Quality Management System Expert Committee (QMS)
Meeting Summary

April 11, 2022

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on April 11, 2022. Attendance is recorded in Attachment A – there were 9 voting members present: There were 20 Associate members present: Joe Manzella, Lizbeth Garcia, Cody Danielson, Karna Holquist, Tiffany Shaw, Debra Zeller, Ty Atkins, Cindy Redmond, Kathleen Lloyd, Brian Lamarsh, Douglas Kablik, Linda O'Donnell, Kristin Brown, Dylan Lyon, Jeanette Hernandez, and Lisa Parks.

The March minutes will be reviewed by email and voted on at the next meeting.

2. Language from ISO/IEC 17011

Debbie shared a copy of the language the committee was sent by LAB Expert Committee to consider for inclusion into Module 2. The LAB Standard is in Volume 2 and most labs do not have a copy of this and are not aware of these requirements. Putting this information in Module 2 will make labs aware of these requirements.

Kathi reviewed the language and proposed language for Module 2:

> **For Draft Standard (end of 1.1 Introduction):**
> Laboratories accredited and seeking accreditation to this standard shall commit to meeting the requirements of this standard, as well as requirements of the accreditation body from whom they seek accreditation. It shall cooperate with the accreditation body to verify its fulfillment of the requirements including providing access to laboratory facilities, personnel, equipment, documents, records, and witnessing of conformity assessment activities to conformity assessment body personnel upon request. If applicable, the laboratory shall have arrangements with its client to provide, on request, access to accreditation body assessment teams to assess the laboratory's performance when carrying out laboratory activities at the client's site. The laboratory shall only claim accreditation for the scope for which it has been granted and shall comply with the accreditation body's policy for the use of the accreditation symbol. The laboratory shall commit to informing the accreditation body of significant changes relevant to its accreditation, and to assist in the investigation and resolution of any accreditation-related complaints referred to it by the accreditation body. The laboratory shall not use its accreditation in such a way that brings the accreditation body into disrepute. The laboratory shall pay fees as determined by the accreditation body.

Debbie asked for comments, but did not receive any.

Carl sent an email on April 6th asking the committee to also consider additional language:

> The first-part ISO/IEC 17011 Standard that invokes testing laboratory requirements by the accreditation body (clause 4.2) is good. I might also recommend the Quality Systems Committee consider clause 4.3.1, as follows:
>
> ISO/IEC 17011:2017(E), Clause 4.3.1
>
> The accreditation body shall take measures to ensure that the accredited conformity assessment body:
>
> *a) fully conforms to the requirements of the accreditation body for claiming accreditation status, when making reference to its accreditation in communication media;*
> *b) does not make any misleading or unauthorized statement regarding its accreditation;*
> *c) upon withdrawal of its accreditation, discontinues its use of any reference to that accreditation;*
> *d) does not refer to its accreditation in a way so as to imply that a product, process, service, management system, or person is approved by the accreditation body;*
> *e) informs its affected clients of the suspension, reduction, or withdrawal of its accreditation and the associated consequences without undue delay.*
>
> Perhaps, the V1M2 language should specify that the accredited testing laboratory comply with these requirements as well.
>
> Also, since the Laboratory Accreditation Body Expert Committee is proposing to add the NOTE for "see clause 8.2.3," it might be a good idea for the Quality Systems Committee to consider ISO/IEC 17011 Clause 8 in general. For example, clause 7.14.1 requires the AB to keep records on accredited laboratories; however, clause 8.1.1 specifies circumstances where that laboratory information could be made publicly available (versus kept confidential).

Debbie is OK with adding information from both of these sections to Module 2, but would like comments. The information Carl sent could be reworded as Kathi did with the other section in question. There were no comments, so Debbie will ask Kathi to reword this section too and place it into the Standard language.

3. QMS Language Updates Workgroup (Nicole)

Nicole reviewed the changes made to the Task 1 and Task 2 summaries included in Attachment B.

