

**Microbiology Expert Committee (MEC)**  
**Meeting Summary**

**July 12, 2016**

**1. Roll Call and Minutes:**

Robin Cook, Chair, called the meeting to order at 1:38pm EST by teleconference on July 12, 2016. Attendance is recorded in Attachment A – there were 4 members present. Associate Member present: None.

Minutes for the May and June meeting were distributed and will be approved by email since there were only 4 members available on the call today and only 3 last month.

*(Addition: A motion was made by Patsy Root to approve the May 10 and June 14, 2016 minutes as written. The motion was seconded by Elizabeth Turner.*

*Vote:*

*Patsy – Motion (7/13/16)*

*Elizabeth – Second (7/13/16)*

*Gary – For (8/19/16)*

*Mary – For (8/19/16)*

*Elizabeth – For (8/19/16)*

*Karla – For (8/19/16)*

*Deb – For (8/19/16)*

*Robin – For (8/21/16)*

*Dwayne – For (8/22/16)*

*Colin – For (8/22/16)*

*The motion was approved.)*

**2. Orange County Meeting Presentation**

Using Webex, Robin pulled up her DRAFT of the Microbiology Standard presentation that she will give next month in Orange County. She walked the group through the slides and made corrections and additions as they came up.

The committee discussed whether additional material is needed in the presentation. Robin wants to be sure the presentation is accurate and informative since the presentation will be later posted on the TNI website. The committee is asked to give the presentation one more review and email comments to Robin. She will make any recommended updates and send it to Ilona in the next week. Ilona will include it as Attachment D to these minutes.

### 3. Small Laboratory Handbook

Robin would like to complete the first DRAFT of the Handbook by the September 13<sup>th</sup> meeting. Everyone should finish up their sections and send them to her.

### 4. Action Items

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

### 5. New Business

None.

### 6. Next Meeting and Close

The next meeting will be held on September 13, 2016 at 1:30pm Eastern.

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

Robin adjourned the meeting at 2:33 pm Eastern.

**Attachment A**  
**Participants**  
**Microbiology Expert Committee (MEC)**

<b>Members</b>	<b>Affiliation</b>	<b>Balance</b>	<b>Contact Information</b>	
Robin Cook (Chair) <b>Present</b>	City of Daytona Beach EML	Lab	(386)671-8885	<a href="mailto:cookr@codb.us">cookr@codb.us</a>
Patsy Root (Vice-chair) <b>Absent</b>	IDEXX Laboratories, Inc	Other	(207)556-8947	<a href="mailto:patsy-root@idexx.com">patsy-root@idexx.com</a>
Karla Ziegelmann- Fjeld  <b>Absent</b>	Microbiologics, Inc	Other		<a href="mailto:kfjeld@microbiologics.com">kfjeld@microbiologics.com</a>
Jessica Hoch  <b>Absent</b>	TCEQ	AB	512-239-2353	<a href="mailto:Jessica.hoch@tceq.texas.gov">Jessica.hoch@tceq.texas.gov</a>
Colin Fricker  <b>Absent</b>	Analytical Services, Inc	Lab		<a href="mailto:colinfricker@aol.com">colinfricker@aol.com</a>
Deb Waller  <b>Absent</b>	NJ DEP	AB	(609)984-7732	<a href="mailto:debra.waller@dep.nj.gov">debra.waller@dep.nj.gov</a>
Dwayne Burkholder  <b>Present</b>	Pennsylvania DEP	AB	(717)346-8213	<a href="mailto:dburkholde@pa.gov">dburkholde@pa.gov</a>
Mary Robinson  <b>Present</b>	Indiana State DOH	AB	(317)921-5523	<a href="mailto:mrobinson@isdh.in.gov">mrobinson@isdh.in.gov</a>
Elizabeth Turner  <b>Present</b>	North Texas Municipal Water District	Lab	(972)442-5405 Ext 535	<a href="mailto:eturner@ntmwd.com">eturner@ntmwd.com</a>
Po Chang  <b>Absent</b>		Other		<a href="mailto:Dr.PoChang@yahoo.com">Dr.PoChang@yahoo.com</a>
Brad Stawick  <b>Absent</b>	Microbac Laboratories	Lab	412-459-1058	<a href="mailto:brad.stawick@microbac.com">brad.stawick@microbac.com</a>
Gary Yakub  <b>Absent</b>	Environmental Standards, Inc.	Other	(610)935-5577	<a href="mailto:gyakub@envstd.com">gyakub@envstd.com</a>
Ilona Taunton (Program Administrator) <b>Present - Recorded</b>	The NELAC Institute	n/a	(828)712-9242	<a href="mailto:Ilona.taunton@nelac-institute.org">Ilona.taunton@nelac-institute.org</a>

