needed to explain what a laboratory is required to do. Also, if you retain, it must be under method selection. Selectivity is a part of the method selection process. Not all methods are selective or need to be selective. For example, gross alpha and beta determination in drinking water is a screening method and not a selective method.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This adds some clarity even though this could use more.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Arms	**Stephen**
9047911502	**steve_arms@doh.state.fl.us**

Comment #: 475

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section 1.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

For clarity and because the Standard has and will be interpreted in this way, language to relate DOC by parameter to accreditation is needed.

Reword the first paragraph of 1.6.1: Prior to acceptance and institution of any method for data reporting and/or accreditation of specific analytes, satisfactory demonstration of method capability is required for each analyte (see Section 1.6.2).

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

see 1.6.2

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
potter	**michele**
(609) 292-3950	**michele.potter@dep.state.nj.us**

Comment #: 161

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section 1.7.1.a

Comment with Rationale and Proposal ***Attached Document*** ☐

different terminology is used to describe the same concep in the document. At section 1.7.1.a the standard refers to nuclear counting when in fact it should be called radiation counting. this is one example of inconsistency that needs to be addressed.

The consistency committee must review the document for uniformity. Also, some reorganization of the material to bring clarity to the module is suggested.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Thank You for your help in doing just what you propose.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 103

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section Section 1.6.2.2(h)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.6.2.2(h): The first sentence contains the term “initial evaluation” while the corresponding sentence in Module 4 uses “initial demonstration.” The last sentence, which is an addition to the corresponding subsection in Module 4, presents a MAJOR problem. The language as written gives the impression that an initial evaluation does not need to be performed for SM7500I B, SM7500Cs B, or the “GA-Tech” method if the laboratory has already performed an initial evaluation for SM7120B. All of these test methods utilize gamma-ray spectrometry as the analysis technology. The intent of the sentence is likely relevant to adding additional radioisotopes to the “photon-emitters” method SM7120B. Therefore, this subsection should be revised to read, “When an analyte not currently found on the laboratory’s list of accredited analytes is added to an existing accredited test method, as initial demonstration of capability must be performed for that analyte. When analytes are added to the same gamma-ray spectrometry test method and quantified, this is not required.”

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Becareful what you ask for, analytes in gamma spec are not spiked for good reason. (Radioactivity)

Comments with TNIQS Response

Last Name	***First Name***
Phone Number	***Email***

Section 1.6.2.2(h): The first sentence contains the term “initial evaluation” while the corresponding sentence in Module 4 uses “initial demonstration.” The last sentence, which is an addition to the corresponding subsection in Module 4, presents a MAJOR problem. The language as written gives the impression that an initial evaluation does not need to be performed for SM7500I B, SM7500Cs B, or the “GA-Tech” method if the laboratory has already performed an initial evaluation for SM7120B. All of these test methods utilize gamma-ray spectrometry as the analysis technology. The intent of the sentence is likely relevant to adding additional radioisotopes to the “photon-emitters” method SM7120B. Therefore, this subsection should be revised to read, “When an analyte not currently found on the laboratory’s list of accredited analytes is added to an existing accredited test method, as initial demonstration of capability must be performed for that analyte. When analytes are added to the same gamma-ray spectrometry test method and quantified, this is not required.”

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Becareful what you ask for, analytes in gamma spec are not spiked for good reason. (Radioactivity)

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 104

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section Section 1.7.2.4(c)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.2.4(c): The section makes reference to additional documents, the GUM and the MARLAP. These references are not found in Module 2 with the other references. Thus, complete references to GUM and MARLAP need to be added to Section 3 in this Module.\

Section 1.7.2.4(c): The section makes reference to additional documents, the GUM and the MARLAP. These references are not found in Module 2 with the other references. Thus, complete references to GUM and MARLAP need to be added to Section 3 in this Module.\

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

They are defined where they are used in this module - no need for definition.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Kircher	**Carl**	***Comment #:***
904-791-1574	**carl_kircher@doh.state.fl.us**	105

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section Section 1.7.2.5(c)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.2.5(c): The acronym ANSI first appears without any prior definition in this module or in Module 2 definitions. The term “American National Standards Institute (ANSI)” should be defined in Section 1.3.1 or else spelled out in this section.

Section 1.7.2.5(c): The acronym ANSI first appears without any prior definition in this module or in Module 2 definitions. The term “American National Standards Institute (ANSI)” should be defined in Section 1.3.1 or else spelled out in this section.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

commonly used

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 102

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section Sections 1.6 & 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

Sections 1.6 and 1.7: These sections make use of the term “instrument.” Module 2 uses “equipment.” The relevant expert committee should review all uses of the terms “instrument” and “equipment” to ensure consistent uses and to contrast use of one term versus another. At first glance, in Module 6 the term “instrument” can be changed to “equipment” as they appear to mean the same thing.

Sections 1.6 and 1.7: These sections make use of the term “instrument.” Module 2 uses “equipment.” The relevant expert committee should review all uses of the terms “instrument” and “equipment” to ensure consistent uses and to contrast use of one term versus another. At first glance, in Module 6 the term “instrument” can be changed to “equipment” as they appear to mean the same thing.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Sometimes they mean different things - We did some cleanup

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 50

Item/Volume and Module

Item 5 VOLUME 1: LABORATORY REQUIREMENTS Module 6 - Radiological Testing

Section Sections 1.6.1 & 1.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.6.1 and 1.6.2: The last 2 paragraphs in Section 1.6.1 and the paragraphs under Section 1.6.2 are duplicative. The relevant expert committee should consider whether these requirements can be consolidated in one section. This comment also applies to Sections 1.6.1 and 1.6.2 in other technical modules in Volume 1.

