## Summary of the Laboratory Accreditation Body Expert Committee Meeting

## Tuesday, July 16, 2019

### 1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting. Attendance is recorded in Attachment 1. The minutes of June 18, 2019, were approved.

### 2. Review of Accumulated Comments

Comments received at all previous public sessions have been recorded in a Response-to-Comments spreadsheet, just as the formal comments on the published draft are being recorded. As previously agreed, all comments will be reviewed and addressed, although for the public sessions, the identity of commenters was not recorded. Carl stated that he wants to begin reviewing the comments on the published draft during the LAB session in Jacksonville, rather than in teleconference sessions such as this one.

This meeting was devoted to review of comments received by email (prior to the formal comment period) and during the public sessions in Albuquerque, January 2018; New Orleans, August 2018; and Milwaukee, January 2019. The comments and the final decisions on how to handle them are in Attachment 2 through 5, below.

#### 3. Next Meeting

The next teleconference meeting will be at conference on Thursday morning, August 8. Teleconference capability will not be available.

The next teleconference meeting will be decided at conference, depending on how many of the formal comments the committee can address. The next scheduled teleconference would be Tuesday, August 20, at 1 pm Eastern, but if adequate progress is made in Jacksonville, that meeting may be cancelled, in which case the next teleconference would be Tuesday, September 17, at 1 pm Eastern.

#### Attachment 1

## LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
William Batschelet Batschelet.william@epa.gov	12/31/2021 (2 <sup>nd</sup> term)	Other – US EPA R8, Lab QAO	No
Nilda Cox nildacox@eurofinsus.com	12/31/2021 (1 <sup>st</sup> term)	Lab – Eurofins Eaton Analytical LLC	Yes
Charles Hartke Charles.hartke@sgs.com	12/31/2020 (1st term)	Lab – SGS Accutest, Dayton, NY	Yes
Catherine Katsikis catherinekatsikis@gmail.com	12/31/2021 (2 <sup>nd</sup> term)	Other – Laboratory Data Consultants	Yes
Carl Kircher, Chair carl kircher@flhealth.gov	12/31/2021 (3 <sup>rd</sup> term, extended)		
Marlene Moore mmoore@advancedsys.com	12/31/2021 (2 <sup>nd</sup> term)	Other – Advanced Systems, Inc., Newark, DE	No
Zaneta Popovska zpopovska@anab.org	12/31/2021 (1st term)	Other – ANAB	No

Alia Rauf arauf@utah.gov	12/31/2020 (1st term)	AB – Utah Department of Health	No
Mei Beth Shepherd, Vice Chair mbshep@sheptechserv.com	12/31/2021 (2 <sup>nd</sup> term)	Other – Shepherd Technical Services	No
Nicholas Slawson nslawson@a2la.org	12/31/2021 (1st term)	AB – A2LA	No
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:			
Yumi Creason ycreason@pa.gov		AB – Pennsylvania	No
Bill Ray bill_ray@williamrayllc.com		Other – William Ray Consulting, LLC	No
Aurora Shields Aurora.Shields@kcmo.org		Lab – Kansas City, MO	No
Ilona Taunton Ilona.taunton@nelac-institute.org		Other – TNI Program Administrator	No

Ve Section/clause	Comment	Committee action	Committee comment
V2M3 §6.121.6	The PA-DEP would like to request that the Accreditation Body Expert Committee remove the following provision from the TNI Standard during the current revision cycle: V2M3: Section 6.121.6 which states, "Only accreditation bodies are allowed to release assessment reports initially. An assessment report shall not be released to the public by an accreditation body until the report has been provided to the laboratory, and until the findings of the assessment and the associated corrective actions have been finalized."	at April 17, 2018 meeting, LAB decided to delete the TNI language that had been inserted into the 2017 version of ISO 17011 at 7.6.7.1, in response to this comment. A PA DEP associate member was on the teleconference and verified with Ms. Alger that removing this language and the accompanying note, leaving only §8.1.1 to address release of reports, would be an acceptable solution. At the July 18, 2019,	with governmental "open records" statutes. No
	This statement violates many/most/if not all of the State and Federal Freedom of Information Acts and Right To Know provisions. It definitely violates the laws of PA which require access to almost all information to the public at their request. It also unreasonably limits the information that secondary ABs have access to when making ongoing compliance and accreditation decisions.	resolution was proposed during this meeting.	

