Microbiology Expert Committee (MEC)
Meeting Summary

April 11, 2017

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:30pm Eastern by teleconference on April 11, 2017. Attendance is recorded in Attachment A – there were 7 members present. Associate Members: Carl Kircher

The February and March minutes were reviewed by email. A motion was made by Deb and seconded by Jessica to approve the February 14, 2017 and March 21, 2017 minutes. The motion was unanimously approved.

2. Charter

Robin emailed the Draft Charter to everyone prior to the meeting. She reviewed it on Webex. She made some format changes since the last meeting and success measures are now under each Objective.

The committee reviewed other committee charters to determine wording for the Decision Making, Available Resources and Meeting Schedule sections.

There was much discussion on the Decision Making section to decide whether to use a narrative or use the table being used by other committees. The committee decided to use the table and reviewed the language.

A motion was made by Deb and seconded by Patsy to accept the Charter (Attachment D). The motion was unanimously approved.

Ilona will clean-up any format issues and forward to Bob Wyeth and Ken Jackson.

3. Checklist

Robin got many of the updated checklists back from committee members.

The committee went through the checklist line by line on screen and compared it to the 2016 Standard. The updates can be found in Attachment E.

Robin will send a copy of the work done to everyone to continue to review. The highlight line is where the committee stopped today. If everyone can continue to review the

information and the final sections can be complete and turned in, perhaps the checklist can be finalized in May.

Committee members can share the work being done, but it can't be distributed until it is final.

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 May 9, 2017 at 1:30pm Eastern. *(Addition: The May meeting was canceled. The next meeting was June 13, 2017.)*

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

   Robin adjourned the meeting at 3:02 pm Eastern.

Attachment A
Participants
Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information	
Robin Cook (Chair) (2019) **Present**	City of Daytona Beach EML	Lab	(386)671-8885	cookr@codb.us
Patsy Root (Vice-chair) (2019) **Present**	IDEXX Laboratories, Inc	Other	(207)556-8947	patsy-root@idexx.com
Karla Ziegelmann-Fjeld (2018) **Present**	Microbiologics, Inc	Other		kfjeld@microbiologics.com
Jessica Hoch (2019*) **Present**	TCEQ	AB	512-239-2353	Jessica.hoch@tceq.texas.gov
Deb Waller (2019) **Present**	NJ DEP	AB	(609)984-7732	debra.waller@dep.nj.gov
Dwayne Burkholder (2019) **Absent**	Pennsylvania DEP	AB	(717)346-8213	dburkholde@pa.gov
Mary Robinson (2017) **Present**	Indiana State DOH	AB	(317)921-5523	mrobinson@isdh.in.gov
Elizabeth Turner (2018) **Present**	North Texas Municipal Water District	Lab	(972)442-5405 Ext 535	eturner@ntmwd.com
Brad Stawick (2019*) **Present**	Microbac Laboratories	Lab	412-459-1058	brad.stawick@microbac.com
Kasey Raley (2020*) **Present**	Eurofins Eaton Analytical, Inc.	Lab	626-386-1141	KaseyRaley@eurofinsUS.com
Vanessa Soto Contreras (2020*) **Present**	Florida DOH	AB	904-791-1582	Vanessa.SotoContreras@flhealth.gov
Gary Yakub (2020) **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	
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	Complete
62	Update Handbook in new format and send to committee members and associate members to discuss by email.	Robin	9/16/16	Complete
64	Update Charter and send to Ilona for review.	Robin	4/4/17	Complete
65	Distribute copy of 2016 Standard to Committee Members.	Ilona	4/4/17	Complete
66	Update copy of 2009 Checklist to 2016 as assigned.	All	4/7/17	Still missing some sections.
67	Update Charter format and send to CSDP.	Ilona	5/1/17	
68	Review Checklist and send comments to Robin.	All	5/8/17	

Attachment C

Backburner / Reminders – MEC

	Item	Meeting Reference	Comments
1	Update charter in October 2016.	n/a	Postponed until TNI develops the new format.

Atttachment D – Final Charter

Microbiology Expert Committee

(MEC)

Charter

(Revised: 4-11-2017)

Mission:

To maintain the Microbiology Standard (TNI Volume1, Module 5) based on input from stakeholder groups and the public; to provide technical assistance, support and training on issues related to microbiology and the TNI standard; and, to develop tools to facilitate the implementation of TNI Microbiology Standard.

Composition of the Committee:

- Composed of balanced membership of no more than 15 members.
- Members from each stakeholder group: Accrediting Bodies, Laboratories, Other.
- Members serve 3 - year terms and are eligible to serve two consecutive terms.
- No one organization can have multiple members on the same committee.
- Associate members are not limited in number and are not required to demonstrate balance in their numbers. Associate members are welcome to actively participate in all open committee meetings.

