Microbiology Expert Committee (MEC)
Meeting Summary

February 4, 2020

1. Roll Call:

Robin, Chair, called the meeting to order at 1pm Pacific on February 4, 2020 Newport Beach, CA. There were 4 voting members in attendance: Cody Danielson, Jody Frymire, Kasey Raley, and Robin Cook (last meeting as voting member). Elisa Snyder was also present as a new member who's term will start after today's meeting.

Committee members and former members thanked Robin for all the work she has done with the Microbiology Expert Committee the last 7 years. Congratulations to Kasey who will step in as Chair of the Committee after this meeting.

2. SIR #301 – Implementation Guidance Document

The Committee continued work on an Implementation Guidance Document for SIR #301:

The standard requires that a blank be done every 10 samples. What denotes a sample?

A sample may be defined as, a portion of material to be analyzed that is contained in single or multiple containers and identified by a unique sample identifier, used to generate a result. For the purposes of Module 5 a single sample includes all sample dilutions. A serial dilution does not create new samples. There is no need to analyze a blank in the middle of a serial dilution series for any given sample as may be the case if it were to be done every 10 plates.

As such, the requirement is to analyze a method blank every 10 samples for each filtration unit used on a manifold in a filtration series, which may include single or multiple filtration units. This would apply to every filtration unit on the manifold if there were more than one being used in a filtration series.

Each filtration unit on a manifold needs to have its own series of method blanks in order to provide information about that unit. While a method blank is intended to gauge the technique of the analyst, it is also used to determine if contamination takes place. Therefore, when multiple filtration units are used simultaneously in a filtration series, each one would need to be considered.

For example, if a laboratory is using 3 separate filtration units on a 3 filtration unit manifold, then a method blank is required for each of the 3 filtration units at the

beginning, after every 10 samples, and at the end of the filtration series. This would result in a minimum of at least 6 blanks for that filtration series.

Kasey shared a serial dilution example – picture.

Robin noted that this applies to all methods unless there is something specific and more stringent in the method.

Paul Junio (by email on 1/14/20): I know we talked about 'sample dilution' in the first paragraph, and I am just second-guessing. Should it say 'serial dilution' as well, for consistency's sake? The Committee agreed and made the change.

Ilona described the differences between Implementation Guidance and SIRs.

One more comment came in. Is it really one sample with multiple containers? Robin and Kasey clarified they are talking about multiple dilutions off a sample. Language was clarified in the second sentence to address this.

The final language after discussion:

> The standard requires that a blank be done every 10 samples. What denotes a sample?
>
> A sample may be defined as, a portion of material to be analyzed that is contained in single or multiple containers and identified by a unique sample identifier, used to generate a result. For the purposes of Module 5 serial dilutions are defined as a single sample. A serial dilution does not create new samples. There is no need to analyze a blank in the middle of a serial dilution series for any given sample as may be the case if it were to be done every 10 plates.
> As such, the requirement is to analyze a method blank every 10 samples for each filtration unit used on a manifold in a filtration series, which may include single or multiple filtration units. This would apply to every filtration unit on the manifold if there were more than one being used in a filtration series.
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> Each filtration unit on a manifold needs to have its own series of method blanks in order to provide information about that unit. While a method blank is intended to gauge the technique of the analyst, it is also used to determine if contamination takes place. Therefore, when multiple filtration units are used simultaneously in a filtration series, each one would need to be considered.
>
> For example, if a laboratory is using 3 separate filtration units on a 3 filtration unit manifold, then a method blank is required for each of the 3 filtration units at

the beginning, after every 10 samples, and at the end of the filtration series. This would result in a minimum of at least 6 blanks for that filtration series.

3 Filtration Unit Manifold example:

The language will be sent around for a final vote by email or it will be finalized at the March meeting.

3. Summary of Suggested Changes to the Standard

Robin and Kasey pulled up a new form to collect suggestions for changes to the Standard. This form will help the Committee prepare for a public webinar to review the changes the Committee thinks need to be made and to ask for more input on other changes needed. The Committee plans to complete this webinar before they get started on updating any language in the Standard.

The following table summarizes the items suggested during the meeting. The information in the table will need to be expanded on and the first column will need to be completed.

Module 5 Standard Update - Summary of Suggested Changes - 2-4-20-v0

Original Text	Suggested Change	Justification
Include reference and language.	*Don't need to work on specific language - just summarize change needed.*	*Why does this need to be changed/updated?*
	Filtration series blanks	Needs clarification
	Specific Conductance vs Conductivity	Need to update language
	Flexibility for new methods	Ex. Legionella
	IRT requirements	Update to match methods 9020B(jax)
	QC checks and Parent locations	Clarification of require. (jax)
	1.7.3.7 Demonstration of procedure	Define procedure for cleaning/verifying cleanliness, contact plates/swabs
	Efficacy of Cl2 checks	Concentrations in sample bottles? Single check at 15 or >
	Sampling accred.	ISO/IEC 17025:2017
	Replicate/Duplicate	Clarify difference
	2016: 1.6.1.2 DOC frequency	Timing of IDC/DOC
	1.7.3.6 viability checks	Captured in QC checks?
1.7.3.7.B.v.	Temperature Distribution	Clarification needed, define requirements? Difference should not vary more than method tolerance.
	Exemptions section	

Discussion:

Suggested Change: Allow substitution of inhibitory residue test.
Justification- bring it up to the changes the consensus groups are making.

Chlorine checks have to be quantifiable. Can't just check to see that it is clear. Strips could be used for checks – though some ABs won't let you use them.

What is Module 2 going to do with Sampling? Does this affect the other modules too? Is there info related to micro sampling that needs to be added to the Micro Standard? Need to consider this.

4. Next Meeting and Close

There will be no conference call in February. The next meeting will be held by teleconference on March 10, 2020 at 1:30pm Eastern.

The meeting was adjourned at 3pm Pacific.