Microbiology Expert Committee (MEC)
Meeting Summary

January 13, 2015

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:35pm EST by teleconference. Attendance is recorded in Attachment A – there were 7 members present. The following associate members were also present: Brad Stawick (Microbac), Jennifer Best (EPA) and Kristen Greenwood (Northeast Ohio Regional Sewer District)

The committee reviewed the minutes distributed by Ilona for 10/28/14, 11/18/14, 12/16/14. Deb moved that the minutes 10/28, 11/18, 12/16/14 be approved. Donna seconded the motion. Vote: For – 7 0 – Against 0 – Abstain. The motion passed.

Jennifer asked if she could review a copy of the minutes before they are posted. Ilona will send her a copy of the above minutes after the meeting.

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 working standard updates.

2. Charter

Robin pulled the Charter up on Webex for review. Ilona made a few changes to get it ready for 2015 and added some of the new language that has been used in the Radiochemistry and Field Activities Committee updates. The committee reviewed the language and the membership renewals.

Deb made a motion to approve the 2015 Charter that includes the membership renewals and Patsy seconded the motion. There was no discussion. It was unanimously approved.

Ilona will finalize the changes to the Charter and send a copy to the CSDP EC.

3. WDS Comment Summary

Ilona added Colin's comments to the Summary table for finalization. Robin and Ilona noted that Colin sent in specific comments and sent in changes to the language that were embedded in a copy of the standard. All comments, additions and deletions are now listed in the Summary Table. Robin plans to update the table after today's discussion to include the text additions/deletions in the same box with the comment.

<u>Comment 24 (Section 1.5.2)</u>

Robin reviewed the language in the Standard. ABs on the call commented that their states have procedures to let a lab use other options. NJ allows a user defined option that has to be approved. They have to show it is a better option. Robin noted that FL does something similar through their SOP approval process. The modified procedures are lab specific and are only granted to the specific lab. Dwayne noted that his state also has procedures for labs to propose new methods.

There were also concerns expressed about the language in 1.5.1 for Accuracy. Robin reminded everyone that the comment period for the MWDS is still open and additional changes people find should be submitted to Robin and Ilona so the comments can be considered as the Voting Draft Standard is developed.

Patsy asked if 1.5.1 should include a requirement that a lab must use at least one known positive pure reference culture. The language currently allows for use of negatives. The committee thought this would be a good addition. Patsy will submit this comment.

The language Colin suggested uses terms like "better" and people were concerned it was not appropriate. Robin thought this might be an area where language could be added to the laboratory handbook. After further discussion, the committee determined that the comment is still Non Persuasive and the response would be: There is already some flexibility in each State's program to allow innovation and improvement. Those protocols would capture the "better" methods.

Comment 25 (Section 1.5.2)

The committee agreed the response is still Non Persuasive and the committee's response should be: The method defines acceptable performance. A naturally contaminated source may produce too much variability to reasonably assess in this instance.

Comment 26 (Section 1.6.1 d)

The committee agreed the response is still Non Persuasive and that it was addressed in another section.

Comment 27 (Section 1.6.3.2)

The committee agreed the response is still Non-Persuasive and that the DW program already requires a 10 sample set. This is covered in Section 1.2 (Scope).

Comment 28 (Section 1.7.1.3.a.i.2)

The committee agreed the response is still Persuasive. The language has already been edited accordingly in the MWDS.

Comment 29 (Section 1.7.3.1.a.i)

The committee agreed the response is still Persuasive. The language has already been edited accordingly in the MWDS.

Comment 30 (Section 1.7.3.1.a.i)

The committee agreed this is still Non Persuasive because the change was already made in the standard. It could be argued that this was Persuasive because the change was made. The committee will leave it as Non Persuasive and let Colin know the language was already changed.

Comment 31 (Section 1.7.3.2.ii)

It is now 1.7.3.2 b) in the MWDS. Robin wanted to be sure that the committee's intent is as Colin stated. Robin noted that beginning and end blanks are always required as they are a method requirement. Method requirements always trump the standard. This comment will be left as Non Persuasive.

