Quality System Expert Committee (QS)
Meeting Summary

January 24, 2018

1. Roll Call:

Paul Junio, Chair, called the meeting to order at 8am Central on January 24, 2018 in Albuquerque, NM. Attendance is recorded in Attachment A – there were 6 members present.

Paul summarized the agenda for the meeting today. The committee will begin looking at the ISO/IEC 17025 2017 Standard and its possible effect on the TNI Standard. The committee will also look at SIRs and Parking Lot items. A copy of the PowerPoint slides used in the meeting can be found in Attachment D.

2. Parking Lot Items

Paul reviewed the Parking Lot document – Attachment E.

3. Review of the Crosswalk

ISO 17025 2017 was approved late 2017. Paul shared slides used by Warren Merkel at the DC meeting August.

- Quality Manager and Technical Director are no longer terms used in the Standard. The "duties" are termed Management now.
- Section 5 does not have sections with separate headings. Paul pulled some topics out of the section from a presentation by A2LA.
- Section 8 – Option A and Option B. Option B states they are 9001 certified, so they don't need to change their system. They will still be assessed to Section 8 – it is not a get out of jail free card. Some people think TNI shouldn't allow for Option B, but others think this is a mistake and it doesn't stick with the spirit of the Standard. It may be run across in an industrial in-house lab. ABs will need training in how to deal with it.

Paul had the group do an exercise. He put the sections and headings for the new ISO/IEC 17025:2017 Standard on the wall. He then took sections from our current standard and had them printed on separate pieces of paper. He asked people to take the stack of pages and put them where they think they belong in the new ISO/IEC 17025:2017 Standard.

A comment was made that the committee needs to add looking at the glossary when working on the new TNI Standard. These definitions should be used when the new TNI Standard is worked on and not add Definitions to each of the sections.

Paul continued to review the sections of the new ISO/IEC 17025:2017 Standard.

Paul noted that we have the OK to make changes to the ISO/IEC 17025:2017 language. The intent can't be changed, but the wording can be changed.

Ilona is concerned that changing language may cause problems for labs that use the TNI Standard accreditation to do international work where compliance to ISO 17025 is needed. Michelle suggested preparing a help document to spell out terms that may be confusing to labs. Chris also agreed with Ilona's concerns. He commented that you don't want to change language in an international Standard. This could also cause problems with the DoD Standard.

Scott Hoatson would prefer to see language simplified. This would help small labs if things were put into plain language. Easier for people to understand "sample" rather than "test item".

It was suggested to use the Glossary to include words where they might mean something else.

Paul shared a Crosswalk that A2LA prepared between the 2005 and 2017 Standard (Attachment F). This was the Final DRAFT comparison, but there were only editorial changes made to the Final version, so this is a valid crosswalk. The actual ISO/IEC language was removed from Attachment F due to possible copyright issues, but the information can be reviewed with an actual copy of the ISO/IEC 17025:2017 Standard.

Sampling.
The Field Activities Expert Committee (FAC) would like to plan a joint meeting to discuss this requirement and the impact on the Quality Systems and Field Standards.

Robin Cook – asked that maybe parentheses can be used to define what some of the language actually means (same idea as Scott's example with "sample".)

Scott Siders comment 4.1.4 and 4.1.5 will be difficult for labs to understand and know how to implement. They could use help here.

Ilona suggested highlighting items that are expected to be difficult for labs so we can consider guidance documents or special trainings on these items. The trainings could include ideas for implementation. A list of these items will be maintained by the committee (see Attachment G).

Chris said the concept of RISK is the four letter word no one wants to talk about. A2LA is telling their assessors that labs are already doing this through ethics training, confidentiality agreements, etc … This is not a new concept. A risk has to be something that will impact data quality.

Jeff Flowers – He can be sued any day. It is not the assessor's responsibility to point out risk. Jeff assumes the risk for his laboratory. You can't tell him what his risks are. This

can be a real slippery slope – his market is constructed a certain way. Sunshine law means there is no confidentiality in Florida. Every aspect of the data is public record when reported to the State of Florida. If Jeff is getting tagged with the risk, he should be given the authority to decide what is risk.

Is it the labs responsibility to take into account all risks? If you hire someone with a spouse that works in another lab, the labs should assess this risk. They should be prepared to note they looked at the risk and decided that it is not a risk. If the assessor later finds there is a problem, then they can be cited.

Example – a sales person promised unachievable turn around times. BOD in 2 days.

4.2.2 in the Standard covers where confidential info must be released. This is a new section.

Michelle reminded everyone that assessors need to have evidence when something is not OK before they can cite it.

On 5.3 – it is listed as new, but Ilona noted that the old Standard did have a requirement that the final report did need to note any analyses/results on the final report that are not on the lab's Scope of accredited methods/analytes. This is a scope issue and is done already. You cannot include things that you sub out as analyses you performed. The lab has the option of stating that certain types of work are not in conformance.

Need to look at the Standard update and make sure all items can be assessed against.

Scott Siders: You have a golden opportunity to look back and see where the issues are in the old Standard. Where are there lapses and weaknesses in the Standard? Where are the language changes needed?

Ilona reminded everyone there is a process for updating the Standard and we are not at the point yet where we are officially getting started on the Standard update. We are doing some pre-work to get ready. The CDSP SOP for Standard development clearly requires that the committee seek input on the Standard. This committee is going through this process to make it easier when we start working with specific comments on changes needed in the Standard. Robin Cook noted that the SOP also requires looking at SIRS which is an excellent place to find where there are problems with current Standard language.

