Quality Management System Expert Committee (QMS)
Meeting Summary

May 8, 2023

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on May 8, 2023. Attendance is recorded in Attachment A – there were 8 voting members present. Associate members present: Ryan McMullin, Alexander Chieh, Kelvin Yuen, Thomas Fritz, Michelle Wade, Sarah Brown, Ty Atkins, Amanda Grande, Cindy Rdmond, Douglas Kablik, Fida Kased, Kathleen Lloyd, Annmarie Beach, Debra Zeller, Hong Yu, Lisa Parks, Linda Odonnell, and Dan Jackson.

Amanda Grande was added to the Committee as a new Associate member and she introduced herself.

2. Language Workgroup –

Internal Audit

Nick gave an update on Internal Audits.

In San Antonio most people thought Internal Audits should be a 3 year cycle, so this is where this time frame comes from. One-third can be done each year.

Debbie pulled up SIR 308 that says it does not have to be every year.

The Workgroup is suggesting 2 or 4 years. There was some concern that 4 years is too long. Would need to show that the schedule is being met and that over the time period they are following it and all methods are being audited. There is a guideline for assessors to focus on the last two years. ABs may not be comfortable with 4 years because that is a long time to find out if there is a problem. Tony would like to add a requirement that each technology needs to be looked at annually, because this may show a problem in a department more quickly.

Large labs would push back on 2 years. There is general agreement that 2 years is not the number. What happens with small labs? Though the number seems low, they are challenged personnel wise.

Debbie recommended keeping 3 years even though the accreditation cycle is 2 years.

Debbie asked about 8.8.3.c. Is it OK that you only do micro one year and chemistry the other year? Nick agrees with what Tony said, but technology would need to be better defined. Jenna would like the wording to require that something from each module that is

applicable be covered each year. Zaneta thinks it should require that each technology is covered every year. Language will be edited to reflect these thoughts.

Language to be placed in DRAFT Standard:

Working Group Language:

8.8.3. In addition to the requirements listed in 8.8.1 and 8.8.2, the internal audit program shall:

a. include a pre-defined schedule covering a 3 year period

b. **includes review of all requirements of TNI Module 2 annually**.

c. includes a review over the course of the audit schedule of all elements of the technical TNI modules 1 and 3-7 as applicable to the laboratory's scope.

i. include a representative selection of analytes, matrices, and technologies annually.

ii. cover all methods under which the laboratory performs its accredited testing within a 3-year period with at least one-third of the methods being reviewed annually.

The Workgroup is interested in additional members. The Definitions Workgroup could also use additional members.

From Last Use – V1M2, 4.13.3.

Debbie received some comments from the NELAP AC on this topic:

I understand the motivation behind the change, but in my opinion it's making a mountain out of a mole hill. One specific example where this change might make sense is for records that are created prior to or in conjunction with first use of a piece of equipment, such as the incubator temperature distribution and equilibration checks. However, I think everyone understands that those records need to be maintained for the life of the equipment and available on demand. I have not run into any other real world situations where this change would be necessary.

I personally don't understand the point of "last use." No records retention rule that I know of does that; they all go by date of generation. I agree that leaving it as stated in the 2016 Standard should suffice.

My opinion: Leave as-is in the 2016 Standard.

Or explain/define what issue of significance someone is trying to fix.
If certain records need to be held longer, like training records, per consensus decision, those should be stated as exceptions. But I think the "at a minimum" language works fine and we don't need to create more rules that need to be audited unless there's a specific, defined need to do so

I see no reason to change that section; the language is clear, and records can be easily traced by analysis date more so than when something was "last used". As stated, what is the issue that they're trying to fix by changing the language, unless they can show clear

reasoning behind why a change is needed? We've never had anyone confused about that section.

I like those comments from the AC. I agree with them that we are maybe trying to fix a problem that doesn't exist. With that said, I'm not sure that it is universally accepted that incubator temperature distribution and equilibration checks are required to be maintained for the life of the equipment. It isn't a bad idea, and that might be why a list of what MUST be kept should be considered.