# ATTACHMENT 2 – Comments Submitted by Email prior to Publication of Outline

e attached a judgement of		
Commonwealth's		
ronmental Hearing Board, the official		
court authority that handles all appeal	3	
other actions of the Department of		
ronmental Protection, that states that it		
e Department's duty to evaluate the		
nittee's, aka: accredited laboratory's,		
inued compliance with all State and		
ral regulations and laws before making		
al permit decision.		
	-	
a provision is not abanged the DA		
is provision is not changed, the PA- will seriously consider this cause for a		
vote.		
vote.		
	_	
have now repeatedly held that a permi		
wal not only creates an opportunity for		
Department to assess whether continued		
ation of the permitted facility is		
opriate, it creates a duty to do so. See bury School v. DEP, 2014 EHB 482,		
Jury School V. DEF, 2014 EHB 482,		
Mgmt. Co. v. DEP, 2011 EHB 203,		
17; Love v. DEP, 2010 EHB 523,		
29; Angela Cres Trust v. DEP, 2009		
342, 359; Wheatland Tube v. DEP,		
EHB 131, 135-36; Tinicum Twp. v.		
, 2002 EHB 822, 835.		
hits are issued with limited terms for		
isely that reason. Indeed, even without		
ewal application pending, the artment is required to "from time to		
, but at intervals not to exceed 5 years,		
•		
w permits issued under [the munic e] article." 25 Pa. Code § 271.211(	-	1

	we again reiterated our support for our holding in Tinicum Township that the Department, and in turn the Board, must ensure that the continuation of a permitted activity is still appropriate in the context of current information and standards: The Department argued [in Tinicum Township] that the Board was only permitted to consider whether the permit limits had changed, and if so, whether the changes were appropriate. We rejected the argument. We explained that, even in the absence of changes to permit terms, the five-year renewal requirement required the Department to ensure that a permit issued years earlier was still appropriate based upon what was known at the time of the proposed renewal. The determinative issue was not whether the permit was appropriate in the first place; it was whether it should have continued in place for another five years. Challenges related to the former	
email 5/10/18	The NJDEP just had our TNI Assessment last week by Steve Arms and I would like it known that the 30 day time frame for assessment reports, needs to be changed to 45 days or more. Because the 30 calendar days can cause problems around holiday periods such as Thanksgiving and Christmas/New Years. So I noted this issue in the TNI "Evaluator Feedback Form". Lynn Bradley suggested that I contact you directly with this item of concern, so when you start updating this section in TNI Standards you would be aware of the NJDEP concern, hence this e-mail.	discussed in committee, 5/15/18, Lab and "other" stakeholders favor keeping the 30 days, AB stakeholders favor lengthening the time, so clearly no consensus to change at this time. Carl will highlight this issue in the "outline" to be published, and await further comments. No change at present. Discussed again, 7/18/19, and resolution will be deferred until consideration of formal comments takes place at conference in Jacksonville, since multiple commenters have raised this

# ATTACHMENT 3 – Comments from Albuquerque Conference

		Comments During Albuquerque Public Session	1	
	Disclaimer: The NEL	AC Institute (TNI) accepts no liability for the content of any comme	ent on a standard. Any vie	
	V Section/clause	Comment	Committee action	Committee comment
59	Clause 7.9.1 – Accreditation Cycle	The concept of accreditation cycle replaces use of the terms surveillance assessment and reassessment. As the ISO language is written, there is no leeway for the plus/minus six months that NELAP ABs have previously used, since some assessment technique must be performed by the two-year mark of the accreditation cycle. Assessment techniques are elsewhere defined, but include review of PT results, document reviews and other sub-sets of what we consider a full assessment.	this requirement could be met by the semiannual PT reviews	discussed 7/18/19
60	Clause 7.9.1 – Accreditation Cycle	Consider adding a new sub-section to address the reporting and corrective action parts of the accreditation cycle (and possibly other items now removed from 17011.)	new language in ISO 17011 addresses this adequately	discussed 7/18/19
61	Clause 7.9.1 – Accreditation Cycle	Be sure that all requirements for the laboratory are placed into Volume 1 as soon as possible, but no later than the next V1 revision cycle.	LAB sent a request to Quality Systems to address this	discussed 7/18/19
62	Clause 7.9.2 – Assessment Program	Each lab must have an individual assessment program that covers activities for the five-year accreditation cycle (or less.) The AB is expected to consider risk management when designing this assessment program, for each lab, so that not every assessment program will be identical but rather customized for the laboratory and its activities and the AB's judgement about the level of risk to be controlled or managed.	no change requested, but the standard does require that risk management be addressed. The appropriate terminology here is that each lab has a customized "assessment plan", since the "assessment program" describes the AB itself or the group of ABs sharing mutual recognitions	discussed 7/18/19