Objectives:

1. Improve the quality and consistency of environmental data by establishing standards for activities related to microbiological testing by:
   a. Review and revise the Microbiology Standard based on input from the stakeholder groups and public;
   b. Review and revise the Microbiology Standard consistent with relevant nation and international standards and guidelines where appropriate; and
   c. Ensure consistency and uniformity between the TNI volumes and modules through interaction with other boards, committees and interested parties as needed.

   Success Measures:
   The TNI Consensus Standard Development Executive Committee endorses any standards developed by the Committee under TNI SOPs.

2. Provide technical assistance, technical support, guidance and training related to Microbiological topics such as:
   a. Tools to facilitate assessment (e.g., assessment checklists)
   b. Guidelines and technical notes (e.g. Standards Interpretation Requests (SIRs))
   c. Guidance to clarify key concepts (e.g., glossary, white papers, etc)
   d. Training for labs on implementation of Module 5.

e. Assessor training
f. Participation in the development of TNI QAM template and Small Lab Handbook as needed

Success Measures:

- Prompt response to Standard Interpretation Responses (SIRs). Responses issued as soon as possible but not later than the second meeting after the request and subsequently accepted by the LASExC.
- Technical support, tools guidance, and training are developed and provided to support the implementation of the standard.

3. The Committee operates according to the relevant policies and procedures of TNI
   Success Measures:
   Microbiology Expert Committee passes regular, routine internal audits.

4. Evaluate the need for new and/or modified standards based on national and international developments in Microbiological testing
   Success Measures:
   New developments are evaluated to determine if they should be addressed in the Microbiology Standard, and if so is the standard flexible enough to allow for new technology, methods, procedures, or is a revision required.

Decision Making:

Decisions can be made by electronic ballot or by the respective votes of the committee member in teleconference or face-to-face sessions. In any case a quorum, representing more than 50% of the committee members must be represented in the voting process.

Decisions will be made, consistent with the requirements as follows:

Type of Decision	Decision-Making Rule
Meeting dates, times	Person-in-charge decides after discussion
Meeting adjournment	Person-in-charge decides after all business is conducted or allotted time expires
Meeting minutes approval	Request for approval by email to all committee members– changes approved if needed from email No Vote
Meeting cancellations	Person-in-charge decides
Addition of Committee Members	At least two-thirds of committee must vote and simple majority vote
Removal of Expert Committee Members	Person-in-charge decides after discussion

Type of Decision	Decision-Making Rule
Approval of Standards– any stage (including persuasive/non	At least two-thirds of committee must vote in the affirmative
Creation of a new	Simple vote of attendees
Election of Committee Chair	Two-thirds of committee must vote and simple Majority vote
Standard Interpretation Requests	Two-thirds of committee must vote and simple majority vote of attendees

Available Resources:

- Volunteer committee members
- TNI Infrastructure
- Environmental technical community and industry experts
- Other TNI expert committees and support
- Teleconference services
- TNI Website and TNI support services (administrative, technical editing, etc.);
- Limited Travel Funding

Anticipated Meeting Schedule:

- Teleconferences: Regular schedule of calls to be published on the TNI website
- Face to Face meetings during the semiannual TNI Forums as needed
- Additional teleconferences and/or face-to-face meetings as needed

Major Topic	Topic	Subject	Category	Citation	Does the laboratory comply with this section?	Yes	No	N/A
2016 Standard								
				V1M5 1	MICROBIOLOGICAL TESTING			
1.1 Introduction					Introduction			
1.1 Introduction				V1M5 1.1	This Standard applies to laboratories undertaking microbiological analysis of environmental samples. Microbiological testing refers to and includes the detection, isolation, enumeration, or identification of microorganisms (and/or their metabolites), or determination of the presence or absence of growth in materials and media. The evaluation of laboratories for this discipline is in conjunction with a quality system as specified in the general requirements module. Adherence to those quality system requirements and all quality control (QC) procedures specified in this module will ensure that microbiological test results are fit for the intended use.			
1.2 Scope				V1M5 1.2	Scope			
1.2 Scope				V1M5 1.2	The essential QC procedures applicable to microbiological analysis are included in this module. Additional QC or program requirements that are either specified by method, regulation or project shall be met by laboratories.			
1.3 Definitions				V1M5 1.3	Terms and Definitions			
1.3 Definitions		Regulatory	Definition	V1M5 1.3	The relevant definitions from TNI, Volume 1, Module 2, Section 3.0 apply. Definitions related to this document, which are used differently or do not exist in the above references, are defined below.			
1.3 Definitions				V1M5 1.3.1	Additional Terms and Definitions			
1.3 Definitions				V1M5 1.3.1	Source Water: When sampled for drinking water compliance, untreated water from streams, rivers, lakes, or underground aquifers which is used to supply private and public drinking water supplies.			
1.3 Definitions				V1M5 1.3.2	Exclusions and Exceptions- Reserved			
1.4 Method Selection				V1M5 1.4	Method Selection			
1.4 Method Selection	Reference Method	Procedure	Requirement	V1M5 1.4	Refer to Volume 1, Module 2, Sections 5.4.2, 5.4.3, and 5.4.4.			