Section 1.6.1 and 1.6.2: The last 2 paragraphs in Section 1.6.1 and the paragraphs under Section 1.6.2 are duplicative. The relevant expert committee should consider whether these requirements can be consolidated in one section. This comment also applies to Sections 1.6.1 and 1.6.2 in other technical modules in Volume 1.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Loewer	**Beth**
239-278-7070	**loewerbl@leegov.com**

Comment #: 327

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.6

Comment with Rationale and Proposal ***Attached Document*** ☐

Demonstration of Capability On-going stock QC cultures should be allowed. They have been proven viable, and there is no good reason not to use them. Counts outside the countable range should be acceptable for DOC use. Count control is not that easily accomplished.
1.6.2.2 Remove last sentence "This shall be documented in the laboratory's Quality Manual." 1.6.2.2 a) Change language to allow for use of on-going stock QC cultures. 1.6.2.2 b) Change language to allow for use of counts outside of countable range for DOC use.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

non persuasive on counts outside range.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Grimes	**Terri**
727-582-2302	**Tgrimes@co.pinellas.fl.us**

Comment #: 346

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.6

Comment with Rationale and Proposal ***Attached Document*** ☑

1.6.2.2: Please reomve the last sentence as you did in the Chemsitry Module, V1M4, section 1.6.2.2) 1.6.2.2.a To prescriptive! Removes a lot of reasonable options-see attachment.

See Attachment

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Arms	**Stephen**
9047911502	**steve_arms@doh.state.fl.us**

Comment #: 473

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

For clarity and because the Standard has and will be interpreted in this way, language to relate DOC by parameter to accreditation is needed.

Reword the first paragraph of 1.6.1: Prior to acceptance and institution of any method for data reporting and/or accreditation of specific organisms, satisfactory demonstration of method capability is required for each organism (see Section 1.6.2).

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

We have added clarity in 1.6.2.2 and Silky says no.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Hassani	**Farzaneh**
813-247-3451	**Farzaneh.Hassani@ci.tampa.fl.us**

Comment #: 386

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

1.6.2 Add “Initial” to heading to be consistent with 1.6.3 “Ongoing…..” 1.6.2 Change proposed standard. The twelve month period is unnecessarily restrictive. Suggest change in wording from “in a twelve month period” to “on an annual basis as defined in the laboratory’s Quality Manual”. This part of the standard would appear to be more appropriately associated with the Ongoing DOC standards. 1.6.2.2.a) Does not allow for the use of a sample for a DOC; which it needs to. Also, a lab should not have to use a different stock culture than an on-going QC. In fact, using a culture that has been passing on-going QC is good because you’ll be able to differentiate between a “bad” culture and bad technique. As long as the culture is viable (meeting QC criteria), then there is no reason not to use it.

Suggested wording: A quality control sample shall be obtained from an outside source, be prepared by the laboratory using stock cultures, or be an appropriate sample for this purpose.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 1.6.2 and changes

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Axelrod	**Steve**
813-264-3887 ext 111	**axelrods@hillsboroughcounty.org**

Comment #: 132

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.6.2.2 (a)

Comment with Rationale and Proposal ***Attached Document*** ☐

A quality control sample shall either be obtained from an outside source or be prepared by the laboratory using stock cultures other than those used for on-going QC purposes. When reviewed by our committee, we felt the proposed change in wording would avoid confusion.

A quality control sample shall either be obtained from an outside source or be prepared by the laboratory using stock cultures from a source or lot different from those used for on-going QC purposes.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Zielke	**Theresa**
574-472-5515	**theresa.j.zielke@us.ul.com**

Comment #: 521

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.6.2.2(a)

Comment with Rationale and Proposal ***Attached Document*** ☐

A second source requirement does not make sense for microbiology. Methods do not require a second source and it is unnecessary to make labs pay for another source only to be used for DOCs.

remove this

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Barron	**Joe**
813-627-2600	**barron@epchc.org**

Comment #: 390

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.6.2.2.a

Comment with Rationale and Proposal ***Attached Document*** ☐

The use of samples should be allowed for a DOC

Add "or an approppriate sample" to 1.6.2.2.a

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Not for initial DOC.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600 x 1032	**jaspard@epchc.org**

Comment #: 428

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.6.2.2.a

Comment with Rationale and Proposal ***Attached Document*** ☐

This does not allow for the use of a sample for a DOC.

Allow samples to be used for DOCs.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Not for initial DOC.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	301

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.3.5.a)ii The request for documentation is too prescriptive and unnecessary for pre-prepared media. Manufacturers have specific procedures to establish and check expiration dates for the lots they produce. If a well-established, reputable manufacturer sets an expiration date, then it should not be questioned, even if it exceeds Table 9020:IV. As long as it is checked by the lab prior to the first use and found to be acceptable, there should be no further documentation required. Please remove this requirement.

remove

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

This documentation is needed.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Grimes	**Terri**
727-582-2302	**Tgrimes@co.pinellas.fl.us**

Comment #: 356

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☑

Too prescriptive. See attachment.

See Attachment.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Must be checked once per month

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Grimes	**Terri**
727-582-2302	**Tgrimes@co.pinellas.fl.us**

Comment #: 354

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☑

1.7.3.7.b)ii: Requiring autoclaves' temperature device to be calibrated annually is cost prohibitive (> $1000 alone) and mostly unnecessary. Require them to be checked and if necessary, calibrated. The Quality Systems module (V1M1) already covers this topic in 5.5.13.1 Support Equipment. To be more consistent through out all modules, remove this entirely or at least change the language to allow verification. Suggested language below. 1.7.3.7.b)iii "Volumetric equipment shall be calibrated as follows:" You changed "calibrated" in item 2 to verified, but it wasn't changed in the first sentence of the same section. Suggested language below.

Suggested Wording: "Autoclave maintenance, either internally or by service contract, shall be performed annually and shall include a pressure and temperature device check or calibration." "Volumetric equipment shall be verified as follows:" Attachment provided as well (same info).

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Grimes	**Terri**
727-582-2302	**Tgrimes@co.pinellas.fl.us**

Comment #: 352

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☑

1.7.3.3: This section does not apply to any currently certifiable methods; please remove. 1.7.3.5.a)ii Pre-preapred, purchased media should not have to adhere to Table 9020:IV. See Attachment. 1.7.3.5.c)v Second sentence. Editorial change-verbiage repetitive & unclear. See Attachment. 1.7.3.5.c)v Last sentence. Unclear & too prescriptive. See Attachment.

