

Akagi, Yone

From: Akagi, Yone
Sent: Thursday, October 22, 2009 4:10 PM
To: Richter, Ann; Edwards, Ryon
Subject: FW: LT2 endpt follow-up.

Ann and Ryon,

I received a response to our method questions from Stephanie on 9/28/09. There were formatting issues with her email that turned all of the previous text black so made it difficult to follow the email chain. Therefore, instead of forwarding her email, I am pasting her responses below.

From: Harris.Stephanie@epamail.epa.gov [<mailto:Harris.Stephanie@epamail.epa.gov>]
Sent: Monday, September 28, 2009 3:28 PM
To: Akagi, Yone
Cc: Richter, Ann; Gray.Fredianne@epamail.epa.gov; Jennings.Marie@epamail.epa.gov
Subject: Re: FW: LT2 endpt follow-up.

Hello Yone,

See my responses below in black. Hopefully the explanation helps in understanding this complicated process. If you have further questions, please don't hesitate to ask! Talk to you tomorrow!

Stephanie

[Responses to Yone's 9/24/09 questions](#)

[Response to Q1:](#) sounds right

[Response to Q2:](#) sounds right

[Response to Q3:](#) MS is required unless the laboratory currently has data on this matrix; MSD is not required except for tier 2 validation. If the laboratory has previously performed an MS on the Portland water using the 50 L and same filter technology as they are going to use for the variance application, then they would just need to analyze an MS every 20 samples during the testing period.

[Responses to Ann's 9/9/09 questions:](#)

[Response to Q1:](#) Yes, the mean of the 15 MS samples would need to meet that criteria, with a 61 % max RPD. The subscript 1 under table 3 & 4 notes that the acceptance criteria for mean MS/MSD recovery serves as the acceptance criteria for MS recovery during routine use of the method.

[Response to Q2:](#) The QA program at the laboratory you are using should be able to provide you with their method precision on an on-going basis. they are required to do this under the program. Although it isn't mentioned in the table you refer to, the method specifies that laboratories should be comparing recovery from MS every 5 samples and developing a precision recovery for each matrix. This can be found in section 9.5.1.4, which refers the user to Tables 3 (Crypto) and 4 (Giardia) The frequency for running the MS is 1 every 20 samples run using that matrix.(Section 9.1.8) Again, the laboratory should be performing this and can provide it to you upon request.

-----Original Message-----

From: Akagi, Yone
Sent: Thursday, September 24, 2009 1:20 PM
To: 'Jennings.Marie@epamail.epa.gov'; Gray.Fredianne@epamail.epa.gov; Harris.Stephanie@epamail.epa.gov
Cc: Richter, Ann
Subject: FW: LT2 endpt follow-up.

Hi Marie,

Below are the two questions from Ann for Stephanie regarding the matrix spike recoveries. Please note that these are for ongoing use of the unmodified method--NOT for a validation of a method modification.

In addition, I just wanted to confirm a few items.

1. You spoke with Carrie and she agreed with Stephanie that changing methods after we have begun our variance sampling would be ok, as long as the method we were changing to was either an approved method, or

was a modification approved by EPA (which we would work closely with you on) and met the criteria "Method modifications should be considered only to improve method performance, reduce cost, or reduce sample processing time. Method modifications that reduce cost or sample processing time, but that result in poorer method performance should not be used."

2. Per the text below from Mike Messner, we can interpret Option 3 as: to sample approximately 10,250 liters of water (which is consistent with option 1) and that all of the samples need to have zero oocysts. It also sounds like average recovery is not a factor in determining this volume of water (10,250L), although mean on-going matrix spike recoveries should meet the acceptance criteria (13-111%) and ORPs should meet the acceptance criteria (11-100%).

3. In our last call, Stephanie had confirmed that if we went with an already approved method (50L) we could start our sampling anytime as long as we started with one (and possibly a second) matrix spike. I'm just wondering how we know if we need to have one or two matrix spikes.

I look forward to speaking with you all next Tuesday. Please send us the final time and call in number when you have it.

I hope having these questions ahead of time is helpful to Stephanie.

Thanks, Yone

-----Original Message-----

From: Richter, Ann

Sent: Wednesday, September 09, 2009 3:46 PM

To: Akagi, Yone

Subject: RE: LT2 endpt follow-up.

Here are my questions about mean recovery and precision for ongoing use of the unmodified method:

Assuming Portland proceeds with Method 1623-Dec2005 (unmodified), please clarify how Portland should calculate mean recovery and precision during routine use of the method as per Table 3 to meet the QC acceptance criteria for routine matrix spikes (13-111% mean recovery and 61% as maximum relative percent difference).

1) Will the mean recovery of the routine matrix spikes be calculated as one figure for all our MS samples during the year of LT2 variance sampling? i.e., if we end up with a total of 15 MS samples, then the average of those 15 samples must be between 13 and 111%?

