Quality System Expert Committee (QS)
Meeting Summary

July 10, 2017

1. Roll Call:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference on July 10, 2017. Attendance is recorded in Attachment A – there were 9 members present. Associate Members: Carl Kircher, Tyler Sullens, Patty Carvajal, Michelle Wade, Robin Cook and Eric Denman.

2. Checklist

An AB pointed out that each question cell needs be a complete thought – a single question. There will be more discussion about the checklist in the future as this document is finalized within TNI. The checklist for Module 2 was completed and sent in for inclusion in the comprehensive TNI checklist.

3. NEMC

The committee will be meeting on Monday, August 7, 2017 at 1pm Eastern. It will be a 2 hour meeting. The topic of the meeting will be review of the Small Laboratory Handbook (SLH).

4. Small Laboratory Handbook (SLH)

A small group (Paul, Silky, Robin Cook and Ilona) was formed to review the SLH and work on language to finish up sections that were incomplete. The group reorganized a few things and some chapters have been put into the final format.

Work has been done on Chapter 2 of the SLH. The first section discusses the big picture and then looks specifically at a laboratory. The new TNI Environmental Laboratory Accreditation by NGABs has been added to the applying for initial accreditation section. Scott Hoatson from Oregon is working on Preparing for Your Assessment. Paul reviewed these sections using Webex.

Silky, Paul and Robin also worked on Volume 1, Module 2 – Section 5.

Paul shared the Radiochemistry module to show the committee what the final format looks like. Ilona summarized some of the styles for format. This section is large – 56 pages.

The committee reviewed the work done by the subcommittee on Module 2, Section 5. Paul went through the section using Webex and incorporated changes as needed (see Attachment D).

Jerry approved the inclusion of the two Chemistry Expert Committee guidance documents regarding detection limits and calibration. These guidance documents will be referred to in the Module 4 section.

5. Action Items

A summary of action items can be found in Attachment B.

SIR 108 – It has been returned to LASEC and it is no longer in Quality Systems.

SIR 246 and 296: More discussion is coming, but the committee needs to be focused on the SLH in order to have a DRAFT ready for discussion in DC.

6. New Business

None.

7. Next Meeting and Close

The next meeting is planned for August 7, 2017 at 1pm Eastern in Washington, DC.

A summary of action items and backburner/reminder items can be found in Attachment B and C.

Paul adjourned the meeting at 2:10pm Eastern.

Attachment A
Participants
Quality Systems Expert Committee (QS)

Members (Exp)	Affiliation	Balance	Contact Information	
Paul Junio (2018) (Chair) **Present**	Northern Lake Service	Lab	262-547-3406	paulj@nlslab.com
Kristin Brown (2016) **Present**	Utah DOH	AB	801-965-2530	kristinbrown@utah.gov
Chris Gunning (2018*) **Present**	A2LA	Other	301-644-3230	cgunning@a2la.org
Sara Hoffman **Present**	Kansas Health and Environmental Laboratories	AB	785-291-3162	Sara.hoffman@ks.gov
Jessica Jensen (2018*) **Present**	Meridian Analytical Labs	Lab	316-618-8787	jessica.j@meridiantesting.com
Silky S. Labie (2018) **Present**	Env. Lab Consulting & Technology, LLC	Other	850-656-6298	elcatllc@centurylink.net
Jacob Oaxaca (2019*) **Absent**	CA Water Board	AB	916-323-3433	Jacob.oaxaca@waterboards.ca.gov
Shari Pfalmer (2018*) **Present**	ESC Lab Sciences	Lab	615-773-9755	spfalmer@esclabsciences.com
Dale Piechocki (2020) **Present**	Eurofins Eaton Analytical	Lab	574-472-5523	DalePiechocki@eurofinsUS.com
Matt Sowards (2020) **Present**	ACZ Laboratories, Inc.	Lab	970-879-6590	matts@acz.com
Lizbeth Garcia (2019*) **Absent**	Oregon Health Authority	AB	503-693-4115	lizbeth.garcia@state.or.us
Janice Willey (2018) **Absent**	NAVSEA Programs Field Office	Other	843-794-7346	Janice.willey@navy.mil
Bill Ray (2020*) **Absent**	William Ray Consulting, LLC	Other	925-352-5205	Bill_Ray@williamrayllc.com
Ilona Taunton (Program Administrator) **Present**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – QS Expert Committee