See Attachment.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	307

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.3.5b) "Reagents and commercial dehydrated powders shall be used within the shelf life..." This is in direct contradiction of Standard Methods 9020 B4.i culture media which reads: "Use opened bottles of media within 6 months." I personally prefer to not have to throw away perfectly good bottles of dehydrated media but there needs to be clarification.
choose one standard or the other

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	306

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.3.5 Quality of Standards, Reagents, and Media 1.7.3.5a)iii. "Any media used past the expiration date must be verified..." This item is in direct conflict with 1.7.3.5a)i.2. which states "Media must be used within the holding time limits specified in the table titled "Holding Times for Prepared Media" from the most recent edition of Standard Methods. Which is it?
Choose one or the other. It's confusing and contradictory as written.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Lab prepared versus Purchased Media

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gibson	**Diane**
8635347377	**dianegibson@polk-county.net**

Comment #: 305

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.3.7.b)iii "Volumetric equipment shall be calibrated as follows:" You changed "calibrated" in item 2 to verified, but it wasn't changed in the first sentence of the section.
Suggested Wording: Volumetric equipment shall be verified as follows:

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gibson	**Diane**
8635347377	**dianegibson@polk-county.net**

Comment #: 304

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.3.7.b)ii Requiring autoclaves' temperature device to be calibrated annually is cost prohibitive (> $1000 alone) and mostly unnecessary. Require them to be checked and if necessary, calibrated. The Quality Systems module (V1M1) already covers this topic in 5.5.13.1 Support Equipment. To be more consistent through out all modules, remove this entirely or change the language to allow verification.

Suggested Wording: Autoclave maintenance, either internally or by service contract, shall be performed annually and shall include a pressure and temperature device check or calibration.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

calibration changed to verification

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	303

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.3.5.c)v "Purchased reagent water held prior to use for longer that the testing intervals specified in items i. through iv. or in the accredited test method must either be re-tested for the required parameters or discarded." This is unclear and too prescriptive. Just like any reagent, when purchased water is received, it should already have an expiration date. If it doesn't, one may be assigned, but this conflicts with the Quality Systems module now (5.6.4.2.b). As long as it is used within the expiration date, there is no need for additional and unnecessary testing. If it is used outside the expiration date, then, yes, retesting may be necessary.

Suggested Wording: Purchased reagent water held longer than the expiration date must either be re-tested for the required analyses or discarded.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Gibson	**Diane**
8635347377	**dianegibson@polk-county.net**

Comment #: 302

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.3.5.c)v "If the provider provides this information, the laboratory may obtain this information from the supplier in lieu of performing the tests." This seems repetitive & doesn't make sense as written."

Suggested Wording: "The supplier may provide this information or the laboratory may obtain this information from the supplier in lieu of performing the tests."

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Loewer	**Beth**
239-278-7070	**loewerbl@leegov.com**

Comment #: 330

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

Technical Requirements 1.7.3.3 Matrix spikes don't belong with micro work. 1.7.3.5 a) ii This documentation should not be necessary for pre-prepared media. The manufacturers' expiration dates should apply. 1.7.3.5 c) v Doesn't make sense with regard to supplier provided information. Also, purchased reagent water, like any other reagent, has an expiration date. If used before that date, it should not require any further testing. It should be discarded if expired. 1.7.3.7 b) ii Annual calibration of autoclaves is very expensive and not necessary. A pressure and temperature check, conducted either by lab personnel or through an outside service contract, should be done annually. If necessary, a calibration procedure should be performed. 1.7.3.7 b) iii Volumetric equipment "calibration" should be changed to "verification." 1.7.5 b) i Many municipal labs have different divisions with different budgets within the same department.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

verified

Comments with TNIQS Response

Last Name	***First Name***
Phone Number	***Email***

1.7.3.3 Remove this section from the module. It does not apply to microbiological work. 1.7.3.5 a) ii Accept manufacturers' expiration dates without further testing and/or documentation. Delete this requirement. 1.7.3.5 c) v Suggest: The supplier may provide this information or the laboratory may obtain this information from the supplier in lieu of performing the tests. Also suggest: Purchased reagent water held longer than the expiration date must be retested or discarded. 1.7.3.7 b) iii Change "Volumetric equipment shall be calibrated as follows:" to Volumetric equipment shall be verified as follows: 1.7.5 b) i Change "...from their laboratory;" to from their organization.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

verified

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Gibson	**Diane**	***Comment #:***
8635347377	**dianegibson@polk-county.net**	300

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7

Comment with Rationale and Proposal ***Attached Document*** ☐

1.7.3.3 Matrix spikes in Micro? Please remove this section.
remove

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Some methods have this.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 466

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Reference to the chemistry module is unfair to a lab who might only be certified for micro

expand without reference or delete.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

See 1.7.1

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Roach	**Kathleen**
727-582-2302	**kroach@pinellascounty.org**

Comment #: 328

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3

Comment with Rationale and Proposal ***Attached Document*** ☐

See comments and proposed changes below for various clauses in this section

1.7.3.5.a.i.2: Don't specifically state "The most recent edition of "Standard Methods for the Examination of Water and Wastewater". First, you are assuming that everyone uses standard methods and that's not necessarily true, and second, some labs are tied to specific editions for approved use, also citing "The most recent version" has become a grey area with standard methods available on-line. Suggested wording: Media must be used within the holding times listed in the corresponding method. 1.7.3.5.a)ii The request for documentation is too prescriptive and unnecessary for pre-prepared media. Manufacturers have specific procedures to establish and check expiration dates for the lots they produce. If a well-established, reputable manufacturer sets an expiration date, then it should not be questioned, even if it exceeds Table 9020:IV. As long as it is checked by the lab prior to the first use and found to be acceptable, there should be no further documentation required.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