Don't necessarily look for one person to do all the responsibilities of the Technical Director. This can be shared.

No longer see Quality Manager, Quality Manual and job descriptions in this section. Scott Siders thinks these things need to be added back in TNI language. John Gumpper says it says you have to document your procedures and you could use a Quality Manual

or some other document system that describes how quality is handled in the lab. Do you have a quality policy?

Scott Siders added, it would feel like the umbrella of the Quality Manual is missing. Scott cautions the QS from removing this requirement.

Michelle sees a lot of Quality Manuals that are never used by the lab. It complies with the Standard, but it is not used. There is a lot of information in a Quality Manual that is not used day to day.

Robin Cook compared the discussion to the removal of the DOC form in the 2009 Standard update from 2003. It is not that it doesn't have to be done, you just have the choice how you want to do it.

Silky Labie – If you have a bunch of procedures in a lab, who is going to say the lab will follow the procedures? There needs to be a policy that says you will follow the procedures. Chris Gunning noted this is the new 5.3 clause.

BREAK – 30 mintutes

We may need some guidance on how to comply with 6.5.1.

6.5.2 b) The primary would need to be certified (comes from an accredited provider following specific requirements). The second source could be a reference material. This really isn't new, but the term certified hasn't been used before. Could be an issue with balance checks?

6.6.3) Is the lab responsible for the sampling bottles it sends out? Media? Labs generally do lot checks.

Chris thinks 6.6 does not require anything new. These are requirements now. In d) it now says you monitor their performance. This could be noting that you receive the right material, lot checks, etc …

Subcontracting now has to have a procedure. It has been combined in the purchasing procedures. It does not say you have to go visit and "audit" them, but they could if that is what they want their procedure to be. Others look at the Scope and Accreditations of the labs they do work with.

The only new requirement for subcontracting is that you have to gain approval from the client.

Silky Labie asked if 4.6.4 is still part of the new Standard. All of this is covered in 6.6.2. The difference is that a list is no longer required. You can keep your record as you choose.

Dorothy Love thinks people are complicating it. A certificate showing they are accredited should be sufficient. They also look for liability insurance.

Kathy K – noted the lab can ask for an example package or a level 4 package for their first subcontracting and use this to evaluate a lab for future work.

Section 7.1.3 is new and could use some clarification.

There are items in the new ISO/IEC 17025:2017 Standard that was previously TNI language. They are listed as new on the crosswalk, but they are not new to TNI labs.

7.8.2.2 – Very proscriptive.

The complaint section has been expanded (Section 7.9). Additional clarification.

Michelle commented that complaints become more important because of the inherent risk issue.

7.9.6) There are possible issues for small labs because you have to have another person. There is another note that this can be handled by an external person.

7.11.4) The LIMS concept is new to the ISO Standard.

Look at 6.6.1 – Not applicable [editor's note – this was a typo in the file. 6.6.1 is applicable]

Section 8 will be reviewed after lunch.

LUNCH

Quality Systems – Albuquerque – Afternoon Session

Section 8 is Option A. While Option B will be foreign to the community, let's not throw it out.

8.2.1/8.2.2 are the only place where policies are required. A2LA will not assess as to whether the policy is there. But if it is then it must meet the requirements.

8.3 – missing 'master list', procedure, pagination. There was much discussion about master lists and alternate ways of accomplishing the same thing.

No comments on 8.4 through 8.6

8.7 – corrective actions – noted that root cause does not exist. There was a question about what does 'deal with the consequences' mean? Seems as though that just stresses to address things. For example, if a temperature excursion occurred in a micro incubator,

you would have to invalidate the samples, AND contact the clients about the need to re-sample.

8.8 – internal audits – there are no timeframes (i.e., no longer annual). No pre-determined schedule. Risk assessment determines where you need to audit.

8.9 – management review – a lot more written, and much of it is good guidance on what should be in management reviews. Again, no annual requirement.

In the upcoming revision, no one took issue with inserting TNI language amongst the ISO language. Silky stated that she didn't like the idea of re-numbering the ISO language. Paul said that isn't what we would do; rather we would insert an additional number/letter/bullet immediately following an item that TNI deemed worthy of comment.

4. Action Items

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

5. New Business

   None.

6. Next Meeting and Close

   The next meeting is planned for February 12, 2018 by teleconference at 1pm Eastern.

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

   Paul adjourned the meeting at 5:00pm Central.

Attachment A
Participants
Quality Systems Expert Committee (QS)

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

Attachment B

Action Items – QS Expert Committee

	Action Item	Who	Expected Completion	Actual Completion
25	Follow-up with Bob Wyeth and Jerry Parr about experience vs. course hours for Technical Directors.	Paul	TBD	
26	Provide in writing, thoughts regarding options for Technical Director approval.	Robin	TBD	
38	Continue SIR 246 and 296 discussions.	All	TBD	
40	Get PT root cause analysis example from Scott Hoatson.	Paul	8/31/17	
45	Review Ch 1 Application section for the use of “shall” and “may”. Are uses correct?	Paul, Sara	11/20/17	
46	The committee should continue review of the SLH and send comments before completion of the Final DRAFT.	ALL	11/20/17	Complete
47				
48				

Attachment C

Backburner / Reminders – QS Executive Committee

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

TNI QUALITY SYSTEMS

Albuquerque – Forum on Environmental Accreditation
01/24/18

Ground Rules

- Silence cell phones
- Please identify yourself and your organization when speaking
- No sidebar discussions
- If you need to leave, please quietly close the door behind you to keep the outside noise out

Quality Systems

Labs (5) – Paul Junio (Chair), Jessica Jensen (Vice Chair), Shari Pfalmer, Dale Piechocki, Matt Sowards

ABs (5) – Kristin Brown, Lisbeth Garcia, Chris Gunning, Sara Hoffman, Jacob Oaxaca

Others (2) –Bill Ray, Michelle Wade

Quality Systems

Module 2 Revision (Again)

- ISO/IEC 17025-2017
- Previous SIRs
- Parking Lot Document
- Others?