## Attachment B

### Action Items – MEC


	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
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	
55	Ask Carl Kircher to prepare a table to list positive and negative organisms for specific tests.	Robin	12/31/15	
61	Send completed Handbook Sections to Robin.	All	9/9/16	

## Attachment C

## Backburner / Reminders – MEC


[illegible]

## Attachment D: Micro Standard Presentation





### TNI Microbiology EC: 2016 Standard - Module 5

National Environmental  
Monitoring Conference,  
August 2016





### Committee Members:

Cook, Robin; Chair – Lab	
Root, Patsy; Vice Chair - Other	
Colin Fricker - Lab	
Deb Waller – AB	4 – Lab
Dwayne Burkholder – AB	4 – AB
Elizabeth Turner – Lab	4 – Other
Karla Ziegelmann-Fjeld - Other	
Mary Robinson - AB	
Po Chang – AB	
Gary Yakub – Other	
Jessica Hoch – AB	
Brad Stawick – Lab	





### 2009 is a good standard so why a new one?

- Still a bit over carry over from the 2003
- 2016 – Experts are the writers
- Microbiologists speaking the same language.
- Tried to anticipate some challenges
- All prior SIRs were considered in this revision.





### Updates to V1M5

- Section 1.2
  - *The essential quality control procedures applicable to microbiological analysis are included in this module. Additional quality control or **program** requirements that are either specified by method, regulation or project shall be met by laboratories.*




### Updates to V1M5

- Section 1.2
  - Added Clarity
  - Reinforce the concept minimum requirements
  - Default to the use of the data




### Updates to V1M5

- 1.5 Method Validation –
  - a. For methods **other than reference methods**, validation must comply with Volume 1, Module 2. This validation must include the minimum requirements outlined in Sections 1.5.1, 1.5.2, and 1.5.3 of this module.
  - b. For both reference and non-standard methods, laboratories shall participate in proficiency testing programs **where available**.
    - 1.5.2 Precision – Perform at least ten (10) replicate analyses with both the proposed and reference method, using a **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.**





## Attachment D: Micro Standard Presentation



### Updates to V1M5



- Section 1.5
  - Added Clarity
  - Allow use of statistically better method
  - Allow for improvement



### Updates to V1M5



- 1.6.2.2.e

*Compare the information from c) above to the corresponding acceptance criteria for precision and accuracy in the method (if applicable) or in laboratory-generated acceptance criteria such as **relative standard deviation** (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters does not*





### Updates to V1M5

- Section 1.6.2.2.e
  - Added Clarity
  - Added guidance for labs





### Updates to V1M5

- 1.6.3.2 added clarity
  - c. Acceptable results for blind proficiency test sample **or sample set, as required by program**, for target organisms in each field of accreditation.
  - f. If a) through e) are not technically feasible, then analysis of real-world samples with results within a **predefined acceptance criteria** (as defined by the laboratory or method) shall be performed.