63	Clause 7.9.3 – Sampling during a lab assessment	Essentially, the former surveillance assessments are replaced by "other assessment techniques." The TNI note carried from V2M1 7.7.2 was placed here – one AB asked that the phrase "among other things" be deleted and that the term surveillance (which no longer has a definition in the revised standard) be replaced (with "assessment technique," probably.)	this is done by the changes in ISO 17011 language	discussed 7/18/19
64	Clause 7.9.3 – Sampling during a lab assessment	Also, there was a request that the plus/minus six months be written into the TNI language here. This is the first use of "assessment technique" (use of techniques other than on-site documented, achieve same objectives as on-site, and justified.)	plus/minus 6 months is still within the accreditation cycle	discussed 7/18/19
65	Clause 7.9.4 – Reassessments	§7.9.4.1 (inserted TNI language) The NELAP ABs formed consensus around having reassessments be required on or before the 3 year time period, and prefer the two-years-plus-orminus-six- months language that stands for NELAP now. There were no strong objections to the need to apply other assessment techniques prior to the two-year timeframe, just some dissatisfaction.	Noted. PTs qualify as "other assessment techniques"	discussed 7/18/19

		Comments During Albuquerque Public Session	n	
66	Clause 7.9.4 – Reassessments	7.9.4.2 (inserted TNI language) – eliminate reference to surveillance and just refer to the assessment report (general agreement on this.)	done	discussed 7/18/19
67	Clause 7.9.4 – Reassessments	7.9.4.3 (inserted TNI language) – while the main clause seems appropriate, a suggestion was made that the note might belong elsewhere. One suggestion was that it could be in section 3.10 of the old V2, wherever that fits)	the note was removed	discussed 7/18/19
68	Clause 7.9.5 – Use of Extraordinary Assessments	Reword the note to say that "examples of changes triggering extraordinary assessments could include"	done	discussed 7/18/19
69	Clause 3.22 – Assessment (plus TNI Note)	Eliminate the term surveillance in the note. Remove the number 2, since there is only one note present. Perhaps as examples of an extraordinary assessment, include items that might formerly have triggered a surveillance assessment. Remove the term follow-up assessment, since that is just another variant of an extraordinary assessment. Verify that surveillance and follow-up terms are not carried over into other sections of TNI language. Modify extraordinary assessment to encompass full or partial assessment. Note that reassessment has its own definition elsewhere.	the entire note was removed	discussed 7/18/19

70	Clause 3.22 – Assessment (plus TNI Note)	Consider deleting the entire note and having all further details go into the ABs' assessment programs (there was consensus around this last idea.)	done	discussed 7/18/19
71	Clause 3.23 – Reassessment	Eliminate the term surveillance in the note. Remove the number 2, since there is only one note present. Perhaps as examples of an extraordinary assessment, include items that might formerly have triggered a surveillance assessment. Remove the term follow-up assessment, since that is just another variant of an extraordinary assessment. Verify that surveillance and follow-up terms are not carried over into other sections of TNI language. Modify extraordinary assessment to encompass full or partial assessment. Note that reassessment has its own definition elsewhere.	the entire note was removed	discussed 7/18/19
72	Clause 3.24 – Assessment Techniques	These are ISO examples of options that the AB can use along with, or in lieu of, the usual on-site assessments that most ABs currently use. NOT a TNI note	the committee cannot change ISO language	discussed 7/18/19
73	Clause 3.25 – Witnessing	This could be watching the method run for a PT sample – it is one specific assessment technique.	Noted. PTs qualify as "other assessment techniques"	discussed 7/18/19
74	Clause 3.26 – Remote Assessment	Just document how and why the AB is using remote assessment techniques and justify the equivalence to a physical site visit.	this is part of implementation and is covered in §7.9, Accreditation Cycle	discussed 7/18/19
75	Clauses 3.8 and 4.6 – Accreditation Scheme	should the TNI standard seek to define the NELAP accreditation scheme or leave that to NELAP to define for itself?	the LAB Expert Committee believes that the standard should not define NELAP or any other accreditation scheme	discussed 7/18/19