Quality Systems

Previous SIRs

- Review all SIRs
- Assure that they are properly addressed in this revision
- Minimal time spent on this here

Quality Systems

Parking Lot Document

- Notes over the years
- Wish lists
- Suggestions
- Requests

Quality Systems

Parking Lot Document

- Volume 2 Module 1 (General Requirements for Accreditation Bodies Accrediting Environmental Laboratories) contains responsibilities of the lab and of the AB
- These items AREN'T listed in any Module that a laboratory is expected to have
- Let's add them

Quality Systems

V2M1 – The Lab shall…

- commit to fulfill the requirements for accreditation set by the AB for the areas where accreditation is sought or granted. This includes agreement to adapt to changes in the requirements for accreditation.
- afford such accommodation and cooperation as is necessary to enable the AB to verify fulfillment of requirements for accreditation.
- provide access to information, documents and records as necessary for the assessment and maintenance of the accreditation.
- provide access to those documents that provide insight into the level of independence and impartiality of the lab from its related bodies, where applicable.

Quality Systems

V2M1 – The Lab shall…

- arrange the witnessing of lab services when requested by the AB.
- claim accreditation only with respect to the scope for which it has been granted accreditation.
- not use its accreditation in such a manner as to bring the AB into disrepute.
- pay fees as shall be determined by the AB.

Quality Systems

V2M1 – The Lab shall…

- Inform the AB of significant changes relevant to its accreditation or
  - its legal, commercial, ownership or organizational status,
  - the organization, top management and key personnel,
  - main policies,
  - resources and premises,
  - other such matters that may affect the ability of the lab to fulfill requirements for accreditation.

Quality Systems

Parking Lot Document

- Ongoing DOC via previous PT Sample (bad idea if analytes aren't present)
- What do Annual, Monthly, Daily mean?
- Document and Record are both nouns and verbs – let's pick one and only one of each of these terms

Quality Systems

ISO/IEC 17025-2017

- New alignment similar to other documents
- Focus on outcome, not prescriptive requirements
- Update / Don't fix what isn't broken

Quality Systems

ISO/IEC 17025-2017

- Five clauses of requirements instead of two
- Focus is on outcomes, resulting in:
  - Less variety in terms used to describe required documentation
  - Elimination of some terms
  - More flexibility for laboratories
- Requirements for records more reflective of current technology
- Many requirements nearly verbatim, but in different places

Quality Systems

ISO/IEC 17025-2017

- 1 Scope
- 2 Normative References
- 3 Terms and Definitions
- 4 General Requirements
- 5 Structural Requirements
- 6 Resource Requirements
- 7 Process Requirements
- 8 Management Requirements

Quality Systems

ISO/IEC 17025-2017

- Two options for the demonstration of a Management System (Section 8)
  - Option A – follow the requirements as described in Section 8
  - Option B – Have demonstrated competency in ISO 9001:2015

Quality Systems

EXERCISE TIME

Mapping TNI Added Requirements to 'their new home'

Quality Systems

17025:2005	17025:2017
4 – Management Requirements	4 – General Requirements
5 – Technical Requirements	5 – Structural Requirements
	6 – Resource Requirements
	7 – Process Requirements
	8 – Management Requirements

Quality Systems

17025:2017

- 4 – General Requirements
  - 4.1 Impartiality
  - 4.2 Confidentiality

Quality Systems
17025:2017

- 5 – Structural Requirements
  - 5.1 Legal identification
  - 5.2 Management identification
  - 5.3 Scope of conformity
  - 5.4 Defined range of activities
  - 5.5 Authority and resource availability
  - 5.6 Personnel identification
  - 5.7 Communication and integrity

Quality Systems
17025:2017

- 6 – Resource Requirements
  - 6.1 General
  - 6.2 Personnel
  - 6.3 Facilities and Environmental Conditions
  - 6.4 Equipment
  - 6.5 Metrological Traceability
  - 6.6 Externally Provided Products and Services

Quality Systems
17025:2017

- 7 – Process Requirements
  - 7.1 Review of Requests, Tenders and Contracts
  - 7.2 Selection, Verification, and Validation of Methods
  - 7.3 Sampling
  - 7.4 Handling of Test or Calibration Items
  - 7.5 Technical Records
  - 7.6 Evaluation of Measurement Uncertainty
  - 7.7 Ensuring the Validity of Results
  - 7.8 Reporting of Results
  - 7.9 Complaints

Quality Systems
17025:2017

- 7 – Process Requirements
  - 7.10 Nonconforming Work
  - 7.11 Control of Data and Information Management

Quality Systems
17025:2017

- 8 – Management System Requirements
  - 8.1 Options
  - 8.2 Management System Documentation
  - 8.3 Control of Management Systems Documents
  - 8.4 Control of Records
  - 8.5 Actions to Address Risks and Opportunities
  - 8.6 Improvement
  - 8.7 Corrective Action
  - 8.8 Internal Audits
  - 8.9 Management Reviews

Questions?