	Action Item	Who	Expected Completion	Actual Completion
9	Look at the Handbook Table of Contents and volunteer for sections.	All	8/10/15	
23	Check with Richard Burrows regarding their committee doing the update on the Handbook.	Paul	3/14/16	Complete – Paul is working on the section and Chemistry Expert Committee will review his work.
24	Summarize format for Handbook and send to committee members and other Expert Committee Chairs.	Paul	6/10/16	Follow-up needed.
25	Follow-up with Bob Wyeth and Jerry Parr about experience vs. course hours for Technical Directors.	Paul	TBD	
26	Provide in writing, thoughts regarding options for Technical Director approval.	Robin	TBD	
32	Send SIR #308 Response to LASEC.	Paul	3/27/17	
33	Review SLH to date and send comments to Paul.	ALL	4/6/17	Ongoing
35	Check with Advocacy about Assessment findings and Assessment Preparation documents.	Paul	6/8/17	
36	Send SIR 246 and 296 to committee members to review DRAFT responses and comment.	Paul	7/9/17	Complete
37	Send SIR 108 question to Lynn Bradley/LASEC.	Paul	7/9/17	Complete
38	Continue SIR 246 and 296 discussions.	All	TBD	

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Update charter in October 2016.	n/a	Delayed. Waiting for format from Policy Committee.

5.0 Technical Requirements

5.1 General

- Definitions
  - Analytical Uncertainty - A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis.
- Key Points
  - 7 factors are identified that affect the correctness and reliability of the test.
  - The laboratory must consider these factors when developing methods, in training and in the selection and use of equipment.
- Discussion

  Sections 5.2 through 5.8 discuss each of the factors including criteria or requirements that must be met so that you can demonstrate that you are controlling/minimizing and monitoring variabilities that are associated with each factor.

  Determine how your laboratory handles each of the requirements and how it documents the procedures (and associated records) in the QM or a standard operating procedure.

  Finally, these factors can affect the analytical uncertainty of the measurement. The impact varies between types of tests, and must be considered when selecting or developing a method; selecting and calibrating equipment, identifying training topics or personnel qualifications.

5.2 Personnel

- Definitions
  - **Authorize** – Means "to give official or legal power to" or "to give power or permission to"
  - **Laboratory Management** - person or group of people who directs and controls an organization at the highest level (ASQ/ANSI E-4:2014) You must decide who your top management is and identify the position(s) in your Quality Management Plan
  - **Technical** - having special and usually practical knowledge especially of a mechanical or scientific subject (Merriam Webster On-line Dictionary
  - **Key Support**- extremely or crucially important (Merriam Webster On-line Dictionary) Key support positions would be technical or non technical positions that contribute to or impact the quality of the final product (data).
  - **Competence** – ability to apply knowledge and skill to achieve intended results(ISO 9000:2105)
- Sections 5.2.1 through 5.2.5
  - Key Points
    - The laboratory management must ensure the competency of all individuals involved in the data generation process including those performing the test, using the equipment, evaluating results, and signing reports. This includes external (e.g. under contract), part-time or temporary personnel (interns, volunteers, etc.).
    - A competent individual is one whose qualifications meet the laboratory requirements for education, training, experience and applicable demonstrated skills

- You must establish goals/requirements for the education, training and skills of your staff.
- You must have job descriptions
- Staff that are being trained must be supervised.
- Management must authorize staff to perform specific laboratory activities. There must be a dated record of all authorizations.
- All records relevant to the competence, education, training, experience, and demonstrated skills must be maintained and be readily available for review.

- Discussion

  Each position must have an appropriate mix of education, experience, training and skills in order to be successful (i.e. competent). It is important that management identify the essential mix of credentials for those individuals who are associated with performing the test, operating equipment, evaluating results and signing reports. An ideal way of documenting these requirements is in the job description for each position.

  A **job description** can meet several requirements:

  1. It is required for all management, technical and key support positions
  2. It can specify the essential mix of education, experience, training, and skills that are required for the position
     - Minimum educational requirements
     - Minimum educational requirements
     - Minimum experience requirements
     - Specific training needs in order to be competent in the position
     - Necessary skills (e.g., proficient in word processing, keyboarding skills required, etc.)
  3. It can also specify the expected managerial and/or technical duties and responsibilities that are assigned to the position
  4. It can also identify key milestones to be met such as initial demonstration of capability, successful completion of PTs, etc.
  5. The job description that contains all the above information documents management's expectations for a competent employee and provides the employee with a written record of the laboratory's expectations.
  6. This type of job description gives management on opportunity to evaluate whether or not additional training is required (also a requirement).

