Quality Management System Expert Committee (QMS)
Meeting Summary

May 9, 2022

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on May 9, 2022. Attendance is recorded in Attachment A – there were 11 voting members present. Associate members present: Carl Kircher, Karna Holquist, Linda O'Donnell, Debra Zeller, Dylan Lyon, Alma McCammond, Valarie Slaven, Patricia Carvajal, Sushmitha Reddy, Rachel Van Exel, Lizbeth Garcia, Lisa Parks, Nicole Van Aken, Cody Danielson, Kathleen Lloyd, Cindy Redmond, Ty Atkins, Annmarie Beach, Tammy Kreutzer, Brian Lamarsh, Tiffany Shaw, Kelvin Yuen, and Paul Junio.

The March minutes were distributed by email. A motion was made by Tony to approve the March 14, 2022 minutes with the following changes: Add a "d" to standard and next meeting date is April 8, 2022. The motion was seconded by Kathi and unanimously approved.

2. ISO Language

The Committee looked at language from 17011:2017, Clause 4.3.1. The language was received from LAB with a request to add this information to the lab Module 2. New language has been proposed:

Proposed new language: Debbie is not sure where in the standard the language will go, so the numbering will be based on it's location.

1. Laboratories shall comply with any requirements from their accreditation body concerning accreditation claims and references to its accreditation in communication media.
2. Laboratories shall not make misleading statements about its accreditation and shall not imply that products, processes, services, management systems, or persons are approved by the accreditation body.
3. Laboratories shall inform affected clients of suspension, reduction or withdrawal of its accreditation in a timely way and shall immediately discontinue referencing that accreditation.

There was another paragraph from Carl about ABs making information public, but Debbie is not sure what to do with that one. In her opinion, the Committee doesn't need to include that in the Standard because it does not require an action from the laboratory – it would only be informative, and this is a standard for laboratory practices, not a guideline.

The Committee worked on Section 4.2 of 17011:2017 last month. This will help labs know that ABs will be looking at the items in Section 4.2.

3. Defitions Work Group

Paul Junio provided an update that is summarized in Attachment B.

4. Crosswalk

The Committee continued to review the Crosswalk and inserting language into the DRAFT Standard starting at Section 5 (see Attachment C).

The Committee ended its work at Section 5.8.

5. SIR

The Committee began work on SIR 433 that it just received:

SIR 433 to QS, May 6, 2022

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	4.13.3

Describe the problem:
Throughout the 2016 TNI Standard, and specifically within section V1M2: 4.13.3, the laboratory is required to produce, ensure, implement, etc., a system that produces records that document all laboratory activities, have documentation that allows historical reconstruction, etc. Labs are also required to have and maintain SOPs that meet all of the method and regulatory requirements as well as accurately reflect the laboratory's operations, and the analysts are required to read, understand, and follow their SOPs.

Question: Is the laboratory required to have a record, that they fill out like a benchsheet or logbook (or whatever terminology the lab might use), electronic or hardcopy, where they document every step of the test or every action that is taken in the laboratory? Such as:
- exact times of each step of a organics sample extraction
- reaction times/wait times of a sample digestion or extraction
- pH checks within a sample digestion/extraction (note, not a pH check for preservation acceptance purposes, but a pH adjustment that is required within a digestion/extraction step)

Or, is having these times, steps, requirements, etc. listed in the SOP acceptable as part of the laboratory's proof of 'historical reconstruction' of all laboratory activities?

Committee Comment:

Response: Proposed - The laboratory does need a record to enable reconstruction of the activity at the time the activity is taking place (see 4.13.2). The SOP would not meet the requirements of record-keeping.

Debbie shared the proposed response with the Committee.

A motion was made by Ashley to approve the proposed response.

Nicole commented that it sounds like the Committee is saying you have to do all this. Is that what is intended? There were more comments about the language.

There was no second to the motion, so the motion was withdrawn. The SIR will be further discussed by email or at the next meeting.

6. New Business

No new business.

7. Next Meeting and Close

The next meeting will be June 13, 2022 by teleconference/Webex at 1pm Eastern.

Debbie adjourned the meeting at 2:24pm 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 **Present**	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 **Present**	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson **Present**	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 **Absent**	ANAB	2025*	AB	zpopovska@anab.org
Amber Ross **Present**	PA DEP/Bureau of Laboratories	2025	AB	ambross@pa.gov
Amy Schreader **Present**	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) **Present**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B: Definitions Workgroup Report

FINISHED 😊

1. **Support equipment** – the goal with this definition is that we won't need to list typical equipment that could be supporting and inadvertently miss one or imply that a piece of equipment is only either support or analytical.