1.5 Method Validation				V1M5 1.5	Method Validation			
1.5 Method Validation	General	Procedure?	Requirement	V1M5 1.5.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.			
1.5 Method Validation	General	PT Program	Requirement	V1M5 1.5.b	For both reference and non-standard methods, laboratories shall participate in proficiency testing (PT) programs, where available			
1.5 Method Validation	General	Documentation	Requirement	V1M5 1.5.c	The laboratory shall maintain documentation of the validation procedure for as long as the method is in use, and for at least five (5) years past the date of last use.			
1.5 Method Validation	1.5.1 Accuracy	Procedure	Option	V1M5 1.5.1	Accuracy – Use at least one (1) known pure positive reference culture at the anticipated environmental conditions and compare the method results to that of a reference method.			
1.5 Method Validation	1.5.2 Precision	Procedure	Option	V1M5 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.			
1.5 Method Validation	1.5.3 Selectivity	Procedure	Option	V1M5 1.5.3	Selectivity (sensitivity) – Verify all responses in at least ten (10) samples using mixed cultures that include the target organism(s) and at varying concentrations (microbial identification testing or equivalent processes may be used). Calculate the number of false positive and false negative results.			
1.6 Demonstration of Capability				V1M5 1.6	Demonstration of Capability (DOC)			
1.6 Demonstration of Capability	1.6.1 General			V1M5 1.6.1	General			

1.6 Demonstration of Capability	1.6.1 General	Initial DOC	Requirement	V1M5 1.6.1.1	An individual who performs any activity involved with preparation and/or analysis of samples must have constant, close supervision (as defined in the laboratory's training procedure) until a satisfactory initial DOC is completed (see Section 1.6.2).			
1.6 Demonstration of Capability	1.6.1 General	Ongoing DOC	Requirement	V1M5 1.6.1.2	Thereafter, ongoing DOC (Section 1.6.3), must be performed and documented at least every twelve (12) months.			
1.6 Demonstration of Capability	1.6.1 General	DOC	Exception	V1M5 1.6.1.3	In cases where an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one (1) year prior to applying for accreditation and where there have been no significant changes in instrument type or method, the ongoing DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate that an initial DOC is not required.			
1.6 Demonstration of Capability	1.6.1 General	Initial DOC Exception	Requirement	V1M5 1.6.1.4	All demonstrations shall be documented. All data applicable to the demonstration shall be retained and readily available at the laboratory.			
1.6 Demonstration of Capability	1.6.2 Initial DOC			V1M5 1.6.2	Initial DOC			
1.6 Demonstration of Capability	1.6.2 Initial DOC	IDOC	Requirement	V1M5 1.6.2	An initial DOC shall be made prior to using any method,			
1.6 Demonstration of Capability	1.6.2 Initial DOC	IDOC Frequency	Requirement	V1M5 1.6.2	An initial DOC shall be made at any time there is a change in instrument type, personnel or method			
1.6 Demonstration of Capability	1.6.2 Initial DOC	IDOC Frequency	Requirement	V1M5 1.6.2	An initial DOC shall be made any time that a method has not been performed by the laboratory or analyst in a twelve (12) month period.			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Documentation	Record	V1M5 1.6.2.1	The laboratory shall document each initial DOC in a manner such that the following information is readily available for each affected employee:			
1.6 Demonstration of Capability	1.6.2 Initial DOC	DOC Record	Contents	V1M5 1.6.2.1 a)	analyst(s) involved in preparation and/or analysis;			