     Note: this description will be more detailed than the job description normally used in larger corporations and government offices. One municipal job description for a laboratory manager was under the general heading of "shop foreman" and none of the generic duties applied to the job description of a laboratory director except that it specified generic educational and experience requirements, and noted that the job was supervisory position. Take away message, laboratory job descriptions must be specific to the position in the laboratory. It could be tailored to a single (or group) of positions that perform the same level of work.

  Competency and Authorizations - An individual in a new position must be supervised, until he or she can operate independently and with competence. You

must have records documenting competency and authorizations to perform specific tasks as identified in 5.2.5. These records must be dated, and signed by the relevant individual(s). Competency to perform analytical tests is usually demonstrated by an Initial or Continuing Demonstration of Capability. Since there must be some written record that acknowledge successful (or unsuccessful) completion, this record could also serve as the authorization to begin (or continue) to perform the test. Since some of the identified positions are not associated with successful complete of a test (e.g. issuing test reports), other records will need to be developed to document these activities/

Training – You must have a stated policy concerning training. This policy could be included in your quality manual, and could be a very simple statement such as "The laboratory is committed to providing each individual with the training and skills necessary to be successful in his/her job." As a hint, this could be part of the quality statement which is required.

Your policy statement must be supported with a procedure to evaluate employee's training needs relative to mandatory training, current and future responsibilities and to arrange for any applicable training. The procedure must also outline how the effectiveness of training will be evaluated and documented.

Records – You must maintain all records pertaining to the credentials (education, experience, skills, etc.) competence, training and relevant authorizations of each individual. These records must be readily available.

> Note: Larger organizations have a Human Resources Department that may insist that some of the records (e.g. employment records, resumes, even some training records) be retained under their control. If you are in that situation, you will need to identify which records are under laboratory control and which records are under the control of a different department. The bottom line: when requested, the records (regardless of the source) must be "readily available".

- 5.2.6 Additional Personnel Requirements
  - Key Points

This section specifies educational and experience requirements for technical managers. Different types of laboratories that are described, and therefore, there may be the need for more than one technical manager in a laboratory.

- 5.2.6.1 Specifies the minimum education and experience requirements for different types of environmental laboratories
- 5.2.6.2 Outlines exceptions to the previous section
  - Wastewater and drinking water facilities labs
  - "Grandfather clause" for certain situations

- Discussion

If this is the first time your laboratory has applied for accreditation or has been required to be accredited, the technical manager(s) in your laboratory may be "grandfathered in" if they have been in that position for at least 12 months prior to application and they meet the experience requirements of that position. They will be approved for those fields of accreditation for which they have been technical manager. Once approved, their status as a technical manager makes them eligible to be a technical manager (for their fields of accreditation) in another accredited laboratory.

Plant operator licenses for domestic wastewater and drinking water may qualify that person to be a technical director provided certain experience requirements have been met. Industrial wastewater employees may also be recognized as a technical director under certain experience restrictions.

If none of the exceptions apply to your laboratory, you must read through the six different laboratory types to determine the qualifications that must be met.

Remember:

1. The "laboratory director" may not always be the technical director.
2. You may need to identify more than one technical director in order to satisfy the educational and experience requirements for a particular laboratory type.

If you have any questions concerning whether or not an individual qualifies as a technical director, you should check with your accrediting body to verify the requirements. (Hint: get that determination in writing!)

In order to document an individual's status as a technical director, you will need to have the supporting records available for review (transcripts, employment records, operator's certifications, etc.).

- 5.2.7 Data Integrity Training
  - Definitions:

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

    In-depth Data Monitoring: When used in the context of data integrity activities, a review and evaluation of documentation related to all aspects of the data generation process that includes items such as preparation, equipment, software, calculations and quality controls. Such monitoring shall determine if the laboratory uses appropriate data handling, data use and data reduction activities to support the laboratory's data integrity policies and procedures.
  - Key Points:
    - Data integrity training must be provided to new employees during employee orientation and to all current employees at least once per year.
    - There must be a written record of attendance that is meant to signify each person's participation and understanding of their obligations as they pertain to data integrity.
    - A copy of the agenda or topics that are addressed in the training must be provided to all in attendance.
    - The training must address five important topic areas as identified in the standard.
    - Each employee must also understand the consequences of a data integrity infraction.
  - Discussion

Understanding Data Integrity - Make sure you understand the above definition of data integrity. Notice: **all data** must be intact, accurate, and whole; and accurately represents how it was generated, and how it met (or did not meet) any stated requirements. This definition does not imply any wrong-doing whether accidental or deliberate. In other words, the laboratory's records, procedures and processes must be designed so that data cannot be altered without cause and all records must accurately reflect the status of the data at the moment the record was generated.