5.5.13.1 Support Equipment

This Standard applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These might include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices), if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume. Depending on the intended use of the data, a device may be considered support equipment in some instances, and analytical equipment in others.

By modifying the paragraph, we feel like we don't need to define 'support equipment'.
The paragraph is titled 'Support Equipment', but then we talk about 'devices'. Should we be consistent and refer to one or the other?

2. **Duplicate** – this was a request from a past meeting; if necessary, it may be helpful to specifically define Sample Duplicate in conjunction with this definition, unless a general definition will cover it.
   DUPLICATE - Two aliquots of the same sample prepared and analyzed with identical procedures.
3. **Customer** – a person or organization that requests analysis from the laboratory. NOTE - a customer may be internal or external to the laboratory.

4. Procedure - written instructions detailing the performance of a task, process, or other laboratory activity.

TO DO ☹

#5 & #6 – asked Chemistry if 17025:2017 language would suffice

5. **Method validation** – this was a request from the chemistry expert committee in the past and again more recently. We have notes that each module should define their own, but there are general boundaries to a validation that differentiate it from a verification. Maybe a definition for "validation" will work instead of "method validation"? May need to reach out to Chemistry and Wet committees on this one.
   Systematic testing of the ability of a new method to measure a particular analyte or set of analytes in a particular matrix, maybe? Needs to include something about being a new method.

6. **Verification** – previous comments state that this is different from Data Validation. On a side note, data validation is only included in the definition of Audit, as far as I can tell. Are we talking about method verification, data verification, or capability verification? I am not sure we can get just one definition that would encompass all of these. As far as I am aware, there's not much in the standard about what most people would call "data validation" as that's usually done by the data user.

(V1M2 Currently) Verification - Confirmation by examination and objective evidence that specified requirements have been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

validation	verification, where the specified requirements are adequate for an intended use. EXAMPLE: A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum TNI "NOTE" - Systematic testing of the ability of a new method to measure a particular analyte or set of analytes in a particular matrix – should this include a measure of precision and accuracy? Is that understood from a requirement to run an IDOC / MDL Studies? Would that be covered by the technical modules?
Verification	Confirmation by examination and objective evidence that specified requirements have been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

verification	*provision of objective evidence that a given item fulfils specified requirements; EXAMPLE 1;Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.: EXAMPLE 2; Confirmation that performance properties or legal requirements of a measuring system are achieved.; EXAMPLE 3; Confirmation that a target measurement uncertainty can be met.; Note 1 to entry: When applicable, measurement uncertainty should be taken into consideration.; Note 2 to entry: The item may be, for example, a process, measurement procedure, material, compound, or measuring system.; Note 3 to entry: The specified requirements may be, for example, that a manufacturer's specifications are met.; Note 4 to entry: Verification in legal metrology, as defined in VIML, and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.; Note 5 to entry: Verification should not be confused with calibration. Not every verification is a validation (3.9).; Note 6 to entry: In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity*

7. **Definitions to consider (from past committee meeting comments)**: policy

   Policy - statement of principles or intent for a particular (general?) task, process, or segment of laboratory activities. [will we even need this – will they become procedures and not policies?]

   Task – review current language to determine if the occurrence of 'Policy' should be changed to 'Procedure' – Prepare to discuss on June 7 at 1PM Eastern

8. **Definitions to consider corrective actions -**

Attachment C:

5.0 Technical Requirements				
5.1 General *(ISO/IEC 17025:2005, Clause 5.1)*			*Reviewed by K Gumpper*	
5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from: *– human factors (5.2);* *– accommodation and environmental conditions (5.3);* *– test and calibration methods and method validation (5.4);* *– equipment (5.5);* *– measurement traceability (5.6);* *– sampling (5.7);* *-- the handling of test and calibration items (5.8).*		*Changed equiv*	**8.1.1 General** The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B. NOTE See Annex B for more information. *I see this as equivalent because it is definitional in nature and the specific elements referenced are all incorporated into Clauses 4 to 7.*	

5.1.2The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.		Changed Not Equiv	**7.2.2.1** The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. NOTE 2 The techniques used for method validation can be one of, or a combination of, the following: a) calibration or evaluation of bias and precision using reference standards or reference materials; b) systematic assessment of the factors influencing the result; c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed; d) comparison of results achieved with other validated methods; e) interlaboratory comparisons; f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method. *This paragraph was mostly definitional in the 2005 standard. While it does give a directive "shall take account", there were more direct requirements in method*	KEEP By making NOTE 2 a requirement, which captures more helpful information than in 2005. Suggested: state that one or more of the 6 items in Note 2 are required for validation of methods in 7.2.2.1.