Comment 32 (Section 1.7.3.3)

The committee agreed this comment was still Non Persuasive. They thought it might be more appropriately handled in the lab handbook being prepared by Quality Systems. It is not appropriate here.

Comment 33 (Section 1.7.3.6.b)

Robin went back into the minutes to find why the committee originally determined this was Non Persuasive. The committee determined there was no added value. The method defines the procedure for confirmation. The committee was still in agreement with this determination.

Comment 34 (Section 1.7.3.6.d.ii.2)

The committee agreed this was still Persuasive. The language has already been edited accordingly in the MWDS.

Ilona noted that there were still a few Non Persuasive comments in the summary that don't have a reason for this determination listed.

- The following language was added to Comment 22: DW systems may use a different type of disinfection such as chloramines, etc.
- The following language was added to Comment 1: The flexibility is already in the method and program requirements always prevail.

Robin will make the updates to the table and send it to Ilona for final clean-up and preparation of the letters to the commenters. The table in Attachment D shows the status of each comment and what was sent to the commenter.

4. MWDS Comment Summary

   Robin let people know that they should get copies of the comments on the MWDS before the meeting. If this occurs, she asked if people can begin reviewing the comments and taking notes. This will speed up the process in Crystal City.

5. Action Items

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

6. New Business

   - The following members will not be attending the meeting in Crystal City – Mary, Donna, Elizabeth, and Dwayne. A phone line will be provided so these members can participate and vote on responses to the comments the committee.

   - Ilona asked if the committee wanted to consider Steve Arms comment on the MWDS. Robin noted that the concern reaches beyond just the Microbiology part of the standard. Ilona suggested that the comment also be sent to the CSDP EC and she will do this. The committee will look at the sections he specifically mentioned in the Microbiology part of the standard.

7. Next Meeting and Close

   The next meeting will be onsite in Crystal City on Feb 3 at 1pm Eastern. .

   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 2:48 pm EST.

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) **Present**	IDEXX Laboratories, Inc	Other	(207)556-8947	patsy-root@idexx.com
Karla Ziegelmann-Fjeld **Present**	Microbiologics, Inc	Other		kfjeld@microbiologics.com
Donna Ruokonen **Present**	Microbac Laboratories, Inc	Lab	(219)769-8378 Ext 110	druokonen@microbac.com
Colin Fricker **Absent**	Analytical Services, Inc	Lab		colinfricker@aol.com
Deb Waller **Present**	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 **Absent**	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	
27	Notify CSDP that Elizabeth will be representative on Standards Review Council.	Robin	10/10/14	Complete
28	Insert Colin's comments into the Comment Summary table and note status – persuasive or non-persuasive with reason.	Robin	11/13/14	Complete
33	Complete presentation and send to Ilona to prepare handout for Webinar.	Robin	12/19/14	Complete
34	Send Steve Arms' comments on the MWDS to the CSDP EC.	Ilona	1/16/15	
35	Update the Comment Summary table discussed during the meeting and send to Ilona.	Robin	1/13/15	
36	Clean-up Summary Table and prepare responses to commenters.	Ilona	1/16/15	
37	Finalize Charter and forward to CSDP.	Ilona	1/16/15	