1.6 Demonstration of Capability	1.6.2 Initial DOC	DOC Record	Contents	V1M5 1.6.2.1 b)	matrix;			
1.6 Demonstration of Capability	1.6.2 Initial DOC	DOC Record	Contents	V1M5 1.6.2.1 c)	organism(s);			
1.6 Demonstration of Capability	1.6.2 Initial DOC	DOC Record	Contents	V1M5 1.6.2.1 d)	identification of method(s) performed;			
1.6 Demonstration of Capability	1.6.2 Initial DOC	DOC Record	Contents	V1M5 1.6.2.1 e)	identification of laboratory-specific SOP used for analysis, including revision number;			
1.6 Demonstration of Capability	1.6.2 Initial DOC	DOC Record	Contents	V1M5 1.6.2.1 f)	date(s) of analysis;			
1.6 Demonstration of Capability	1.6.2 Initial DOC	DOC Record	Contents	V1M5 1.6.2.1 g)	summary of analyses, including information outlined in Section 1.6.2.2.c.			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Requirement	V1M5 1.6.2.2	If the method or regulation does not specify an initial DOC, the following procedure is acceptable. It is the responsibility of the laboratory to document that other approaches to initial DOC are adequate.			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Option	V1M5 1.6.2.2 a)	The target organism(s) shall be diluted in a volume of sterile, quality system matrix (a sample in which no target organisms or interferences are present at concentrations that will impact the results of a specific method).			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Option	V1M5 1.6.2.2 a)	When required by method, the diluent shall be sterile buffered water and/or sterile peptone water unless specified by the manufacturer. Prepare at least four (4) aliquots at the concentration specified, or if unspecified, to the countable range for plate methods or working range for most probable number (MPN) type methods.			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Option	V1M5 1.6.2.2 b)	At least four (4) aliquots shall be prepared and analyzed according to the method either concurrently or over a period of days.			

1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Option	V1M5 1.6.2.2 c)	Using all of the results, convert these results to logarithmic values, then calculate the mean recovery and standard deviation of the log converted results in the appropriate reporting units for each organism of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence, the laboratory shall assess performance against established and documented criteria.			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Option	V1M5 1.6.2.2 d)	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.			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Option	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 (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 meet the acceptance criteria, the performance is unacceptable for that parameter.			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Option	V1M5 1.6.2.2 f)	When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst shall proceed according to i) or ii) below.			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Option	V1M5 1.6.2.2 f) i.	Locate and correct the source of the problem and repeat the initial DOC for all parameters of interest beginning with b) above.			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Option	V1M5 1.6.2.2 f) ii.	Repeat the initial DOC for all parameters that failed to meet criteria.			
1.6 Demonstration of Capability	1.6.2 Initial DOC	Procedure	Option	V1M5 1.6.2.2 g)	Repeated failure, however, confirms a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all organisms of interest beginning with b) above.			
1.6 Demonstration of Capability	1.6.3 Ongoing DOC			V1M5 1.6.3	Ongoing DOC			

1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Documentation	Procedure	V1M5 1.6.3.1	The laboratory shall have a documented procedure describing ongoing DOC that includes how the lab will identify data associated with ongoing DOCs.			
1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Analyst	Requirement	V1M5 1.6.3.1	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.			
1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Analyst	Requirement	V1M5 1.6.3.1	If 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.			
1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Alternate Procedures	Requirement	V1M5 1.6.3.1	It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate.			
1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Procedure		V1M5 1.6.3.2	This ongoing demonstration may include one of the following , or by performing another initial DOC.			
1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Procedure	Option	V1M5 1.6.3.2 a)	Analysis of one (1) sample of clean matrix that is fortified with a known quantity of the target organism, with results meeting the laboratory acceptance criteria for accuracy and, where applicable to the testing technique, also meeting the observational details expected for the presumptive, confirmed and completed phases defined in the method.			
1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Procedure	Option	V1M5 1.6.3.2 b)	Analysis of one (1) positive sample in duplicate for each target organism and test, with results meeting the laboratory acceptance criterion for precision.			
1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Procedure	Option	V1M5 1.6.3.2 c)	Acceptable results for a blind proficiency test sample or sample set, as required by the program, for target organisms in each field of accreditation.			
1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Procedure	Option	V1M5 1.6.3.2 d)	Performance of an alternate adequate procedure for the field of accreditation, the procedure and acceptance criteria being documented in the laboratory's quality system.			