			validation, in equipment and in personnel training and qualification that better describe the general tone of what is being required. That said, there might be an advantage in making the NOTE 2 a requirement instead of a note so it becomes citable.	
5.2 Personnel *(ISO/IEC 17025:2005, Clause 5.2)*				
5.2.1The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.		*Changed*	***6.2.3** The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.* ***AND*** ***6.2.2** The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.* *Missing that the responsibility is on management.*	DROP Management is part of the lab and sometimes the person who can best evaluate competence is not in management.
5.2.1 NOTE 1: In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the customer.		*Deleted*	*NOTE wasn't made a TNI requirement and can be disregarded*	DROP This is something a lab can choose to do without a NOTE in the standard.

5.2.1 NOTE 2: The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have: – *relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;* – *knowledge of the general requirements expressed in the legislation and standards; and* *-- an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.*		*Deleted/changed* *Changed – not equivalent*	*NOTE wasn't made a TNI requirement. This is covered, however, in* ***6.2.6** The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:* *b) analysis of results, including statements of conformity or opinions and interpretations*	DROP Language in 6.2.6 is sufficient to ensure people are qualified to the extent necessary for the lab to perform tasks.
5.2.2The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.		*Changed/deleted* *Changed – not equivalent*	***6.2.2** The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience AND* ***6.2.5** The laboratory shall have procedure(s) and retain records for:* *c) training of personnel* *Missing responsibility on management and looking at "anticipated tasks."*	DROP I'm not sure about "anticipated tasks." I think if you have requirements for education for lab activities, that's sufficient.

5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.		*Changed/deleted* *Changed – equivalent if contracted personnel are external lab personnel?*	***6.2.1*** *All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system* *No requirement for supervision of contracted personnel.*	DROP Sections 6.2.2, 6.2.5, and 6.6.3 added to 6.2.1 are sufficient.
5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.		*Changed*	***6.2.2*** *The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience*	DROP 2017 is worded more generally, but is sufficient to ensure competence. Lab qualifications are not necessary for some management levels. TNI section 4.2.8.4.g covers the need for job descriptions.

5.2.4 NOTE: Job descriptions can be defined in many ways. As a minimum, the following should be defined: – *the responsibilities with respect to performing tests and/or calibrations;* – *the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;* – *the responsibilities for reporting opinions and interpretations;* – *the responsibilities with respect to method modification and development and validation of new methods;* – *expertise and experience required;* – *qualifications and training programmes managerial duties.*		*Deleted*	*NOTE wasn't made a TNI requirement and can be disregarded*	DROP This may be helpful to someone writing job descriptions for the first time, but is not necessary here.

5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.		*Changed*	***6.2.5** The laboratory shall have procedure(s) and retain records for:* *c) training of personnel* ***6.2.6** The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:* *a) development, modification, verification and validation of methods;* *b) analysis of results, including statements of conformity or opinions and interpretations;* *c) report, review and authorization of results.* ***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*	DROP Between 7.5.1, 6.2.5 and 6.2.6, this section should be covered.

			are made and shall be identifiable with the specific task.	

Reference: 17025:2005	**Mark E if Exact Match**	**Indicate whether the language 'Changed - Equiv ' 'Changed - Not Equiv 'or was 'Deleted'.**	**17025:2017 reference (add the language if different from 2005)** *Give an opinion of whether the rewording is equivalent to the previous language*	**Drop** 2005 language or **Keep**
5.3 Accommodation and Environmental Conditions ***(ISO/IEC 17025:2005, Clause 5.3)***			*Reviewed by K Gumpper*	

5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations. The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.		Changed Equiv.	**6.3.1** The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results. NOTE Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration. 6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented. 6.3.5 When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met. *Although the list of potential sources of important environmental conditions was moved to a note, and the requirement is rephrased, and divided into separate paragraphs, it is nearly identical in content.*	

5.3.2The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.		Changed Equiv.	**6.3.3** The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results. *Although the list of potential sources of important environmental conditions was moved to the note in 6.3.1 above, the monitoring requirement is nearly identical. The requirement for stopping testing is the logical outfall of the requirement in 6.3.1 that conditions "shall not adversely affect validity of results" (see above)*	
5.3.3There shall be effective separation between neighbouring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.		Changed Equiv.	**6.3.4** Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to: b) prevention of contamination, interference or adverse influences on laboratory activities; c) effective separation between areas with incompatible laboratory activities.	