Attachment C

Backburner / Reminders – MEC

	Item	Meeting Reference	Comments
1	Update charter in October 2014	n/a	

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
7	1.5.2	We specify here that the precision should not be significantly different from the reference method. Why? We don't specify it for accuracy, selectivity, false positives, negatives etc. What if the precision was significantly better for the test method? Would we then reject it? ***Suggested edit:*** Precision – Perform at least ten (10) replicate analyses with both the proposed and reference method, using a naturally contaminated sample containing the target microorganisms of choice. The results shall show that the precision of the proposed method is statistically equivalent or better than that of the reference method.	Comment: Non Persuasive. There is already some flexibility in each State's program to allow for innovation and improvement. Those protocols would capture the "better" methods.	24
7	1.5.2	Should this use a naturally contaminated sample or a pure culture? Should the reps be done under inter or intra laboratory conditions?	Comment: Non Persuasive. The method defines acceptable performance. A naturally contaminated source may produce too much variability to reasonably assess in this instance.	25
7	1.6.1.d.	Does the DOC involve a comparison with a trained (supervisor) member of staff? If so it should say so and should also say what criteria are used to accept or deny DOC. ***Suggested Edit***: Where possible the DOC shall be performed in conjunction with a supervisor for the appropriate method. In situations where no suitable	Comment: Non Persuasive This is already addressed in a later section.	26

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		supervisor exists, or for a first DOC in the laboratory, the use of proficiency samples or certified reference materials is required.		
2	1.6 .2	Could we use proficiency test samples for the target organism in each field of accreditation towards analyst IDOC's or will we be only required to use the methods listed in Sections 1.6.2.2 a-g.	Comment: Non persuasive. There is sufficient flexibility to allow for other procedures including PTs.	11
1	1.6.2.2	SM 9020B. 1 (2005) states "An employee training record and performance score obtained by analyzing single-blind samples should be maintained. Initial demonstration of capability prior to generating data, and an ongoing demonstration of capability for each analytical method conducted should be recorded." Our interpretation of this is that a DOC for a SM micro method may consist of the satisfactory analysis of one single blind sample. Because of the issues commented on, in the sections of 1.6.2.2 below, we encourage clear language stating the option for single-blind samples as viable for microbiology DOCs. Single-blind samples are currently widely acceptable as microbiological DOCs.	Robin- Believe should say single blind sample 'sets'. Mary agrees that a set would be required for DW. Elizabeth-Allowing for single blind is already included. This is just a suggestion. Robin-Clarify that program requirements must be met. Comment – Non Persuasive. The flexibility is already in the method and program requirements always prevail.	1
1	1.6.2.2.a.	The only reasonable way we can expect a lab to obtain 4 aliquots containing the target organism(s) in a countable range is for the lab to purchase four QC samples from a provider. Very few laboratories have the capability to make	Comment – Non Persuasive. Language is sufficient for allowing this.	2

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		(in-house) a known concentration of bacterial cells. There are two problems with the laboratories purchasing four known QC samples: 1) It is expensive to purchase four known QC samples. 2) Laboratories may try to save money by purchasing one known QC sample and using four aliquots of the sample to create four dilutions. Few laboratories make dilutions as part of their normal testing and inaccuracies would be introduced into the analysis of the QC sample dilutions that do not reflect the actual competence of the lab or the new analyst. We recommend that microbiology laboratories be allowed to use the satisfactory analysis of one QC sample as an initial DOC for microbiological testing. The language should reflect the recommendation for this reliable and more reasonable means of achieving the goal stated.		
1	1.6.2.2.b.	Aliquots containing bacterial organisms will not give comparable results if analyzed over a period of days. All of the aliquots must be analyzed as a batch.	Comment - Persuasive. Strike out 'period'. The language was edited accordingly. *At least four (4) aliquots shall be prepared and analyzed*	3

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
			concurrently according to the method.	
7	1.6.2.2.d	Glucuronidase is not a metabolite, it is an enzyme. The metabolites are the products of the enzymatic reaction in the case methyl umbelliferone and glucuronic acid ***Suggested edit***: For qualitative tests, acceptable performance in a blind study, either internally or externally generated, may be used to meet this Standard, provided that the study consists of a minimum of a blank, a negative culture, and a positive culture for each target organism or ~~metabolite~~ indicator enzyme (e.g. b-glucuronidase in E. coli.).	Comment – Persuasive. The language was edited accordingly.	4
7	1.6.3.2	If this is a presence/absence test then performing a single proficiency test means that even a completely untrained analyst has a 50% chance of generating an acceptable result. Should it not be some multiple number of samples? Minimum three? ***Suggested Edit***: Acceptable results for a minimum of three blind proficiency test samples for target organisms in each field of accreditation.	Comment: Non Persuasive. The DW program already requires a 10 sample set. This is covered in the Section 1.2 Scope.	27