Please remove this requirement. 1.7.3.5.c)v "Purchased reagent water held prior to use for longer that the testing intervals specified in items i. through iv. or in the accredited test method must either be re-tested for the required parameters or discarded." This is unclear and too prescriptive. Just like any reagent, when purchased water is received, it should already have an expiration date. If it doesn't, one may be assigned, but this conflicts with the Quality Systems module now (5.6.4.2.b). As long as it is used within the expiration date, there is no need for additional and unnecessary testing. If it is used outside the expiration date, then, yes, retesting may be necessary. 1.7.3.5.a.ii) "…If the manufacturer's expiration date is greater than those noted in 1.7.3.5.a)i.2. above, the laboratory must request, and have available documentation from the manufacturer demonstrating media quality for the extended time period." Why not allow the lab to demonstrate this quality/reliability, like you do in the Quality Systems General Requirements module (5.6.5.a)? Suggest changing to "…from the manufacturer or lab demonstrating…" 1.7.3.5.d.i) "…and the pH of the media" For purchased, pre-prepared, ready-to-use media, does this mean that the pH measured by the manufacturer; or is the lab required to measure it again (thus having two pH values)? 1.7.3.7.b..iii First sentence – "Volumetric equipment shall be calibration as follows:" We do not calibrate volumetric equipment, but we can verify it! Suggest using the word verified instead. 1.7.3.7.iii.3 – delete this requirement as you have covered it in 1 and 2 above, it's redundant

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Barron	**Joe**
813-627-2600	**barron@epchc.org**

Comment #: 392

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.3

Comment with Rationale and Proposal ***Attached Document*** ☐

Matrix spikes are not applicable in micro.
Remove 1.7.3.3.a

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Some methods have this.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600 x1032	**jaspard@epchc.org**

Comment #: 430

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.3

Comment with Rationale and Proposal ***Attached Document*** ☐

A matrix spikes section is not needed in the microbiology module.
Please remove this section.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Some methods have this.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Zielke	**Theresa**
574-472-5515	**theresa.j.zielke@us.ul.com**

Comment #: 522

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.5 d) i and ii

Comment with Rationale and Proposal ***Attached Document*** ☐

Documenting the amount of media or reagents received does not affect the quality of the data. This is not a requirement in the Chemistry or General modules, it should not be required for Micro either.

i. Remove "and amount of media received" ii. Remove "and amount"

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 465

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.5 i.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Labs should not be required to use the most recent edition of SM, but the SM that is required by thier clients or by the EPA

above

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Currently approved

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600	**jaspard@epchc.org**

Comment #: 431

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.5.a ii

Comment with Rationale and Proposal ***Attached Document*** ☐

The request for documentation is unnecessary for pre-prepared media.

Please remove this requirement.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Yes

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
potter	**michele**
(609) 292-3950	**michele.potter@dep.state.nj.us**

Comment #: 156

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.5.a)2)

Comment with Rationale and Proposal ***Attached Document*** ☐

the citation currently states to follow Standard Methods for media expiration dates. if the lab is not accredited for standard methods how can you enforce SM requirements on the lab.
the citation needs to also include the EPA method citations for media storage when/if applicable.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Same table

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Barron	**Joe**
813-627-2600	**barron@epchc.org**

Comment #: 393

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.5.a)ii

Comment with Rationale and Proposal ***Attached Document*** ☐

Documentation is unnecessary, regulation should be at the manufacturer level.
remove section 1.7.3.5.a)ii

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Needed documentation - not in control by lab accreditation.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Broderick	**James**
518-573-7548	**jdb10@health.state.ny.us**

Comment #: 397

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.5.a.ii

Comment with Rationale and Proposal ***Attached Document*** ☐

Does this section include dehydrated powders that are laboratory prepared too (rehydrated media)? There is some lack of clarity in the phrases "laboratory prepared" and "ready-to-use" - into which category does dehydrated media prepared by the lab fall? I am hoping that "laboratory prepared media" (1.7.3.5.a.i.) refers only to media made from raw products, not dehydrated media.

Ready-to-use and lab rehydrated media shall be used...

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600 x1032	**jaspard@epchc.org**

Comment #: 432

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.5.c v

Comment with Rationale and Proposal ***Attached Document*** ☐

Purchased water has a vendor designated expiration date. So long as it is used by that date, there is no need for additional testing.
Purchased water shall be tested only if it is held past its expiration date. Water held past the expiration date shall be either re-tested or discarded.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Barron	**Joe**
813-627-2600	**barron@epchc.org**

Comment #: 396

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.5.c)v

Comment with Rationale and Proposal ***Attached Document*** ☐

Wording is unclear. Documentation is provided or the tests should be performed. Regent water used after stated expiration date should be retested, but no if within the expiration date, no testing should be required.

The lab may provide documentation from the supplier in lieu of performing the tests. Purchased reagent water held longer than the expiration date must be retested prior to use.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 464

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.6 d)

Comment with Rationale and Proposal ***Attached Document*** ☐

It should be allowed that if the lot of the medium has a certificate showing the manufacturer has done this and records the results and can be traced to the lot, that would be acceptable.

above

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Must do this

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Axelrod	**Steve**
813-264-3887 ext 111	**axelrods@hillsboroughcounty.org**

Comment #: 134

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.7 (b)(ii)

Comment with Rationale and Proposal ***Attached Document*** ☐

"The selected biological indicator must be effective at the sterilization temperature and time needed to sterilize carbohydrate media." Comment: While this technical specification for the indicators probably isn't necessary, would you please re-word it to be more understandable?
Suggest removal or clarification of specification.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Axelrod	**Steve**	***Comment #:***
813-264-3887 ext 111	**axelrods@hillsboroughcounty.org**	135

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.7 (b)(iii)

Comment with Rationale and Proposal ***Attached Document*** ☐

"Volumetric equipment shall be calibrated as follows:"
"The calibration of volumetric equipment shall be calibrated verified as follows:"

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 463

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.7 b)i, paragraph 3 & 4

Comment with Rationale and Proposal ***Attached Document*** ☐

With regard to pressure check: since PV=nRT, checking the temperature and assuring no leaks (so that V is constant) is sufficient to meet the requirements of this standard. This is an interpretaion in the NELAC archives and should be added as a note.

above

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600 x1032	**jaspard@epchc.org**

Comment #: 433

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.7.b ii

Comment with Rationale and Proposal ***Attached Document*** ☐

Requiring autoclaves' temperature device to be calibrated annually is expensive and unnecessary.

