Field Activities Expert Committee (FAC)

Meeting Summary
June 3, 2019

1. Roll call:

   Chair, Scott Haas, called the FAC meeting to order on June 3, 2019 at 11am Eastern by teleconference and Webex. Attendance is recorded in Attachment A – there were 6 members present. Associate Members: Bruce Weckworth.

   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

   Scott and Shannon weren't able to work on the duplicate language since the May meeting, so the committee continued its review of the combined Standard to look for duplicate language. The Committee started at Section 7.9.

   The Committee will want to use the TNI Glossary as they start updating the Standard. New definitions need to be communicated to Paul Junio and Bob Wyeth.

   A copy of track changes made to the combined document during the meeting can be found in Attachment E. The Committee completed the review. Attachment E provides a summary of the changes for the notes, but all the changes are in one document that has been stored with Track Changes turned on and it has been distributed to all the Committee members.

   Shannon asked if more will be added to the Standard now that we've finished up going through the language and working on format. Yes.

   Ilona noted that next steps will include discussion on items to add/delete to the Standard. This will help us put together our outline for our first public meeting (Webinar) to get feedback on the Standard revision.

   Scott will go back through his notes and see what is left to be done with the merging of ISO/IEC 17011:2017 and 2014 Field AB Standard.

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, July 1st by teleconference at 11am Eastern. *(Addition: The July meeting was canceled. The next meeting will be the face-to-face in Jacksonville on Thursday, August 8th at 1pm Eastern. A phone line will be available so all committee members can participate in the continued updating of the Standard and the initial discussion of what to add to the Standard.)*

The meeting was adjourned at 12:35pm Eastern. (Motion: Shannon Second: Kira Unanimously approved.)

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 **Absent**	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 **Present**	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 **Absent**	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	20th 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 Querry
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 11th, 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 23rd, 2013	John Moorman
Illinois Association of Environmental Testing Labs	Midwest Environmental Stakeholder Summit	Speaking	December 6th, 2013	Jerry Parr
TWUA	??	Speaking	March 10th, 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 Defensibile?	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				

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 ◦ 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 ◦ Interview data user/engineering firms ◦ AB survey current FSMO ▪ 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 • Plan Update w/ABs	All	Added 9/18/18: 10/1/18	
162	Color code DRAFT AB Standard.	Scott	TBD	
167	Finish up review of duplicate language and send to Committee for review during June meeting.	Scott Shannon	5/20/19	Done in June Meeting instead. Complete.
168				

Attachment D

Backburner / Reminders – FAC

	Item	Meeting Reference	Comments
2	Review charter in October 2018.	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			

Attachment E.

7.8.4.2

7.8.4.3

7.8.5 Reporting sampling – specific requirements

f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

and latitude, longitude, and altitude when sample point is not otherwise identified; see *Clause 5.1.3*;

including a description of sample preservation, transportation and storage and sample containers as on a chain of custody for example; see *Clauses 5.4.2.1, 5.5.4.1, and 5.5.6.1*;

7.8.6 Reporting statements of conformity

7.8.6.1

7.8.6.2

b)

7.8.7 Reporting opinions and interpretations

7.8.7.1

7.8.7.2

7.8.7.3

Commented [SH1]: Stopping point 4/15/2019

Deleted: 5.10.10 Reports of Sampling¶
¶
→The FSMO shall provide a unique identifier for each individual sample container. All relevant information, including special conditions, sampling and/or measurement dates and times, methods, all sampling and handling procedures used and items as described in sections 5.7.4 and 5.7.5, must be retained in the sampling records. ¶
¶
¶
5.10.11 Reports of Monitoring Instruments¶
¶
→Reports shall indicate whether the data are raw instrument readings or have been adjusted for calibration drift. Reports should include or indicate the availability of the categories of supporting and methodological information listed in *Clause 5.10.1*.¶

Deleted: *5.10.4.4 →A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. This requirement may be superseded by legal regulations.¶*

Deleted: *ISO/IEC 17025:2005(E) Clause 5.10.3.2*¶
¶
In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the... [1]

Deleted: *d) →a reference to the sampling plan and procedures used;*¶

Commented [SH3]: Previously inserted.