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
7	1.7.1.3.a.i.2	Is this appropriate for double strength media or other concentrates? ***Suggested Edit***: Where media are made as concentrates (e.g. double strength, then the medium shall be diluted to working strength with sterile deionized water before testing.	Comment: Persuasive. The language was edited accordingly.	28
5	1.7.3.1.a.	Include "with non-selective growth media" statement to ii and iii for consistency with the other sections of 1.7.3.1.a. Recommended change: *ii. For pre-sterilized single use funnels, a sterility check shall be performed on one funnel per lot with non-selective growth media. For laboratory-sterilized funnels, a sterility check shall be performed on one funnel per sterilization batch with non-selective growth media.* *iii. Sterility checks on sample containers shall be performed on at least one (1) container for each lot of purchased, pre-sterilized containers with non-selective growth media. For containers prepared and sterilized in*	Comment: Persuasive. The language was edited accordingly. **Need more detail. Just say that we did an edit to accommodate the comment as this particular one went through a couple of edits. .**	16

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		the laboratory, a sterility check shall be performed on one (1) container per sterilized batch with nonselective growth media.		
4	1.7.3.1.a, 1.7.3.1.a.iii.	Question: Does this first sentence mean that even sterile pipettes require verification? Comment: Requiring laboratory verification of sterility of purchased sterile containers (and pipettes) is overly redundant if these supplies are purchase from an ISO accredited, laboratory approved vendor. ISO accredited vendors are under the same quality system that the laboratory is under. There is no difference in a laboratory outsourcing to a contract laboratory and using that contract labs certificate than using the vendor certificate. In fact, this section of the standard does not even require that the contracted lab be accredited. In contrast, an ISO approved vendor undergoes far more rigorous and robust sterility verification than any individual laboratory would utilizing the standard requirements in section 1.7.3.1.a.iii. Verifying a single container from a lot of how many? Does lot size matter? Unlike the procedures used by an ISO accredited manufacturer, this procedure is not statistically relevant. Consequently, there are many small laboratories that may only perform a single Colilert test on a monthly basis who	Comment: Non Persuasive. This is required by EPA and ABs.	14

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		have very little true microbiology testing experience that are forced to purchase non-selective media at comparatively considerable expense in order to verify IDEX or similar sterile containers on a lot of bottles that they will use for 2 years. Preparing this media for this verification now requires that they have an autoclave, perform spore checks and all of the additional requirements for media preparation and documentation which may go well beyond their experience. Often this media ends up expiring long before it is ever used again. This sterility check requirement is certainly necessary for laboratories that sterilize their own containers. However, I hope that the committee will reconsider this requirement for laboratories purchasing from ISO accredited laboratory approved vendors and allow for the use of vendor provided COAs. If there is concern that something may happen during shipping perhaps some language may be included in the standard that requires a visual inspection.		
7	1.7.3.1.a.i	'Performed' instead of 'analyzed'	Comment: Persuasive. The language was edited accordingly.	29

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
7	1.7.3.1.a.ii	Do we need to specify how? ***Suggested edit***: The sterility check should involve the processing of a deionized water sample and incubation of the membrane in a suitable non-selective medium such as tryptone soya broth.	Comment: Non Persuasive. This change was already made to the Standard. – already addressed **Where addressed? Committee had already addressed this concern in an intermediate edit. The new std has this concept in it. We could change this to persuasive as we did make a change but we did that on our own before receiving the comment.**	30
1	1.7.3.1.b.i. and ii.	There should be the same requirement #3 here calling for documentation of detailed testing criteria, etc., called for in 1.7.3.1.b.i.3. above.	Comment: Persuasive. The language was added.	5
4	1.7.3.1.d.	This section deals with requirements for testing reagent water, but does not list acceptance criteria for these required tests. The *AOAC Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals* has similar requirements. The 2005 edition removed the actual acceptance criteria and added the following language: *The water used in the laboratory shall be fit for*	Comment: Persuasive. The language was edited accordingly. *The laboratory must define the criteria and ensure the water is fits that criteria.* Results of the above analyses shall meet the specifications of the required method and records of analyses shall be maintained for five (5) years.	15