Paul Junio
Chair – Quality Systems Committee
Northern Lake Service
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715-219-2662

Attachment E - Parking Lot Document

Does this address clearly whether or not individual sample containers must be uniquely identified?

The laboratory shall have a documented system for uniquely identifying the sample containers that hold samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates.

SIR 200

incoming question: TNI 2009: V2M1, V2M3, 8.1.2b, 7.b

> A laboratory in our program states that the standard does not require it to notify the accreditation body if there is a change of quality assurance officer. The question is "Is a change of quality assurance officer considered a change of 'key personnel' such that the laboratory is required to notify the accreditation body of this change within thirty (30) days?" Thank you for your assistance.

From the AC: SIR 200 is about a laboratory requirement that is mentioned only in Volume 2 of the 2009 TNI Standard – notification of personnel changes. This and other similar requirements ("responsibilities of a CAB" that are referred to in V2M1 §8 and V2M3 §7) need to be in Volume 1 of the standard, not just V2, because state ABs that incorporate the NELAP standard "by reference" are unable to enforce against a lab for a requirement that is solely in Volume 2.

V2M1 Section 8

8 Responsibilities of the accreditation body and the CAB

8.1 Obligations of the CAB

8.1.1 The accreditation body shall require the CAB to conform to the following.

a) The CAB shall commit to fulfil continually the requirements for accreditation set by the accreditation body for the areas where accreditation is sought or granted. This includes agreement to adapt to changes in the requirements for accreditation, as set out in 8.2.4.

b) When requested, the CAB shall afford such accommodation and cooperation as is necessary to enable the accreditation body to verify fulfilment of requirements for accreditation. This applies to all premises where the conformity assessment services take place.

c) The CAB shall provide access to information, documents and records as necessary for the assessment and maintenance of the accreditation.

d) The CAB shall provide access to those documents that provide insight into the level of independence and impartiality of the CAB from its related bodies, where applicable.

e) The CAB shall arrange the witnessing of CAB services when requested by the accreditation body.

f) The CAB shall claim accreditation only with respect to the scope for which it has been granted accreditation.

g) The CAB shall not use its accreditation in such a manner as to bring the accreditation body into disrepute.

h) The CAB shall pay fees as shall be determined by the accreditation body.

8.1.2 The accreditation body shall require that it is informed by the accredited CAB, without delay, of significant changes relevant to its accreditation, in any aspect of its status or operation relating to

a) its legal, commercial, ownership or organizational status,

b) the organization, top management and key personnel,

c) main policies,

d) resources and premises,

e) scope of accreditation, and

f) other such matters that may affect the ability of the CAB to fulfil requirements for accreditation.

8.2 Obligations of the accreditation body

8.2.1 The accreditation body shall make publicly available information about the current status of the accreditations that it has granted to CABs. This information shall be updated regularly. The information shall include the following:

a) name and address of each accredited CAB;

b) dates of granting accreditation and expiry dates, as applicable;

c) scopes of accreditation, condensed and/or in full. If only condensed scopes are provided, information shall be given on how to obtain full scopes.

8.2.2 The accreditation body shall provide the CAB with information about suitable ways to obtain traceability of measurement results in relation to the scope for which accreditation is provided.

8.2.3 The accreditation body shall, where applicable, provide information about international arrangements in which it is involved.

8.2.4 The accreditation body shall give due notice of any changes to its requirements for accreditation. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes. Following a decision on, and publication of, the changed requirements, it shall verify that each accredited body carries out any necessary adjustments.

7 Accreditation process

7.1 Accreditation criteria and information

7.1.1 The general criteria for accreditation of CABs shall be those set out in the relevant normative documents such as International Standards and Guides for the operation of CABs.

7.1.2 The accreditation body shall make publicly available, and update at adequate intervals, the following:

a) detailed information about its assessment and accreditation processes, including arrangements for granting, maintaining, extending, reducing, suspending and withdrawing accreditation;

b) a document or reference documents containing the requirements for accreditation, including technical requirements specific to each field of accreditation, where applicable;

c) general information about the fees relating to the accreditation;

d) a description of the rights and obligations of CABs;

e) information on the accredited CABs as described in 8.2.1;

f) information on procedures for lodging and handling complaints and appeals;

g) information about the authority under which the accreditation programme operates;

h) a description of its rights and duties;

i) general information about the means by which it obtains financial support;

j) information about its activities and stated limitations under which it operates;

k) information about the related bodies as described in 4.3.7, if applicable.

7.2 Application for accreditation

7.2.1 The accreditation body shall require a duly authorized representative of the applicant CAB to make a formal application that includes the following:

a) general features of the CAB, including corporate entity, name, addresses, legal status and human and technical resources;

b) general information concerning the CAB such as its activities, its relationship in a larger corporate entity if any, and addresses of all its physical location(s) to be covered by the scope of accreditation;

c) a clearly defined, requested, scope of accreditation;

d) an agreement to fulfil the requirements for accreditation and the other obligations of the CAB, as described in 8.1.