1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Procedure	Option	V1M5 1.6.3.2 e)	A documented process of reviewing samples QC sample performed by an analyst, or groups of analysts, relative to the QC requirements of the method, laboratory SOP client specifications, and/or this Standard. The review can be used to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary.			
1.6 Demonstration of Capability	1.6.3 Ongoing DOC	Procedure	Option	V1M5 1.6.3.2 f)	If a) through e) are not technically feasible, then analysis of real-world samples with results within predefined acceptance criteria (as defined by the laboratory or method) shall be performed.			
1.7 Technical Requirements				V1M5 1.7	Technical Requirements			
1.7 Technical Requirements	1.7.1 Calibration			V1M5 1.7.1	Calibration			
1.7 Technical Requirements	1.7.1 Calibration	Calibration	Procedure	V1M5 1.7.1.1	The laboratory shall have documented procedures for calibration, verification, and QC of support equipment including conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments.			
1.7 Technical Requirements	1.7.1 Calibration	Procedure Origin	Requirement	V1M5 1.7.1.1	These procedures shall refer to applicable reference methods.			
1.7 Technical Requirements	1.7.1 Calibration	Continuous Monitors		V1M5 1.7.2	For instruments that are continuous monitors, such as in-line specific conductance meters:			
1.7 Technical Requirements	1.7.1 Calibration	Continuous Monitors	Requirement	V1M5 1.7.1.2 a)	The laboratory shall document acceptable calibration verification at least once a month.			
1.7 Technical Requirements	1.7.1 Calibration	Continuous Monitors	Requirement	V1M5 1.7.1.2 b)	An initial calibration shall be performed if a continuing calibration is unacceptable, or when the instrument is being returned to service after having been taken off line.			
1.7 Technical Requirements	1.7.1 Calibration	Continuous Monitors	Requirement	V1M5 1.7.1 b) ii.	An initial calibration shall be performed when the instrument is being returned to service after having been taken off-line.			
1.7 Technical Requirements	1.7.2 Continuing Calibration			V1M5 1.7.2	Continuing Calibration - Reserved for specific procedures.			
1.7 Technical Requirements	1.7.3 Quality Control			V1M5 1.7.3	Quality Control			

1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.			V1M5 1.7.3.1	Quality and Sterility of Standards, Reagents, Materials, and Media			
	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1	The laboratory shall demonstrate and document that the quality of the reagents and media used is appropriate for the test concerned including, but not limited to, test conditions and incubation times			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.			V1M5 1.7.3.1 a)	Sterility Checks			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 a)	All materials and supplies that are needed to process the sample and are required to be sterile prior to use (whether sterilized in the laboratory or purchased as sterilized) must be checked by the laboratory once per purchased or prepared lot using non-selective growth media as appropriate.			
	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 a)	Certificates of analysis provided by vendors shall be verified by the laboratory and retained in accordance with V1M2 5.6.4.2.a).			
	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.			V1M5 1.7.3.1 a)	These checks shall include, but are not limited to:			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Sterility Checks - Media	Requirement	V1M5 1.7.3.1 a) i.	The laboratory shall perform a sterility check for each lot of prepared ready to use media and on each batch of media prepared in the laboratory.			

1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Sterility Checks - Media	Requirement	V1M5 1.7.3.1 a) i.a	For chromo/fluorgenic media: add media to sterile deionized water and incubate at the appropriate temperature and time.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Sterility Checks - Media	Requirement	V1M5 1.7.3.1 a) i.b	For all other media, incubate uninocculated at the appropriate temperature and time. 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.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Sterility Checks - Filter Funnels	Requirement	V1M5 1.7.3.1 a) ii.	The laboratory shall perform a sterility check on one (1) funnel per lot of pre-sterilized single use funnels using non-selective growth media.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Sterility Checks - Filter Funnels	Requirement	V1M5 1.7.3.1 a) ii.	The laboratory shall perform a sterility check on one (1) funnel per batch of laboratory-sterilized funnels, using non-selective growth media.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Sterility Checks - Sample Containers	Requirement	V1M5 1.7.3.1 a) iii.	The laboratory shall perform a sterility check on at least one (1) container for each lot of purchased, pre-sterilized sample containers with non-selective growth media.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Sterility Checks - Sample Containers	Requirement	V1M5 1.7.3.1 a) iii.	The laboratory shall perform a sterility check on one (1) container/object per sterilization batch sterilized in the laboratory with nonselective growth media.			
	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Sterilty Check - Dilution Water	Requirement	V1M5 1.7.3.1 a) iv.	The laboratory shall perform a sterility check on each batch of dilution water prepared in the laboratory and on each lot of pre-prepared, ready-to-use dilution water with non-selective growth media. The concentration of the non-selective growth media shall be single strength after the addition of dilution water.			

	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Sterilty Check - Membrane Filters	Requirement	V1M5 1.7.3.1 a) v.	The laboratory shall perform a sterility check on at least one (1) filter from each new lot of membrane filters with nonselective growth media.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Performance Checks	Option	V1M5 1.7.3.1 b)	Media – Culture media may be prepared from commercial dehydrated powders or may be purchased ready-to-use.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 b) i.	All media 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.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 b) ii.	The laboratory shall use all media within the expiration date or shelf life provided by the manufacturer			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 b) iii.	The laboratory shall use all laboratory-prepared media within the holding time limits specified in the accredited method.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 b) iv.	The laboratory shall have detailed testing criteria information defined in the laboratory's methods, SOPs, or similar documentation			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	General - Shelf life	Requirement	V1M5 1.7.3.1 c)	The laboratory shall use reagents, media and commercial dehydrated powders within the shelf life of the product,			