<u>Task 1</u>

See section with Clean Copy of Final Language.

A question was asked about use of the terms “document”, “procedure” and “instruction”. It is confusing. Seems like the ISO/IEC language generally refers to documented procedures, why was this changed? Nicole noted they actually tried to better match the language in the 2017 version of ISO/IEC 17025. She provided some examples. Debbie’s thoughts are to go ahead and put this language into the Standard and she will put a note off to the side to look at use of “instructions” verse “procedures”.

The 3 comments included in the workgroup document should be retained when the document is pasted into the Standard.

There were no further comments. Task 1 is complete.

Task 2

They removed a lot from this section. They removed the idea of “ID code”. You have to have unambiguous identification from the time the sample is received by the lab through the time it is reported.

Jenna asked if there could be some confusion on the term “test item”. Would everyone know this is a sample and not a piece of equipment? Nicole noted that this is ISO/IEC 17025 language. Nicole reminded people that this includes samples, extracts, etc. Add the following sentence: Test items may include samples, sample containers, subsamples, and subsequent extracts and/or digestates.

Kathleen (Section 5.8.5.a) – She is not sure that this thought is captured in the new language. Nicole reminded the group that the ISO/IEC 17025 language is also included. This takes care of the concern. Nicole noted that they added the need to document the system because the assessors were going to want to see something in writing.

Debbie added this new language to the Standard document. Task 2 is complete.

There are 3 more tasks the Workgroup is working on.

4. Crosswalk

The Committee continued to review the Crosswalk and adding language to the Standard starting at Section 4.10.

The Committee worked through Section 5.0. See blue language in Attachment C.

5. New Business

No new business.

6. Next Meeting and Close

The next meeting will be May 8, 2022 by teleconference/Webex at 1pm Eastern.

Debbie adjourned the meeting at 2:15 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) **Absent**	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 **Absent**	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Carla McCord **Present**	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Stephanie Atkins **Absent**	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson **Present at 1:43pm Eastern**	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen **Absent**	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak **Present**	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Zaneta Popovska **Present**	ANAB	2025*	AB	zpopovska@anab.org
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 **Absent**	KC Water	2024*	Lab	ashley.larssen@kcmo.org
Ilona Taunton (Program Admin) **Absent - Recorded**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B.

See PDF attachments sent with minutes. They will be inserted here.

Attachment C.

4.10 Improvement *(ISO/IEC 17025:2005, Clause 4.10)* *The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.*		*Changed – Not Equiv*	**8.6 Improvement (Option A)** **8.6.1** The laboratory shall identify and select opportunities for improvement and implement any necessary actions. NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results. ***Comment - New language is more open ended with specific examples being moved to a NOTE. Removes the implication that the lab must use all of the examples to identify improvements.***	DROP The items in the note are also required in other sections of the standard. No need to include them in a required paragraph.
4.11 Corrective Action *(ISO/IEC 17025:2005, Clause 4.11)*		*Changed – Equiv*	**8.1.2.B6 Option A** As a minimum, the management system of the laboratory shall address the following: — corrective actions (see 8.7);	

4.11.1 General *The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.*		*Changed – Not Equiv*	**8.7.1** When a nonconformity occurs, the laboratory shall: a) react to the nonconformity and, as applicable: — take action to control and correct it; — address the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: — reviewing and analysing the nonconformity; — determining the causes of the nonconformity; — determining if similar nonconformities exist, or could potentially occur; ***Comment - Requirement to have a specific CA policy/procedure is removed (could still be deemed required under 5.5.c). New version includes evaluation of need for CA versus correction. Previous version seems to imply that CA is needed for all non-conformances and does not distinguish between a correction and corrective action.*** **5.6** The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:	DROP The way 17025:2017 is written will continue to ensure non-conforming work is corrected.