7.2.2 The accreditation body shall require the applicant CAB to provide at least the following information relevant to the accreditation prior to commencement of the assessment:

a) a description of the conformity assessment services that the CAB undertakes, and a list of standards, methods or procedures for which the CAB seeks accreditation, including limits of capability where applicable;

b) a copy (on paper or in electronic form) of the quality manual of the CAB, and relevant associated documents and records, such as information on participation in proficiency testing as described in 7.15, where applicable.

7.2.3 The accreditation body shall review for adequacy the information supplied by the CAB.

We understand that the requirements themselves flow from ISO 17011 and not 17025, and that's why the CSD EC is included in this message. A related point that arose during this discussion was that labs need to be required to submit to the on-site assessment process -- that fact is nowhere mentioned in V1. At the same time, these requirements need to remain in V2 as well, since they are from ISO 17011 and not ISO 17025.

If the AC can assist with resolving the problems that might come with including these items in both V1 and V2, please ask.

4.2.8.6 – create – Management shall submit to onsite assessments as required by the AB

1.6.3.2 This on-going demonstration may be one of the following:

a) acceptable performance of a blind sample (single blind to the analyst) or successful analysis

of a blind performance sample on a similar method using the same technology (e.g., GC/MS

volatiles by purge and trap for Methods 524.2, 624 or 5030/8260);

I would recommend that the “samples” have known or accepted or verified nonzero Assigned Values and then be submitted single-blind to the analyst(s) for capability demonstrations.

Acceptable performance of sample(s) that have known accepted values, single-blind to the analyst

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Educational requirements – see Gary Ward for plan of attack – consider accredited degrees

Quality Manager has no specified requirements of education and/or experience

Technical Director for micro has explicit tests listed that don’t consider newer tests

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Batch, Preparation: A preparation batch is composed of one (1) to twenty (20) environmental samples of the same quality systems matrix that are prepared together with the same process and personnel, using the same lot(s) of reagents, with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four (24) hours.
Note: Preparation batches are only applicable for tests that require physical or chemical preparation that affects the outcome of the test.

Why do we care about all those things that HAVE to be on the final report? Do they matter?

Annual – where does it appear and what does it mean in each case (i.e., every 11-13 months, each calendar year, something else)

Define reagent

Should Module 2 make it the lab's job to notify all ABs if their accreditation is revoked.

Under technical manager, experience should be expanded as 'representative experience'.

We use the terms document and record as both verbs and nouns. It would be great and clearer if we only used one of them as a noun, and the other as a verb.

Change all instances of Standard to TNI Environmental Laboratory Standard

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Appendix F: Crosswalk

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
1		**SCOPE**
	ISO/IEC Language can be found in the new ISO/IEC 17025: 2017 Standard	
2		**NORMATIVE REFERENCES**
		Section 2
3		**TERMS AND DEFINITIONS**
3		Section 3
3.1		
3.2		
3.3		
3.4		
3.5		
3.6		NEW
3.7		NEW
4		**GENERAL REQUIREMENTS**
4.1		Impartiality
4.1.1		4.1.4; 4.1.5 (d)(e)(f) isn't 4.1.5 (b) also covered or related to impartiality - i.e., free from undue pressure?
4.1.2		4.1.5 (b)
4.1.3		4.1.5 (b)
4.1.4		NEW
4.1.5		NEW
4.2		Confidentiality
4.2.1		NEW - but related to 4.1.5 (c); 4.7.1; 5.4.7.2 (b)
4.2.2		NEW
4.2.3		NEW
4.2.4		NEW
5		**STRUCTURAL REQUIREMENTS**
5.1		4.1.1 - legal entity
5.2		4.1.5 (h) - technical management
5.3		NEW, but also note what didn't comply with the requirements on final report

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
5.4		4.1.2 - carry out testing and calibration to meet the needs of... 4.1.3 - permanent facilities etc...
5.5		
5.5 a)		4.1.5 (e) - parent organization
5.5 b)		4.1.5 (f) - specify responsibility
5.5 c)		4.2.1 - establish, implement and maintain a management system
5.6		4.1.5 (a)
5.6 a)		4.1.5 (a); 4.2.2 (e)
5.6 b)		4.1.5 (a)
5.6 c)		4.1.5 (a)
5.6 d)		4.1.5 (i)
5.6 e)		4.1.5 (i); 4.2.3
5.7		4.1.6
5.7 a)		4.1.6; 4.2.3
5.7 b)		4.2.7
6		**RESOURCE REQUIREMENTS**
6.1		General
		~~not applicable~~
6.2		Personnel
6.2.1		4.1.5 d - impartiality; 5.2.1 - competence; 5.2.3 - employ; this could also be related to 4.1.4 (defining responsilities to identify potential conflicts of interest), as this is one mechanism that could be used to help assure that personnel act impartially
6.2.2		4.3.1 document control; 5.1.2 - qualification; 5.2.1 - competence, education, skills, experience; 5.2.4 - job descriptions; 5.5.2 - competence, education, skills, experience
6.2.3		4.1.5 (k); 5.2.5; 5.4.3
6.2.4		4.2.1, 4.2.4
6.2.5		