Deleted: *e) →details of any environmental conditions during sampling that may affect the interpretation of the test results;*¶
¶ ... [2]

Deleted: 5.6.2.1 Calibration (*ISO/IEC 17025:2005(E), Clause 5.6.2.1)*¶
¶
5.6.2.1.1 →For calibration laboratories, the programme for calibration of equipment shall be... [3]

Deleted: *5.10.4.2 →The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.*¶... [4]

Deleted: *<#>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 ... [5]

Deleted: 5.10.5 →Opinions and Interpretations *(ISO/IEC 17025:2005(E) Clause 5.10.5)*¶
¶
When opinions and interpretations are included, the laboratory shall document the basis upon which the... [6]

7.8.8 Amendments to reports

7.8.8.1

4.13.2.3 *ISO/IEC 17025:2005(E), Clause 4.13.2.3*

When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

7.8.8.2

7.8.8.3

7.9 Complaints

7.9.1

7.10 Nonconforming work

7.10.2

7.11 Control of data and information management

7.11.2

7.11.3 *The laboratory information management system(s) shall:*

Deleted: 5.10.5 Opinions and Interpretations (*ISO/IEC 17025:2005(E) Clause 5.10.5)*¶
¶
¶
NOTE 3: In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.¶

Commented [sm12]: From crosswalk, maybe does not fit?

Deleted: <#>Amendments to Test Reports and Calibration Certificates (*ISO/IEC 17025:2005(E) Clause 5.10.9)*¶

Deleted: *Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:*

Deleted: *"Supplement to Test Report [or Calibration Certificate], serial number... [or as otherwise identified]", or an equivalent form of wording. Such amendments shall meet all the requirements of this International Standard.*
¶

Deleted: <#>Amendments to Test Reports and Calibration Certificates (*ISO/IEC 17025:2005(E) Clause 5.10.9)*¶
<#>
When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.¶

Deleted: 5.10.7 Electronic Transmission of Results (*ISO/IEC 17025:2005(E) Clause 5.10.7)*¶
¶
In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the ... [7]

Deleted: ¶

Deleted: ***<#>Complaints (ISO/IEC 17025:2005(E) Clause 4.8)***¶
<#>¶ ... [8]

Deleted: ***<#>Control of Nonconforming Work (ISO/IEC 17025:2005(E) Clause 4.9)***¶
<#>¶ ... [9]

Deleted: *4.13.1.2 ISO/IEC 17025:2005(E), Clause 4.13.1.2*¶
¶ ... [10]

Deleted: *4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's* ... [11]

Deleted: *5.4.7.2 When computers or automated equipment are used for the acquisition, processing* ... [12]

Deleted: 5.5.2 *ISO/IEC 17025:2005(E), Clause 5.5.2*¶
¶ ... [13]

a) be protected from unauthorized access;

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:

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;

b)

c) be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

a) be maintained in a manner that ensures the integrity of the data and information;

e) .

7.11.5

7.11.6

8 Management system requirements

8.1 Options

8.1.1 General

4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;

b) the management's statement of the laboratory's standard of service;

c) the purpose of the management system related to quality;

Deleted: 4.13.1.4 ISO/IEC 17025:2005(E), Clause 4.13.1.4¶
¶
The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.¶
¶
4.13.1.4.1 Records that are stored only on electronic media shall be supported by the hardware and software necessary for their retrieval. ¶
¶
4.13.1.4.2 Records that are stored or generated by computers or personal computers shall have hard copy or secure backup copies. ¶

Commented [SH18]: Previously inserted.

Commented [SH19]: Should be included for more than just the LIMS system.