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		use and there are various documents that define this, such as USP, EP, ASTM, and SMEWW. The laboratory must define the use of the water and ensure the water is fit for that use. A laboratory therefore, may use criteria from SMEWW, but they must define the criteria in their procedures and then ensure that the water meets that criterion.	Edit accordingly **Edit accordingly? SAME as above**	
7	1.7.3.2.ii	I read this as saying that if you use UV then you don't need method blanks. Is that what we want? How do we know that the UV is working? ***Suggested edit***: The filtration series is considered ended when more than thirty (30) minutes elapses between successive filtrations. During a filtration series, filter funnels shall be rinsed with three (3) 20-30 ml portions of sterile rinse water after each sample filtration. In addition, laboratories shall insert a method blank after every ten (10) samples. Deleted: or sanitize filtration units by UV light (254-nm) after each sample filtration	Comment: Non Persuasive. Beginning and end blanks are always required as they are a method requirement.	31
7	1.7.3.3	Percentages are very difficult here unless you specify the counting range. For example, if the count is less than ten and there are two analysts the count must be exactly the same. If less than 20 and one analyst, it must be the same. It is more important to state that any differences should be	Comment: Non Persuasive. This may be appropriate for the lab handbook being prepared, but is not appropriate here.	32

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		investigated since it is important to know whether the difference is simply due to missing a colony, counting one twice or more importantly not recognizing a positive colony and being positive. ***Suggested Edit***: For methods that specify colony counts such as membrane filter or plated media, duplicate counts shall be performed monthly on one positive sample, for each month that the test is performed. If the laboratory has two or more analysts, each analyst shall count typical colonies on the same plate containing a minimum of twenty (20) target colonies.		
7	1.7.3.6.a	*All growth and recovery media shall be checked to assure that the target organism(s) respond in an acceptable and predictable manner.* – How often?	Comment: Persuasive. Each lot or batch.	6
7	1.7.3.6.b.	The confirmation procedure is the most important part of this and the media mentioned are not particularly good. How can we include something that says that the best possible confirmation method should be used? ***Suggested edit***: If there is any doubt as to the validity of the result then the target organism shall be identified using commercially available metabolic identification tests.	Comment: Non Persuasive. There is no added value. The method defines the procedure for confirmation.	33
1	1.7.3.6.d.	1.7.3.6.d.i.2 – "…shall be analyzed with one or more known negative culture controls (i.e. non-target organisms)…" 1.7.3.6.d.ii.2 – "…shall be tested with at least one pure	Comment: Persuasive. The following change was made: known **pure** positive culture	7

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		culture of a known positive reaction as appropriate to the method…" The language in the sections above should be standardized to refer to bacterial controls as "known positive and negative control cultures". Change 1.7.3.6.d.ii.2. to read "~~one pure culture of a known positive reaction~~ known positive culture control (i.e. target organism)".	control (i.e. target organism)".	
7	1.7.3.6.d.ii.2.	Can we mention here that quantitative or semi-quantitative are preferable? ***Suggested edit***: Each pre-prepared, ready-to-use lot of medium (including chromo/fluorogenic reagent) and each batch of medium prepared in the laboratory shall be tested with at least known pure positive culture control (i.e target organism) as appropriate to the method. Tests should be quantitative wherever possible. This shall be done prior to first use of the medium.	Comment: Persuasive. The language was edited accordingly.	34
1	1.7.3.7.a.	Animals should be added to the list of prohibited items.	Comment: Non persuasive. Pets are not allowed in lab area.	8
5	1.7.3.7.b.	Does the statement "Detailed testing criteria information shall be defined in the laboratory's methods, SOPs or similar documentation" apply to ready-to-use media as well as laboratory prepared media?	Comment: Persuasive. The language was edited accordingly.	17