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
6.2.5 a)		5.2.5 5.2.1
6.2.5 b)		
6.2.5 c)		5.2.2
6.2.5 d)		4.1.5 g
6.2.5 e)		5.2.5; 5.4.3
6.2.5 f)		5.2.1
6.2.6		5.2.5
6.2.6 a)		5.2.5; 5.4.3
6.2.6 b)		5.2.5
6.2.6 c)		4.14.1; 5.2.5
6.3		Facilities and environmental conditions
6.3.1		5.3.1; 5.4.7.2 c) computers and automated equipment
6.3.2		5.3.1 P2; last sentence
6.3.3		5.3.2
6.3.4		
6.3.4 a)		5.3.4
6.3.4 b)		5.3.2
6.3.4 c)		5.3.3
6.3.5		5.3.1 P2; Colleen - think this is also related to 4.1.3 - system covers work at sites outside the main facility
6.4		Equipment
6.4.1		5.5.1 first sentence; 5.5.2 1st sentence
6.4.2		5.5.1 2nd sentence
6.4.3		5.4.1 Instructions for use and operation; 5.4.7.2 - Computers and automated equipment; 5.5.3; 5.5.6
6.4.4		5.4.7.2 a) computer software developed by the user; 5.5.2 3rd & 4th sentence
6.4.5		5.4.7.2 a) computer software developed by the user; 5.5.2 1st sentence; 5.6.3.3 - intermediate checks

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
6.4.6		5.6.1, 5.6.2.2.1, 5.6.3.1 In the old standard it spoke of "effect on the accuracy or validity of the result" and did not include measurement uncertainty which is critical in the decision rule process.
6.4.7		5.6.1, 5.5.2 2nd sentence
6.4.8		5.5.8
6.4.9		5.5.7
6.4.10		5.5.10; 5.6.3.2, 5.6.3.3
6.4.11		5.5.11
6.4.12		5.1.2; 5.5.12
6.4.13		5.5.5
6.4.13 a)		5.5.5 a)
6.4.13 b)		5.5.5 b)
6.4.13 c)		5.5.5 c)
6.4.13 d)		5.5.5 d)
6.4.13 e)		5.5.5 f)
6.4.13 f)		**NEW in 2017**
6.4.13 g)		5.5.5 g)
6.4.13 h)		5.5.5 h)
6.5		Metrological traceability
6.5.1		5.6.2.1.1 Para 2 Sentence 1
6.5.2		5.6.2.1.1
6.5.2 a)		5.6.2.1.1 P2
6.5.2 b)		**NEW - use of certified reference material term is new**
6.5.2 c)		5.6.2.1.1 P2
6.5.3		5.6.2.1.2
6.5.3 a)		5.6.2.2.2
6.5.3 b)		5.6.2.2.2, 5.6.2.1.2
6.6		Externally provided products and services (4.5, 4.6)
6.6.1		4.6.2
6.6.1 a)		4.6.2, 4.6.3
6.6.1 b)		4.5.3
6.6.1 c)		4.6.1
6.6.2		4.6.1

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
6.6.2 a)		**NEW! - applies to purchasing and subcontracting both**
6.6.2 b)		4.6.1
6.6.2 c)		4.6.2
6.6.2 d)		**NEW! - continuing evaluation, not "annual"**
6.6.3		4.6.3
6.6.3 a)		4.6.2
6.6.3 b)		4.6.3
6.6.3 c)		**NEW!**
6.6.3 d)		**NEW!**
7		**PROCESS REQUIREMENTS**
7.1		Review of requests, tenders and contracts
7.1.1.		4.4.1 - establish and maintain procedures
7.1.1 a)		4.4.1 (a)
7.1.1 b)		4.4.1 (b)
7.1.1 c)		4.4.3 - coverage of subcontracted work; 4.5.2 - advising customer of subcontracting
7.1.1 d)		4.4.1 (c); 5.4.2 - selection of methods
7.1.2		5.4.2 (last paragraph)
7.1.3		**NEW!**
7.1.4		4.4.1 (last paragraph); the second part is "new" but could be related to 5.4.2
7.1.5		4.4.4
7.1.6		4.4.5
7.1.7		4.7.1
7.1.8		4.4.2
7.2		Selection, verification and validation of methods
7.2.1		
7.2.1.1		5.4.1
7.2.1.2		5.4.1 - 2nd paragraph; 4.3 - document control
7.2.1.3		5.4.2 - first paragraph
7.2.1.4		5.4.2 - second paragraph
7.2.1.5		5.4.2 - end of 2nd para
7.2.1.6		5.4.3; 5.4.5.3 NOTE 2
7.2.1.7		5.4.1

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
7.2.2		
7.2.2.1		5.4.5.2
7.2.2.2		5.4.5.2, NOTE 3
7.2.2.3		5.4.5.3
7.2.2.4		
7.2.2.4 a)		5.4.5.2
7.2.2.4 b)		5.4.5.3, NOTE 1
7.2.2.4 c)		5.4.5.3, NOTE 1
7.2.2.4 d)		5.4.5.2
7.2.2.4 e)		5.4.5.2
7.3		Sampling
7.3.1		5.7.1
7.3.2		Note 2 under 5.7.1
7.3.2 a)		Note 2 under 5.7.1
7.3.2 b)		Note 2 under 5.7.1
7.3.2 c)		Note 2 under 5.7.1
7.3.3		5.7.3
7.3.3 a)		5.7.3
7.3.3 b)		**New to ISO**
7.3.3 c)		**New**
7.3.3 d)		5.7.3
7.3.3 e)		**New**
7.3.3 f)		5.7.3
7.3.3 g)		5.7.3
7.3.3 h)		**New**
7.4		Handling of test or calibration items
7.4.1		Combined 5.8.1 and part of 5.8.4
7.4.2		5.8.2
7.4.3		5.8.3
7.4.4		5.8.4
7.5		Technical Records
7.5.1		4.13.2.1, 4.13.2.2
7.5.2		**NEW, 4.13.2.3-like**
7.6		Evaluation of measurement uncertainty
7.6.1		5.4.6.2 - sort of!
7.6.2		5.4.6.1
7.6.3		5.4.6.2
7.7		Assuring the quality of results
7.7.1		5.9.1

