Microbiology Expert Committee (MEC)
Meeting Summary

February 17, 2015

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:30pm Eastern by teleconference. Attendance is recorded in Attachment A – there were 6 members present. Associate Members: Carl Kircher, Jennifer Best, Krista Greenwood, and Mike Antoine.

The meeting minutes for the January and Crystal City meetings were distributed by email. The committee reviewed the minutes. A motion was made by Elizabeth to approve both sets of minutes. The motion was seconded by Donna and they were unanimously approved without any further discussion.

Associate members need to let Robin and Ilona know they own a copy of ISO 17025 so they can be included in distributions of the draft Standard updates.

2. Standard Interpretation Request (SIR) – SIR #285

The question (Section 1.7.3.2 of 2009 Standard):
Can you please clarify what is meant by "methods that specify colony counts such as membrane filter or plated media." Does this mean all methods that are enumeration? Or just the membrane filter and plated media methods?
Thank you!

Robin thinks the language is pretty clear. "Such as" is meant to be an example – it is not an all inclusive list.

Everyone thinks it is clear. Quanteray is not a colony count. Patsy noted by email: *SM is pretty clear that this counting is for MF methods only, which does end up on a plate.*

Robin reminded everyone that the committee can't change the current language – the response needs to be based on the language that is there.

The answer is yes. And then clarify this language in the 2015 Standard. The intention was for all enumerated methods to have duplicate counts. The TNI 2015 Standard will be edited to include this clarification. Robin will work on a response for the committee to review by email or at the next meeting.

3. MWDS Comment Summary

The comments received on the Modified Working Draft Standard (MWDS) were compiled into a summary table and sent to the committee to discuss. Each comment was numbered in the table.

Robin noted that she thinks some of the comments are really how to comments instead of real comments on the Standard.

Comment 33 and 34:

Non-Persuasive on both. Method specifics beyond the scope of the Standard.

Comment 35:

Non-Persuasive. Method specific.

Comment 36:

Non-persuasive: This type of specificity is beyond the scope of the Standard

Comment 38:

Robin can understand his question. When the lab checks the samples for chemistry – every sample is checked. This is actually an exception – not a requirement.

a) Persuasive. This can be done – combine b and c.
b) Yes based on the Standard.
c) Robin feels the response is yes.

Elizabeth commented that she is OK with how it is. Dwayne agrees – b and c can be combined, but the rest is fine. The combination is not necessary.

The committee decided it is a Non-Persuasive comment. This type of specificity is beyond the scope of the Standard.

Carl asked if it is OK to respond to these questions. If so, the language can be left as it is. The comment should be Non-Persuasive since no language is being improved/changed.

Robin will send these responses out to the committee for final review (see Attachment D).

Looking back at Comments that needed further review based on the last meeting discussion:

Comment 15:
It is non-persuasive.

Comment 29:

Robin got pushback from labs on the text that is in green. Should "… prior to performing analysis" be added?

Carl is OK with a lab putting the 4 QC samples on before the actual samples – this is the lab's risk. If the 4 QC samples don't pass – the sample results are not valid. He does not think the language prevents labs from continuing to do what they are already doing. Prior to is prior to … and running the 4 QC samples before the samples

The green language should be incorporated into the final response.

Comment 6/7:

Robin had a note in the Standard – under reagents. Should the general requirements be pointed out? Does Module 2 need to be referenced? It is stated that Module 5 is a supplement to Module 2.

Section 5.6.4.2 does specifically reference media, so does this really need to be added to Module 5. Robin asked if anything needs to be added to c).

Dwayne doesn't have a problem referring to another section or part of the Standard where needed.

The following language was deleted: Certificates of analysis provided by vendors shall be verified by the laboratory. These sterility checks may be performed by a contracted laboratory if the laboratory does not have the requisite equipment to perform them.

The following language was added: "checked by the laboratory once per purchase … ".