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		Recommended change: *ii. Ready-to-use media* *1. See 1.7.3.1(b)(i)(1) and 1.7.3.1(b)(i)(3)* *2. Any ready-to-use media shall be used within the expiration date provided by the manufacturer*	– edit accordingly.	
1	1.7.3.7.b.iii. 2.	Should the reference to glassware be changed to "non-ASTM Class glassware"?	Comment: Persuasive. The typo was corrected - Equipment such as filter funnels, bottles, non-Class **A** glassware, and other containers with volumetric markings (including sample analysis vessels) shall be verified once per lot prior to first use.	9
5	1.7.3.7.b.iii. 2.	Correction – include missing "non-Class A" Recommended change: *2. Equipment such as filter funnels, bottles, non-Class A glassware, and other containers with volumetric markings (including sample analysis vessels) shall be verified once per lot prior to first use.*	Comment: Persuasive. The typo was corrected: Equipment such as filter funnels, bottles, non-Class **A** glassware, and other containers with volumetric markings (including sample analysis vessels) shall be verified once per lot prior to first use.	18
5	1.7.3.7.b.v.	The current standard is confusing and contradictory between paragraphs. Why does a laboratory only need a system in place to ensure that the temperature monitoring requirements are meet on weekends and holidays? Can	Comment: Persuasive. The language was edited accordingly. Did not include portions about weekends and holidays.	19

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx				Contact:
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		data loggers and continuous temperature monitoring devices be used only on holidays and weekends? The exception in paragraph 3 appears to eliminate the requirements in the first two paragraphs. This exception can be eliminated and listed as a Note with an example to describe the intent of the section above. Recommended change: *v. Incubators, and Water Baths* 1. *The uniformity of temperature distribution in incubators and water baths shall be established prior to first use.* 2. *During periods when samples are under test, the laboratory must have a system in place to ensure the ~~T~~temperature of incubators and water baths are taken and documented twice daily, at least four hours apart~~, on each day of use when samples are under test~~. Under test is defined as the time period that the sample is in an incubation phase of the method, including weekends and holidays. Data loggers, continuous temperature monitoring devices, or other temperature monitoring equipment can be used as long as they can be calibrated in accordance with TNI, Volume 1, Module 2, Section 5.5.13.1 for Support Equipment. NOTE: There is no intent to take the temperature of incubation units during periods when there are no samples under test. For example if samples are*		

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		placed into the incubator at 11 AM on day 1 and incubation ends at 11 AM on day 2 then an acceptable system would have readings taken the morning on day one, the afternoon on day one and the morning on day 2. *3. ~~For tests where samples are under test during weekends or holidays, t~~The laboratory must have a system in place to ensure that the temperature monitoring requirements are meet for the entire incubation period. Data loggers, continuous temperature monitoring devices, or other temperature monitoring equipment can be used as long as they can be calibrated in accordance with TNI, Volume 1, Module 2, Section 5.5.13.1 for Support Equipment.~~* *4. ~~An exception to the twice-daily temperature measurement documentation is permitted for the last day of the incubation period when samples are removed from the incubator or waterbath, the initial temperature(s) is subsequently measured and documented, and no other samples are or will be present in the incubator or waterbath that day.~~*		
6	1.7.3.7.b.v.	If a lab is using a calibrated temperature monitoring device (min/max thermometer or data logger), does this eliminate the need to take temperatures twice daily? If this practice is acceptable during the weekends and holidays why is it not acceptable for weekdays? This may be a future item, since min/max and data loggers are better indications of the	Comment: Persuasive. The ABs all agree that data loggers are acceptable. ~~(For tests~~ where samples are under test, ~~during weekends or holidays,~~ the laboratory must have a system in place to ensure that the temperature monitoring requirements are met for the	21