Deleted: 4.13.1.3 ISO/IEC 17025:2005(E), Clause 4.13.1.3¶
¶
All records shall be held secure and in confidence.¶

Moved down [1]: 4.13.1.4 ISO/IEC 17025:2005(E), Clause 4.13.1.4¶
¶
The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.¶
¶
4.13.1.2 ISO/IEC 17025:2005(E), Clause 4.13.1.2¶
¶
All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.¶

Deleted: 4.13.1.2 ISO/IEC 17025:2005(E), Clause 4.13.1.2¶
¶
All records shall be legible and shall be stored and ... [14]

Deleted: 4.13.1.2 ISO/IEC 17025:2005(E), Clause 4.13.1.2¶
¶
All records shall be legible and shall be stored and ... [15]

Moved down [2]: 5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval

Deleted: **4.13 Control of Records *(ISO/IEC 17025:2005€ Clause 4.13)*** ↵
¶ ... [16]

Deleted: ¶

Deleted: <#>Control of Data (*ISO/IEC 17025:2005(E), Clause 5.4.7)*¶
<#>¶ ... [17]

Moved (insertion) [3]

d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

e) the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system.

NOTE: The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.

NOTE See Annex B for more information.

8.1.2 Option A

8.2 Management system documentation (Option A)

8.2.1

8.2.2

4.1.5 ISO/IEC 17025:2005(E), Clause 4.1.5

b)

j)

8.2.3

Commented [SH31]: Included previously.

Moved (insertion) [4]

Commented [SH32]: Annex B will need to be incorporated

Moved up [3]: 4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;

b) the management's statement of the laboratory's standard of service;

c) the purpose of the management system related to quality;

Moved up [4]: 4.2.5 The quality manual shall include or make reference to the supporting procedures including

Deleted: The laboratory shall ... [18]

Deleted: have arrangements to ensure that its management and personnel are free from any ... [19]

Deleted: e) define the organization and management structure of the laboratory, its place ... [20]

Deleted: f) specify the responsibility, authority and interrelationships of all personnel who ... [21]

Deleted: documentation required shall include a clear description of the lines of responsibility in the ... [22]

Deleted: g) provide adequate supervision of testing and calibration staff, including trainees, by ... [23]

Deleted: h) have technical management which has overall responsibility for the technical ... [24]

Deleted: i) appoint a member of staff as quality manager (however named) who, irrespective of ... [25]

Deleted: j) appoint deputies for key managerial personnel (see Note);

Deleted: k

Deleted: ensure that its personnel are aware of the relevance and importance of their activities ... [26]

Commented [SH34]: This is a repeat entry of this section and subpoints. All have been inserted previously. ... [28]

Deleted: NOTE: Individuals may have more than one function and it may be impractical to ... [27]

Deleted: 4.2.3 Top management shall provide evidence of commitment to the development and ... [29]

8.2.5

8.3 Control of management system documents (Option A)

8.3.1

8.3.2 *The laboratory shall ensure that:*

[4.3.2.2] The procedure(s) adopted shall ensure that:

b)

4.3.3

4.3.3.1

d)

e)

f)

8.4 Control of records (Option A)

[4.3.1 NOTE 2]: The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.

8.4.2

4.13.1.4 ISO/IEC 17025:2005(E), Clause 4.13.1.4

The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

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:

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;

Deleted: *all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work;¶*

Deleted: *[4.3.1 –General]¶ –The laboratory shall establish and maintain procedures to control all documents that form part of its –management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, –specifications, instructions and manuals.¶*

Deleted: *NOTE 1: –In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.¶*

Commented [SH39]: Previously included

Deleted: *4.3.2.2.b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;¶*

Deleted: *4.3.2.2a) authorized editions of appropriate documents are available at all locations where operations –• –essential to the effective functioning of the laboratory are performed;¶*

Deleted: *4.3.2.3 –Management system documents generated by the laboratory shall be uniquely identified. Such –identification shall include the date of issue and/or revision identification, page numbering, the total –number of pages or a mark to signify the end of the document, and the issuing authority(ies).¶*

Deleted: *4.3.2.2c) –invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;¶*

¶

4.3.2.2d) –obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.¶

Commented [SH43]: Previously included

Commented [SH44]: Consider revising to provide reference to all areas where records are covered in the standard.