Comment 8 above:

There are some states that are accepting a certificate of analysis. Texas is accepting the certificates from IDEXX. Jennifer is concerned that an AB is not following the Standard – since the language is "shall". Jennifer feels strongly that the labs should run their own positive/negative controls and not just use the vendors. The Standard does not specify who is supposed to do it.

Carl feels the culture control checks must be done in the lab. This is supported by Module 2 and 5.

Robin looked at the language regarding certificates in the Standard the committee is working on.

Robin came across the part of the Standard on incubation times. She asked if the text works for everyone now – after discussion and examples given by Carl – the committee is OK with this language – as was Carl.

Robin will send everyone the clean document and asked that everyone look for passive vs. active voices. Are there parts that should be changed to "Shall be …" others that should be "should be …"? She asked that people comment immediately so language can be finalized for a vote early next week.

Ilona noted that there is still some green language in the table that needs to be addressed in the Standard before it will be ready for a vote. Robin will take care of this before she sends it out to the committee to prepare for approval.

Robin would like to call for an email vote on Monday to approve the changes she will make to the Standard and the comment table.

4. Action Items

A summary of action items can be found in Attachment B. The action items were reviewed and updated.

5. New Business

- Paul Junio mentioned that the information on thermometer checks in Module 5 may be in conflict with what is in Module 2. Unless there is a technical reason that Module 5 should be less stringent, Module 2 must be followed. He plans to bring this up to the CSDP as part of the SRC Module 5 review. Paul is hoping to change Module 2 if possible.

6. Next Meeting and Close

The next meeting will be by teleconference and planned by email.

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

Robin adjourned the meeting. The meeting ended at 3:20 pm EST. (Motion: Dwayne Second: Karla Unanimously approved.)

Attachment A
Participants
Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information	
Robin Cook (Chair) **Present**	City of Daytona Beach EML	Lab	(386)671-8885	cookr@codb.us
Patsy Root (Vice-chair) **Absent**	IDEXX Laboratories, Inc	Other	(207)556-8947	patsy-root@idexx.com
Karla Ziegelmann-Fjeld **Present**	Microbiologics, Inc	Other		kfjeld@microbiologics.com
Donna Ruokonen **Present until 2pm**	Microbac Laboratories, Inc	Lab	(219)769-8378 Ext 110	druokonen@microbac.com
Colin Fricker **Absent**	Analytical Services, Inc	Lab		colinfricker@aol.com
Deb Waller **Absent**	NJ DEP	AB	(609)984-7732	debra.waller@dep.state.nj.us
Dwayne Burkholder **Present**	Pennsylvania DEP	AB	(717)346-8213	dburkholde@pa.gov
Mary Robinson **Present**	Indiana State DOH	AB	(317)921-5523	mrobinson@isdh.in.gov
Elizabeth Turner **Present**	North Texas Municipal Water District	Lab	(972)442-5405 Ext 535	eturner@ntmwd.com
Po Chang **Absent**	Texas Commission on Environmental Quality	AB	(512)239-4876	Po.chang@tceq.texas.gov
Gary Yakub **Absent**	Environmental Standards, Inc.	Other	(610)935-5577	gyakub@envstd.com
Ilona Taunton (Program Administrator) **Present**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – MEC

	Action Item	Who	Expected Completion	Actual Completion
1	Review Method Codes and send comments to Robin for Dan Hickman.	Deb	TBD	
4	Review Handbook and Method Codes before next meeting.	ALL	5/7/13	Handbook Complete.
12	Research possible effects of using bromine and whether it needs to somehow be included in the Standard. Does not look like it.	Deb	November 2013 Meeting	
19	Provide EPA interpretation on temperature readings to Ilona. She will have it posted on the website.	Robin	1/31/14	
38	Update MWDS table with comments from 2/3 meeting. Distribute to committee.	Ilona	2/13/15	Complete
39	Update the MWDS-Final-Track Changes with the changes discussed.	Robin	2/16/15	Complete
40	Send CSDP EC a copy of the edited Standard ASAP so the SRC can begin a review before the VDS is finalized.	Robin/Ilona	TBD	Complete
41	Prepare Draft Response to SIR for committee review.	Robin	3/10/15	
42	Update Standard and Comment Table based on changes made during the 2/17 meeting. Distribute to committee.	Robin	ASAP	