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		correct incubation temperature than twice per day readings.	entire incubation period. *NOTE: There is no intent to take the temperature of incubation units during periods when there are no samples under test. ~~For example if samples are placed into the incubator at 11 AM on day 1 and incubation ends at 11 AM on day 2 then an acceptable system would have readings taken the morning on day one, the afternoon on day one and the morning on day 2.)~~*	
2	1.7.3.7.v.	Incubators and water baths, just needed to confirm whether the uniformity of temperature distribution in incubators and water baths is required only prior to first use, and not an annual requirement. We currently perform uniformity studies annually all incubators and water baths in the Microbiology laboratory.	Comment: Persuasive. The language was edited accordingly. The uniformity of temperature distribution in incubators and water baths shall be established prior to first use. – **After install or service** Edit accordingly **What does edit accordingly mean? Use all language above? Just say that we did an edit to account for the comment. We may not have used the actauuly language provided but addressed the comment as a whole.**	12
1	1.7.5.a.i	There is an extra period here.	Comment: Persuasive The typo was corrected.	10
3	1.7.5.a.i.	Sample Handling ….."In these cases, the samples shall be considered acceptable if the samples were received nestled	Comment: Persuasive.	13

"

Microbiology Expert Committee				
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14				
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx			Contact:	
Who	**Section/ Clause no.**	**Comments**	**Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive**	
		in ice and evidence the cooling process has begun and the temperature of the sample……is less than the temperature recorded at the time of sampling." In Texas, the MMF does not have a space for "Field Temperature". So I think that part of the sentence needs to be removed and leave it at the "sample is in ice and cooling has begun."	The language was edited accordingly.	
5	1.7.5.a.i.	Remove section after "the cooling process had begun". I don't believe there is a requirement to take temperatures at the time of collection. Would this then impose that requirement? The way the sentence is worded a tenth of degree drop in 7 hours would be acceptable according to this standard, but would not ensure that samples were preserved within 15 minutes of collection as required. Recommended change: i) *Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of Section 1.7.5.a) or the method, if the time frame between collection and delivery is too short for the cooling process to complete. ~~.~~ In these cases, the samples shall be considered acceptable if the samples were received nestled in ice with evidence that the cooling process has begun ~~and the temperature of the sample(s) (or representative sample) is recorded upon receipt and is less than the temperature recorded at the time of sampling.~~*	Comment: Persuasive See comment #13. (Comment 13 - Sample Handling ….."In these cases, the samples shall be considered acceptable if the samples were received nestled in ice and evidence the cooling process has begun and the temperature of the sample……is less than the temperature recorded at the time of sampling." In Texas, the MMF does not have a space for "Field Temperature". So I think that part of the sentence needs to be removed and leave it at the "sample is in ice and cooling has begun." Comment: Persuasive. – The language was edited accordingly.)	20

"

Microbiology Expert Committee	
Document No./Title: STD-2-ELV1M5-Micro-WDS-8-5-14	
Commenter (Who): 1-xx,2-xx,3-xx,4-xx,5-xx,6-xx,7–xx	Contact:

Who	Section/ Clause no.	Comments	Comment Resolution. Committee vote, P=persuasive, NP=Non Persuasive	
			Earlier comment? Number 13	
6	1.7.5.b.	The standard needs to address what a lab must do if a sample has chlorine present when tested for chlorine. The sample must be invalidated and adding sodium thiosulfate to neutralize the sample once received at the lab is not acceptable. The standard needs to define what type of chlorine should be tested: free, combined or total chlorine. I believe the standard should say free chlorine.	Comment: Non Persuasive. DW systems may use a different type of disinfection such as chloramines, etc. 10/28: Ruled non-persuasive – DW systems may use a different type of disinfection such as chloramines, etc.	22
6	1.7.5.b.iv.	Please consider adding to the field chlorine check, if the client indicates the source is not from a chlorinated source, has not been chlorinated and no chlorine has been added to the sample. Many labs receive samples that are not chlorinated and the customer would not have chlorinated them. This will reduce the time labs are spending looking for chlorine in samples the lab knows will be absent for chlorine.	Comment: Non–persuasive. This is already in the standard.	23

"