		Comments During Albuquerque Public Sessio	on	
76	Clauses 3.8 and 4.6 – Accreditation Scheme	NELAP, PT, NGAB, NEFAP are all accreditation schemes, as is drinking water certification in nonNELAP states, plus the Defense Department and Energy Department accreditations. One commenter noted that the TNI language within ISO 17011 defines the NELAP accreditation scheme sufficiently.	LAB believes that TNI language within ISO 17011 defines the NELAP accreditation scheme and other environmentnal laboratory testing accreditation schemes sufficiently	discussed 7/18/19
77	Clauses 3.8 and 4.6 – Accreditation Scheme	Perhaps a Note 2 to 3.8 should say that TNI ELSS Volume 1 defines the NELAP accreditation scheme?	no	discussed 7/18/19

78	Clauses 3.8 and 4.6 – Accreditation Scheme	To meet clause 4.6.3, ABs could simply add a sentence to their quality manual saying that they implement the NELAP accreditation scheme	the Certificate of Recognition announces the accreditation to the TNI standard; the AB's quality system documents how the AB implements it	discussed 7/18/19
79	Clause 7.4.4 – AB documented procedures to assess labs, plus assessment techniques to be used	The note is in the correct place, but should be unnumbered.	there is no note in §7.4.4 (presumably this was a typo but no way to backtrack now)	discussed 7/18/19
80	Clause 7.4.5 – "sample of conformity assessment activities" and "sample of locations and personnel"	Keep the note, as edited	there is no need for the note	discussed 7/18/19
81	Clause 7.4.7 – AB develops the assessment plan and assessment techniques to be used (could vary by lab!)	Suggest writing into the plan the opportunity to modify it if warranted. Departure from the plan would need approval from the AB itself. Make the note a requirement ("shall have") and move it to 7.6.3 or 7.6 somewhere.	This will be considered along with the formal comments on the outine and draft, at conference in Jacksonville	discussed 7/18/19
82	Clause 7.6.3 – OSA conducted based on the assessment plan	7.6.3.1 - fits better under 6.2.2. Also would prefer that it apply to others beyond assessors. Be clear that assessors are included.	okay as is	discussed 7/18/19
83	conducted based on	7.6.3.3 – specify a blank checklist or eliminate the checklist. About a "standard form?" What if a non=standard form is used? How does one transfer the checklist/form from a tablet computer used to record the site visit observations? Consensus was to remove section b from the TNI language part (b is about checklists.)	b was removed and the following items renumbered	discussed 7/18/19

	Comments During Albuquerque Public Session
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84	Clause 7.14.3 – Additional TNI language	This section should apply to assessments, not reassessments. Timing should be previous two assessment cycles. ABs prefer that it be a specific number of years. Several ABs noted that their state laws or regulations may direct that records be retained (or destroyed) in a timeframe different than that is specified in this TNI language, and that they will have to comply with state requirements, so this language should be revised to state that the minimum time is either what the state specifies or the ISO language.	§7.14.3 was removed	discussed 7/18/19
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## ATTACHMENT 4 – Comments from New Orleans Conference