Attachment C

Backburner / Reminders – MEC

	Item	Meeting Reference	Comments
1	Update charter in October 2015.	n/a	

Attachment D:
Version: 2-17-15-v5

Microbiology Expert Committee				
Document No./Title: STD-ELV1M5-Micro-MWDS-11-21-14				
Commenter (Who):				
Number	**Section/ Clause No.**	**Comments**	**Comment Resolution. P = Persuasive NP = Non-Persuasive**	
1	1.1	I normally do not make comments on fluff, which is what this section mostly is, but the last sentence here caught my attention. I do not believe it is necessarily true that, as worded, adherence to quality system requirements will ensure that all quality control procedures in Module 5 will be met. If you are into opportunities for improvement, I would word the last sentence as: "Adherence to those quality system requirements and all quality control procedures specified in this module will ensure that microbiological test results are fit for the intended use."	Persuasive. Edited accordingly.	2
2	1.5.1	I would like to suggest that this section: 1.5.1 Accuracy – Use at least one (1) known pure reference culture at the anticipated environmental conditions, and compare the method results to that of a reference method. Be changed to this: 1.5.1 Accuracy – Use at least one (1) known positive pure reference culture at the anticipated environmental conditions, and compare the method results to that of a reference method.	Persuasive. Edited accordingly.	4

3	1.5.1	Comment on Section 1.5.1: Accuracy – Use at least one (1) known pure reference culture at the anticipated environmental conditions, and compare the method results to that of a reference method. The Standard only states that the method may be validated by comparing a pure culture with a reference method. The Standard does not require that the results compare well with the method. In addition, based on the above, laboratories could theoretically compare negative culture results to a method and assume all is well. Suggested language: Accuracy – Use at least one (1) known pure positive reference culture at the anticipated environmental conditions. Results should be comparable and compare the method results to that of a reference method.	Persuasive. See Comment #2 above.	5
4	1.5.2	The last sentence requires the precision of the proposed method shall not be statistically different. Than what, or from what? I would recommend retaining a part of the strike-through language so that the sentence reads: “The results shall show that the precision of the proposed method is not statistically different than that of the reference method.”	Persuasive. Edited accordingly.	2

29	1.6.1.2 1.6.3.1	Propose adding a language to clarify the requirement for each analyst to have documentation of a continuing DOC every 12 months 1.6.1.2 Thereafter, ongoing DOC (Section 1.6.3), must be performed and documented at least every 12 months as per the quality control requirements in Section 1.7.3, is required. 1.6.3.1 The laboratory shall have a documented procedure describing ongoing DOC that includes how the laboratory will identify data associated with ongoing DOCs. The analyst(s) shall demonstrate ongoing capability by routinely meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. If an analyst has not documented ongoing DOC within the previousIf the method has not been performed by the analyst in a twelve (12) month period, an initial DOC (Section 1.6.2) shall be performed prior to performing analysis. It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate.	Persuasive. The language in 1.6.1.2 was changed to: Thereafter, ongoing DOC (Section 1.6.3), must be performed and documented at least every 12 months. Edit to 1.6.3.1 - "... prior to performing analysis". Persuasive. : 1.6.1.2 Thereafter, ongoing DOC must be performed and documented at least every 12 months.	9
5	1.6.3.2.b	As worded, two “non-detect” sample results on the same sample can be adequate for a new-analyst demonstration of capability? That is the meaning when you combine 1.6.1.1 (new analyst IDOC), 1.6.2 (change in personnel to add a new analyst), and 1.6.1.3 (can do CDOC in place of IDOC if lab using the method without significant changes for at least 1 year). If that was the committee¹s intent, then so be it. Otherwise, please revise if you think more should be needed for the new analyst. Maybe “Analysis of one positive sample in duplicate Š” would fix it?	Persuasive. “Positive” has been added between “one” and “sample”. It now reads: Analysis of one positive sample …	2