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
7.7.1 a)		5.6.3.1; 5.6.3.2; 5.9.1 (a)
7.7.1 b)		**NEW??**
7.7.1 c)		**5.5.10 ?**
7.7.1 d)		5.9.1 (a)
7.7.1 e)		5.6.3.3
7.7.1 f)		5.9.1 (c)
7.7.1 g)		5.9.1 (d)
7.7.1 h)		5.9.1 (e)
7.7.1 i)		**NEW??**
7.7.1 j)		**NEW??**
7.7.1 k)		**NEW??**
7.7.2		
7.7.2 a)		5.9.1 (b)
7.7.2 b)		**NEW**
7.7.3		5.9.2
7.8		Reporting of results
7.8.1		
7.8.1.1		Kind of "new"? 5.4.7.1 - data transfers subject to checks; 5.10.2 (j) - authorizing the test report
		5.10.1; 4.13.2.1 - the lab shall retain records of...
7.8.1.2		5.10.1
7.8.2		
7.8.2.1		5.10.2
7.8.2.1 a)		5.10.2 (a)
7.8.2.1 b)		5.10.2 (b)
7.8.2.1 c)		5.10.2 (b)
7.8.2.1 d)		5.10.2 (c)
7.8.2.1 e)		5.10.2 (d)
7.8.2.1 f)		5.10.2 (e)
7.8.2.1 g)		5.10.2 (f)
7.8.2.1 h)		5.10.2 (g)
7.8.2.1 i)		5.10.2 (g)
7.8.2.1 j)		**NEW?**
7.8.2.1 k)		5.10.2 (h)
7.8.2.1 l)		5.10.2 (k)
7.8.2.1 m)		5.10.2 (i)
7.8.2.1 n)		5.10.3.1 (a)
7.8.2.1 o)		5.10.2 (j)
7.8.2.1 p)		5.10.6

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
7.8.2.2		**NEW**
7.8.3		
7.8.3.1		
7.8.3.1 a)		5.10.3.1 (a)
7.8.3.1 b)		5.10.3.1 (b)
7.8.3.1 c)		5.10.3.1 (c)
7.8.3.1 d)		5.10.3.1 (d); 5.10.5
7.8.3.1 e)		5.10.3.1 (e)
7.8.3.2		5.10.3.2
7.8.4		
7.8.4.1		
7.8.4.1 a)		5.10.4.1 (b)
7.8.4.1 b)		5.10.4.1 (a)
7.8.4.1 c)		5.10.4.1 (c)
7.8.4.1 d)		5.10.4.3
7.8.4.1 e)		5.10.4.2
7.8.4.1 f)		5.10.5
7.8.4.2		Kind of "new"; tried to align the section on cal certificates with the testing reports
7.8.4.3		5.10.4.4
7.8.5		
7.8.5		Kind of "new"; while the requirements were in 2005, this version has a whole section, with the thought that a separate "sampling report" could be generated
7.8.5 a)		5.10.3.2 (a)
7.8.5 b)		5.10.3.2 (b)
7.8.5 c)		5.10.3.2 (c)
7.8.5 d)		5.10.3.2 (d)
7.8.5 e)		5.10.3.2 (e)
7.8.5 f)		**NEW?**
7.8.6		
7.8.6.1		**New in 2017**
7.8.6.2		5.6.2.1.1 for calibration; 5.10.3.1 (b) for testing
7.8.6.2 a)		5.10.4.2
7.8.6.2 b)		5.10.4.2
7.8.6.2 c)		**New in 2017**
7.8.7		

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
7.8.7.1		5.2.5 - authorization, including test reports and cal certificates; 5.10.5
7.8.7.2		5.10.5; 5.10.4.2
7.8.7.3		5.10.5, Note 3
7.8.8		
7.8.8.1		4.13.2.3 - mistakes in records
7.8.8.2		5.10.9
7.8.8.3		5.10.9
7.9		Complaints
7.9.1		4.8
7.9.2		
7.9.3		4.8
7.9.3 a)		
7.9.3 b)		4.8
7.9.3 c)		
7.9.4		
7.9.5		
7.9.6		**NEW**
7.9.7		
7.10		Management of nonconforming work
7.10.1		4.9.1
7.10.1 a)		4.9.1 (a)
7.10.1 b)		4.9.1 (a)
7.10.1 c)		4.9.1 (b)
7.10.1 d)		4.9.1 (c)
7.10.1 e)		4.9.1 (d)
7.10.1 f)		4.9.1 (e)
7.10.2		4.13.1.2
7.10.3		4.9.2
7.11		Control of data – Information management
7.11.1		
7.11.2		5.4.7.2 (a) and the NOTE in this section
7.11.3		
7.11.3 a)		4.13.1.4 - procedures to prevent unauthorized access; 5.4.7.2 (b)
7.11.3 b)		4.13.1.4 - procedures to prevent amendments
7.11.3 c)		4.13.1.2, 5.4.7.2 (c)