1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	General - Records retention	Requirement	V1M5 1.7.3.1 c)	and shall maintain documentation as per Volume1, Module 2 Quality Systems: General Requirements, Section 5.6.4.2			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.			V1M5 1.7.3.1 d).	Reagent Water			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 d) i.	The laboratory shall monitor the quality of the reagent water used in the laboratory, which will come into contact with test organisms and is used in preparation of media, solutions, and buffers, for bactericidal and inhibitory substances. This water shall be distilled water, deionized water, or reverse-osmosis-produced water.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 d) ii.	The laboratory shall monitor the quality of the water for disinfectant residual, specific conductance, total organic carbon, and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month. Analysis may be performed by another certified laboratory.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 d) iii.	The laboratory shall monitor the quality of the water for metals (Cd, Cr, Cu, Ni, Pb, and Zn) and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) annually. Analysis may be performed by another certified laboratory.			
1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Exception	V1M5 1.7.3.1 d) iii.	An exception to performing the Bacteriological Water Quality Test shall be given to laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for High Quality (Type I) or Medium Quality (Type II) reagent water.			

	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.	Records Retention	Requirement	V1M5 1.7.3.1 d) iv.	Results of the above analyses shall meet the specifications of the required method. Records of analyses shall be maintained for five (5) years.			
	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 d) v.	Reagent water purchased from an outside source and used for the preparations of media, solutions and buffers shall meet the criteria specified in items ii) and iii) above. The laboratory shall have documented records of this information.			
	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.			V1M5 1.7.3.1 d) vi.	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 Quality and Sterility of Standards, Reagents, Materials, and Media.			V1M5 1.7.3.1 e).	Dilution water, however used, includes buffer water and/or peptone water.			
	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 e).	The laboratory shall monitor the quality of the dilution water for sterility, pH and volume once per lot or batch whether purchased or lab prepared.			
	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 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. Records shall be retained by the laboratory in accordance with Volume 1, Module 2, Section 5.4.6.2.			

1.7 Technical Requirements	1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media.		Requirement	V1M5 1.7.3.1 f).	Documentation for media purchased pre-prepared, ready-to-use (including reagent water purchased from outside sources) shall include manufacturer, lot number, type of media received, date of receipt, expiration date of the media, and pH of the media. Records shall be retained by the laboratory in accordance with Volume 1, Module 2, Section 5.4.6.2.			
1.7 Technical Requirements	1.7.3.2 Method Blanks			V1M5 1.7.3.2	Method Blanks			
1.7 Technical Requirements	1.7.3.2 Method Blanks		Requirement	V1M5 1.7.3.2	The laboratory shall demonstrate that the filtration equipment and filters, sample containers, media, and reagents have not been contaminated through improper handling or preparation, or environmental exposure.			
	1.7.3.2 Method Blanks			V1M5 1.7.3.2 a)	For filtration technique, the laboratory shall conduct method blanks per the analytical method. At a minimum, the filtration series shall include a beginning and ending blank. The filtration series may include single or multiple filtration units, which have been sterilized prior to beginning the series.			
	1.7.3.2 Method Blanks			V1M5 1.7.3.2 b)	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.			
	1.7.3.2 Method Blanks			V1M5 1.7.3.2 b)	In addition, laboratories shall insert a method blank after every ten (10) samples or sanitize filtration units by UV light (254-nm) after sample filtration.			
	1.7.3.2 Method Blanks			V1M5 1.7.3.2 c)	For pour plate technique, method blanks of the medium shall be made by pouring, at a minimum, one (1) uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory.			

1.7 Technical Requirements	1.7.3.3 Test Variability	Duplicate Counts	Requirement	V1M5 1.7.3.3	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.			
1.7 Technical Requirements	1.7.3.3 Test Variability	Duplicate Counts	Requirement	V1M5 1.7.3.3	If the laboratory has two (2) or more analysts, each analyst shall count typical results on the same sample. Counts shall be within ten percent (10%) difference to be acceptable.			
1.7 Technical Requirements	1.7.3.3 Test Variability	Duplicate Counts	Requirement	V1M5 1.7.3.3	In a laboratory with only one (1) microbiology analyst, the same sample shall be counted twice by the analyst, with no more than a five percent (5%) difference between the counts.			
1.7 Technical Requirements	1.7.3.4 Sample Specific Controls			V1M5 1.7.3.4	Sample Specific Controls (where applicable)			
1.7 Technical Requirements	1.7.3.4 Sample Specific Controls	Matrix Spike	Requirement	V1M5 1.7.3.4 a)	Matrix spikes shall be performed per method requirements.			
1.7 Technical Requirements	1.7.3.4 Sample Specific Controls	Sample Matrix Duplicates	Requirement	V1M5 1.7.3.4 b)	Sample matrix duplicates shall be performed per method requirements.			
1.7 Technical Requirements	1.7.3.5 Data Reduction			V1M5 1.7.3.5	Data Reduction			
1.7 Technical Requirements	1.7.3.5 Data Reduction	Calculations and Statistics	Requirement	V1M5 1.7.3.5	The calculations, data reduction and statistical interpretations specified by each method shall be identified and followed.			
1.7 Technical Requirements	1.7.3.6 Selectivity			V1M5 1.7.3.6	Selectivity			
1.7 Technical Requirements	1.7.3.6 Selectivity	Media checks	Requirement	V1M5 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 once per lot or batch.			