Require them to be checked, and if necessary, calibrated.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Jaspard	**Dawn**
813-627-2600 x1032	**jaspard@epchc.org**

Comment #: 434

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.7.b iii

Comment with Rationale and Proposal ***Attached Document*** ☐

You use the word "calibrated" in the phrase: "Volumetric equipment shall be calibrated as follows:," while using the word "verified" in item 2. Do these words have the same meaning here?
Change the phrase to: "Volumetric equipment shall be verified as follows:"

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Barron	**Joe**
813-627-2600	**barron@epchc.org**

Comment #: 398

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.7.b)ii

Comment with Rationale and Proposal ***Attached Document*** ☐

Autoclave does not need to be calibrated annually, only verified.

Autoclave maintenance shall be performed annually and shall include a temperature and pressure check.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Roach	**Kathleen**
727-582-2302	**kroach@pinellascounty.org**

Comment #: 329

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.7.b.ii

Comment with Rationale and Proposal ***Attached Document*** ☐

This change is important $$$$ 1.7.3.7.b.ii Fourth paragraph: “Autoclave maintenance, either internally or by service contract, shall be performed annually and shall include a pressure check and calibration of temperature device. “ Our maintenance contact does not include a "CALIBRATION" of the temperature device, but the vendor will perform this for a cost of $1000!

Please remove this requirement. You already have other checks in place to verify effective sterilization. If an autoclave is working properly, there is no justification to require labs to pay a vendor $1000.00 to CALIBRATE the temperature device every year.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Riskowitz	**Kevin**
727 892-5696	**k1riskow@stpete.org**

Comment #: 509

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.3.7b.ii

Comment with Rationale and Proposal ***Attached Document*** ☐

Under autoclave maintenance the annual pressure check should be removed. There was some discussion at the Denver conference regarding this.

Autoclave maintenance, either internally or by service contract, shall be performed annually and shall include calibration of temperature device.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Evans	**James**	***Comment #:***
614-644-4222	**james.evans@epa.state.oh.us**	512

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.5

Comment with Rationale and Proposal ***Attached Document*** ☐

Added clarity.

Drinking water sample holding time shall not exceed 30 hours (per 40 CFR 141.21 (f)(3))

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Only drinking water matrix. The standard applies to all programs.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Axelrod	**Steve**
813-264-3887 ext 111	**axelrods@hillsboroughcounty.org**

Comment #: 136

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.5 (b)

Comment with Rationale and Proposal ***Attached Document*** ☐

Laboratories that receive samples from potable water sources (including source water) that have a demonstrated history of acceptable preservation may check a sample from each source at a frequency of once per month if: i. the laboratory can show that the received sample containers are from their laboratory The inclusion of the phrase "from potable water sources (including source water)" can be misconstrued as to exclude labs that have other sources such as chlorinated wastewater effluents. Sample collection may be handled by a section outside of the laboratory.
Laboratories that have a demonstrated history of acceptable preservation may check a sample from each source at a frequency of once per month if: i. the laboratory can show that the received sample containers are from their organization

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Monthly is required. This has been discussed at previous meetings

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Wentland	**Leslie**
435-634-5849	**lwentland@sgcity.org**

Comment #: 456

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.5 a)iii

Comment with Rationale and Proposal ***Attached Document*** ☐

This criteria makes the lab refrigerate a sample that the lab will run that day and it needs to be brought to room temperature. It should really require that the sampler puts the sample in the fridge if that lab can't recieve it directly

Thermal preservation is not required in the field if the lab receives the sample or the field sampler refrigerates the sample within 15 minutes of collection

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Jaspard	**Dawn**	***Comment #:***
813-627-2600 x1032	**jaspard@epchc.org**	435

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.5.b

Comment with Rationale and Proposal ***Attached Document*** ☐

Laboratories that supply all sampling bottles to their samplers, and therefore do not receive bottles from outside sources, and that perform the 15 mg/L thio check per lot of containers, should not have to perform a chlorine check each month.

State that laboratories that need not check for the absence of chlorine if the laboratory can show that all samples are provided by them and that the 15 mg/L thio check is performed.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The Laboratory must verify that which is out of their control.

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Barron	**Joe**	***Comment #:***
813-627-2600	**barron@epchc.org**	410

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.5.b

Comment with Rationale and Proposal ***Attached Document*** ☐

The need to check for check for chlorine residual once month for each source is too prescriptive. If the four conditions are met, there is no need to test. Sample containers should not be limited to a specific laboratory, rather the entire organization.

Laboratories need not perform chlorine residual tests if the following conditions are met: In 1.7.5.b)i, change Laboratory to organization.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

The Laboratory must verify that which is out of their control.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Schantz	**Leonard**
585-428-7378	**lgs@cityofrochester.gov**

Comment #: 140

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 1.7.5aii

Comment with Rationale and Proposal ***Attached Document*** ☐

calibration of psi gauge and temp device is costly and unnecessary because of the routine checks that are associated with each autoclave run (max temp, autoclave tape, monthly spore ck). Requirement adds little value but adds a significant cost, especially for the small labs.
Drop the requirement

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
potter	**michele**
(609) 292-3950	**michele.potter@dep.state.nj.us**

Comment #: 155

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section 7.7.3.1.a

Comment with Rationale and Proposal ***Attached Document*** ☐

the requirement for ending blanks has been removed. ending blanks are only found for Standard Method procedures (SM 9020B.9.a.4) and are not addressed in the EPA methods. the EPA methods only require a beginning blank and a blank every 10 samples. a final ending blank determines the potential for carry over contamination when there are less than 10 samples in a batch for the filtration series
language reguarding beginning AND ending blanks from the previous NELAC standard needs to be added back in

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
CARPENTER	**DAVID**
217-698-0642	**dcarpenter@tmilab.com**

Comment #: 3

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section not appl

Comment with Rationale and Proposal	***Attached Document*** ☐
bESURE TO CHANGE SPELLING OF MICROBIOLIGICAL TO MICROBIOLOGICAL	
SEE ABOVE	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 99

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section Section 1.6.2.2(b)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.6.2.2(b): The acronym MPN first appears without any prior definition in this module or in Module 2 definitions. The term “Most Probable Number (MPN)” should be defined in Section 1.3.1 or else spelled out in this section.

