

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

September 13, 2016

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:38pm EST by teleconference on September 13, 2016. Attendance is recorded in Attachment A – there were 6 members present. Associate Members present: Carl Kircher (30 min) and Randi McCuin.

Minutes from the July meeting were distributed by email. A motion was made by Karla to approve the 7/12/16 meeting with the correction of a spelling error. The motion was seconded by Jessica and unanimously approved.

2. Small Laboratory Handbook

Robin asked Carl if there are any specific examples he would like to see in the Handbook (he has to sign-off early). He commented that anything that helps a lab keep the requirements straight would be helpful. This would apply to the discussion part of the Handbook and examples.

Robin shared an example the Radiochemistry Expert Committee provided of the work they have done on the Small Laboratory Handbook. The Quality Systems Expert Committee decided that they like the format used and would like all sections of the Handbook to use a similar format.

Quality Systems would like to receive the DRAFT from this committee before the end of the year – preferably by the end of November. Robin thinks 70% of the content has already been prepared and this seems doable.

The committee started working on the Handbook as Robin displayed it on screen using Webex. Robin used the example from Radiochemistry and put the information already developed by the committee into that format in the remaining hour of the meeting. The updates made during the call are included in Attachment D.

Robin will take the sections she already has and put them into the new format. She asked Dwayne to forward the incubator information and he thought he thought he could get it out in the next day. She will send the Handbook to everyone on Friday. She asks that everyone continue to comment by email. She will also send it to Associate Members for comment.

3. Action Items

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

4. New Business

FSEA will have an implementation training during their meeting in October. Jerry Parr and Paul Junio will be coming to make presentations.

5. Next Meeting and Close

The next meeting will be held on October 11, 2016 at 1:30pm Eastern. *(Addition: The October meeting was canceled.)*

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

Robin adjourned the meeting at 2:57 pm Eastern.

**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
Jessica Hoch Present	TCEQ	AB	512-239-2353	Jessica.hoch@tceq.texas.gov
Colin Fricker Absent	Analytical Services, Inc	Lab		colinfricker@aol.com
Deb Waller Absent	NJ DEP	AB	(609)984-7732	debra.waller@dep.nj.gov
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		Other		Dr.PoChang@yahoo.com
Brad Stawick Absent	Microbac Laboratories	Lab	412-459-1058	brad.stawick@microbac.com
Gary Yakub Absent	Environmental Standards, Inc.	Other	(610)935-5577	gyakub@envstd.com
Ilona Taunton (Program Administrator) Present - Recorded	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	Ongoing
62	Update Handbook in new format and send to committee members and associate members to discuss by email.	Robin	9/16/16	

Volume 1 Module 5

QUALITY SYSTEMS FOR MICROBIOLOGICAL TESTING

1.1 – 1.3 Introduction/Scope/Terms

Key Points - The Standard contains detailed quality control requirements for environmental testing activities for microbiological analysis that include the detection, isolation, enumeration, and identification of microorganisms and/or their metabolites. Adherence to the Quality Systems Module 2 procedures, QC requirements specified by the reference method, regulation or project shall be met by the laboratory.

Discussion –The lab always has to keep in mind the client’s requirements such as analyzing water samples for compliance to a regulation or a specific project. Writing the requirements into SOPs will help ensure that the lab will handle, analyze, and report results within the client’s requirements. Be sure you keep your client informed of any deviations from requirements, so that recollection and reanalysis is an option to avoid rejection from Regulators. The TNI standard, test method requirements, state regulations, program requirements, and client needs all need to be considered when analyzing samples for compliance.

1.3.1 Key Terms and Definitions

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.

1.4 Method Selection

The TNI Standard generally assumes that the laboratory will use reference methods and that the method selection will be done based on regulatory drivers. For those situations where a reference method is not specified in a regulation, any applicable reference method may be used. Under unique situations where no reference method is available the method used must be validated. In all cases, method selection must be approved by the client when doing work for others or by the appropriate regulatory body when performing compliance work. For those laboratories where the analytical work is being done to support in-house functions such as for waste water

and drinking water facilities, the method must be approved for the regulatory work being conducted. In general, these will be defined in the facility permits.

Key Points:

- Verify the use of the data.
- Methods may be defined in a permit for in-house labs.

1.5.1 Validation of Methods

This section applies to methods that are developed or modified by the lab in order to meet objectives other than those specified in a given reference method.

Key Points:

- The validation must follow a documented procedure.
- The validation must address detection capability of the method and include precision, bias, measurement uncertainty, and selectivity/sensitivity where applicable.
- The validation records must be maintained for the life of the method and be readily retrievable.
- All methods, both reference and non-reference, require participation in proficiency testing (PT) when PT samples are available.

Discussion:

- Standard methods should also be validated if they are partly or fully out of the scope of the test requirements.
- Introduction of laboratory-developed methods should be introduced following a plan.
- The following parameters should be considered for validating in-house developed methods: limit of detection, limit of quantitation, accuracy, selectivity, linearity, repeatability and/or reproducibility, robustness, and linearity, where applicable.
- Exact validation experiments should be relevant to sample and required information.
- All nonstandard test methods, lab-developed methods, and standard methods used outside their approved scope must be validated before being placed into use.
- Validation includes specification of the requirements and scope, determination of the characteristics of the methods, appropriate tests to

- prove that the requirements can be fulfilled by using the method and a statement on the validity.
- Due to the nature of microbiological testing, non-target organisms may be detected. Therefore, the appropriate reaction must be considered.

Examples:

- Accuracy: Use at least one (1) known pure positive at the anticipated environmental conditions and compare the methods results to that of a reference method.
- 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.

Note: **How might they determine statistically equivalent?**

- Selectivity/sensitivity: 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.

Note: **Sample Calculation?**