	Title V2M1 comments on "outline" from NOLA conference August 2018         Disclaimer: The NELAC Institute (TNI) accepts no liability for the content of any comment o				
	Vote	Section/clause	Comment	Committee action	Committe comment
85	N/A	V2M1, 4.2.6	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
86	N/A	V2M1, 5.1.2	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
87	N/A	V2M1, 6.1.3 (and V2M3, 4.1.3)	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
88	N/A	V2M1, 6.2.3 (and V2M3, 4.2.6)	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
89	N/A	V2M1, 6.2.4 (and V2M3, 4.2.7)	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
90	N/A	V2M1, 6.4.2 (and (V2M3, 4.3.1)	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
91	N/A	V2M1, 7.4.2(c)	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
92	N/A	V2M1, 7.10.2	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
93	N/A	V2M1, 7.10.3	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
94	N/A	V2M1, 7.11	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
95	N/A	V2M1, 8.1.1(d)	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
96	N/A	V2M1, 8.2.1	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
97	N/A	V2M1, 8.2.2	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
98	N/A	V2M1, 8.3.2(b)	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
99	N/A	V2M1, 8.3.2(d)	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
100	N/A	V2M3, 4.3.5	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
101	N/A	V2M3, 4.4.1	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
102	N/A	V2M3, 6.3.2	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
103	N/A	V2M3, 6.9.1	see minutes of 8/6/18, ok to eliminate	affirm prior decision	
104	N/A	V2M3, 6.9.2	see minutes of 8/6/18, ok to eliminate	affirm prior decision	

105	N/A	V2M3, 6.12.3	see minutes of 8/6/18, ok to eliminate	affirm prior decision
106	N/A	2003 NELAC 6.1	see minutes of 8/6/18, ok to eliminate, replaced by SOP 3-102 & policies	affirm prior decision
107	N/A	2003 NELAC 6.2, entire	see minutes of 8/6/18, ok to eliminate, replaced by SOP 3-102 & policies	affirm prior decision
108	N/A	2003 NELAC 6.3, entire	see minutes of 8/6/18, ok to eliminate, replaced by SOP 3-102 & policies	affirm prior decision
109	N/A		automation issues are adequately addressed in language about remote assessments	committee agrees

110	N/A	discussion about the wording of "failure to pass" an assessment was undefined. That phrasing should refer to non- compliance with requirements of the standard; this language should also be included in Volume 1 so that labs can see it, as well. Sections 7.7.5 and 7.11.1 define not meeting the requirements for accreditation in the 2017 version of ISO 17011.	This will be considered along with the formal comments on the outline and draft, at conference in Jacksonville
111	N/A	the revised V2M1 should keep the note (formerly 7.8.1.h) about encouraging ABs to upload CAB fields of accreditation into LAMS.	

<b>ATTACHMENT 5 Comments from Milwauke</b>	e Conference
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Comments from Milwaukee			
	Section/clause	Comment	Committee action
112	3.6	ISO/IEC 17025 now includes sampling, and one committee member asked whether sampling should become part of the V2M1 definition of the term "scope of accreditation". This issue remains to be considered by the full committee.	sampling for subsequent environmental testing (under ISO 17025) is different than the samplinjg of Fields of Accreditation (FoAs) during the on-site evaluation for conformance with ISO 17011
113	3.22	Will NELAP ABs adapt to flexible scopes of accreditation? NGABs use it now (having moved to the 2017 revisions of ISO/IEC 17011), so the NGAB usage needs to be accommodated in this module (not directly relevant to the text of slide 7)	the use of flexible scopes is not restricted but neither is it required (see §7.8.4)
114	6.1.2.9.1	(assessor qualifications) $-2^{nd}$ bullet requires clarification of "verified assessment".	<pre>§6.1.3.2.1 describes a "verified assessment"</pre>

115	6.1.2.9.2	3 <sup>rd</sup> bullet – is a test adequate or must there be assessor training followed by a test? One participant commented that the "test only" concept was a way of grandfathering in the existing assessors but should no longer be relevant. Is it adequate to accept a certificate of training for the hiring of an experienced assessor without requiring a repeat of training, but possibly with a test (or test results/score from that training demonstrated by certificate)? (Possibly John Gumpper will provide draft language for this, §6.1.2.9.1 or § 6.1.3.2.1.) Another participant commented that her AB hires assessors from its state lab, so that they are already trained in the methods, and thus should only need to demonstrate knowledge by passing a test, expressing a strong sentiment that the AB itself should be able to determine who is qualified. Yet another participant commented that training would better ensure consistency in assessments.	draft language never submitted. Existing language requiring a test is considered adequate. ABs may impose additional personnel qualifications as they choose
116	6.1.2.9.3	One participant wants there to be a combination of training and experience for the evaluation of assessor capabilities. (Mohan from IAS offered to provide some draft language for this.)	draft language not submitted. Committee considers language acceptable as is
117	6.1.3.7	Make this new language into active voice.	done