6 / 7	1.7.3.1.a	If a material were shipped out to a contract lab to be tested for sterility, and the results came back as not sterile, how would one ascertain as to whether the compromise of the material occurred to the original lot or to the portion that was reshipped? I would recommend deleting this sentence. Where such a test may need to be subcontracted, I would defer to the professional judgment of the AB as to whether it is acceptable rather than including this provision in the Standard). Certificates of analysis provided by vendors shall be verified by the laboratory. ~~These sterility checks may be performed by a contracted laboratory if the laboratory does not have the requisite equipment to perform them.~~	Persuasive. The following language was deleted: ~~Certificates of analysis provided by vendors shall be verified by the laboratory. These sterility checks may be performed by a contracted laboratory if the laboratory does not have the requisite equipment to perform them.~~ The following language was added: "checked by the laboratory once per purchase … ". Sterility check …. Must be checked "by the lab" once perpurchased …, remove sentences 2 and 3. leave in last sentence. Find place to add something about retaining certificates of analysis for documentation. V1M2 5.6.4.2.a talks about CoA being kept.	1
8	1.7.3.1.a.i.1	Would recommend including language describing what to do if the sterility check/blank comes back positive (indicating there was contamination). For materials- they may need to be resterilized (if the material permits). For media, however, the batch should be disposed of - or the manufacturer contacted and a replacement requested. Under no circumstances should media be resterilized, as excessive heat exposure will cause degradation of the medium.	Persuasive. This was added to Section x. persusive, but add to a different section TBD; should also be in the small lab handbook.	1
33	1.7.3.1.a.i.2	**a**. If media validation is performed on each batch of prepared media in bulk, using a positive, negative and blank control is there a need to perform further sterility testing, if all controls pass. **b**. If the media batch is separated in multiple smaller containers (1 liter) for long term storage, does a sterility check or validation need to be performed after melting the media before use in petri plates. **c**. Since the agar turns to a solid form upon cooling how would a sterility check be performed? i. Would an overlay assay be acceptable method to validate sterility ii. Would incubating a blank media plate at method specified temperature and time be an acceptable method to validate sterility.	Non-peruasive: Method specifics beyond the scope of the Standard.	10

34	1.7.3.1.a.ii	Funnel sterility check per autoclaved batch. Why is a sterility check needed to be performed on specific piece of equipment (funnel), as long as one piece of equipment or item from each autoclave batch is tested for sterility? For instance can a graduated cylinder, or milk dilution bottle be used.	Non-peruasive: Method specifics beyond the scope of the Standard.	10
9	1.7.3.1.a.iii	This section should indicate a recommended/minimum incubation time that the sterility check should be incubated. (EPA lab cert manual recommends 48 hours). One would want to ensure any slow growing contaminants would be detected. Since samples may be in a bottle longer than the incubation period of the method (often the sample collection vessel is the same as that used for testing), a longer incubation time of the sterility test may be warranted. For example, if a sample is held for 30 hours and then incubated with medium for another 24 hours with medium - a 24 hour sterility test may not capture slow growers that could be present.	Persuasive. The language was changed to: xxx **persuasive:** verify at intended use, Quality and Sterility of Standards, reagents, materials and media. The lab shall ensure that the quality of the reagents and media is appropriate for the test concerned and intended use … or duration of incubation.. Dixie recommended: The laboratory shall ensure that all media testing and quality of the reagents and media used is appropriate for the test concerned.	1
10	1.7.3.1.a.iv	Again, I would recommend inclusion of a minimum incubation time. (see my previous comment)	See response to Comment #9.	1