			b) identification of deviations from the management system or from the procedures for performing laboratory activities; c) initiation of actions to prevent or minimize such deviations; ***Comment - Requirement to have appropriate authorities for identification and implementation of CA is equivalent.***	
4.11.1 NOTE: A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, and feedback from customers and from staff observations.		*Deleted*		DROP No need to state since it is obvious.
4.11.2 Cause Analysis *The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.*		*Changed – Not Equiv*	**8.7.1.b.** When a nonconformity occurs, the laboratory shall:…. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: — reviewing and analysing the nonconformity; — determining the causes of the nonconformity; — determining if similar nonconformities exist, or could potentially occur; ***Comment - Bullet point 3 adds emphasis on risk analysis as part of the cause analysis and corrective action process.*** *Missing the concept of root cause and no need for procedure.*	KEEP It would be better to have a procedure to ensure all items are covered. We also need to specify that the cause identified needs to be the root cause or the correction will not prevent the problem.

4.11.2 NOTE: Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.		*Deleted*		KEEP It is important to clarify that the root cause is not obvious and thus… Root cause could be defined in the Terms and Definitions section (3.1).
4.11.3 Selection and Implementation of Corrective Actions *Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.*		*Changed – Not Equiv*	**8.7.1** When a nonconformity occurs, the laboratory shall: c) implement any action needed; e) update risks and opportunities determined during planning, if necessary; f) make changes to the management system, if necessary. ***Comment – e and f added*** *Missing the requirement to identify potential corrective actions.*	DROP One has to identify actions needed to be able to implement.
4.11.3 (cont.) Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.		*Changed – Equiv*	**8.7.2** Corrective actions shall be appropriate to the effects of the nonconformities encountered.	

4.11.3 (cont.) The laboratory shall document and implement any required changes resulting from corrective action investigations.		*Changed – Equiv*	**8.7.1** When a nonconformity occurs, the laboratory shall: c) implement any action needed; f) make changes to the management system, if necessary. **8.7.3** The laboratory shall retain records as evidence of: a) the nature of the nonconformities, cause(s) and any subsequent actions taken; b) the results of any corrective action. ***Comment - Additional detail added for what documentation is necessary.***	
4.11.4 Monitoring of Corrective Actions *The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.*		*Changed - Equiv*	**8.7.1** When a nonconformity occurs, the laboratory shall: d) review the effectiveness of any corrective action taken;	

4.11.5 Additional Audits *Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.*		*Deleted*	***Comment - Deleted however additional audits could be considered as optional parts of the effectiveness review (8.7.1.d) or risk assessment (8.7.1b.B3).***	DROP This section is redundant when we take into account the need to investigate nonconforming work and the requirement to review the effectiveness of any corrective actions taken.
4.11.5 NOTE: Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.		*Deleted*		DROP See note in 4.11.5.
4.12 Preventive Action ***(ISO/IEC 17025:2005, 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.		*Changed – Equiv*	*8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions.* <u>Additional clauses that relate to preventive action:</u> *8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:* *c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;* *d) achieve improvement.* *8.5.2 The laboratory shall plan:* *a) actions to address these risks and opportunities;* *b) how to:* *— integrate and implement these actions into its management system;* *— evaluate the effectiveness of these actions.* I would consider the intent equivalent when all sections above are taken collectively.	

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.		*Deleted*	No requirement for a preventive action or improvement procedure found. Just a plan as noted in clause 8.5.2 above.	DROP 2017 now uses Risks and Opportunities which are the same when used properly. The section on Improvement is also involved.
4.12.2 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.		*Deleted*	No similar note	DROP No need as we move toward Risk & Opportunities and Improvement.
4.12.2 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.		*Changed – Equiv.*	*8.6.1 NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing 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**
4.13 Control of Records ***(ISO/IEC 17025:2005, Clause 4.13)***				
4.13.1 General				

4.13.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.		*Changed – Not Equiv*	*8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.* *8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.* I don't believe these sections are equivalent. No requirement for a procedure. Does not detail the types of records.	DROP 5.5.c includes a requirement to have procedures where needed. Records that fulfill the requirements of this document is a better way of explaining which records to keep.