118	6.2.2.3	is there still a need for a signed statement for every assessment? Suggestion that a hand-inscribed signature on paper is overkill. An AB commented that the AB needs to have procedures for determining whether a conflict of interest exists, or not; having specific language in the module may not work for all ABs and should probably be deleted.	leave as is, pending further	
119	7.2	Note 2 is not appropriate.	removed	

120	7.4.2.1	preferred language would be "ABs are allowed to conduct" and the text about "initial assessments shall be announced" conflicts with at least one AB's regulations (either PA or VA, notes are unclear) and must be removed. The Chair requested proposed wording for both the note and normative language; the issue was not resolved in the session.	This will be considered along with the formal comments on the outine and draft, at conference in Jacksonville
121	7.4.2 second note deleted	Participant requests that the reason for deleting this language be noted in the outline of proposed changes.	OBE
122	7.6.2.1	Considerable discussion about whether the appropriate term is "document" or "record" (both verbs here). ISO does not use "record" and "document" is always followed by a process. Suggest revising the language to say that the "AB should retain a record of", thus using the noun word instead.	"shall be documented" is normative language; the remainder is in a note

123	7.6.3.3	The term "team leader" in ISO language adds confusion with how that term is used in AB personnel structures. Request to use "assessment team leader" or rephrase to say "assessment team should consult". Again, the Chair requested that someone submit draft language.	no draft language was received; no changes made
124	7.6.6.a	one participant objects to §7.6.6.a, the note, that assessors must take their findings to the AB before releasing the written report, and also NGABs sometimes DO leave a written report at the closing meeting. Requests making the note the normative language, something like "the AB shall be considered to have met this requirement by providing [oral report at closing meeting followed by written report later] and deleting the current normative language. (This was done in the draft module as distributed to the committee after conference.)	done
125	7.6.6.b	there was a clear desire to allow exceptions to the 30 day "for good cause" or to consider changing it to accommodate holidays (perhaps 30 business days?) – proposed language was that the "AB may extend the time on request due to unforeseen circumstances. Another participant requested adding language about communicating delays and the reason for them, between the lab and the AB.	This will be considered along with the formal comments on the outine and draft, at conference in Jacksonville

126	7.6.7.1	The proposed deleted language about report sharing brought comments that TX needs it but it violates PA and FL law/regulations. ABs may need to share for purposes of mutual recognition but there may also be other reasons. ABs might be satisfied with exception language, saying "unless superseded by state regulations". (Aaren Alger agreed to submit draft language.) Also, a crossreference with §8.1 may provide adequate exception.	This will be considered along with the formal comments on the outine and draft, at conference in Jacksonville
127	7.7.6.1.11	Participants requested eliminating the word "reasonable". Also, while ISO does not address secondary accreditations, this language may have more applicability to secondary accreditations, since denials are already allowed but not required. NOTE: ensure that primary AB is defined in the glossary, as well as secondary AB.	this appears to have been done. The committee was unable to identify the language where reasonable might have existed any text added to the revised draft would not leave a "trail" in the Word document, when deleted.

128	7.8.3	the point was made that "scope" defines matrix/technologymethod/analyte, as defined in the standard but that may not be information that needs to be provided to the labs. Additionally, there were objections to LAMS nomenclature being enforced for use by the ABs. This language may not be needed here but rather in §7.8.3.d, with the LAMS reference removed (please).	additional terms were added for clarity
129	7.8.3	A request was made to put the note at the top of the section. Also, eliminate mention of Volume 4 in this module.	done but the V4 reference was retained

130	7.9.3 note	"Surveillance" is no longer a concept in the ISO language and has thus been removed. In the 3 <sup>rd</sup> bullet, remove "reasonable".	there are no bullets; the term "surveillance" is no longer present	
131	7.13.8 or 7.14.3 (slide 29)	Remove the 2 <sup>nd</sup> bullet, as it is redundant, and note the reason for deletion in the outline.	OBE	
132	8.1.5	Rephrase to include "or reference through applicable laws or regulations" – it's not clear that a regulation would qualify as the ISO- required "document" that requires a procedure or process, as currently written.	done	
133	9.7.5	Note that "redundant" is the reason for deletion in the outline.	OBE	