In-Depth Monitoring - Part of a good data integrity program should include processes to ensure that records can withstand technical scrutiny, and that data that goes into a system can be retrieved from the system in the same condition as it was input.

Data integrity involves the entire data generation process from sample collection through data reporting and includes every intermediate step in the data generation process. Data integrity is based on the accurate collection and documentation of all information related to every step in the analytical process.

Traceability of records is the primary process by which data integrity is demonstrated and the procedure for reviewing these records for a single (or multiple) result is defined as in-depth monitoring. Every analytical result reported by a laboratory should be traceable to original records such as:

- All log-in information and chains-of-custody.
- Identity of every individual involved in the analytical process (collection, log-in, preparation, analysis, disposal).
- All methods and Standard Operating Procedures used.
- Identification of critical time elements (collection, log-in, preparation, clean-up, analysis; this is especially important when the hold time is <72 hours).
- Instrument performance checks (MS tunes, stability checks, interference checks).
- Preservations used and preservation checks made.
- Traceability of sample material including dilutions and preparations.
- Identification and traceability to original containers of every analytical standard material used in the analysis (calibration, calibration verification, spiking standards for laboratory control samples, and matrix spikes).
- Traceability of reagents and diluents.
- Calibration and calibration verification data.
- Any equipment certificates of calibration.
- Data reviews, calculations, software used.
- Any additional documentation including instrument print-outs.
- All correspondence and case narratives.
- Any non-conformances and corrective actions associated with the result.

Training- Every new employee must have training in data integrity. This training must encompass more than the organization-wide ethics policies and procedures to include laboratory-specific data integrity policies and procedures.

All employees (includes all management) must have an annual refresher course in data integrity. There are many organizations that offer training courses in data integrity, but these cannot address some of the requisite organization-specific topics such as the laboratory's mission statement, the laboratory's data integrity procedures, and in-depth data monitoring. A review of a detailed, comprehensive data integrity SOP may address all the laboratory-specific training requirements with the exception of in-depth data monitoring which could be done as small group exercises.

At the conclusion of the training, there must be a written record of employee attendance. This could be a signed attendance sheet, or a signed data integrity statement, or another record type that indicates that the individual has participated and understands their obligations as they relate to the data integrity process.

Short meeting about what's happening now; not necessarily an all day meeting; can be shorter when there is less laboratory turnover; say what you are going to do in your Quality Manual, then do it; new person needs that bigger session

5.3 Accommodation and Environmental Conditions

- Definitions
- 5.3.1
  - Key Points

    The laboratory facility cannot invalidate any laboratory test. This can include energy sources, lighting, vibrations, noise, air quality and even the floor plan. When there are technical requirements for a condition that affects the test, the condition must be controlled and monitored (records!)
  - Discussion

    Check method, manufacturer's specifications, the TNI Technical sections and other documents for operating conditions or other environmentally related requirements. Create a procedure and records for monitoring these conditions.

    Note: Some conditions do not apply to the entire laboratory. Sterility, for instance needs to be controlled and monitored in the microbiology laboratory but not in the inorganics section. Temperatures need to be controlled for BOD and for TCLP extractions, for example, but not for all tests.

    Make sure that the facility is conducive to producing valid results
- 5.3.2
  - Key Points

    As implied in 5.3.1, you must monitor, control and record environmental conditions when there are specifications in the method or if certain conditions could impact the test results. You must also have procedures to follow when conditions are not met
  - Discussion

    Control, monitor and record conditions. Have a plan for when conditions can't be met. The plan should include stopping the test and perhaps arranging for external laboratory emergency testing.
- 5.3.3
  - Key Points

    Separate areas of incompatible activities.
  - Discussion

    Think about any incompatible tests or conditions: Volatile organics should not be tested in the same room as organic extractions; Nitric acid should not be kept in a hood that is used to prepare samples for nitrates; raw sewage samples for micro should not be stored in the same refrigerator or shelf as samples of finished drinking water; etc. You must prevent cross-contamination whether by separation, physical barriers, or environmental changes (e.g. hoods).
- 5.3.4
  - Key Point

Control access to testing areas of the laboratory

- Discussion

  Implement a controlled access plan. This can be very simple or very elaborate. Some laboratories control access by key card entry. Other laboratories have a policy that requires any external visitor to be escorted through the testing areas.

❖ 5.3.5

- Key Point

  The laboratory must ensure good housekeeping

- Discussion

  Consider laboratory "spring cleaning", and technical requirements (5.3.2 above). When cleaning service are contracted, you need to make sure that their cleaning supplies do not contribute contamination (e.g., cleaning solutions containing ammonia) and identify restricted areas (actively running instruments, or equipment). One laboratory has determined that all testing areas are off limits, and designates one day each month for cleaning under close scrutiny of the technicians and analysts.