I would add that method validation for lab-develop methods must also be kept while any results from the method are required to be kept because there is no published method to fall back on for information on purpose or fitness for use.

The previous work done on this issue can be found in Attachment B.

"Last use" instead of "Last entry" could be a big change for many and does this make sense to push? People would prefer to keep it as is. Perhaps leave it and then state what records should be kept longer than 5 years. For example, method validation for a lab created method should always be kept. Standards that can be kept past 5 years would need to keep traceability records for any related data set. Another could be keeping equilibrium checks. It is done at first install and after any major service. Instrument records.

This issue is being transferred to the Language Workgroup to work on.

3. SIR Review Continued

Ilona sent Debbie the additional SIR information requested, so the group can continue with the SIR review to determine if any changes need to be made to the DRAFT Standard.

The group started at SIR 318 and ended at SIR 66. See Attachment C for result of review.

While reviewing SIR 318, Kathi recommended looking at some changes made by DoD in the QSM. This was forwarded to the Committee for future consideration.

4. New Business

No new business.

5. Next Meeting and Close

The next meeting will be by teleconference on June 12, 2023 at 1pm Eastern.

Debbie adjourned the meeting at 2:25pm Eastern.

Attachment A

Participants

Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) **Present**	Alabama Power	2023*	Lab	dbond@southernco.com
Kathi Gumpper (Vice-Chair) **Present**	ChemVal Consulting	2024	Other	kgumpper@chemval.com
Nicole Cairns **Present**	NYSDOH	2024	Lab	nicole.cairns@health.ny.gov
Michael Demarais **Absent**	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis **Present**	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Carla McCord **Present**	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Stephanie Atkins **Absent**	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson **Absent**	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen **Absent**	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak **Present**	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Zaneta Popovska **Present**	ANAB	2025*	AB	zpopovska@anab.org
Sean Hayes **Present**	ORELAP	2026*	AB	sean.hayes@oha.oregon.gov
Amy Schreader **Absent**	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Alyssa Wingard **Absent**	NAVSEA LQAO	2024	Other	alyssa.wingard@navy.mil
Ashley Larssen **Present**	KC Water	2024*	Lab	ashley.larssen@kcmo.org
Ilona Taunton (Program Admin) **Absent - Recording**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Task #4: V1M2, 4.13.3 b) – change the word “entry” to “use” or other change that clarifies that while the record is in use and up to 5 years after last use, it must be retained.

Suggested Change	Justification
Change the word entry to use or add a part in the section about personnel training and initial demonstration and or all training records on the analyst until 5 years after they leave the company. If we change the language to use this would take care of CRM and IDOC as the initial record would be ‘used’ every time the standard is reference or a CDOC is done.	Training records are different than othe to have clarification within this section. Make a guidance document for record required for keeping (IDOC, maintenar

Under *Control of Records (ISO/IEC 17025:2005, Clause 4.13)* – See *ISO/IEC 17025:2017, Clause 7.5 (technical records) & Clause 8.4 (control of records)*

4.13.3 Additional Requirements

~~a) The laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.~~

~~b~~a) The laboratory shall retain all records for a minimum of five (5) years from ~~generation of~~ the last ~~entry in~~use of the records. Records are considered “in use” when they are required to support current laboratory activities.
Note: Examples of records that are required to support current laboratory activities include, but are not limited to, method validation records, training records of personnel, equipment installation and calibration records, and records of standard preparation.

~~c~~b) Records shall be available to the accreditation body.

~~d) Records that are stored only on electronic media shall be supported by the hardware and software necessary for their retrieval.~~

~~e~~c) Access to archived records~~information~~ maintained in hardcopy shall be ~~documented~~controlled ~~with an access log~~.