30	1.7.3.1.b	Propose re-writing setion 1.7.3.1.b to remove redundancy and confusion. b. Media – Culture media may be prepared from commercial dehydrated powders or may be purchased ready-to-use. i. Laboratory-Prepared Media 1. Media prepared by the laboratory from basic ingredients and/or commercial dehydrated powder shall be tested for performance (e.g., for selectivity, sensitivity, sterility, growth promotion, and growth inhibition). These tests shall be performed at a minimum with first use. 2. Media shall be used within the holding time limits specified in the accredited method. 3. Detailed testing criteria information shall be defined in the laboratory's methods, SOPs, or similar documentation. ii. Ready-to-Use Media 1. See 1.7.3.1.b.i.1. 2. Any ready-to-use media shall be used within the expiration date provided by the manufacturer. 3. Detailed testing criteria information shall be defined in the laboratory's methods, SOPs, or similar documentation. c. Reagents and commercial dehydrated powders shall be used within the shelf life of the product, and shall be documented as per TNI Volume 1, Module 2 Quality Systems General Requirements. b. Media – Culture media may be prepared from commercial dehydrated powders or may be purchased ready-to-use. i. Ready-to-use media and laboratory prepared media shall be tested for performance (e.g., selectivity sensitivity, sterility, growth promotion, and grown inhibition). These tests shall be performed at a minimum with first use.	Persuasive. Edited accordingly.	9

11	1.7.3.1.b.ii.1	The section says “See 1.7.3.1(b)(i)(1).” Yes, I see it, per se. So? Why not write out the approx. 4 lines of requirements to be absolutely sure what is required for the ready-to-use media.	Persuasive. Edited accordingly. See Comment #30. persusive and edit accordingly; take lang out and put wording instead of reference number	2
31	1.7.3.1.c	Rewrite to: c. Reagents - All reagents, buffers and supplies shall be used within the shelf life of the product and shall be documented as per TNI Volume 1, Module 2 Quality Systems General Requirements.	Persuasive. Edited accordingly. See Comment #30. persusive and edit accordingly; take lang out and put wording instead of reference number	9
12	1.7.3.1.d	There is a subsection (ii) in the text I have that does not have any language after it. Was that meant for the paragraph that is above it? Or is it to be held in reserve for a future requirement?	Non-Persuasive. The committee does not see this issue in their version of the Standard.	2
13	1.7.3.1.d.i	The first sentence says to monitor laboratory reagent water for bactericidal and inhibitory substances. What are these substances? Were they meant to be the compounds and elements listed further in the section? Do all assessors and ABs universally agree on the all-inclusive list of what bactericidal and inhibitory substances need to be monitored?	Non-Persuasive. There was no intent to include an all inclusive list. non persuasive; see section 1.7.3.1.d iii	2
14	1.7.3.1.f	Documentation for media and reagents prepared in the laboratory shall include date of preparation, preparer’s initials, type, manufacturer, lot number, final pH, expiration date, and the amount of reagents used. Documentation for media purchased pre-prepared, ready-to-use (including reagent water purchased from outside sources) shall include manufacturer, lot number, type of medium received, date of receipt, expiration date of the media, and pH of the medium.	Persuasive. This is covered in V1M2 Section 5.6.4.2. A reference to this Section will be added. persuasive, covered in section V1M2 5.6.4.2 documentation of labeling of reagents and reference material. Add a reference to V1M2 for reagents.	1
15	1.7.3.2.b	The last sentence says to insert a method blank after every 10 filtration samples or sanitize filtration units by UV light (254-nm) after sample filtration. Under the latter option, sanitation must be done after EACH sample, right? If that is not the committee’s intent, a revision or clarification is needed.	Non-Persuasive. It is correct - sanitize after each sample if using UV. There will be no change in language. **persuasive:** sanititize after each sample if using UV.	2
16	1.7.3.3	As worded, this section requires laboratories to prepare and analyze a positive sample monthly (for 2 or more analysts to count colonies) if all its regular samples do not produce any colony counts in the given month. Is this correct? Fine with me if that is the committee’s intent.	Non-Persuasive. This is correct. A positive sample must be used. this is correct. A + sample has to be used.	2