5.4 Environmental Methods and Method Validation

Ignore requirements specific to Calibration Laboratories or Calibration Methods

❖ 5.4.1 General

- Key Points
  - Use appropriate methods including sampling, handling, transport and storage.
  - Have copies of instrument/equipment operating instructions.
  - All test related documents (SOPs, operating instructions, etc.) must be up-to-date and accessible to the analyst.
  - You must have a procedure for deviating from the method.
- Discussion

  Make sure that you are using are appropriate methods including how samples are handled, transported, stored and prepared

  You must have (and use) the most up-to-date instructions (or SOPs) for operating the equipment specified in the method.

  All reference materials and SOPs must be up-to-date. "Up-to-date" does not necessarily mean "the most current version." For example: EPA periodically publishes a "Method Up-Date Rule (MUR)". When the final rule is published in the Federal Register, the methods within that rule become "the most current version", however, many states must adopt the MUR into their regulations, before the methods becomes "Up-to-date methods" in that state. Further, some permits are written with "the most current version" of the MUR, but may be valid for 5 to 10 years. At the end of the permit cycle the permit "up-to-date version" may be several MUR cycles older than the currently accepted/approved version. Bottom line: you need to be aware of both state requirements, and client-specific requirements. There is a possibility that you may need to test the same analyte by two versions of the same method.

You must have a procedure for handling any deviations from the method that is consistent with the requirements of this standard. Such deviations must be approved (accepted) by the customer.

- 5.4.2 Selection of the method
  - Key Points
    - Method must meet your clients' needs.
    - The most recent version of a method must be used unless circumstances require the use of an older method (e.g., permit-specified, contract-specified, etc.)
    - You must have a procedure for selecting a method, if it is not specified by the client.
    - Laboratory-developed methods must be validated and must be appropriate for the intended use.
    - All methods are subject to some level of confirmation or validation before use.
  - Discussion
    - You must be aware of all required statutory or permit method requirements, and compare those with your clients' request. You are under obligation to inform your client when their requested method is not appropriate or is out-of-date. See discussion under 5.4.1 concerning the most "up-to-date version" (latest valid edition).
    - When a method is not specified, you must select a method that will meet the client's intended use. The standard discusses options for sources of a method. Once selected you must inform the customer of your selection.
    - Before you use the method for client samples, you need to make sure that you can perform the method by properly validating the method as outlined in the technical sections of this standard (this includes reference methods).
- 5.4.3 Laboratory Developed Methods
  - Key Points
    - Any laboratory-developed method must be the result of a planned process.
    - The requirement of that process includes communication among all participants in the study.
  - Discussion
    - See the "Note" in 5.4.4 for some of the information that could be part of the planning process
    - Consider:
      - Determining if the method meets the client's needs
      - If necessary, determining if the method is acceptable to the applicable regulatory authorities (including the accreditation body).
      - Establishing goals for method quality objectives (e.g., precision, accuracy, bias, etc.)
      - Preparing a draft SOP of the method
      - Establishing milestones and an anticipated schedule to meet the stated goals
      - Encouraging active feedback among all involved personnel
- 5.4.4 Non-Standard Methods
  - Requirements
    - The use of a non-standard method must be approved by the client
    - The method must be validated (see technical modules)
    - A standard operating procedure must be written

- Discussion
  - Obtain permission from the client
    - The agreement must include clear specifications for the use of the method and the purpose of the method
  - Validate the method per requirements in the technical module
  - Prepare a standard operating procedure for the method, using the requirements in 4.2.8.5 f

❖ 5.4.5 Validation of Methods

- Definition:

  Verification: Confirmation by examination and objective evidence that specified requirements have been met. (TNI Section 3)
  Validation: confirmation, through the provision of **objective evidence**, that the **requirements** for a specific intended use or application have been fulfilled (TNI EL1V2 Section 5.4.5.1)
  Reference Method: (To be used to determine the extent of method validation in Modules 3-7) A reference method is a published method issued by an organization generally recognized as competent to do so. (When the ISO language refers to a "standard method", that term is equivalent to reference method). When a laboratory is required to analyze an analyte by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another reference method of the same matrix and technology. (TNI EL1V2 Section 3)
  Accuracy: closeness of agreement between a **quantity value** obtained by **measurement** and the **true value** of the **measurand** (International vocabulary of basic and general terms in metrology (VIM))
- Key Points
  - Understand the definition of method validation
  - The laboratory must confirm that all non-standard methods, laboratory-developed methods, standard methods used outside their intended scope (e.g., using a water method for testing soil, adding an analyte to a method), and modifications to standard methods are fit for the intended use.
  - Validated methods must meet the range and accuracy (as characterized by certain parameters) required for the intended use, and must meet the client's needs.
  - All method must be validated before use. The extent of the validation is dependent on the type of method and the specific validation requirements in the technical modules.
- Discussion