~~f) All information necessary for the historical reconstruction of data shall be maintained by the laboratory.~~
~~i. all raw data, whether hard copy or electronic, for calibrations, samples and QC measures, including analysts' worksheets and data output records (chromatograms, strip charts, and other instrument response readout records);~~
~~ii. a written description or reference to the specific method used, which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;~~
~~iii. laboratory sample ID code;~~

Commented [CNL(1]: ***7.5 Technical records***
7.5.1 *The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.*
7.5.2 *The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.*

Commented [CNL(2]: ***8.4 Control of records (Option A)***
8.4.1 *The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.*
8.4.2 *The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.* … [1]

Commented [CNL(3]: Redundant with ISO 17025:2017
7.5.1 *The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the* … [2]

Commented [PJ4]: This should be redundant with the requirements that are included in the paraphrase of ISO language. "All items identified in this document shall be available for an on-site assessment." That will appear at the beginning of Section 1, or at least it is there right now.

Commented [CNL(5]: Redundant with section ISO 71025:2017 ***8.4.2*** *The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to* … [3]

Commented [PJ6]: Aren't ALL records required to be controlled?

Commented [CNL(7]: Also redundant with ISO 17025:2017 report requirements in ***7.8.2.1 f)*** *identification of the method used;*

Commented [CNL(8]: Also redundant with ISO 17025:2017 report requirements in ***7.8.2.1 g)*** *a description, unambiguous identification, and, when necessary, the condition of the item;*

~~iv. date of analysis;~~
~~v. time of analysis is required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., extractions and incubations);~~
~~vi. instrumentation identification and instrument operating conditions/parameters (or reference to such data);~~
~~vii. all manual calculations;~~
~~viii. analyst or operator initials/signature or electronic identification;~~
~~ix. sample preparation, including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;~~
~~x. test results;~~
~~xi. standard and reagent origin, receipt, preparation, and use;~~
~~xii. calibration criteria, frequency and acceptance criteria;~~
~~xiii. data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;~~
~~xiv. QC protocols and assessment;~~
~~xv. electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;~~
~~xvi. method performance criteria including expected QC requirements;~~
~~xvii. proficiency test results;~~
~~xviii. records of demonstration of capability for each analyst; and~~
~~xix. a record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record.~~

~~g~~d) All ~~generated~~non-electronic data~~, except those that are generated by automated data collection systems,~~ shall be recorded ~~legibly~~ in permanent ink.
~~i. An individual making corrections to records shall date and initial the correction.~~
~~ii. Corrections due to reasons other than transcription errors shall specify the reason for the correction.~~

~~h~~e) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business. In addition, appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

Clean Copy of Final Language

4.13.3 Additional Requirements

a) The laboratory shall retain all records for a minimum of five (5) years from the last use of the records. Records are considered "in use" when they are required to support current laboratory activities.
Note: Examples of records that are required to support current laboratory activities include, but are not limited to, method validation records, training records of personnel, equipment installation and calibration records, and records of standard preparation.

b) Records shall be available to the accreditation body.

c) Access to archived records maintained in hardcopy shall be controlled.

Commented [CNL(9]: Also redundant with ISO 17025:2017 report requirements in ***7.8.2.1 i)*** *the date(s) of performance of the laboratory activity;*

Commented [CNL(10]: The 72-hour specification may need to be kept, but it is currently within 2016 TNI V1M2 in additional reporting requirements, so if retained will be covered. ***5.10.11 Additional Requirements***
a) Time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to seventy-two (72) hours.