5.3.4Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.		Changed Equiv**.**	**6.3.4** Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to: a) access to and use of areas affecting laboratory activities;	
5.3.5Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.		Changed Equiv**.**	**6.3.2** The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented. **6.3.4** Measures to control facilities shall be implemented… *This paragraph was redundant with the requirements previously stated in 5.3.1 – 5.3.4 in the 2005 document. Although the phrasing was changed, the meaning is still consistent in the 2017 document.*	

Reference: 17025:2005	**Mark E if Exact Match**	**Indicate whether the language 'Changed - Equiv ' 'Changed - Not Equiv 'or was 'Deleted'.**	**17025:2017 reference (add the language if different from 2005)** *Give an opinion of whether the rewording is equivalent to the previous language*	**Drop** 2005 language or **Keep**
5.4 Environmental Methods and Method Validation				

5.4 (cont.) All references to Calibration Laboratories and Calibration Methods in *ISO/IEC 17025:2005* in these Clauses are not applicable to environmental testing.		Deleted	I could not find this statement or anything relevant to this statement in the 2017 standard. (From KG) Note – this language is actually TNI language, not ISO language. IMO, The exemption probably shouldn't be made if the laboratory is performing its own calibrations of measuring equipment, Testing laboratory activities are clearly included in the subparagraphs of 5.4.6. I'm not sure why this statement was included in the standard and my personal recommendation would be to remove it, however, for this activity (assessing the need for 17025:2005 language), this particular paragraph should not be handled here, it should be handled in the "additional TNI requirements" evaluations.	Address this in sections 6.5 and 7.8, if needed.

5.4.1General (ISO/IEC 17025:2005, Clause 5.4.1)The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.		Changed, Equiv	The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.	

5.4.1(cont.) The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3). Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.		Changed, Equiv Exact for the portion in yellow	*7.2.1.3* The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application. 7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3). **7.2.1.7** Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.	

5.4.1 NOTE: International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.	*E*		NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.	

5.4.2 Selection of Methods (ISO/IEC 17025:2005, Clause 5.4.2) *The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.*		Changed Not Equiv.	**7.2.1.3** The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application. NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details. Things that are not quite the same: 1.It doesn't specify 'test or calibration' (since method could apply to either), it doesn't specifically list sampling methods, since the word method, as used, would also apply to sampling methods. 2.The requirement for methods published in international, regional or national standards shall be 'preferably' used was not	DROP Use of method applies to both test and calibration. Information in the note is covered by TNI language in 5.4.2.

			included, however there is still a requirement that methods meet customers' needs. It is difficult from an accreditation standpoint to assess whether the lab is compliant regarding the 'preferably" requirement. In fact, in our industry, it is often not possible to use the most recently published version of a method since these methods are not yet promulgated or approved and may not be for a number of years.	

5.4.2 (cont.1) When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.		Changed Equiv.	**7.2.1.4** When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used. *The 2005 standard sounds better to me like it is more detailed. They are kind of similar but the wording in the 2005 is more concise.*	
5.4.2 (cont.2) The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.		*Changed Equiv.*	7.1.2 The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.	

5.4.3 Laboratory-Developed Methods (ISO/IEC 17025:2005, Clause 5.4.3) *The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.*		*Changed Equiv.*	*7.2.1.6* When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.	
5.4.4 Non-Standard Methods (ISO/IEC 17025:2005, Clause 5.4.4) *When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.*		Changed - Equivalent	7.2.1.7 Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. **7.2.2.1** The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.	

5.4.4 NOTE: For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information: *a) appropriate identification;* *b) scope;* *c) description of the type of item to be tested or calibrated;* *d) parameters or quantities and ranges to be determined;* *e) apparatus and equipment, including technical performance requirements;* *f) reference standards and reference materials required;* *g) environmental conditions required and any stabilization period needed;* *h) description of the procedure, including* *affixing of identification marks, handling, transporting, storing and preparation of items,* *checks to be made before the work is started,* *checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,* *the method of recording the observations and results,* *any safety measures to be observed;* *i) criteria and/or requirements for approval/rejection;* *j) data to be recorded and method of analysis and presentation;* *the uncertainty or the procedure for estimating uncertainty.*		*NA*	*NA*	Decide to keep or not when reviewing the draft standard.
5.4.4.1 The note in 5.4.4 above, which includes a – k, shall be considered during the development of the method.	*N/A*	*N/A*	*Note: This is TNI language that changed the note for 5.4.4 to a requirement – There is no need to look for it in 17025:2017, but I kept it here to make sure we don't lose track of the fact that the Note is more than just a note.*	
5.4.5 Validation of Methods *(ISO/IEC 17025:2005, Clause 5.4.5)*				