35	1.7.3.4	**a**. Method 1603 has specific requirements for matrix spike recovery that cannot be consistently met using bioballs as listed in the method. Spike recovery can be poor using selective growth media and when incubation occurs at a temperature > 35°C, if there organisms are not thermo-tolerant. The vendor of the bioballs states that selective media, the use of membrane filtration and temperatures >35°C will decrease recovery. **b**. This would require the laboratory to culture a thermo-tolerant strain of E. coli, which contradict the strain recommended for use in method 1603. This would add a lot of additional labor for small laboratories.	Non-persuasive: Method Specific	10
17	1.7.3.6.b	To ensure that analysis results are accurate, target organism identity shall be verified as specified in the method (e.g., by use of the completed test, or by use of secondary verification tests such as a catalase test, or by the use of a selective medium such as *Brilliant Green Lactose Bile Broth* (BGLB) or ~~*E. coli* (~~EC or EC + MUG~~)~~ broth~~)~~.	Persuasive. Edited accordingly. persuasive, make suggested changes. Re-look at formatting	1
18	1.7.3.6.b	Is a citation needed for formulation of BGLB or EC/EC-MUG broth (ie 9221)?	Non-Persuasive. They may not be using Standard Methods and sometimes it is on the bottle. Methods and programs typically cover it. not persuasive, directions are on the bottle, or they may not be using *Standard Methods*	1
19	1.7.3.6.c	Seems like everything described in "C" would fit better in "D" below - "culture controls"	Non-Persuasive. "c" is selectivity, reference cultures and "d" relates to working cultures. not persuasive, C is selectivity, reference cultures and D relates to working cultures	1

20	1.7.3.6.d.ii.2	Positive and negative cultures are for testing if the media works on the control cultures, and the media lot comparison is to show if the new media gives the same quantitation as the old media. It would be such a burden for small labs to obtain quantitative Standards to use every time they made a batch of media. See excerpt from from SM 22nd edition (2011) below. We recommend that the additional quantitative requirement for control cultures to check media be removed from the Standard. Also, not all certified, approved micro methods are for quantitative analysis. The method is for P/A. Thank you. SM 9020 4,5) Quality control of prepared media—Maintain in a bound book a complete record of each prepared batch of medium with name of preparer and date, name and lot number of medium, amount of medium weighed, volume of medium prepared, sterilization time and temperature, pH measurements and adjustments, and preparations of labile components. Compare quantitative recoveries of new lots with previously acceptable ones. Include sterility and positive and negative control culture checks on all media as described below. 7. c. Internal QC: The written analytical methods should contain required QC checks of positive and negative control cultures, sterile blank, replicate analyses (precision), and a known quantitative culture, if available. 8. Analytical Quality Control Procedures 3) Control cultures—For each lot of medium check analytical procedures by testing with known positive and negative control cultures for the organism(s) under test. See Table 9020:V for examples of test cultures.	Persuasive. The language was changed to: ... with one or more known pure target organisms that produce typical results based on the method. Email Response from Robin on 1/13: I understand your point but want to offer some background as a perspective. Say you are using Total by MF for DW, for example. This is not a program that requires a number so therefore any checks would not require a number, even though SM 922B is qualitative in nature if you are using it for the DW only then comparing the numbers would not apply here. P/A status prevails of course as that is all the program requires. So having said that, if you use SM 9222D, SM 9222B for non-potable, SM 9221 A-E, SM 9223 with quauntitray or any of those methods where a number is reported, then this clarification is relevant. The clarification has always been implied under the old language as the default position has been the method requirements. But maybe we need to say that it only applies to programs that require a qualitative result. In section 1.2 SCOPE we address the fact that these are minimums and any method or program requirements also must be followed. In the section you provided it indicates the need to compare qualitative recoveries. I offer this prospective so you can see why we reached a certain position. Our minutes capture these discussion fairly well. Please feel free to review any of them.	6