### Updates to V1M5

- Section 1.6.3.2
  - Added Clarity
  - Added guidance for labs




### Updates to V1M5

- 1.7.3 Quality Control – Basic Outline
  - 1.7.3.1 Quality and Sterility of Standards, Reagents, Materials and Media
    - + A. Sterility Checks
    - + B. Media
    - + C. Shelf Life
    - + D. Reagent Water
    - + E. Dilution Water
    - + F. Documentation


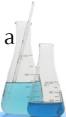


## Attachment D: Micro Standard Presentation





### Updates to V1M5

- 1.7 QC Sections – The whole section reorganized to specify the “before” requirements and the “during” requirements.
  - Previous section 1.7.3.5 of the 2009 TNI std (media checks, reagent water checks, supply checks) and sterility checks have been combined into section 1.7.3.1 to represent the “before”
  - Method blanks are done “during” – now a completely separate section





### Updates to V1M5

- Section 1.7 QC regarding Blanks and check
  - Added Clarity
  - Sterility and performance checks are for materials
  - Blanks are for method and technique





### Updates to V1M5 Section 1.7 cont

- 1.7.3.1.d.vi  
*Purchased reagent water that has been **opened** for longer than the testing intervals specified in items i) through iv), or in the accredited method shall either be re-tested or discarded.*
- 1.7.3.1.e  
*e. Dilution Water, however used, includes buffer water and/or peptone water. The quality of the dilution water shall be monitored for sterility, pH and volume once per lot or batch whether purchased or lab prepared.*





### Updates to V1M5

- Sections 1.7.1.1.d.vi and 1.7.3.1.e
  - Added guidance for labs
  - Dilution water  $\neq$  reagent water
  - Individual requirements for each more clear.




### Updates to V1M5 Section 1.7 cont.

- 1.7.3.3 Test Variability/ Reproducibility  
*For methods that specify counts (i.e. cfu/100mL or MPN/100mL) such as membrane filter, plated media or other methods which specify a quantitative result, duplicate counts shall be performed monthly on one (1) positive sample, for each month that the test is performed.*




### Updates to V1M5

- Sections 1.7.1.1.d.vi and 1.7.3.1.e
  - Added guidance for labs
  - Applies to any method where a number is reported.





## Attachment D: Micro Standard Presentation



### Updates to V1M5



- 1.7.3.6 Selectivity – added phrases to improve clarity and flexibility
  - a. All growth and recovery media shall be checked to assure that the target organism(s) respond in an acceptable and predictable manner *once per lot or batch*.
  - 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 (BG) or E. coli (EC or EC + MUG broth).



### Updates to V1M5



- 1.7.3.6.d.ii.2 – added clarity

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 *one or more known pure positive culture controls (i.e. target organism) as appropriate to the method (i.e. quantitative results for quantitative method)*. This shall be done prior to first use of the medium.



### Updates to V1M5

- Sections 1.7.3.3.6.ii.2
  - Added guidance for labs
  - Like for like
  - Get a number not just “present” for qualitative tests





### Updates to V1M5

- 1.7.3.7.b.i



*The laboratory shall use temperature measuring devices such as liquid-in-glass thermometers, thermocouples, or platinum resistance thermometers to assess and document equipment temperatures. The temperature measuring devices shall be appropriate quality to meet specification(s) in the method.*

*The graduation and range of the temperature measuring devices shall be appropriate for the required accuracy of the measurement. Temperature measuring devices shall be verified to national or international standards for temperature. Verification shall be performed at least annually (see TNI Volume 1, Module 2, Section 5.5.13.1). This verification may be accomplished by a single point provided that it represents the method mandated temperature and use conditions.*




### Updates to V1M5

- Sections 1.7.3.7.b.i
  - Added guidance for labs
  - Single point calibration
  - Appropriate use conditions




### Updates to V1M5

- 1.7.3.7.b.ii –
  - Ovens and autoclaves in the same section.
  - Now “Sterilization Equipment”





## Attachment D: Micro Standard Presentation





### Updates to V1M5

- 1.7.3.7.b.iii Volumetric Equipment clarifying language added: *The laboratory shall verify equipment used for measuring volume as follows:*
- Added 1.7.3.7.b.iii.4 –  
*4. Verification of volume shall be considered acceptable if the accuracy is within 2.5% of expected volume. This verification can be volumetric as compared to Class A or gravimetric.*