Moved (insertion) [1]

Commented [SH45]: Previously inserted.

Commented [SH46]: Consider keeping this as a note.

Moved (insertion) [2]

Commented [SH47]: Previously inserted.

8.5 Actions to address risks and opportunities (Option A)

NOTE 2: The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programmes using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

8.6 Improvement (Option A)

8.6.2

4.12 Preventive Action (*ISO/IEC 17025:2005(E) Clause 4.12)*

4.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

4.12.2 Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective.

NOTE 1: Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

NOTE 2: Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

8.7 Corrective actions (Option A)

8.7.1

8.7.2

8.8 Internal audits (Option A)

8.8.1

b) is effectively implemented and maintained.

Deleted: *4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:*
a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);
b) the laboratory has the capability and resources to meet the requirements;
c) the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements (see 5.4.2).
Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both ... [30]

Deleted: *NOTE 1: The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time* ... [31]

Commented [SH50]: Is this a note that should be retained?

Deleted: *NOTE 3: A contract may be any written or oral agreement to provide a customer with testing and/or calibration services.*

Deleted: **4.10 Improvement (*ISO/IEC 17025:2005(E) Clause 4.10)*** ... [32]

Deleted: *4.7.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management* ... [33]

Moved (insertion) [5]

Deleted: ***4.11 Corrective Action (ISO/IEC 17025:2005(E) Clause 4.11)***
4.11.1 General ... [34]

Deleted: *4.11.3 Selection and Implementation of Corrective Actions*
Where corrective action is needed, the laboratory ... [35]

Deleted: *4.11.4 Monitoring of Corrective Actions*
The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

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* ... [36]

Commented [SH51]: Previously inserted.

Deleted: *NOTE: The cycle for internal auditing should normally be completed in one year.*

4.14.1.1

4.14.2 *ISO/IEC 17025:2005(E), Clause 4.14.2*

8.8.2 *The laboratory shall:*

[4.11.5]

NOTE:

8.9 Management reviews (Option A)

8.9.1

- *the results of interlaboratory comparisons or proficiency tests;*
- *recommendations for improvement;*

NOTE 1: A typical period for conducting a management review is once every 12 months.

8.9.3 *The outputs from the management review shall record all decisions and actions related to at least:*

4.15.2 ISO/IEC 17025:2005(E), Clause 4.15.2

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.¶
¶ ... [37]

Deleted: *<#>ISO/IEC 17025:2005(E), Clause 4.14.3*¶
<#>¶ ... [38]

Deleted: *<#>ISO/IEC 17025:2005(E), Clause 4.14.4*¶
<#>¶ ... [39]

Deleted: *Such additional audits often follow the implementation of the corrective actions to confirm their effectiven…*

Moved up [5]: **4.12 Preventive Action (*ISO/IEC 17025:2005(E) Clause 4.12)***¶

Deleted: **4.15 Management Reviews *(ISO/IEC 17025:2005(E) Clause 4.15)***¶
4.15.1 *ISO/IEC 17025:2005(E), Clause 4.15.1*¶

Deleted: *In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of* ... [40]

Deleted: *<#>assessments by external bodies;*¶

Deleted: *<#>changes in the volume and type of work;...*¶
¶ ... [41]

Deleted: *<#>*¶
<#>customer feedback

Commented [SH58]: *8.9.3.b, 8.9.2 k*

Deleted: *<#>complaints;*¶

Deleted: *<#>other relevant factors, such as quality control activities, resources and staff training.* ¶

Commented [SH60]: Should this be a requirement instead of a note.

Commented [SH61]: Should management review identified issues be translated into corrective actions?

Deleted: *Findings from management reviews and the actions that arise from them shall be recorded.*

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