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.		Changed, Equiv.	3.9 validation verification (3.8), where the specified requirements are adequate for an intended use I prefer the 2005 language. Seems more detailed.	
5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.		Changed Equiv.	**7.2.2.1** The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.	
5.4.5.2 NOTE 1: Validation may include procedures for sampling, handling and transportation.		Changed Equiv.	7.2.2.1 NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items.	

5.4.5.2 NOTE 2: The techniques used for the determination of the performance of a method should be one of, or a combination of, the following: – *calibration using reference standards or reference materials;* – *comparison of results achieved with other methods;* – *interlaboratory comparisons;* – *systematic assessment of the factors influencing the result;* *assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.*	*E*		7.2.2.1 Note 2 The techniques used for method validation can be one of, or a combination of, the following: a) calibration or evaluation of bias and precision using reference standards or reference materials; b) systematic assessment of the factors influencing the result; c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed; d) comparison of results achieved with other validated methods; e) interlaboratory comparisons; f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.	
5.4.5.2 NOTE 3: When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.		Changed Equiv.	7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.	

5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.		Changed Equiv.	7.2.2.3 NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias. Verbiage has changed but references the same things for the most part.	

5.4.5.3 NOTE 1: Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.		*EQUIV*	No relevant language found. **7.2.2.4** The laboratory shall retain the following records of validation: a) the validation procedure used; b) specification of the requirements; c) determination of the performance characteristics of the method; d) results obtained; e) a statement on the validity of the method, detailing its fitness for the intended use. *6/18/2021: Though there is not a list of what a validation includes, there is now a requirement of what the validation record shall include. dab*	

5.4.5.3 NOTE 2: As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.		*Changed, Equivalent*	7.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.	

5.4.5.3 NOTE 3: Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.		Deleted	No relevant language found. (From KG) While this is partially true, the thing that changed in this note was the allowance for a "giving the information simplified way due to lack of information". If anything, the 2017 standard could be seen as more prescriptive, but it's still just a note, thus not assessable. ISO 17025:2017 7.2.2.3 NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.	DROP No need to include because it's a note that doesn't really provide any better information than the note in 7.2.2.3.

5.4.6 Estimation of Analytical Uncertainty Clause 5.4.6 of the *ISO/IEC/IEC 17025:2005* concerning calibration testing does not apply. The following requirement 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.	*N/A*	*N/A*	*This is TNI language specifically dropping the 5.4.6 requirement. It is included only to remind us to think about whether the requirement should remain dropped*	
5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.		Changed, Equiv.	7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.	

5.4.6.2 Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. 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. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.		Changed, Equiv.	A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method. A lot of the verbiage has been shortened but states the same end goal.	

5.4.6.2 NOTE 1: The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as: – *the requirements of the test method;* – *the requirements of the customer;* *the existence of narrow limits on which decisions on conformity to a specification are based.*		EQUIV	No relevant language found (From KG) There isn't a note with the same language. Instead there is a requirement (see the paragraph above) that states that the lab has to do the best they can. In my opinion, the note as written in 2005 language does not provide any significant guidance and could be eliminated. ISO17025:2017 **7.6.3** A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.	
5.4.6.2 NOTE 2: In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).	E		7.6.3 NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.	

5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.		Changed, Equiv	Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.	
5.4.6.3 NOTE 1: Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.		Deleted	No relevant language found (From KG) I'm not sure this note is very helpful to our labs since none of them do a "bottom up approach to uncertainty estimation". In reality, only a few of our labs do any kind of uncertainty estimate at all and some couldn't even tell you what it is. Additionally, I don't have access to the referenced ISO standards/guide from 17025:2017 Note 3, but it is likely that this concept is discussed extensively in one or all of them.	DROP See KG note.
5.4.6.3 NOTE 2: The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.		Deleted	No relevant language found (From KG) I'm not sure this note is particulatly helpful to our labs.	DROP

5.4.6.3 NOTE 3: For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see Bibliography).	E		7.6.3 NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.	
5.4.7 Control of Data *(ISO/IEC 17025:2005, Clause 5.4.7)*				
5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.	E		7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.	
5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:		Changed - equiv. (most relevant language I could find)	**7.11.2** 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.	

5.4.7.2 a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;		Changed - Equivalent (most relevant language I could find)	**7.11.2** 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.	

5.4.7.2 b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;		Changed – Equiv.	**7.11.3** The laboratory information management system(s) shall: a) be protected from unauthorized access; 7.11.3 d) The Laboratory information management system (s) shall be maintained in a manner that ensures the integrity of the data and information; ***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.* Missing requirement to have a procedure; this section is specific to LIMS and does not	DROP It's not necessary to have a procedure for controlling records.

			mention other non-LIMS data storage systems. (from KG) There is no requirement for a procedure except where it says in 7.11.5 that "instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel." I don't know that we could require a lab to write a procedure without the previous language. They would only have to make any instructions that DO exist available. My recommendation would be to add a requirement for a procedure RE: "does not mention other non-LIMS data storage systems" - In the ISO LIMS definition in 7.11.2, it encompasses more than what we often think of as LIMS… "The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data " They are talking about computer systems, not a particular piece of software. I don't think under the 17025 standard there is such a thing as "non-LIMS" electronic	

			data storage. There are additional requirements for records found in the general records and technical records sections. This section is specifically devoted to computer systems, but more broadly applied than a “LIMS software package” might include.	

5.4.7.2 c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.		Changed, Equiv.	7.11.3 c The Laboratory information management system (s) shall be operated in an environment that complies with provider or laboratory specifications …. 7.11.3 d) The Laboratory information management system (s) shall be maintained in a manner that ensures the integrity of the data and information; The verbiage is different. This is the only relevant language I can find that is similar to the 2005 standard. (From KG) although the language is not exact, in my opinion, it carries the same meaning.	

5.4.7.2 c) NOTE: Commercial off-the-shelf software (e.g. word processing, database and statistical programmes) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2 a).		Changed, Equiv.	7.11.2 NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated. **7.11.2** 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.	

Reference: 17025:2005	**Mark E if Exact Match**	**Indicate whether the language 'Changed - Equiv ' 'Changed - Not Equiv 'or was 'Deleted'.**	**17025:2017 reference (add the language if different from 2005)** *Give an opinion of whether the rewording is equivalent to the previous language*	**Drop** 2005 language or **Keep**
5.5 Calibration Requirements *(ISO/IEC 17025:2005, Clause 5.5)*				
ISO/IEC Clauses 5.5.1 to 5.5.12 apply with respect to equipment in environmental testing laboratories.		**Deleted**	**This is a TNI note that is no longer needed. The difference between calibration labs and environmental labs is of less concern and need not be distinguished.**	DROP

5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). *In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.*		*Changed Equiv*	**6.4.1** The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results. NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability. NOTE 2 ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials. **6.4.2** When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.	

5.5.2Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. *Calibration programmes shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.* *Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).*		*Changed Equiv*	**6.4.5** The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. **6.4.7** The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration. **6.4.4** The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service. **6.4.6** Measuring equipment shall be calibrated when: — the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or — calibration of the equipment is required to establish the metrological traceability of the reported results. NOTE Types of equipment having an effect on the validity of the reported results can include: — those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;	

			— those used to make corrections to the measured value, e.g. temperature measurements; — those used to obtain a measurement result calculated from multiple quantities.	

5.5.3Equipment shall be operated by authorized personnel. *Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.*		*Changed Equiv*	**6.2.3** The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations. **6.4.12** The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results. **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. **6.2.6** The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following: **7.2.1.2** All methods, procedures and supporting documentation, such as instructions, standards, manuals and	

			reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3). *If we include 7.2.1.2, these may be equivalent.*	
5.5.4Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.		*Changed Equiv*	**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;	
5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:		*Changed Equiv*	**6.4.13** Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:	
5.5.5 a) the identity of the item of equipment and its software;		*Changed Equiv*	6.4.13 a) the identity of equipment, including software and firmware version;	
5.5.5 b) the manufacturer's name, type identification, and serial number or other unique identification;	*E*		6.4.13 b) the manufacturer's name, type identification, and serial number or other unique identification;	

5.5.5 c) checks that equipment complies with the specification (see 5.5.2);		*Changed Equiv*	6.4.13 c) evidence of verification that equipment conforms with specified requirements;	
5.5.5 d) the current location, where appropriate;		*Changed Equiv*	6.4.13 d) the current location;	
5.5.5 e) the manufacturer's instructions, if available, or reference to their location;		*Changed – Equiv (manufacturer's instructions are external documents)*	**8.3.1** The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document. NOTE In this context, "documents" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.	
5.5.5 f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;		*Changed Equiv*	6.4.13 e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;	
5.5.5 g) the maintenance plan, where appropriate, and maintenance carried out to date;		*Changed Equiv*	6.4.13 g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;	

5.5.5 h) any damage, malfunction, modification or repair to the equipment.		*Changed Equiv*	6.4.13 h) details of any damage, malfunction, modification to, or repair of, the equipment.	
5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.		*Changed Equiv*	**6.4.3** The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.	
5.5.6 NOTE: Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.		*Changed Equiv*	**6.4.2** When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.	

5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).		*Changed Equiv*	**6.4.9** Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).	
5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.		*Changed Equiv*	**6.4.8** All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity. 6.4.13 f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;	

5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.		*Changed Equiv*	**6.4.2** When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.	
5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.		*Changed Equiv*	**6.4.10** When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.	
5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.		*Changed Equiv*	**6.4.11** When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.	
5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.		*Changed Equiv*	**6.4.12** The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.	

Reference: 17025:2005	Mark E if Exact Match	Indicate whether the language 'Changed - Equiv ' 'Changed - Not Equiv 'or was 'Deleted'.	17025:2017 reference (add the language if different from 2005) *Give an opinion of whether the rewording is equivalent to the previous language*	**Drop** 2005 language or **Keep**
5.6 Measurement Traceability			*The 2005 standard separates "calibration laboratories" & "testing laboratories". The 2017 puts them together.*	

5.6.1 General (ISO/IEC 17025:2005, Clause 5.6.1) *All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.*		Changed - Equiv	**6.4.4** The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service. **6.4.5** The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. **6.4.6** Measuring equipment shall be calibrated when: — the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or — calibration of the equipment is required to establish the metrological traceability of the reported results. NOTE Types of equipment having an effect on the validity of the reported results can include: — those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement; — those used to make corrections to the measured value, e.g. temperature measurements; — those used to obtain a measurement result calculated from multiple quantities.	

			6.4.7 The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.	
5.6.1 NOTE: Such a programme should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.		*Deleted*	*The note itself is deleted but the content is basically a summary of everything in 6.4.9 so the note itself doesn't seem necessary*	Pull some form of this language into draft standard- Drop
5.6.2Specific Requirements (ISO/IEC 17025:2005, Clause 5.6.2)				
5.6.2.1 Calibration				
5.6.2.1.1 For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (Système international d'unités).		Changed - Equiv	**6.5.1** The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty". NOTE 2 See Annex A for additional information on metrological traceability.	

5.6.2.1.1 (cont.) A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).			**6.5.2** The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through: a) calibration provided by a competent laboratory; or NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent. c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards. NOTE 3 Details of practical realization of the definitions of some important units are given in the SI brochure.	

5.6.2.1.1 NOTE 1: Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.		Changed - Not Equiv	6.5.2 a) calibration provided by a competent laboratory; or LP: NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent. I would consider Note 1 under 6.5.2 to make it "equivalent". We'll leave as Not Equivalent to review again as a group.	This c
5.6.2.1.1 NOTE 2: Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).		Changed - Not Equiv	6.5.2 b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or	
5.6.2.1.1 NOTE 3: Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.		Changed - Not Equiv	6.5.2 c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.	

5.6.2.1.1 NOTE 4: The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.		*Deleted*	*7.8.4.1.e* In addition to the requirements listed in 7.8.2, calibration certificates shall include the following: e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);	
5.6.2.1.1 NOTE 5: When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.		*Deleted*	Exact note deleted but implied in 6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through: c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.	
5.6.2.1.1 NOTE 6: Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located.		*Deleted*	Exact note deleted but implied by simply stating the measurement has to be traceable to SI	
5.6.2.1.1 NOTE 7: If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.		*Deleted*	Exact note deleted but implied by simply stating the measurement has to be traceable to SI	

5.6.2.1.1 NOTE 8: The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.		Changed - Equiv	**A.2.1** Metrological traceability is established by considering, b) a documented unbroken chain of calibrations going back to stated and appropriate references (appropriate references include national or international standards, and intrinsic standards); c) that measurement uncertainty for each step in the traceability chain is evaluated according to agreed methods; d) that each step of the chain is performed in accordance with appropriate methods, with the measurement results and with associated, recorded measurement uncertainties; e) that the laboratories performing one or more steps in the chain supply evidence for their technical competence.	

5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as: • *the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;* • *the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.* *Participation in a suitable programme of interlaboratory comparisons is required where possible.*		Changed - Equiv	**6.5.3** When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.: b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.	
5.6.2.2 Testing				

5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.		Changed - Equiv	**6.4.5** The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. **6.4.6** Measuring equipment shall be calibrated when: — the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or — calibration of the equipment is required to establish the metrological traceability of the reported results. NOTE Types of equipment having an effect on the validity of the reported results can include: — those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement; — those used to make corrections to the measured value, e.g. temperature measurements; — those used to obtain a measurement result calculated from multiple quantities. **6.4.7** The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.	

5.6.2.2.1 NOTE: The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.		*Deleted*		
5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).		Changed - Equiv	**6.5.3** When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.: a) certified values of certified reference materials provided by a competent producer; b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.	
5.6.3 Reference Standards and Reference Materials *(ISO/IEC 17025:2005, Clause 5.6.3)*				

5.6.3.1 Reference Standards *The laboratory shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.*		Changed - Equiv	**6.4.7** The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration. **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;	

5.6.3.2 Reference Materials *Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.*		Changed - Equiv	**6.5.2** The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through: a) calibration provided by a competent laboratory; or NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent. b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent. c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards. **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; **6.4.10** When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.	
5.6.3.3 Intermediate Checks *Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.*		Changed - Equiv	**6.4.10** When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.	
5.6.3.4 Transport and Storage *The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.*		Changed - Equiv	**6.4.3** The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.	
5.6.3.4 NOTE Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.		Changed- Equiv	**6.4.2** When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met. Mentioned in 6.4.2	

Reference: 17025:2005	**Mark E if Exact Match**	**Indicate whether the language 'Changed - Equiv ' 'Changed - Not Equiv 'or was 'Deleted'.**	**17025:2017 reference (add the language if different from 2005)** *Give an opinion of whether the rewording is equivalent to the previous language*	**Drop** 2005 language or **Keep**
5.7 Collection of Samples ***(ISO/IEC 7025:2005, Clause 5.7)***		*Changed – Equiv*	**7.3 Sampling**	

5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.		*Changed – Equiv*	**7.3.1** The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. ***Comment – Combined sampling plan and sampling procedure into sampling method. Rearranged sentences.***	

5.7.1 NOTE 1: Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g. forensic analysis), the sample may not be representative but is determined by availability.		*Deleted*		DROP *Current 2016 definition "Sampling: Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure."* *Note 1 should remain "dropped" and the definition in module 2 should be more robust.*

5.7.1 NOTE 2: Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.		*Changed – Not equiv*	**7.3.2** The sampling method shall describe: a) the selection of samples or sites; b) the sampling plan; c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration. ***Comment - Content is equivalent but changed from note to requirement (should to shall).***	DROP (& keep below) Note 2 is a repeat of verbiage in 5.7.1 so was not necessary originally. The addition of 7.3.2 in the 2017 Standard should not be incorporated into the next TNI Standard. In my opinion requiring a laboratory to be prescriptive in a sampling method (other than how the samples are processed once they are accepted into the lab) places more responsibility

				on the laboratory than any other entity who may sample, handle and submit samples for laboratory analysis. KEEP I would incorporate (keep) 7.3.2 c) in some form for how a laboratory treats submitted samples and let the FSMOs address sampling. 5/9/22 – Section 7.3.1 is clear that this section is for labs performing sampling. No need to add

				anything to the standard.
5.7.2Where the customer requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.		*Changed – Not equiv*	**7.3.3** The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant: h) deviations, additions to or exclusions from the sampling method and sampling plan. ***Comment – Previous standard implied that sampling deviations be documented on the final report to the client. Unless you interpret "method" in 7.8.2.1.n. to include "sampling method" (below). Also previously required communication to personnel which seems obvious anyway.*** **7.8.2.1.n** Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse: n) additions to, deviations, or exclusions from the method;	Drop

5.7.3The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.		*Changed – Not equiv*	**7.3.3** The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant: a) reference to the sampling method used; b) date and time of sampling; c) data to identify and describe the sample (e.g. number, amount, name); d) identification of the personnel performing sampling; e) identification of the equipment used; f) environmental or transport conditions; g) diagrams or other equivalent means to identify the sampling location, when appropriate; h) deviations, additions to or exclusions from the sampling method and sampling plan. ***Comment – Items b,c, and e are added to the list. All list items are now under the "where relevant" umbrella. Reference to statistics removed. No emphasis on having a procedure only what records are necessary.***	Drop keep 2017 ISO language as is. Separate sampling done outside lab vs in lab. Consider