Commented [CNL(11]: Also redundant with ISO 17025:2017 ***7.8.1.2*** *The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.*

Commented [CNL(12]: Also redundant with current TNI 2016 V1M2 language if kept; ***5.6.4.2 Documentation and Labeling of Standards, Reagents, and Reference Materials*** *Documented procedures shall exist for the purchase, receipt and storage of consumable materials* ... [4]

Commented [CNL(13]: Also redundant with ISO 17025:2017 **6.4.13** Records shall be retained for ... [5]

Commented [CNL(14]: Also redundant with ISO 17025:2017
7.7 Ensuring the validity of results ... [6]

Commented [CNL(15]: Also redundant with ISO 17025:2017 ***7.11.2*** for reporting database *The laboratory information management system(s) used for the collec* ... [7]

Commented [CNL(16]: Also redundant with ISO 17025:2017 ***7.2.1.5*** *The laboratory shall verify that it can properly perform methods before introducing them by* ... [8]

Commented [CNL(17]: Also redundant with ISO 17025:2017 ***8.4.1*** *The laboratory shall establish and* ... [9]

Commented [CNL(18]: Also redundant with ISO 17025:2017 ***6.2.5*** *The laboratory shall have procedure(s) and retain records for:* ... [10]

Commented [CNL(19]: Do we need to keep this one? If so, maybe make this a requirement under ISO 17025:2017 **6.2 Personnel.** Maybe 6.2.6 under authorizations. ... [11]

Commented [CNL(20]: Legible is redundant with ISO 17025:2017 7.5.1

Commented [PJ21]: How about 'All data shall be recorded in a permanent manner'? This would include both electronic and non-electronic - they both need to be permanent.

Commented [CNL(22]: Redundant with ISO 17025:2017 7.5.2

Commented [PJ23]: If the laboratory goes out of business, there's no action that can be taken for failing to follow its plan. On that basis, the plan is only a feel-good thing ... [12]

d) All non-electronic data shall be recorded in permanent ink.

e) All information necessary for the historical reconstruction of data shall be maintained by the laboratory.

f) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business. In addition, appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

Commented [BD24]: From SIR 329 review: Consider re-wording so that labs are clear that the data may not just be disappeared. Consider using 'responsible party' and 'legal entitiy' to specify what we mean.

Page 1: [1] Commented [CNL(2] Cairns, Nicole (DOH) 12/1/22 9:18:00 AM

8.4 Control of records (Option A)

8.4.1 *The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.*

8.4.2 *The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.*

NOTE Additional requirements regarding technical records are given in 7.5.

Page 1: [2] Commented [CNL(3] Cairns, Nicole (DOH) 12/1/22 9:19:00 AM

Redundant with ISO 17025:2017 ***7.5.1*** *The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original….*

AND

8.4.1 *The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.*

Does not add value & is poorly worded.

Page 1: [3] Commented [CNL(5] Cairns, Nicole (DOH) 12/1/22 9:22:00 AM

Redundant with section ISO 71025:2017 ***8.4.2*** *The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.*

Page 2: [4] Commented [CNL(12] Cairns, Nicole (DOH) 12/1/22 9:25:00 AM

Also redundant with current TNI 2016 V1M2 language if kept; ***5.6.4.2 Documentation and Labeling of Standards, Reagents, and Reference Materials***
Documented procedures shall exist for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory.
a) The laboratory shall retain records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, and recommended storage conditions.

c) Records shall be maintained on standard, reference material, and reagent preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

Page 2: [5] Commented [CNL(13] Cairns, Nicole (DOH) 12/1/22 9:26:00 AM

Also redundant with ISO 17025:2017 **6.4.13** Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:

a) the identity of equipment, including software and firmware version;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) evidence of verification that equipment conforms with specified requirements;

d) the current location;

e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;

f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;

Page 2: [6] Commented [CNL(14] Cairns, Nicole (DOH) 12/1/22 9:26:00 AM

Also redundant with ISO 17025:2017

7.7 Ensuring the validity of results

7.7.1 *The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:*

a) use of reference materials or quality control materials;

b) use of alternative instrumentation that has been calibrated to provide traceable results;
c) functional check(s) of measuring and testing equipment;

d) use of check or working standards with control charts, where applicable;

e) intermediate checks on measuring equipment;

f) replicate tests or calibrations using the same or different methods;

g) retesting or recalibration of retained items;

h) correlation of results for different characteristics of an item;

i) review of reported results;

j) intralaboratory comparisons;

k) testing of blind sample(s).