  All methods (including reference methods) must be validated before use. Each of the technical modules (M 3, 4, 5, 6 and 7) discusses the requirements for validating both reference and non-standard methods. Use the applicable requirements for generating the data to be used in evaluating the method. You will need a procedure if you intend to validate any non-reference (or lab-created) method. If you plan only to use mandated methods, you are not required to have a procedure for a comprehensive validation.

Reference methods must also be validated, and in most cases the data from an initial demonstration of capability will be acceptable. If your SOP does not mention validating the method, you should add a section on validation.

When validation has been complete, you must assess the accuracy and range against the intended use, to determine if the method is able to meet the expectations or requirements. For example: If your client had a permit with a stated action level at a low concentration (with no method requirement), and the method you normally use had a stated method detection limit of a concentration that was 2 times higher than the required level, your method, while "approved" does not meet the usability requirement for range and cannot be used to test your client's samples.

- 5.4.6 Estimation of Analytical Uncertainty
  - Definition: **Analytical Uncertainty** – a subset of Measurement Uncertainty that includes all laboratory activities performed as a part of the analysis
  - Key Point
  - You must have a procedure for estimating analytical uncertainty
  - Discussion
    - There are many workshops, webinars and papers on analytical uncertainty. You must select a procedure that is applicable to the type of work done by your laboratory.
    - Develop an SOP on how your laboratory intends to estimate uncertainty
    - The standard allows the use of quality control measurement data for determining analytical uncertainty
- 5.4.7-Control of Data
  - Key Points
    - Have a procedure to systematically check calculations and data transfer
    - When automated or electronic equipment is used for acquiring the data or any subsequent processing, storage or other activity that is performed by the equipment, the laboratory must
      - Make sure that the software is documented and validated
      - Have procedures to protect the data so that intentional or unintentional changes cannot be made
      - Have procedures to ensure that the equipment is functioning properly.
  - Discussion

    Controlling data is a critical process for monitoring data integrity. You must have a procedure that checks all manually calculated test results, dilutions (samples, standards, reagents), and other record entries that might involve a calculation. Devise a strategy on how often checks are made, and a process to address situations where an error occurred. These types of checks are also applicable to data transfers (both manual and electronic)

    Any electronic or automated equipment that might be used to acquire data, or perform subsequent calculations, or is used as a repository for data must also be subject to checks.

      - If the software is developed or modified in house, it must be validated before putting into production, and records of the modifications and validation process must be retained. If the software is purchased, you should ask for documentation or evidence that the software was validated before purchase.

- You must have a procedure for correcting errors such that the original entry is not lost. Some data acquisition systems have an audit trail that captures changes to information. Some software data sheets have mechanisms to flag changed cells.
- You should also have procedures to ensure that the equipment is functioning properly. Electronic systems are fine as long as they work. You need to have a procedure to periodically verify that the equipment is still meeting your expectations.

5.5 Calibration Requirements

- Definition:

  Support Equipment – Devices that may not be the actual test instrument but are necessary to support laboratory operations (EL V1M2 5.5.13.1)

  Traceable International System of Units (SI) or another **system of units** (such as National Institute of Standards and Technology – NIST) - property of measurement results enabling them to be compared because they are metrologically traceable to the same stated metrological reference

- Key Points
  - Well-functioning, performing, and maintained equipment are prerequisites to ensure ongoing accurate test results. This section deals with the capacity and quality of equipment. The whole idea is to make sure that the instrument is suitable to perform selected tests and is well characterized, calibrated and maintained. You must use equipment that provides the expected performance. This applies to equipment you own as well as rent or lease.
  - Equipment performance must meet method quality control requirements as well as specification and configuration requirements.
    - New equipment must be checked/calibrated before routine use. These checks must verify that the equipment is working properly.
    - You must have procedures to perform subsequent intermediate checks
  - Equipment must be operated by authorized personnel.
  - Equipment and software must be uniquely identified and detailed records must be maintained (see standard)
  - You must have procedures for
    - handling, storage, transport and maintenance
    - Correction factors
    - Dealing with equipment that is returned to the laboratory after being used/repaired
    - Safeguarding equipment and software from adjustments that would invalidate the test.
  - If equipment is not functioning properly, it must be taken out of service, and clearly labeled as such until it has been repaired. You must also determine if the problem had an effect on data and take actions on non-conforming work.
  - You must follow the requirements related to support equipment that are included in the standard.
- Discussion

This section deals with ensuring that the test and support equipment that you use performs within specifications set by the manufacturer, the method and your client. The goal is to use equipment that always meets expectations.