Section 1.6.2.2(b): The acronym MPN first appears without any prior definition in this module or in Module 2 definitions. The term “Most Probable Number (MPN)” should be defined in Section 1.3.1 or else spelled out in this section.

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 100

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section Section 1.7.3.5(b)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.3.5(b): This section refers to “INELA V1M4 general requirements.” The relevant module has been changed to “V1M2” (without the INELA reference) and should be reflected as such in the text in this section.

Section 1.7.3.5(b): This section refers to “INELA V1M4 general requirements.” The relevant module has been changed to “V1M2” (without the INELA reference) and should be reflected as such in the text in this section.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 101

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section Section 1.7.3.6(b)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.3.6(b): The acronyms BG and EC first appear without any prior definition in this module or in Module 2 definitions. The term for “EC” and “BG” should be defined in Section 1.3.1, but they could be omitted without changing the applicable requirement to do the completed test.

Section 1.7.3.6(b): The acronyms BG and EC first appear without any prior definition in this module or in Module 2 definitions. The term for “EC” and “BG” should be defined in Section 1.3.1, but they could be omitted without changing the applicable requirement to do the completed test.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 51

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section Sections 1.6.1 & 1.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.6.1 and 1.6.2: The last 2 paragraphs in Section 1.6.1 and the paragraphs under Section 1.6.2 are duplicative. The relevant expert committee should consider whether these requirements can be consolidated in one section. This comment also applies to Sections 1.6.1 and 1.6.2 in other technical modules in Volume 1.

Section 1.6.1 and 1.6.2: The last 2 paragraphs in Section 1.6.1 and the paragraphs under Section 1.6.2 are duplicative. The relevant expert committee should consider whether these requirements can be consolidated in one section. This comment also applies to Sections 1.6.1 and 1.6.2 in other technical modules in Volume 1.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Howell	**David**
813.247.3451 ext.206	**david.howell@ci.tampa.fl.us**

Comment #: 360

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section see attached file

Comment with Rationale and Proposal	***Attached Document*** ☐
See attached file	
See attached file	

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Grimes	**Terri**
727-582-2302	**Tgrimes@co.pinellas.fl.us**

Comment #: 357

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section V1M5

Comment with Rationale and Proposal ***Attached Document*** ☐

This module went through a drastic transformation! I suggest doing what was done last year; keep this as a working draft standard and allow the process of input from labs to continue until the majority of the "bugs" get worked out. The worst thing you could do is rush this through the process. Thank you for the opportunity to comment!

Keep as a working draft standard; allow for further input.

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would introduce a concept that had not been subject to public review by being included in a related proposal as published in the Draft Interim Standard.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Roach	**Kathleen**
727-582-2302	**kroach@pinellascounty.org**

Comment #: 246

Item/Volume and Module

Item 6 VOLUME 1: LABORATORY REQUIREMENTS Module 5 - Microbioligical Testing

Section Volume 1, Module 5

Comment with Rationale and Proposal ***Attached Document*** ☑

This entire module has numerous rewrites that we would like to see changed before voting in the affirmative. See below for comments and suggested changed throughout this section

Volume 1, Module 5, Microbiological Testing 1.6 Demonstration of Capability This should somewhat match the verbiage in the chemistry section. In this last round of comments some of the verbiage was changed the better in the chemistry module, but the changes were not carried over to this microbiology module. This entire section could use a little reorganization, because the info listed in 1.6.2 contains both General DOC information and Initial DOC information. We suggest breaking this section into 3 Parts: 1.6.1 General DOC Information 1.6.2 Initial Demonstration of Capability 1.6.3 Continuing (or On-going) Demonstration of Capability 1.6.2: Move the various verbiage in this section "Demonstration of Capability" and put it in the corresponding section listed above. The first

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Last Name	*First Name*
Phone Number	*Email*

paragraph/sentence belongs in the General Information and the second sentence belongs in the Initial DOC section, and third sentence belongs under General Information. We do not like the added/underlined statement in section 1.6.2, and recommend it's deletion or change the wording: "A demonstration of capability shall be conducted prior to using any test method and at any time there is a change in instrument type, personnel or test method or anytime that a method has not been performed by the laboratory or analyst in a twelve month period."

This gets dicey with auditors and staff in complying with a twelve month period, some labs are set up annually, some per fiscal year and others every 365 days. But what happens if a continuing DOC is done at day 366? We give employees a slight grace period which is defined in our quality manual. Suggested wording: ….anytime that a method has not been performed by the laboratory or analyst annually, as defined in the quality manual, or not to exceed 13 months. 1.6.2.2 Second sentence: "It is the responsibility of the laboratory to document that other approaches to DOC are adequate. This shall be documented in the laboratory's Quality Manual." We would like to see this changed to, "This shall be referenced in the laboratory's Quality Manual." The Quality Manual is a more general document for a lab that contains it's "…overall policies and objectives…" (NELAC 2003 5.4.2.2). The Quality Manual then should "…make reference to the supporting procedures…" Note that this was already changed in the Chemistry Module during the last round of comments but not here. 1.6.2.2.a Says: a quality control sample shall either be obtained from an outside source or be prepared by the laboratory using stock cultures, other than those used for on-gong QC purposes." We recommend deleting the underlined section.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	***First Name***
Phone Number	***Email***

We cannot understand why our stock cultures cannot be used for a DOC. Also you are no longer allowing the use of actual samples for a DOC, which the current and past standards have allowed us to use. Please continue to allow this! 1.6.2.2.b This is way to prescriptive. When setting up DOCs for multiple analysts over the course of a couple of days, the counts could conceivably be outside the method-recommended countable range. There needs to be verbiage that allows for counts outside the countable range to be acceptable for DOC purposes. 1.7.1 Some of the equipment in this section cannot be "Calibrated", but their readings can be "Verified". We suggest replacing the work calibrated with verified.