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Clause	**Statement**	**2005 Crosswalk (Student)**
7.11.3 d)		4.13.1.2; - legible, readily retrievable; 4.13.2.1 - sufficient information to establish an audit trail
7.11.3 e)		Kind of 'new' but really is just part of a non-conformance system?
7.11.4		**NEW?!**
7.11.5		4.13.1.1 - procedures for records; 4.3.2 - doc control
7.11.6		5.4.7.1
8		**MANAGEMENT REQUIREMENTS**
8.1		Options
8.1.1		
8.1.1		
8.1.2		
8.1.2B1		
8.1.2B2		
8.1.2B3		
8.1.2B4		
8.1.2B5		
8.1.2B6		
8.1.2B7		
8.1.2B8		
8.1.3		
8.1.3		
8.2		Management system documentation (Option A)
8.2.1		4.2.1, 4.2.2 - establish, implement and maintain a mgmt system; communicate; 4.1.5 (k) - personnel aware of relevance and importance
8.2.2		???first apearance of 'policies'
8.2.3		4.2.3 (almost verbatim, except we got rid of the term "top management"
8.2.4		4.2.5 - quality manual shall include or make reference to supporting and technical procedures
8.2.5		4.2.1 - system's documentation shall be available to the appropriate

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Clause	**Statement**	**2005 Crosswalk (Student)**
		personnel
8.3		Control of management system documents (Option A)
8.3.1		4.3.1 - general doc control
8.3.2		
8.3.2 a)		4.3.2.1-prior to issue; 4.3.3.1 - changes approved
8.3.2 b)		4.3.2.2 (b)
8.3.2 c)		4.3.3.2 - altered or new text; 4.3.2.3 - revision identification
8.3.2 d)		4.3.2.2 (a) - availability; 4.3.2.1 - distribution
8.3.2 e)		4.3.2.3
8.3.2 f)		4.3.2.2 (c) and (d)
8.4		Control of records (Option A)
8.4.1		4.13.1.2
8.4.2		4.13.1.1, 4.13.1.2, 4.13.1.3
8.5		Actions to address risks and opportunities (Option A)
8.5.1		
8.5.1 a)		
8.5.1 b)		
8.5.1 c)		
8.5.1 d)		
8.5.2		
8.5.2 a)		
8.5.2 b)		
8.5.2 b)B1		
8.5.2 b)B2		
8.5.3		
8.6		Improvement (Option A)
8.6.1		4.10 - Improvement 4.12 - Preventive Action
8.6.2		4.7.2
8.7		Corrective action (Option A)
8.7.1		4.9 Control of Non-conforming Work
8.7.1 a)		4.9.1 (b)
8.7.1 a) B1		4.9.1 (c)
8.7.1 a) B2		**????**
8.7.1 b)		4.11 - Corrective action
8.7.1 b) B1		4.11.2

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
8.7.1 b) B2		4.11.2
8.7.1 b) B3		4.9.2/4.11.2
8.7.1 c)		4.11.3
8.7.1 d)		4.11.4
8.7.1 e)		**NEW**
8.7.1 f)		4.10 - Improvement 4.11.3 - documenting and implementing any required changes
8.7.2		4.11.3 (2nd para.)
8.7.3		4.13 - Control of Records
8.7.3 a)		4.13 - Control of Records
8.7.3 b)		4.13 - Control of Records
8.8		Internal audits (Option A)
8.8.1		4.14.1
8.8.1 a)		
8.8.1 a) B1		4.14.1
8.8.1 a) B2		4.14.1
8.8.1 b)		4.14.2
8.8.2		
8.8.2 a)		4.14.1
8.8.2 b)		4.14.1
8.8.2 c)		4.14.1
8.8.2 d)		4.14.2
8.8.2 e)		4.14.3
8.9		Management reviews (Option A)
8.9.1		4.15.1
8.9.2		
8.9.2 a)		new
8.9.2 b)		new
8.9.2 c)		ok
8.9.2 d)		new
8.9.2 e)		ok
8.9.2 f)		ok
8.9.2 g)		ok
8.9.2 h)		ok
8.9.2 i)		ok
8.9.2 j)		ok
8.9.2 k)		new
8.9.2 l)		ok
8.9.2 m)		new

FDIS ISO/IEC 17025:2017 (Balloted Version 8/2017)		
Clause	**Statement**	**2005 Crosswalk (Student)**
8.9.2 n)		ok
8.9.2 o)		ok
8.9.3		4.15.2
8.9.3 a)		new
8.9.3 b)		new
8.9.3 c)		new
8.9.3 d)		new
OTHER 1.		
OTHER 2.		
OTHER 3.		
OTHER 4.		
OTHER 5.		
OTHER 6.		
OTHER 7.		**New to 2017**

Attachment G:

List of Sections in the ISO/IEC 17025:2017 Standard that may cause confusion for laboratories:

4.1.4
4.15
5.3
5.6
6.5.1
6.6 (6.6.1 – 6.6.3)
7.1.3
7.9.6

3.7 – Decision Rule (see also 7.1.3)
4.1.4 & 4.1.5
5.3
5.6 (stress that multiple people can fill those roles – need not be one person)
You asked about the 'not applicable'. It was actually 6.1. I'll ask Chris Gunning, as I'm not sure why that would be labeled that way. [note – this was an error and 6.1 is applicable]
6.6, including 6.6.1, 6.6.2, and 6.6.3, especially as it relates to BOTH sub-contracting and purchasing
Big picture – 'policies' only appear in Section 8. We should make sure we don't use the term in Section 1 like we do now.
8.8.2 d) correction, which is different from corrective action (as both are required in that item)