- You must make sure that new equipment or equipment that is returned to the laboratory after repair or used by outside sources functions as expected.
- In addition to calibrations and calibration checks that are included in the technical sections of this standard and in 5.5.13.1 of this standard, you must keep your equipment in top working order. This section discusses the need to have routine maintenance procedures and records, as well as procedures to be followed when equipment is not working properly, or needs correction factors.

All equipment and associated software must be uniquely identified. Use a system that works best for your laboratory. Some laboratories use a simple numerical order ID, others use the manufacturer's serial number, or organization's property number. One laboratory has even allowed the analyst to name their instrument. In all cases, you must have a record that links the unique identifier to a specific piece of equipment or software and all other information that is required by the standard (see section 5.5.5).

The standard requires that equipment must be operated by authorized personnel (see 5.2. for discussions on what this means and the documentation associated with the authorization.). These individuals must have access to the up-to-date manufacturer's manuals for the instrument's make and model. These manuals should include how to operate and maintain the instrument.

When an instrument is operating within expectations you want to make sure that no further adjustments are made unless technically justified.

- For equipment where physical adjustments (knobs and buttons) are made, the best policy is to ensure that all visitors are escorted in the laboratory, and that janitorial tasks are done when there are laboratory personnel present to oversee the work.
  For instruments or equipment with automatic software or and Laboratory Management System, levels of authority must be assigned with only a few individuals having the ability to make changes/corrections to the original entries.

Support equipment is handled and documented in the same manner as analytical instruments (maintenance, identification, proper functioning, etc.). The standard also includes specific intervals for monitoring, checking or verifying the working condition of the equipment.

- Where possible, equipment must be calibrated or verified with a NIST traceable reference material or device. This is different from monitoring the temperature of a refrigerator on a daily basis. This is checking the thermometer that is used to monitor the refrigerator against a NIST traceable thermometer to verify the accuracy of the refrigerator thermometer.
- Working weights for balances, and temperature sensing devices (thermometers, IR guns, thermistors) are the two most common types of equipment that need NIST traceable weights and thermometers, respectively.
- You must verify the stated unit (e.g. 100 mg) or over the range of use (100 – 180 °C). The observed value must be within the tolerance established by NIST. Remember to record the results if you plan to verify the equipment in the laboratory. If performed by an outside source, you must obtain a certificate or statement attesting to the accuracy of each item that was calibrated/verified.

- Volumetric devices must also be checked at a stated frequency when quantitative results are dependent on their accuracy (e.g. standard preparation, measuring/dispensing a specified volume of sample, dilutions, etc.). Only Class A glassware and glass microliter syringes (with a certificate) are exempt from this check. Some of the common devices include Eppendorf®-like pipettes, automatic diluters, automatic volume dispensers, sterile and non-sterile transfer pipets, and graduated cylinders.

The Standard is silent regarding how frequently you have to have your "certified" weights or "certified" thermometers calibrated by an outside source (note – these aren't the ones that you use every day, these are the ones that are stored separately with a certificate issued by the vendor and are only used to verify that the thermometers and weights that are used daily are still ok). Check with your accrediting body to assure that your process is acceptable. At least one every five years is generally considered acceptable.

EXAMPLES – gather all refrigerator thermometers into a single refrigerator, along with the NIST traceable thermometer, and check them all at the same time

1. So if you use an oven at 105°C (103-105) then only a single point is necessary. If you use the oven (or thermometer) for TSS (105) and TDS (180C) - You have to bracket the range since it is more than 10°C.

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

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

- Volumetric devices can be verified by weighing repeated measurements and calculating the appropriate weight based on temperature and volume (water weighs different amounts at different temperatures). Pay close attention to whether your dispensing device is a "To Contain" or "To Deliver". Graduated cylinders are generally constructed as "To Contain", while syringes and pipets are generally constructed "To Deliver".

5.0 Technical Requirements

5.6 Measurement Traceability

This section applies to all equipment used for testing, calibration or sampling which will have a significant effect on the accuracy and validity of the result.