This section says to calibrate this according to the support equipment requirements discussed in the chemistry technical module - there is no such requirements listed in this module. Need to delete or rectify this. 1.7.3.5.a.i.2: Don't specifically state "The most recent edition of "Standard Methods for the Examination of Water and Wastewater". First, you are assuming that everyone uses standard methods and that's not necessarily true, and second, some labs are tied to specific editions for approved use, also citing "The most recent version" has become

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*

Arms	**Stephen**	***Comment #:***
9047911502	**steve_arms@doh.state.fl.us**	476

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section 1.6.1

Comment with Rationale and Proposal ***Attached Document*** ☐

For clarity and because the Standard has and will be interpreted in this way, language to relate DOC by parameter to accreditation is needed.
Reword the first paragraph of 1.6.1: Prior to acceptance and institution of any method for data reporting and/or accreditation of specific parameters and/or endpoints, satisfactory demonstration of method capability is required for each parameter and/or endpoint (see Section 1.6.2).

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

see 1.6.2.1

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 106

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.5.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.5.1: The sentence appears to be a statement or description, not a requirement. The sentence should be deleted, or else requirements on “Method Validation” should be added.

Section 1.5.1: The sentence appears to be a statement or description, not a requirement. The sentence should be deleted, or else requirements on “Method Validation” should be added.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Requires assessment of the intended use.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 107

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.6.3.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.6.3.1: This section contains language that refers to section 1.6.3.2(a), which does not exist. The correct section should be listed, if it exists. In addition, requirements for Initial Demonstration of Capability and On-Going Demonstration of Capability appear to have references to other sections, which in turn refer to other sections. Ultimately, both the initial and on-going requirements appear to point to Section 1.7.1.2 (unless alternate approaches in the Quality Manual are used). The whole Section 1.6 should be examined and the language simplified to contain what the Demonstration of Capability requirements actually are.

Section 1.6.3.1: This section contains language that refers to section 1.6.3.2(a), which does not exist. The correct section should be listed, if it exists. In addition, requirements for Initial Demonstration of Capability and On-Going Demonstration of Capability appear to have references to other sections, which in turn refer to other sections. Ultimately, both the initial

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Last Name	*First Name*
Phone Number	*Email*

and on-going requirements appear to point to Section 1.7.1.2 (unless alternate approaches in the Quality Manual are used). The whole Section 1.6 should be examined and the language simplified to contain what the Demonstration of Capability requirements actually are.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 109

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.1.2(a)(i)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.2(a)(i): A closing parentheses should be added to the end of “SRT.”

Section 1.7.1.2(a)(i): A closing parentheses should be added to the end of “SRT.”

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 108

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.1.2(a)(i)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.2(a)(i): A closing parentheses should be added to the end of “SRT.”

Section 1.7.1.2(a)(i): A closing parentheses should be added to the end of “SRT.”

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 110

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.1.2(a)(iii)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.2(a)(iii): The last paragraph in this section contains the term “sensitivity,” whose meaning may differ from the definition for “sensitivity” given in Module 2. This Committee recommends that a different noun (e.g, acceptability and viability) be selected to describe the batch of Toxicity test organisms.

Section 1.7.1.2(a)(iii): The last paragraph in this section contains the term “sensitivity,” whose meaning may differ from the definition for “sensitivity” given in Module 2. This Committee recommends that a different noun (e.g, acceptability and viability) be selected to describe the batch of Toxicity test organisms.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Sensitvity is different for this module and a clarifying statement has been added to Terms and Definitions.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 111

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.1.6(e)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.6(e): This section makes use of the term “instrument.” Module 2 uses “equipment.” The relevant expert committee should review all uses of the terms “instrument” and “equipment” to ensure consistent uses and to contrast use of one term versus another. At first glance, in Module 6 the term “instrument” can be changed to “equipment” as they appear to mean the same thing.

Section 1.7.1.6(e): This section makes use of the term “instrument.” Module 2 uses “equipment.” The relevant expert committee should review all uses of the terms “instrument” and “equipment” to ensure consistent uses and to contrast use of one term versus another. At first glance, in Module 6 the term “instrument” can be changed to “equipment” as they appear to mean the same thing.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 112

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.1.6(o)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.6(o): The last sentence in this section refers to “referenced manuals.” Are these manuals the laboratory methods manuals (SOPs), Toxicity test methods, or some other reference? The last sentence should be revised and clarified accordingly.

Section 1.7.1.6(o): The last sentence in this section refers to “referenced manuals.” Are these manuals the laboratory methods manuals (SOPs), Toxicity test methods, or some other reference? The last sentence should be revised and clarified accordingly.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

test method

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 113

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.1.6(p)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.6(p): The first sentence in this section refers to "methods manuals." Are these manuals the laboratory methods manuals (SOPs), Toxicity test methods, or some other reference? This sentence should be revised and clarified accordingly.

Section 1.7.1.6(p): The first sentence in this section refers to "methods manuals." Are these manuals the laboratory methods manuals (SOPs), Toxicity test methods, or some other reference? This sentence should be revised and clarified accordingly.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

test method

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 114

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.1.6(w)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.6(w): This whole section has confusing wording. It is all run together as one sentence, contains the two-way phrase “if and only if” in one sense, and contains the one-way phrase “if” in another part. Is the intended meaning the following: “Dissolved oxygen and pH in aquatic tests shall be within acceptable range at test initiation and at test solution renewals. Aeration (minimal) is provided to tests if acceptable dissolved oxygen concentrations cannot be otherwise maintained or if specified by the test method”?