1.7 Technical Requirements	1.7.3.6 Selectivity	Organism Verification	Requirement	V1M5 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 *EC* or *EC + MUG* broth.			
1.7 Technical Requirements	1.7.3.6 Selectivity	Reference Cultures	Requirement	V1M5 1.7.3.6 c)	In order to ensure identity and traceability, reference cultures used for positive and negative controls shall be obtained from a recognized national collection, organization, or manufacturer recognized by the accreditation body.			
1.7 Technical Requirements	1.7.3.6 Selectivity	Reference Cultures	Option	V1M5 1.7.3.6 c)	Microorganisms may be single use preparations or cultures maintained for their intended use by documented procedures that demonstrate the continued purity and viability of the organism.			
1.7 Technical Requirements	1.7.3.6 Selectivity	Reference Cultures	Requirement	V1M5 1.7.3.6 c) i.	Reference cultures may be revived (if freeze-dried) or transferred from slants and sub-cultured once to provide reference stocks.			
1.7 Technical Requirements	1.7.3.6 Selectivity	Reference Cultures	Requirement	V1M5 1.7.3.6 c) i.	The reference stocks shall be preserved by a technique that maintains the characteristics of the strains.			
1.7 Technical Requirements	1.7.3.6 Selectivity	Reference Cultures	Requirement	V1M5 1.7.3.6 c) i.	Reference stocks shall be used to prepare working stocks for routine work.			
1.7 Technical Requirements	1.7.3.6 Selectivity	Reference Cultures	Requirement	V1M5 1.7.3.6 c) i.	If reference stocks have been thawed, they shall not be refrozen and re-used.			
1.7 Technical Requirements	1.7.3.6 Selectivity	Working Stocks	Requirement	V1M5 1.7.3.6 c) ii.	Working stocks shall not be sequentially cultured more than five (5) times and shall not be sub-cultured to replace reference stocks.			
1.7 Technical Requirements	1.7.3.6 Selectivity	Culture Controls		V1M5 1.7.3.6 d)	Culture Controls (i.e. working cultures)			
1.7 Technical Requirements	1.7.3.6 Selectivity	Negative Culture Control		V1M5 1.7.3.6 d) i.	Negative Culture Controls			
1.7 Technical Requirements	1.7.3.6 Selectivity	Negative Culture Control		V1M5 1.7.3.6 d) i. a.	Negative culture controls demonstrate that the medium does not support the growth of non-target organisms or does not exhibit the typical positive reaction of the target organism(s).			

1.7 Technical Requirements	1.7.3.6 Selectivity	Negative Culture Control	Requirement	V1M5 1.7.3.6 d) i. b.	Each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent) and each batch of selective medium prepared in the laboratory shall be analyzed with one or more known negative culture controls (i.e. non-target organisms), as appropriate to the method. This shall be done prior to first use of the medium.			
1.7 Technical Requirements	1.7.3.6 Selectivity	Positive Culture Control		V1M5 1.7.3.6 d) ii.	Positive Culture Controls			
1.7 Technical Requirements	1.7.3.6 Selectivity	Positive Culture Control		V1M5 1.7.3.6 d) ii. a.	Positive culture controls demonstrate that the medium can support the growth of the target organism(s), and that the medium produces the specified or expected reaction to the target organism(s).			
1.7 Technical Requirements	1.7.3.6 Selectivity	Positive Culture Control	Requirement	V1M5 1.7.3.6 d) ii. b.	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 (1) or more known pure positive culture controls (i.e. target organism) as appropriate to the method and that produce typical results based on the method. This shall be done prior to first use of the medium.			
1.7 Technical Requirements	1.7.3.7 Test Conditions			V1M5 1.7.3.7	Constant and Consistent Test Conditions			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Laboratory Facilities		V1M5 1.7.3.7 a)	Laboratory Facilities			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Laboratory Facilities	Requirement	V1M5 1.7.3.7 a)	Floors and work surfaces shall be non-absorbent and easy to clean and disinfect.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Laboratory Facilities	Requirement	V1M5 1.7.3.7 a)	Work surfaces shall be adequately sealed.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Laboratory Facilities	Requirement	V1M5 1.7.3.7 a)	Laboratories shall provide sufficient storage space, and shall be clean and free from dust accumulation.			