21	1.7.3.6.d.ii.2	Comment turned in based on Robin's response to Victoria's comment within this summary: Notice she keeps saying qualitative at the bottom? We don't really have to make the STP guys buy expensive quantitative control cultures, do we? I still say if they just compare the old vs. the new lot of media with a sample that gives a countable result, that shows that the new media is acceptable quantitatively. That is what SM says to do!	See Comment #20 above. persuasive, this is what we meant, no change required	8
22	1.7.3.7.a	Please look again at this one [shown below] , as I believe it was misunderstood. My statement was that animals should be "prohibited" and the response was that pets are not allowed in the lab area … but I am not aware of anywhere that information stated within the Standard. It is not stated in the list of prohibited things that I had referenced. Please look again at this one [shown below] , as I believe it was misunderstood. My statement was that animals should be "prohibited" and the response was that pets are not allowed in the lab area … but I am not aware of anywhere that information stated within the Standard. It is not stated in the list of prohibited things that I had referenced.	Persuasive. The last sentence was removed. See V1M2 Section 5.8. Robin's response to Cathy on 1/20: Robin: We understood, but feel that this prohibition could be taken out of context as well. WET testing uses animals. Granted they are very specific animals but they are animals none the less. Cathy: The comment was made regarding the microbiology WDS, V1M5. Toxicity testing is addressed in V1M7. Robin: Agreed but there may be labs doing both and therefore they would be a conflict.	7

32	1.7.3.7.b.ii	Instead of bullets for each paragraph include letter designations 1. Autoclaves a) The performance of each autoclave shall be initially evaluated by establishing its functional properties and performance, for example, heat distribution characteristics with respect to typical uses. Autoclaves shall meet specified temperature tolerances. Pressure cookers shall not be used for sterilization of growth media. b) Demonstration of sterilization temperature shall be provided by use of a continuous temperature recording device or by use of a maximum registering thermometer with every cycle. At least once during each month that the autoclave is used, appropriate biological indicators shall be used to determine effective sterilization. The selected biological indicator shall be effective at the sterilization temperature and time needed to sterilize lactose based media. Temperature sensitive tape shall be used with the contents of each autoclave run to indicate that the autoclave contents have been processed. c) Records of autoclave operations shall be maintained for every cycle. Records shall include: Date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analyst's initials. d) Autoclave maintenance, either internally or by service contract, shall be performed annually, and shall include a pressure check and verification of temperature device. Records of the maintenance shall be maintained in equipment logs. When it has been determined that the autoclave has no leaks, pressure checks can be documented using the formula PV = nRT. e) The autoclave mechanical timing device shall be checked quarterly against a stopwatch and the actual time elapsed documented.	Persuasive. Edited accordingly.	9