Section 1.7.1.6(w): This whole section has confusing wording. It is all run together as one sentence, contains the two-way phrase “if and only if” in one sense, and contains the one-way phrase “if” in another part. Is the intended meaning the following: “Dissolved oxygen and pH in aquatic tests shall be within acceptable range at test initiation and at test solution renewals. Aeration (minimal) is provided to tests if acceptable dissolved oxygen concentrations cannot be otherwise maintained or if specified by the test method”?

Disposition Persuasive

CommitteeComments

Module revised - The Quality Systems Expert Committee has revised the applicable section based on the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 115

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.1.6(x)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.6(x): Do the “test soils and sediments” contained in this section refer to reference soils and sediments used for negative controls, or do they refer to the soil and sediment sample tested for toxicity or bioaccumulation? Clarifying language should be added.

Section 1.7.1.6(x): Do the “test soils and sediments” contained in this section refer to reference soils and sediments used for negative controls, or do they refer to the soil and sediment sample tested for toxicity or bioaccumulation? Clarifying language should be added.

Disposition Hold for Next Revision Cycle

CommitteeComments

The comment would introduce a concept that had not been subject to public review by being included in a related proposal as published in the Draft Interim Standard.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

We think samples.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 116

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.1.6(y)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.1.6(y): This whole section is apparently worded as a description rather than as a requirement. If it is a description, the wording should be presented as a "Note." If it is a requirement, the section needs to be reworded to reflect the intent more accurately.

Section 1.7.1.6(y): This whole section is apparently worded as a description rather than as a requirement. If it is a description, the wording should be presented as a "Note." If it is a requirement, the section needs to be reworded to reflect the intent more accurately.

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

That is right for toxicology. This is a concept

Comments with TNIQS Response

Last Name	*First Name*	
Phone Number	*Email*	
Kircher	**Carl**	***Comment #:***
904-791-1574	**carl_kircher@doh.state.fl.us**	119

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.2.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Paragraph 6: Section 1.7.2.1, paragraph 6: It is not clear whether this paragraph is meant as a description or as a requirement. If these are to be requirements, the use of "shall" needs to be used, so that the paragraph reads, "In the case of reference toxicant data which fails to meet control chart acceptance criteria, the test data shall be examined for defects, corrective action shall be taken and the test repeated if necessary, using a different batch of organisms, or else the data shall be qualified."

Section 1.7.2.1, paragraph 6: It is not clear whether this paragraph is meant as a description or as a requirement. If these are to be requirements, the use of "shall" needs to be used, so that the paragraph reads, "In the case of reference toxicant data which fails to meet control chart acceptance criteria, the test data shall be examined for defects, corrective action shall be taken and the test repeated if necessary, using a different batch of organisms, or else the data shall be qualified."

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Organisms do not always behave.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
904-791-1574	**carl_kircher@doh.state.fl.us**

Comment #: 118

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.2.1

Comment with Rationale and Proposal ***Attached Document*** ☐

Paragraphs 2 & 4: Section 1.7.2.1, paragraphs 2 and 4: These paragraphs appear to be descriptions do not appear to contain requirements. If this is the case, for clarity, these paragraphs should each be presented as a “Note.”

Section 1.7.2.1, paragraphs 2 and 4: These paragraphs appear to be descriptions do not appear to contain requirements. If this is the case, for clarity, these paragraphs should each be presented as a “Note.”

Disposition Non-Persuasive

CommitteeComments

Please see the additional comment section listed below for committee comment.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Organisms do not always behave.

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
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Comment #: 117

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.2.3

Comment with Rationale and Proposal ***Attached Document*** ☐

Paragraph 3: Section 1.7.2.1, paragraph 3: This paragraph should be split into three sentences, to read, “For endpoints that are point estimates, the cumulative CV is calculated. For endpoints from hypothesis tests, the PMSD is calculated. These values shall be maintained on control charts.”

Section 1.7.2.1, paragraph 3: This paragraph should be split into three sentences, to read, “For endpoints that are point estimates, the cumulative CV is calculated. For endpoints from hypothesis tests, the PMSD is calculated. These values shall be maintained on control charts.”

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
Phone Number	*Email*
Kircher	**Carl**
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Comment #: 120

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Section 1.7.2.3(b)

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.7.2.3(b): This section is worded as a “should.” Thus, this section needs to be displayed as a “Note” rather than given equal billing with Section 1.7.2.3(a), which expresses a requirement.

Section 1.7.2.3(b): This section is worded as a “should.” Thus, this section needs to be displayed as a “Note” rather than given equal billing with Section 1.7.2.3(a), which expresses a requirement.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment:

Comments with TNIQS Response

Last Name	*First Name*
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Kircher	**Carl**
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Comment #: 52

Item/Volume and Module

Item 7 VOLUME 1: LABORATORY REQUIREMENTS Module 7 - Toxicity Testing

Section Sections 1.6.1 & 1.6.2

Comment with Rationale and Proposal ***Attached Document*** ☐

Section 1.6.1 and 1.6.2: The last 2 paragraphs in Section 1.6.1 and the paragraphs under Section 1.6.2 are duplicative. The relevant expert committee should consider whether these requirements can be consolidated in one section. This comment also applies to Sections 1.6.1 and 1.6.2 in other technical modules in Volume 1.

Section 1.6.1 and 1.6.2: The last 2 paragraphs in Section 1.6.1 and the paragraphs under Section 1.6.2 are duplicative. The relevant expert committee should consider whether these requirements can be consolidated in one section. This comment also applies to Sections 1.6.1 and 1.6.2 in other technical modules in Volume 1.

Disposition Persuasive

CommitteeComments

Module revised - The Quality System Expert Committee has revised the applicable section of this module using language similar to the proposed language.

The section below is addtional comments from the Quality System Expert Committee that pertains to the disposition of this specific comment: