

Field Activities Expert Committee (FAC)

Meeting Summary March 19, 2019

1. Roll call:

Chair, Scott Haas, called the FAC meeting to order on March 19, 2019 at 11am Eastern by teleconference and Webex. Attendance is recorded in Attachment A – there were 7 members present. Associate Members: None.

Meeting minutes are sent to the committee by email. If no comments are received within one week of the email notification, they are considered approved and are posted on the TNI website.

2. Standard Update

The committee continued its review of the combined Standard to look for duplicate language.

A copy of track changes made to the combined document during the meeting can be found in Attachment E. The Committee stopped at Section 7.2.1.7.

3. New Business

None.

4. Action Items

The table in Attachment C summarizes all action items. See notes on table.

5. Next Meeting

The next meeting will be on Monday, 4-1-19 by teleconference at 11am Eastern. Ilona will send out the Webex invitation on 4/1/19.

The meeting was adjourned at 12:33pm Eastern.

Attachment A

**Participants
TNI Field Activities Committee**

| Members | Term Expires | Affiliation | Balance | Contact Information |
|---|---------------------|------------------------------------|----------------|--|
| Scott Haas (Chair) Present | 2022 | Environmental Testing, Inc. | FSMO | shaas@etilab.com |
| Shannon Swantek (Vice-Chair) Present | 2020 | ESI | Other | sswantek@envstd.com |
| Kevin Holbrooks Present | 2020 | Jacksonville Electric Authority | Other | holbke@jea.com |
| Doug Berg Absent | 2020* | PJLA | AB | dberg@PJLabs.COM |
| David Fricker Present | 2022* | A2LA | AB | dfricker@a2la.org |
| Kieth Klemm Absent | 2021* | ANAB | AB | kklemm@anab.org |
| Marlene Moore Present | 2021* | Advanced Systems, Inc. | Other | mmoore@advancedsys.com |
| Andora Nguyen Absent | 2022 | Eurofins Eaton Analytical | Other | AndoraNguyen@eurofinsUS.com |
| Bill Ray Absent | 2021* | William Ray Consulting, LLC | Other | Bill_Ray@williamrayllc.com |
| Russell Schindler Absent | 2021* | SampleServe | FSMO | schindler@sampleserve.com |
| Kira Stokes Present | 2021* | HRSD | FSMO | Kstokes@HRSD.com |
| Tyler Sullens Present | 2021* | Alabama Power Company | FSMO | tasullen@southernco.com |
| Elizabeth West Absent | 2021* | Louisiana DEQ | AB | elizabeth.west@la.gov |
| Ilona Taunton (Program Administrator) Present | | The NELAC Institute | | Ilona.taunton@nelac-institute.org |

Attachment B

NEFAP ADVOCACY SCHEDULE

| Organization | Event | Type of Presentation | Event Dates | Presenter |
|---|--|----------------------|------------------|---|
| Past Events | | | | |
| Midwest Groundwater Association | 2009 Annual Midwest Groundwater Conference | Poster | October 15, 2009 | Justin Brown |
| National Groundwater Association | 2010 National Groundwater Summit | Speaking | April 13, 2010 | Justin Brown |
| US Department of Defense | 2010 EDQW | Speaking | April 15, 2010 | Justin Brown |
| AEHS Foundation, Inc | 26th Annual International Conference on Soils, Sediments, Water, and Energy | Poster | October 18, 2010 | Declined Invitation (nobody to present) |
| US Environmental Protection Agency | 20 th Annual Quality Assurance Conference | Speaking | October 20, 2010 | Jo Ann Boyd |
| Pacific Northwest Clean Water Association | 2010 Annual Conference | Speaking | October 26, 2010 | Keith Champman |
| NWEC | 2010 Northwest Environmental Conference | Speaking | December 6, 2010 | Scott Hoatson |
| Midwest Water Analysts Association | 2011 Winter Expo | Speaking | January 28, 2011 | Justin Brown |
| Battelle | Battelle for the International Conference on Remediation of Contaminated Sediments | Poster | February 7, 2011 | Declined Invitation (nobody to present) |
| SSAAP | Stationary Source Sampling and Analysis for Air Pollutants XXXV Conference | Speaking | March 20, 2011 | Scott Evans |
| American Water Works Association | 2011 Watercon | Speaking | March 20, 2011 | Justin Brown |
| US Department of Defense | 2011 EDQW | Speaking | March 28, 2011 | Justin Brown |
| ASQ | 2011 ASQ Energy and Environment Conference | Speaking | | Randy Query |
| US Environmental Protection Agency | 2011 Annual EPA Quality Assurance Conference | Speaking | October 18, 2011 | Jo Ann Boyd |
| Midwest Environmental Laboratory Stakeholders | 2011 MELSS Annual Meeting | Speaking | December 2, 2011 | Justin Brown |

| Organization | Event | Type of Presentation | Event Dates | Presenter |
|--|--|--------------------------------|-----------------------------------|---|
| | 2012 Environmental Regulatory and Compliance Conference | Speaking | | Calista Daigle |
| US Environmental Protection Agency | 2012 On-site testing conference | Speaking | January 23, 2012 | Lauren Smith |
| US Department of Defense | 2012 EDQW | Speaking | March 2012 | Justin Brown/ Marlene Moore |
| Stack Testing Accreditation Council | 2012 Source Evaluation Society Annual Conference | Speaking | March 7, 2012 | Maggie Cangro |
| Texas Commission for Environmental Quality | 2012 TCEQ Environmental Trade Fair and Conference | Speaking | May 1, 2012 | Mike Shepard |
| US Environmental Protection Agency | 2012 Annual EPA Quality Assurance Conference | Speaking | October 15, 2012 | Jo Ann Boyd |
| PIANC USA/ COPRI ASCE | 2012 Dredging PIANC/ COPRI ASCE | Speaking | October 22, 2012 | Declined Invitation (nobody to present) |
| Environmental Protection Agency / Dept. of Homeland Security | 2013 On-site Analysis Conference | Speaking | January 23, 2013 | Lauren Smith |
| Louisiana Water Environment Association | 21st Annual Technical Exhibition and Conference Louisiana Water Environment Association Conference | Speaking | April 18, 2013 | Tracy Szerszen |
| Oregon Environmental Laboratory Association | OELA/ORELAP Annual Environmental Lab Workshop | Speaking | May 16, 2013 | Kim Watson |
| Florida Society of Environmental Analysts | 2013 FSEA Annual Spring Meeting and Technical Session | Speaking/ Technical Seminar | May 22, 2013 | John Moorman |
| State Assessor Forum | Conference Call | Speaking / Q&A | July 22, 2013 | Justin Brown Marlene Moore |
| US Army Corp of Engineers | Regional Workshop | Speaking | September 11 th , 2013 | John Moorman |
| US Environmental Protection Agency | 2013 Annual EPA Quality Assurance Conference Conference | Speaking | October 14, 2013 | Jo Ann Boyd |
| Florida Society of Environmental Analysts | Field Quality Systems Workshop | Speaking | October 23 rd , 2013 | John Moorman |
| Illinois Association of Environmental Testing Labs | Midwest Environmental Stakeholder Summit | Speaking | December 6 th , 2013 | Jerry Parr |
| TWUA | ?? | Speaking | March 10 th , 2015 | JoAnn Boyd |

| Organization | Event | Type of Presentation | Event Dates | Presenter |
|------------------------------------|---|-----------------------------|--------------------|--|
| US Environmental Protection Agency | 2014 Annual EPA Quality Assurance Conference | Speaking | October 24, 2014 | Jo Ann Boyd |
| TCEQ | TCQ Trade Fair | Speaking | May 5, 2015 | Marlene Moore |
| NEMC/TNI | NEMC Conference – Full Day Training: Sample Collection Design and Accreditation – Is Your Sample Data Defensible? | Speaking | July, 17, 2015 | Marlene Moore |
| FSEA | FSEA Meeting Workshop | Speaking | October 28, 2015 | John Moorman (Additional: Mitzi Miller, Katie Strothman, Kelly feist, Mike Shepherd, Chris Gunning, Doug Berg) |
| FSEA | FSEA Meeting Workshop – NEFAP Forum | Speaking | May 25, 2016 | John Moorman (Additional: Calista Daigle, Katie Strothman, Mike Shepherd, Chris Gunning, Doug Berg) |
| TNI | NEFAP Forum | Webinar | June 13, 2016 | John Moorman |
| NEMC/TNI | NEFAP Workshop | Speaking | August 10, 2016 | John Moorman |
| Dallas – Pretreatment Coordinators | Dinner Meeting | Speaking | March 6, 2017 | Jerry Parr |
| | | | | |
| Upcoming Events | | | | |
| | | | | |
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Attachment C

Action Items – FAC

| | Action Item | Who | Expected Completion | Actual Completion |
|-----|--|--------------------|---|--|
| 47 | Update Presentation Summary and distribute before meetings. (Prepare table of speaking engagements. This will be added to minutes and website. Follow-up with Scott Hoatson, Jan and other committee members to find out about other speaking engagements to add to the summary table being prepared.) | JoAnn Justin | Each Meeting | Ongoing 1-15-13: Ilona meeting with William to set this up to add to website. 4/20/13: Ilona requested status update from William. |
| 132 | Plan Tools Subcommittee Meeting after the Orange County meeting. | Ilona/Kevin | 8/31/16 | In Progress |
| 142 | Send Scott Scope Subcommittee Charter and DRAFT update to Charter. | Kevin | 7/17/17 | |
| 144 | Review last Standard Update information in upcoming committee meeting. | All | TBD | |
| 152 | Compare 2014 FSMO Standard to new ISO/IEC 17025:2017. Move language into new format – first DRAFT. | Shannon | 5/21/18 | Still in progress. |
| 153 | Send Shannon a copy of the current LAB Standard. Shannon will forward to the Committee. | Marlene Shannon | 7-9-18 | |
| 154 | Comment on the DRAFT AB Standard with the 2014 Standard language transferred into the new ISO/IEC 17011:2017 document. Did things get moved to the right sections? Was everything moved? | All | 7-16-18 | |
| 155 | Compare the DRAFT Field AB Standard to work being done at LAB. Present to FAC. | Marlene | Before next meeting after receiving document based on Action item #154. | |

| | Action Item | Who | Expected Completion | Actual Completion |
|-----|--|------------|------------------------------|--------------------------|
| 156 | Read NEFAP: 2014 and ISO/IEC 17025:2017 | All | Added 9/18/18: 10/1/18 | |
| 157 | From NOLA Meeting: Discern added value to be included <ul style="list-style-type: none"> ◦ Make a list ◦ Prioritize Items ◦ Start with Section 4 ISO/IEC 17025:2017 (Marlene) ◦ Evaluate Section 4 at next FAC meeting and assign new sections | All | TBD | |
| 158 | From NOLA Meeting: Seek Stakeholder Input for the new outline <ul style="list-style-type: none"> ◦ Interview data user/engineering firms ◦ AB survey current FSMO <ul style="list-style-type: none"> ▪ What is value added? | All | TBD | |
| 159 | From NOLA Meeting: Public Meeting/Webinar for Input | All | TBD | |
| 160 | From NOLA Meeting: Read ISO 17011:2017 <ul style="list-style-type: none"> • Plan Update w/ABs | All | Added 9/18/18: 10/1/18 | |
| 162 | Color code DRAFT AB Standard. | Scott | TBD | |
| 167 | | | | |
| 168 | | | | |
| 169 | | | | |
| 170 | | | | |

Attachment D

Backburner / Reminders – FAC

| | Item | Meeting Reference | Comments |
|---|--|--------------------------|--|
| 2 | Review charter in October 2019. | 2/2/11 | Standing task. 12/3/18: Will be done in Milwaukee. |
| 3 | Analyze container issue and present initial plan to committee. Started in 2014 and summarized 4/24/15 and at the Chicago meeting in July 2015. Subcommittee: Justin, Terrence, Kevin, Scott | 2014 | There was not enough interest to form a subcommittee with the proper representation, so this has been tabled until there is more interest. |
| 4 | | | |
| | | | |
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Attachment E.

6.2.5 The laboratory shall have procedure(s) and retain records for:

f) monitoring competence of personnel.

4.2.8 The data integrity procedures shall provide assurance that a highly ethical approach to field sampling and measurement is a key component of all FSMO planning, training and method implementation.

The data integrity procedures shall include provisions for the following:

- a) data integrity training provided as an element of new-hire employee training and during refresher training at least annually;
- b) formal commitment to data integrity procedures signed by all FSMO employees;
- d) in-depth periodic review of data to verify its integrity and compliance with data integrity procedures;
- e) the data integrity procedures shall be signed and dated by senior management;
- f) the data integrity procedures and the associated implementation records shall be properly maintained; and
- g) the data integrity procedures shall be reviewed annually and updated by management as needed.

6.2.6

a)

B)

Commented [SH1]: Stopping point for 3/4/2017 meeting.

Deleted: ISO/IEC 17025:2005(E), Clause 5.2.1

The 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.

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.

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...

Commented [SH2]: Review in the future, do we want to keep this level of prescription in the new standard.

Deleted: development, modification, verification and validation of methods;...

Deleted: 5.2.5 ISO/IEC 17025:2005(E), Clause 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...

Deleted: 5.4.3 Laboratory-Developed Methods (ISO/IEC 17025:2005(E), 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...

Deleted: analysis of results, including statements of conformity or opinions and interpretations;

Deleted: 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...

Deleted: 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...

a) report, review and authorization of results.

5.3 Accommodation and Environmental Conditions (ISO/IEC 17025:2005(E) Clause 5.3)

5.3.1

NOTE: Field personnel should document sampling and measurement conditions that may affect the quality of results including, but not limited to, air temperature, ambient conditions, weather conditions, tides, stream stage, etc. Descriptions of sample conditions (e.g. turbidity, odor, less than optimal sample quantity, etc.) should also be noted.

6.3.2

6.3.3

6.3.4

a) access to and use of areas affecting laboratory activities;

b) prevention of contamination, interference or adverse influences on laboratory activities;

6.3.5

6.4 Equipment

5.5 Equipment (ISO/IEC 17025:2005(E) Clause 5.5)

6.4.2

Deleted: 4.14 Internal Audits (ISO/IEC 17025:2005(E) Clause 4.14)¶

¶ 4.14.1 ISO/IEC 17025:2005(E), Clause 4.14.1¶

¶ The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard. The internal audit programme shall address all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.¶ ... [6]

Deleted: 5.2.5 ISO/IEC 17025:2005(E), Clause 5.2.5¶ ... [7]

Deleted: Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to ensure that the quality of the tests and/or calibrations shall be... [8]

Deleted: 5.4.7.2 When computers or automated equipment are used for the acquisition, processing, and storage of test results, the laboratory shall ensure that the equipment is... [9]

Deleted: 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 ensure that the quality of the tests and/or calibrations shall be... [10]

Deleted: 5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures, or as otherwise specified in the test methods. [11]

Deleted: Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to: [12]

Deleted: 5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled to prevent contamination, interference or adverse influences on laboratory activities. [12]

Deleted: 5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures, or as otherwise specified in the test methods. [13]

Deleted: ¶ c) effective separation between areas with incompatible laboratory activities.¶ [14]

Deleted: 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 ensure that the quality of the tests and/or calibrations shall be... [14]

Deleted: 4.1.3 ISO/IEC 17025:2005(E), Clause 4.1.3(Maybe ?)¶ ... [15]

Deleted: 5.5.1 ISO/IEC 17025:2005(E), Clause 5.5.1¶ The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the tests and/or calibrations. [16]

Deleted: 5.5.2 ISO/IEC 17025:2005(E), Clause 5.5.2¶ The laboratory shall ensure that the equipment is maintained in a state of good working order and that it is calibrated and verified at specified intervals, and before use, against national or international standards. [17]

6.4.3

5.5.3 ISO/IEC 17025:2005(E), Clause 5.5.3

5.5.6 ISO/IEC 17025:2005(E), Clause 5.5.6

6.4.4

6.4.5

6.4.6 Measuring equipment shall be calibrated when:

- those used to obtain a measurement result calculated from multiple quantities.

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.

6.4.7

Calibration programmes shall be established for key quantities or values of the instruments where these properties have a significant effect on the results

5.6.2.1.4 Instruments/equipment used for environmental sampling and field measurement activities shall be calibrated (where applicable) prior to use. The following items are essential elements of initial instrument/equipment calibration:

Deleted: 5.5.9 ISO/IEC 17025:2005(E), Clause 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

Deleted: 5.5.1 ISO/IEC 17025:2005(E), Clause 5.5.1
 ¶ 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...

Deleted: 5.4 Methods and Method Validation (ISO/IEC 17025:2005(E) Clause 5.4)
 ¶
 5.4.1 General (ISO/IEC 17025:2005(E), Clause 5.4.1)
 ¶
 ¶ The laboratory shall have instructions on the use and operation of all relevant equipment, and on...

Deleted: ¶
 5.4.7.2—When computers or automated equipment are used for the acquisition, processing, recording...

Deleted: Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including...

Deleted: The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure...

Deleted: 5.4.7.2—When computers or automated equipment are used for the acquisition, processing...

Deleted: 5.4.7.2—When computers or automated equipment are used for the acquisition, processing...

Deleted: 5.5.2—ISO/IEC 17025:2005(E), Clause 5.5.2
 ¶ Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy...

Deleted: 5.6—Measurement Traceability (ISO/IEC 17025:2005(E) Clause 5.6)
 ¶
 General (ISO/IEC 17025:2005(E), Clause 5.6.1) ¶...

Deleted: 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...

Commented [SH3]: Also see 7.6

Deleted: 5.6.3—Reference Standards and Reference Materials (ISO/IEC 17025:2005(E) Clause 5.6.3)
 ¶
 ... [27]

Deleted: 5.6.1 General (ISO/IEC 17025:2005(E), Clause 5.6.1)
 ¶
 ... [28]

Commented [SH4]: This appears to have originated from 5.5.2. It is only a portion of this section.

Commented [SH5]: This sentence needs to be rewritten per discussion 3/19/2019.

a) The details of the initial instrument/equipment calibration procedures including calculations, integrations, acceptance criteria and associated statistics shall be documented.

b) Sufficient raw data records shall be retained to permit reconstruction of the initial instrument/ equipment calibration (e.g., calibration date, method, instrument/equipment ID, analyte(s) being calibrated, calibrator's initials or signature, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument/equipment responses to concentration).

c) Criteria for the acceptance of an initial instrument/equipment calibration and calibration verification shall be established. The criteria used shall be appropriate to the calibration technique employed.

d) If the initial instrument/equipment calibration or applicable calibration verification results are outside established acceptance criteria, corrective actions shall be performed and all associated samples reanalyzed if possible.

e) When continuing calibration checks are needed to maintain confidence in the calibration status of the instrument/equipment, these checks shall be carried out according to a defined procedure.

f) Data associated with an unacceptable initial or continuing instrument/equipment calibration shall be reported with appropriate data qualifiers.

g) Records of reference standard used for calibrations and reference material certificates shall be retained.

6.4.8

6.4.9

6.4.10

6.4.11

Commented [SH6]: Does this belong here with 6.4 Equipment or 6.5 Metrological traceability.

Deleted: 5.5.8—ISO/IEC 17025:2005(E), Clause 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.

Deleted: 5.5.7—ISO/IEC 17025:2005(E), Clause 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).

Deleted: 5.5.10—ISO/IEC 17025:2005(E), Clause 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.¶

Deleted: 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.

Deleted: ¶
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...

Deleted: 5.5.11—ISO/IEC 17025:2005(E), Clause 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....

6.4.12

5.1.2 ISO/IEC 17025:2005(E), Clause 5.1.2

The 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.

Commented [SH7]: Previously inserted.

Deleted: 5.5.12 -ISO/IEC 17025:2005(E), Clause 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.

Deleted: 5.5.4.1 -Records shall be maintained of the specific items or types of equipment used to collect a sample or to complete a measurement.

Page Break

ISO/IEC 17025:2005(E), Clause 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:

6.4.13

a)

Deleted: 5.5.5 a) the identity of the item of equipment and its software

b)

Deleted: 5.5.5 b) the manufacturer's name, type identification, and serial number or other unique identification:

c)

5.5.4 -ISO/IEC 17025:2005(E), Clause 5.5.4
Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

d)

Deleted: 5.5.5 c) checks that equipment complies with the specification (see 5.5.2);

e)

Deleted: 5.5.5 d) the current location, where appropriate

f)

Deleted: 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

g)

Deleted: 5.5.5 g) the maintenance plan, where appropriate, and maintenance carried out to date

h)

Deleted: 5.5.5 h) any damage, malfunction, modification or repair to the equipment.
5.5.5 e) -the manufacturer's instructions, if available, or reference to their location

6.5 Metrological traceability

6.5.1

NOTE 2 See Annex A for additional information on metrological traceability.

Commented [SH8]: Will need to incorporate Annex A from ISO 17025, 2017

Deleted: 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 ... [29]

6.5.2

Deleted: 5.6.2-Specific Requirements (ISO/IEC 17025:2005(E), Clause 5.6.2)
5.6.2.1-Calibration (ISO/IEC 17025:2005(E))[30]

a) calibration provided by a competent laboratory; or

NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.

6.5.3

a)

b)

6.6 Externally provided products and services

4.5 Subcontracting of Environmental Sampling and Field Measurement Activities (ISO/IEC 17025:2005(E) Clause 4.5)

4.5.4 A competent subcontractor is one that, for example, complies with this TNI Standard for the work in question.

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 :

a) ;

b) ;

c) ;

4.4.3 The review shall also cover any work that is subcontracted by the laboratory.

Deleted: 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 ¶

Deleted: 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. ¶

... [31]

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 ¶

... [32]

Deleted: 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 ¶

... [33]

Deleted: 4.5.1 —When a laboratory subcontracts work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising) ¶

... [34]

Commented [SH9]: Reword to “accredited” per 3/19/2019 conference call.

Deleted: 4.6 → Purchasing Services and Supplies (ISO/IEC 17025:2005(E) Clause 4.6) ¶

¶ 4.6.1 —The laboratory shall have a policy and procedure(s) for the selection and purchasing of ¶

... [35]

Deleted: 4.4 —Review of Requests, Tenders and Contracts (ISO/IEC 17025:2005(E) Clause 4.4) ¶

4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these ... ¶

... [36]

Deleted: 4.4.1 a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2); ¶

Deleted: 4.4.1 (b) the laboratory has the capability and resources to meet the requirements; ¶

From FSMO 2014 Section 4.5.2

The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

d)

7.1.2

7.1.4

7.1.5

7.1.6

4.7 Service to the Customer (ISO/IEC 17025:2005(E) Clause 4.7)

4.7.1

a)

7.1.8

NOTE: For review of routine and other simple tasks, the date and the identification (e.g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1

Commented [SH10]: Should the requirement for "in writing" be retained?

Commented [SH11]: Previously included

Deleted: 4.4.1 (c) the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements (see 5.4.2).
5.4.2 Selection of Methods (ISO/IEC 17025:2005(E), Clause 5.4.2)
The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the Standard shall be supplemented with additional details to ensure consistent application.

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

Deleted: 5.4.2—Selection of Methods (ISO/IEC 17025:2005(E), Clause 5.4.2) ... [38]

Deleted: 4.4.1—
Any differences between the request or tender and the contract shall be resolved before any work ... [39]

Deleted: 4.4.4 The customer shall be informed of any deviation from the contract.

Deleted: 4.4.5 —If a contract needs to be amended after work has commenced, the same contract —review process shall be repeated and any amendments shall be communicated to all —affected personnel.

Deleted: The laboratory shall be willing to cooperate with customers or their representatives in —clarifying the customer's request and in monitoring the laboratory's performance in relation —to the work... [40]

Deleted: NOTE 1: —Such cooperation may include: —
providing the customer or the customer's ... [41]

Deleted: b) —preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.

Deleted: 4.4.2 —Records of reviews, including any significant changes, shall be maintained. Records shall —also be maintained of pertinent discussions with a customer relating to the customer's —requirements... [42]

Commented [SH12]: May be more appropriate in Section 6 per conference call 3/19/2019.

NOTE "Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.

7.2.1.2

7.2.1.3

7.2.1.4

5.4.3 Laboratory-Developed Methods (ISO/IEC 17025:2005(E), 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.

7.2.1.5

7.2.1.6

Stopped at Section 7.2.1.7

Deleted: 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.~~

Deleted: 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 ...~~ [43]

Deleted: 5.4.1 ~~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, ...~~ [44]

Deleted: 4.3 ~~Document Control (ISO/IEC 17025:2005(E) Clause 4.3)~~
4.3.1 ~~General~~ ... [45]

Deleted: 5.4.2 ~~Selection of Methods (ISO/IEC 17025:2005(E), Clause 5.4.2)~~
The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the customer and which are... [46]

Deleted: 5.4.2 ~~Selection of Methods (ISO/IEC 17025:2005(E), Clause 5.4.2)~~
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 ... [47]

Deleted: 5.4.2 ~~Selection of Methods (ISO/IEC 17025:2005(E), Clause 5.4.2)~~
The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

Deleted: 5.4.3 ~~Laboratory-Developed Methods (ISO/IEC 17025:2005(E), 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. ... [48]

Deleted: 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~~ [49]

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