AND with current language in 2016 TNI V1M2 if retained ***5.9.3 Essential Quality Control Procedures***
These general QC principles shall apply, where applicable, to all testing laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (i.e., asbestos, chemical, microbiological, radiological, toxicity) and are further described in Technical

Modules. The standards for any given test type shall assure that the applicable principles are addressed:
a) All laboratories shall have detailed written protocols in place to monitor the following quality controls:

c) The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist.

Page 2: [7] Commented [CNL(15] Cairns, Nicole (DOH) 12/1/22 9:26:00 AM

Also redundant with ISO 17025:2017 ***7.11.2*** for reporting database *The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.*

Page 2: [8] Commented [CNL(16] Cairns, Nicole (DOH) 12/1/22 9:27:00 AM

Also redundant with ISO 17025:2017 ***7.2.1.5*** *The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary. Also covered by* ***7.7 Ensuring Validity of Results***

Page 2: [9] Commented [CNL(17] Cairns, Nicole (DOH) 12/1/22 9:27:00 AM

Also redundant with ISO 17025:2017 ***8.4.1*** *The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.*

AND

7.7.2 *The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:*

a) participation in proficiency testing;

Page 2: [10] Commented [CNL(18] Cairns, Nicole (DOH) 12/1/22 9:27:00 AM

Also redundant with ISO 17025:2017 ***6.2.5*** *The laboratory shall have procedure(s) and retain records for:*

a) determining the competence requirements;

b) selection of personnel;

c) training of personnel;

d) supervision of personnel;

e) authorization of personnel;

f) monitoring competence of personnel.

Page 2: [11] Commented [CNL(19] Cairns, Nicole (DOH) 12/1/22 9:28:00 AM

Do we need to keep this one? If so, maybe make this a requirement under ISO 17025:2017 **6.2 Personnel.** Maybe 6.2.6 under authorizations.

Page 2: [12] Commented [PJ23] Paul Junio 12/19/22 2:08:00 PM

If the laboratory goes out of business, there's no action that can be taken for failing to follow its plan. On that basis, the plan is only a feel-good thing. I would delete this. I understand that this is a position that isn't shared by many.

ATT C #	2016	Actual Request	Final Response	Comment	Paul Comments	Revise or No Revision
318	5.2.7	Does a simple signature sheet of attendance suffice as data integrity training documentation since language in VIM2 5.2.7 states "The data integrity procedures MAY also include written ethics agreements..." If yes, does that adequately fulfill requirements mentioned in V1M2 4.2.8.1, statement 2, line 2? If no, may the laboratory cite specific business Personnel Policies and	Determined not to be an SIR.	4.2.8.1 item 2) It should specify that data integrity training record is needed.		NO REVISION 4.2.8.1 requires a data integrity policy that includes training; 5.2.7 outlines what the training includes and that we need documentation of the annual and refresher training.
180	5.4.2	5.4.2 includes the following statement: "The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so." In general, it seems that most certification authorities certify for the method, but not the version, allowing any version that is still valid to be run, which seems to violate/contradict this statement. Does this statement mean that all previous valid method versions are NOT to be used and that the lab MUST update to the newest version of a standard? For example, if the lab runs EPA 8270C which is still valid, must the lab update to 8270D if it can? In other words, does running 8270C (when 8270D is the latest version) become a violation of the standard?	The term "Standard", as defined by ISO, is as follows: "Standard: document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. NOTE - Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits." "Standard" refers to the source document or publication that mandates the "approved test method." For laboratories, this use of the term "standard" in V1M2 Section 5.4.2 is a reference to the most current publication(s) that define or require certain methods/actions based on program or regulatory need, such as: - International (global documents), - Regional (i.e., requirements specific to State, local, EPA Region, etc.), or - National (i.e., requirements by Federal Regulation/Agency via the Code of Federal Regulations (CFR). Additional analytical requirements can be listed in/by reputable technical organizations (i.e., AOAC, AIHA, etc.), scientific texts/journals and manufacturers (i.e., instrument specific, process requirements, etc.). Analytical methods ("test methods" in the ISO language) used by the environmental laboratory industry are driven by regulations where governing programs exist. The "standard" that mandates the	This language is unchanged in the 2016 standard. The SIR is still valid.	Has this been addressed in an FAQ or through Technical Advice? If so, that language should be added for clarity (2003 maybe?) There are 2 different SIRs relating to 5.4.2	NO REVISION The standard is clear.