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.		*Changed - Equiv*	*8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.* *8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.* I believe these sections taken together are equivalent to this clause.	

4.13.1.2 NOTE: Records may be in any media, such as hard copy or electronic media.		*Deleted*	No Note	DROP Record is defined in SOP 1-104 Control of TNI Documents as both paper and electronic. This definition could be added to the standard.
4.13.1.3 All records shall be held secure and in confidence.		*Changed - Equiv*	*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.* I believe this clause includes language that is equivalent	

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.		*Changed - Equiv*	*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.* I believe this clause includes language that is equivalent	
4.13.2 Technical Records				

4.13.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.		*Changed – Equiv*	*7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.* I don't believe these are equivalent, but taken with the general "control of records" section 8.4, I think covers all requirements. 7.5.1 is missing retention requirement, but those are covered in 8.4.	
4.13.2.1 NOTE 1: In certain fields it may be impossible or impractical to retain records of all original observations.		*Deleted*		DROP Adds confusion (original observations can always be kept even if original records cannot) and it was a note.

4.13.2.1 NOTE 2: Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.		*Deleted*		DROP This is a note that contains a list that is not as helpful as the general requirement in 8.4.1 & 8.4.2
4.13.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.	*E (last sentence of new clause)*		*7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.*	

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.		*Changed – Not Equiv*	*7.5.2 The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.* I don't believe these are equivalent. New language is not as specific in how to amend but does cover the intent in today's more electronic world. This section is also specific to Technical Records only.	KEEP This language accomplishes the same as the 2005 language but covers electronic records better without being too specific with one way of getting it done. NOTE: Consider including language that specifies personnel responsible for alterations has indicated he/she made the alteration.

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**
4.14 Internal Audits *(ISO/IEC 17025:2005, Clause 4.14)*			**Opinion: As many have discussed already, this section really wants to make the leap to risk based verbiage. I gave a class on this three years ago; the basis of which, was that ABs/Assessors would find it difficult to create "checklists" that were generic enough to provide similar assessments to the different types/sizes of environmental laboratories – thus every assessment would be in a sense "unique." I believe assessors like conformity, without it, their workload is going to increase. We will need heavy input from ABs to see if they can convince their state's to move towards risk based assessment. Without this input, it becomes difficult for TNI to use the ISO language in the manner it is intended.**	

*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.*		**Changed - Not Equiv**	8.8.1 The laboratory shall conduct internal audits at **planned intervals** to provide information on whether the **management system**: a) Conforms to: - the laboratory's own requirements for its management system, including the laboratory activities; - the **requirements of this document** b) is effectively implemented and maintained 8.8.2 The laboratory shall: a) plan, establish, implement and maintain an audit programme including the **frequency**, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits; **The term "procedure" is not in the new standard. The Quality Manager is missing, as well as an independent person to audit.**	DROP The records retained will show auditing was done properly. An independent person to audit is covered by conflict of interest language. Quality Manager responsibilities are listed under 5.6 (2017) from 2016 TNI 4.1.7.1.

4.14.1 NOTE: The cycle for internal auditing should normally be completed in one year.		**Deleted**	8.8.1 The laboratory shall conduct internal audits **at planned intervals** to provide information on whether the management system: *No note in the 2017 standard, but TNI requirements on audit frequency would take care of this.*	DROP Revised TNI language covers this.
*4.14.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and **shall notify customers** in writing if investigations show that the laboratory results may have been affected.*		**Changed - Equiv**	8.8.2 The laboratory shall: ensure that the results of the audits are reported **to relevant management**; *See 7.10.1e.*	

*4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them **shall be recorded**.*		**Changed - Equiv**	***8.8.2*** *The laboratory shall:* *a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;* *b) define the audit criteria and scope for each audit;* *c) ensure that the results of the audits are reported to relevant management;* *d) implement appropriate correction and corrective actions without undue delay;* *e) retain records as evidence of the implementation of the audit programme and the audit results.*	
4.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.		**Changed - Equiv**	8.8.2 The laboratory shall: implement appropriate correction and corrective actions without undue delay; *Missing the need to verify effectiveness, but corrective action section may bring in the effectiveness review.* Reviewing the effectiveness is covered in the Corrective Action section.	