### Updates to V1M5



- Sections 1.7.3.7.b.iii and iii.4
  - Clarification
  - All pieces measuring volume not just pipettes.
  - Acceptance criteria for the volumetric check.
  - Only a baseline. Program requirements supersede



### Updates to V1M5

#### Section 1

*The laboratory shall establish the uniformity of temperature distribution and equilibrium conditions in incubators and water baths prior to first use after installation or service. The equilibrium check shall include time required after test sample addition to re-establish equilibrium conditions under full capacity load appropriate for the intended use.*





### 1.7.3.7.b.v Cont

#### Section 2



*During periods when samples are under test, the laboratory shall have a system in place to monitor and document the temperature of incubators and water baths twice daily, at least four hours apart. "Under test" is defined as the time period that the sample is in the incubation phase of the method. 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 V1 M2 Section 5.5.13.1 for Support Equipment. Records shall be maintained in accordance with V1M2 4.13 Records Maintenance*

*NOTE: There is no intent to take the temperature of incubation units during periods when there are no samples under test.*




### Updates to V1M5

- 1.7.3.7.b.v
  - SIR regarding frequency of temp readings
  - Flexibility for staffing issues and periods of non-use
  - Clarification on equilibrium condition testing




### Updates to V1M5

- 1.7.3.7.b.vi- Inhibitory Residue Testing
  - 3. Labware that is washed and reused shall be tested for possible presence of residues that may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test *initially* and each time the lab changes the detergent *formulation* or washing procedures.





## Attachment D: Micro Standard Presentation





### Updates to V1M5

- 1.7.3.7.b.vi
  - Reduced frequency of Inhibitory Residue Testing
  - In line with EPA cert manual





### Updates to V1M5

- 1.7.5 Sample Handling –
  - Receipt of samples must comply with V1 M2 Sections 5.8.6 and 5.8.7, as well as:*
  - 1.7.5.1 Samples that require thermal preservation shall be considered acceptable if the arrival temperature of a representative sample container meets the method or mandated temperature requirement. 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 or the 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.*





*NOTE: The intent is for the samples to be preserved immediately and analyzed as soon as possible.*





### Updates to V1M5

- 1.7.5
  - Reasonable latitude in sample receipt
  - Clarify “cooling process”




### Updates to V1M5

- 1.7.5 – REMOVE THE MONTHLY Cl<sub>2</sub> CHECK
  - 1.7.5.2 Microbiological samples from known chlorinated sources (such as wastewater effluent), unknown sources where **disinfectant** (e.g. chlorine) usage is suspected (such as a new client or a new source) and all potable water supplies (including source water) shall be checked for absence of **disinfectant residual in the laboratory unless all of the following conditions are met:***
    - a. The laboratory can show that the received sample containers are from their laboratory or have been appropriately tested and documented;*
    - b. Sufficient sodium thiosulfate was in each container before sample collection to neutralize at minimum 5 mg/l of chlorine for drinking water and 15 mg/l of chlorine for wastewater samples;*
    - c. One container from each batch of laboratory prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 mg/l chlorine or 15 mg/l chlorine as appropriate and the check is documented;*
    - d. Disinfectant residual is checked in the field and actual concentration is documented with sample submission.*




### Updates to V1M5

- 1.7.5.2 An important note:
  - Exemption
  - Not a requirement
  - Each sample checked if all 4 conditions are not met





## Attachment D: Micro Standard Presentation





### One Pretty Big Change

“The laboratory shall.....”




### Updates to V1M5

- Passive vs. active voice.
- Active voice as much as possible.
- Will help the assessors and the labs.
- Had been assumed that the lab shall....but not always the case.
- Enough flexibility for ABs to make some reasonable calls.



### Take home message:

- ❑ Examples provided are not the only way
- ❑ Be creative- find what works for your lab
- ❑ New and Better std
- ❑ Talk to the ABs – we all have the same goal



### Thank You

Contact: Robin Cook  
CookR@codb.us