					1.7.3.7 b) i though iii			
1.7 Technical Requirements	1.7.3.7 Test Conditions	UV Instruments		V1M5 1.7.3.7 b) iv.	UV Instruments			
1.7 Technical Requirements	1.7.3.7 Test Conditions	UV Instruments	Requirement	V1M5 1.7.3.7 b) iv.	The laboratory shall evaluate UV instruments used for sanitization quarterly for effectiveness with an appropriate UV light meter, by plate count, agar spread plates, or other methods providing equivalent results such as UV-cide strips.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	UV Instruments	Requirement	V1M5 1.7.3.7 b) iv.	Replace bulbs if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Incubators, Water Baths		V1M5 1.7.3.7 b) v.	Incubators, Water Baths, Ovens			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Incubators, Water Baths	Requirement	V1M5 1.7.3.7 b) v.a	The laboratory shall establish the uniformity of temperature distribution and equilibrium in incubators and water baths prior to first use after installation or service.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Incubators, Water Baths	Record	V1M5 1.7.3.7 b) v.a	The equilibrium check shall include time requried after test sample addition to re-establish equilibrium conditions under full capacity load appropriate for the intended use.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Incubators, Water Baths	Requirement	V1M5 1.7.3.7 b) v.b	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.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Incubators, Water Baths	Option	V1M5 1.7.3.7 b) v.b	Data loggers, continuous temperature monitoring devices, or other temperature monioting equipment can be used as long as they can be calibrated in accordance with V1M2, Section 5.5.13.1 for Support Equipment.			

1.7 Technical Requirements	1.7.3.7 Test Conditions	Incubators, Water Baths	Record	V1M5 1.7.3.7 b) v.b	Records shall be maintained in accordance with V1M2 Section 4.14: Records Maintenance.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Labware		V1M5 1.7.3.7 b) vi.	Labware (Glassware and Plasticware)			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Labware	Procedure	V1M5 1.7.3.7 b) vi.a	The laboratory shall have a documented procedure for washing labware, if applicable. Detergents designed for laboratory use shall be used.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Labware	Requirement	V1M5 1.7.3.7 b) vi.b	Glassware shall be made of borosilicate or other non-corrosive material, free of chips and cracks, and shall have readable measurement marks.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Labware Inhibitory Residue	Requirement	V1M5 1.7.3.7 b) vi.c	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 annually, and each time the lab changes the lot of detergent or washing procedures.			
1.7 Technical Requirements	1.7.3.7 Test Conditions	Labware Residue	Requirement/ Record	V1M5 1.7.3.7 b) vi.d	Washed labware shall be tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one piece of labware with a suitable pH indicator such as bromothymol blue. Records of tests shall be maintained.			
1.7 Technical Requirements	1.7.4 Data Acceptance / Rejection			V1M5 1.7.4	Data Acceptance/Rejection Criteria			
1.7 Technical Requirements	1.7.4 Data Acceptance / Rejection	Method Procedures	Requirement	V1M5 1.7.4	Method criteria and evaluation methods shall be used.			
1.7 Technical Requirements	1.7.5 Sample Handling			V1M5 1.7.5	Sample Handling			
1.7 Technical Requirements	1.7.5 Sample Handling	Receipt of Samples	Requirement	V1M5 1.7.5	Receipt of samples must comply with V1M2 Sections 5.8.6 and 5.8.7 in addition to the Standard requirements below.			
1.7 Technical Requirements	1.7.5 Sample Handling	Thermal Preservation	Requirement	V1M5 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.			

1.7 Technical Requirements	1.7.5 Sample Handling	Thermal Preservation	Option	V1M5 1.7.5.1	Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of Section 1.7.5 or the method or the regulatory requirements. In these cases, the samples **may** be considered acceptable if the samples were received on ice with evdience that the cooling process has begun. NOTE: The intent is for the samples to be preserved immediately and analyzed as soon as possible.			
1.7 Technical Requirements	1.7.5 Sample Handling	Chlorine Checks	Requirement	V1M5 1.7.5.2	Microbiological samples from known chlorinated sources (such as wastewater effluent), unknown sources where disinfectant usage is suspected (such a new client or a new source) and all potable water sources (including source water) shall be checked for absence of disinfectant residual in the laboratory unless all of the following conditions are met:.			