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**
4.15 Management Reviews *(ISO/IEC 17025:2005, Clause 4.15)*				
4.15.1 In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:		Changed – Not Equiv	**8.9.1** The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document. **8.9.2** The inputs to management review shall be recorded and shall include information related to the following:	DROP Yes, Changed – Not Equiv but do we need in include testing activities? Internal audit should include testing activities and the suitability of policies and procedures should take care of the documents.

4.15.1 item 1 -- the suitability of policies and procedures;	*E*		*8.9.2* c) suitability of policies and procedures;	
4.15.1 item 2 -- reports from managerial and supervisory personnel;		*Deleted*	*But implied by 8.9.2* The inputs to management review shall be recorded and shall include information related to the following:	DROP Captured in 8.9.2
4.15.1 item 3 -- the outcome of recent internal audits;	*E*		e) outcome of recent internal audits;	
4.15.1 item 4 -- corrective and preventive actions;		*Changed – Not Equiv*	f) corrective actions; k) effectiveness of any implemented improvements; *Preventive actions are not specifically included, but the* **effectiveness** *of improvements is.*	DROP Covered by the review of implemented improvements.
4.15.1 item 5 -- assessments by external bodies;	*E*		g) assessments by external bodies;	
4.15.1 item 6 -- the results of interlaboratory comparisons or proficiency tests;		*Changed – Not Equiv*	*n) outcomes of the assurance of the validity of results; and* o) other relevant factors, such as monitoring activities and training. *Interlaboratory comparisons and proficiency tests are monitoring activities, but we will probably need to specifically include in the Standard*	KEEP need to be explicit about PTs
4.15.1 item 7 -- changes in the volume and type of the work;		*Changed - Equiv*	h) changes in the volume and type of the work or in the range of laboratory activities; *2017 includes all 2005 language but adds "range of activities"*	

4.15.1 item 8 -- customer feedback;		*Changed - Equiv*	i) customer and personnel feedback; *2017 includes all 2005 language but adds "personnel feedback"*	
4.15.1 item 9 -- complaints;	*E*		j) complaints;	
4.15.1 item 10 -- recommendations for improvement;		*Changed – Not Equiv*	*8.9.3 [outputs]* *b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;* d) any need for change.	DROP Need for change is equivalent to recommendation for improvement.
4.15.1 item 11 -- other relevant factors, such as quality control activities, resources, and staff training.		*Changed - Equiv*	o) other relevant factors, such as monitoring activities and training l) adequacy of resources; n) outcomes of the assurance of the validity of results; and *This section does not explicitly state to review QC activities, but they would be included in both o) and n).*	
4.15.1 NOTE 1: A typical period for conducting a management review is once every 12 months.		*Deleted*		DROP – not assessable TNI language covers this

4.15.1 NOTE 2: Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.		*Deleted*		DROP – not assessable Should happen when needs for change are ID'd.
4.15.1 NOTE 3: A management review includes consideration of related subjects at regular management meetings.		*Deleted*		DROP – not assessable
4.15.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.			**8.9.3** The outputs from the management review shall record all decisions and actions related to at least: a) the effectiveness of the management system and its processes; b) improvement of the laboratory activities related to the fulfilment of the requirements of this document; c) provision of required resources; d) any need for change. *This section is missing the requirement to ensure actions are "carried out within an appropriate and agreed timescale".*	KEEP Add: *The management shall ensure that those actions are carried out within an appropriate and agreed timescale.*

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**