- Key Points
  - 5.6.1 Calibration of this equipment will be:
    - Part of an established program/procedure
    - Performed prior to fist use.
    - Basis on appropriate statistical methods
    - Factors to be controlled to ensure the validity of the data
  - 5.6.2 The program for the calibration of equipment must be designed such that the calibrations are traceable to *International System of Units (SI)* or a certified reference material.
    - This traceability is established by means of an unbroken chain to the relevant primary standard.
    - This link may also include reference to a national measurement standard.
    - When using external calibration services, use providers that are capable and competent to do the calibrations/verifications.
    - Certificates issued by external calibration service providers must contain
      (i) Measurement results,
      (ii) Measurement uncertainty,
      (iii) A statement of compliance with the identified metrological specification.
  - 5.6.3 Reference Standards and Reference Materials:
    - Have a procedure
    - Traceability
    - Materials to be checked as far as is practicable
    - Transported and stored in a way to prevent contamination or deterioration
  - 5.6.4 Clarifications
    - Participate in inter-laboratory comparisons, proficiency testing, or independent analysis to prove correlation of results.
    - Documented procedure for purchase, receipt and storage of materials used in technical operations. Retain the records.
- Discussion
  - Traceability is the primary means by which data integrity is established. Having information through the life cycle of the data will aid in the evaluation of the validity and integrity of the results.
  - The program should include details on how you selected, calibrated, checked, controlled, and maintained the standards, reference materials and equipment.
  - Establishing a tracking system is very useful here. This is not a one-size-fits-all. Do what works in your lab for your use. Just be sure to get all of the elements.
  - When making a prepared solution form a standard material, include the recipe along with the maker and an expiration date. If this prepared solution has to be

standardized, the primary standards need to be traceable and the results of the standardization need to be retained as well.

5.7 Handling Samples and Test Items

- Key Points

  Sampling – *A procedure whereby part of a substance, material, product is taken to provide for the testing or calibration of a representative sample of the whole.* (EL V1M2 5.7.1 Note)

  - 5.7.1 The lab must have a sampling plan and a procedure for sampling when appropriate. This plan includes:
    - The actual procedures for sampling
    - The location of the sampling
    - Basis on appropriate statistical methods
    - Factors to be controlled to ensure the validity of the data
  - 5.7.2 Customer required deviations of the sampling plan must be recorded in details, included on all the documents, and be communicated to the appropriate personnel.
  - 5.7.3 When sampling forms part of the testing, the lab must have a procedure for recording the relevant data and operations. These records must include:
    - Sampling procedure used
    - Identification of the sampler
    - Environment conditions, where applicable
    - Diagrams or other means of identifying locations
    - Statistical basis of the sampling
  - 5.7.4 Documentation must also include the date and time of sampling. Any deviations must be documented.

- Discussion
  - The procedure also apply to internal sub-sampling as well as field sampling.
  - The procedures should address how you made selection of sites, why you decided to use one procedure over another, etc.
  - For the purposes of the standard, any activities that are under the direct control or management of the lab need to be addressed. Therefore, the requirements may be slightly different for a small commercial lab vs. a municipal lab. If lab staff does not perform the sampling, portions of this standard may not apply. Also, in the case of “process control” samples that have no regulatory implication and are only used to help the operation staff with the running of a plant, the standard may not apply.

5.8 Handling Samples and Test Items

- Key Points
  - Have a procedure for transport, receipt, handling, storage, and disposal of samples and materials.
    - Sample Acceptance Policy- written
      (i) Full and complete documentation
      (ii) Proper labelling with unique ID
      (iii) Appropriate sample containers,
      (iv) Adhere to hold times
      (v) Procedures for noting damage, contamination or inappropriate preservation
      (vi) Qualify data that does not met the requirements.
    - Sample Receipt Protocols
      (i) Procedure to verify preservation
      (ii) When the acceptance criteria are not met, retain the documentation as to the rejection or the determination that the appropriate qualification of the data will be done.
      (iii) Permanent chronological record
      (iv) Keep all the documentation
    - Legal Chain of Custody Protocols
    - Sample Storage and Disposal
      (i) Store as per conditions specified
      (ii) Store away for standards
      (iii) Includes, fractions, leachates, or other sample pre materials
      (iv) Have an SOP
  - Provide unique identification to maintain the link with the field ID
  - Laboratory ID placed on container with a durable mark.
  - Prevent cross-contamination
  - Record and deviations from your procedures and why

- Discussion
  - The procedure must accommodate sub-sampling, dilutions, etc.
  - Be sure to record any anomalies
  - Any written policies need to account for the use of the data in terms of program, the method requirements, customer requirements and this standard.