21	5.4.4 and 5.4.5	1) EPA 245.1 vs SW846 7470: SW requires heating the standards, the EPA method doesn't. Is it acceptable to do the same for both (i.e., batch them together), and still be accredited for both methods in non-potable water? The Standard says validation is to be as extensive as necessary and C3.3b) only applies if the method was not in use prior to 7/03. If there are 20 years of at least 4 PT standards per year without a failure, the method should be sufficiently validated. This can't be left to individual state interpretation since one lab could be required to do two digestions/calibrations and other labs not, depending on where they're located. What if a lab is bidding on work in a state that allows the modification, but the home state doesn't? The real question is: Who decides if the modification is acceptable, if it has been sufficiently validated, and whether a lab can be accredited for "the method"? (especially when something is common practice) 2) Same issue with using HCL instead of H2SO4 to make the stannous chloride solution (the instrument manufacturer recommends HCl although the method says H2SO4).	Note: Laboratories should attempt to reconcile all differences in the interpretation of the NELAC 2003 standards and/or analytical methods with the applicable EPA Program, Regional office and/or NELAC accreditation body. The following response was obtained from EHSG MICE. *First off, we would like to clarify a common misnomer pertaining to SW-846 methods that is alluded to in question one. Please stress to this member that Methods 245.1 and 7470 are in fact both EPA publications. The former from the Office of Water while the latter is published by the Office of Solid Waste. Now to answer the questions, it is recognized that historically the most common practice was to digest the calibration standards in the same manner as the samples. However, with the newer instrumentation direct calibration using an aqueous standard is now possible, so the digestion steps are no longer necessary. So, in this particular case it depends more on the instrumentation and the manufacturer's calibration requirements rather than what is specified in the method. In addition, using EPA OSW's PBMS approach any calibration format is considered acceptable as long as adequate performance data are generated. If the desired sensitivity is attainable and QC data meet the project requirements, the practice of not digesting standards should be considered acceptable. The direct calibration option we alluded to will be included in the revised mercury Methods 7470A and 7471B that are due to be published with the SW-846 Fourth Edition update, hopefully late next year. Using this same logic, if the instrument manufacturer recommends HCl to prepare the stannous chloride*	The 2009 standard moved this language into Module 4, but 2016 corrected this and moved it back into Module 2. The SIR is still valid.	This should not be an SIR, but a method interpretation	NO REVISION

66	5.4.6	Please explain what types of procedures for estimating uncertainty of measurements. I am not sure which area you mean.	Section 5.5.4.6 "Estimation of Uncertainty of Measurement" has created some confusion. Please note that as a laboratory it is impossible for you to calculate "Total Uncertainty" unless you are given all of the additional pieces from external sources to the lab itself. This section is intended to advise a laboratory to have a "Procedure on Uncertainty for the Laboratory Portion" in place, so that if requested by a client it could be determined. The key language within this section can be found in Section 5.5.4.6.2, " … In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. …" The laboratory can arrive at an estimation of uncertainty through a review	This section was rewritten in the 2009 (and 2016) standards to state "Quality control measurement data may be used to determine analytical uncertainty." This definition was also added: "Analytical Uncertainty: A subset of Measurement Uncertainty that	17025-2017 7.6 addresses uncertainty in greater depth than the previous Standard. I don't feel that the Committee intends to reply with a how-to document.	NO REVISION note that radiological requirements are well defined and are addressed in Module 6, and may also be addressed by WET methods