36	1.7.3.7.b.ii.1	Does the temperature and pressure printout on the autoclave meet the criteria of a continuous recording device or must a data logger or maximum registering thermometer. If the pressure sensing device and temperature probe are checked and validated quarterly by a certified technician, would these measurements be considered traceable and valid.	Non-persuasive: This type of specficity is beyond the scope of the Standard	10
37	1.7.3.7.b.v.1	How shall "Full Capacity" of an incubator be determined?	Non-persuasive: This type of specficity is beyond the scope of the Standard	10
23	1.7.3.7.b.v.2	When continuous monitoring devices (such as dataloggers) are used, it is important that the records be maintained and available to the auditor. I see in vi.4 below you have included "Records of tests shall be maintained" - so it might be appropriate to add such a sentence where dataloggers are mentioned.	Non-persuasive. It is already covered in V1M2: Sections 4.13.2 and 4.13.3. Records maintenance covers this for data loggers - a printout or file is needed. non-persuasive; V1M2 Records maintenance (included electronic records) covers this for data loggers. Auditor will need to see the record, which would mean a print out. V1M24.13.2 and 4.13.3	1
24	1.7.3.7.b.vi.3	As worded, that means that the lab can keep its current soap for 5 years or longer and not need to ever do a second Inhibitory Residue Test (IRT)? Also, as worded, the lab can just get a new lot of Alconox (to pick one brand) and say that the IRT results on file for some previous lot is okay? I defer to the committee experts to verify that this is the intent of this Microbiology Standard.	Non-Persuasive. This was the intent.	2
25 / 26	1.7.5.1	Where a regulation states a temperature requirement, that temperature requirement must be met. So, for example, under the Surface Water Tx Rule, a sample must be held at 10 for up to 8 hours. However, EPA has stated in the Lab Cert Manual (a guidance doc) that samples received within 2 hours of collection are considered acceptable, if not at required temperature, under this rule. If the TNI Standard reiterated this 2 hour requirement, as consistent with EPA guidance, it would be acceptable. However, as this language is currently written, it could be interpreted by a laboratory as allowing samples to be received outside of 2 hours that were not in compliance with the regulatory requirement. Therefore, I would recommend deletion of this sentence or include the 2 hour provision. I know some on the committee expressed concern with the 2 hour provision, in which case - I would recommend simply deleting this sentence. Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of this section or the method of regulatory requirement. ~~In these cases, the samples may be considered acceptable if the samples are received on ice with evidence that the cooling process has begun.~~	Persuasive. " … regulatory requirement" was added the first sentence and the second sentence was left in. persuasive but only add 'or regulatory requirement'… but leave in the sentence that was struck by the commentor	1

27	1.7.5.2.a	There is a grammatical problem with a pronoun and its antecedent. The section should read: “The laboratory can show that the received sample containers are from its laboratory Š”	Persuasive. Edited accordingly.	2
38	1.7.5.2.d	**a**. Can items b and c be combined since they essentially state the same thing. **b**. If the laboratory can meet the requirements a – through c, is it really necessary to have the field chlorine documented? **c**. If the chlorine is checked in the field and found to be negative does it need to be checked in the lab even if items a – c are not met?	Non-persuasive: This type of specficity is beyond the scope of the Standard	10

28	All	In general, whenever a Standard is written in the passive voice it is be unclear as to “whom” is expect to do whatever it is that the Standard is requiring. The problem is magnified when the Standard is taken out of context, such as when a Standard is turned into a checklist item. The place where this has been especially troublesome is in the Microbiology Standard, although there are many examples throughout the TNI Standards. I suspect this is because the Micro Standards contain numerous advance QC checks to help ensure that the reagents, media, equipment and consumables used are adequate and appropriate for the testing they are doing. Sometimes, the intent of the language might actually be to allow a third party (the vendor or another lab, for example) to perform the QC, but that needs to be explicit, too. When the intent is for the accredited lab itself to perform the QC checks, and the language does not explicitly say so, then we have to rely on an interpretation or maybe even our intuition to decide. Neither of these works well when our interpretation differs from that of a lab manager. You don’t have to look far to find a Standard written in the passive voice. Some of the worst offenders are throughout 1.7.3.5 and 1.7.3.6. Even the opening sentence to 1.7.3.5 doesn’t help much, although we have had to point to it. It actually raises another flawed way to say what we want done. “The laboratory shall ensure that the quality of the reagents and media used is appropriate for the test concerned.” How do they “ensure?” Can they read a manufacturer’s certificate and ensure it says what they want or does the lab actually need to ensure by performing an analysis? It’s a thankless and complex task to write Standards that everyone can agree on and use, but this one thing would go a long way towards making the intent clear to the reader. All the expert committees need to do this globally. And we shouldn’t worry if the language sounds stilted by repetitively saying “the laboratory shall do something” rather than “something shall be done.” Thanks again for the chance to comment.	Persuasive. Changes were made where the intention is for the lab to perform the act. persuasive and will review. Robin will look for input from the committee before deciding what to change.	3