2) Do we need to calculate relative percent difference as per Table 3 for our routine matrix spikes? It appears that RPD is only calculated for method modifications, using the MS and MSD. Assuming no method modifications are made, please specify whether Portland needs to calculate precision, and if so, supply the equation and how it should be used for routine matrix spikes.

-----Original Message-----

From: Akagi, Yone

Sent: Wednesday, September 02, 2009 4:31 PM

To: 'Jennings.Marie@epamail.epa.gov'; 'harris.stephanie@epa.gov'

Subject: FW: LT2 endpt follow-up.

Hi Marie & Stephanie,

I inserted my comments/follow-up questions into the text below. My additions are in purple.

I thought it would be helpful for you both to see my questions before our call tomorrow. I will be in meetings from 8:30-12, so hopefully we can talk anytime after that. Please let me know when you are available.

Thanks,
Yone

-----Original Message-----

10/28/2009

From: Jennings.Marie@epamail.epa.gov [mailto:Jennings.Marie@epamail.epa.gov]
Sent: Tuesday, September 01, 2009 12:08 PM
To: Akagi, Yone
Subject: LT2 endpt follow-up.

Hi Yone

Below is dialogue incorporated into your questions.

Hi Marie & Stephanie,
 In our recent matrix spike experiments, Portland had difficulties filtering high volumes of water. Therefore, we have decided not to pursue validating higher volume samples using the Envirochek HV filter. **Stephanie: I assume also, that they have decided to use just the standard 50 L HV filter method without the additives mentioned in previous discussions?**

I do have a few additional clarifying questions regarding the variance sampling. Between 2002 - 2009, Portland collected five 50 liter matrix spikes per method 1623. All of Portland's historical 50 liter matrix spike data is pasted below. If we plan to sample 50 liters using an unmodified method 1623, I can only assume we will have similar matrix spike recoveries. **Mike Messner: I understood from discussions with Jeff Rosen last week that Portland has new data from new spikes of 50-liter samples and that recoveries were in the neighborhood of 10%. (Recoveries at higher volumes were even worse.) Their recovery difficulties were not limited to the high volume method. Marie, I suggest you ask Yone about recent matrix spike data. Stephanie: I assume that these recoveries are not the method OPRs, but are the spiked raw water. (Yone=yes, raw water) I would expect some variability like shown here, except for the very low spiked recoveries in August of 2007. Do they have an idea of what was going on at that time - change in water quality, lab or something?**

There seems to be some confusion. We did not do any new spikes for 50 liters samples. The best estimate for our 50 liter recoveries is our historical data. All of which is shown in the table below.

All of the data shown below was generated using the same LT2-approved lab. It is likely that the low recovery in August of 2007 is due to a season change in water quality, as we were having similarly low recoveries in our water this past August.

It is important to keep in mind that the work we are doing and have done in the last few weeks is exploratory. The matrix spike data is the measuring stick that we are using to find a method that will give us good results for estimating the occurrence of Crypto in the Bull Run.

Date	Volume (L)	Crypto Spike Dose	Crypto Recovery	Giardia Spike Dose	Giardia Recovery	Comments
12/17/2002	49.2	99	20%	99	69%	LT2 Data
6/15/2004	50	99	57%	99	55%	LT2 Data
2/15/2006	52.2	99	21%	100	47%	LT2 Data
8/15/2007	50	99	2%	99	41%	LT2 Data
3/18/2009	50	100	41%	101	42%	LT2 Data

Therefore,

1. In our last conference call with EPA, I thought I heard Carrie Miller state that the acceptance criteria for mean MS recovery during the routine use of the method was 13-111% as stated in Table 3. What happens if one of the routine matrix spikes taken during our 1 year sampling period falls outside of this range? **Mike: This is a question for Carrie. My opinion: If spike recovery falls outside the QC limits, the measurement system is not in a state of**

control, so the data shouldn't be used. Carrie, aren't there also some QC limits for the standard deviation of recovery between spike duplicates? **Stephanie: in the method the precision for matrix spikes is set at (RPD = 61). If the variability exceeds this then their laboratory system is out of control and the MS and MSD would need to be repeated before further samples could be analyzed.**

I think my question might have been misunderstood. I was referring to routine ongoing matrix spikes (once every 20 samples), not matrix spikes associated with any validation. I believe matrix spike duplicates are only required during a validation.

Table 3 in Method 1623 (page 59) lists Mean recovery superscript 1, 2 (as percent) as 13-111% with the footnote (1) The criteria for the mean MS/MSD recovery serves as the acceptance criteria for MS recovery during routine use of the method. I think this is what Carrie was referring to in one of our calls. Since the table specifies "mean recovery", I assume that this refers to the average matrix spike recoveries and not a individual matrix spike results. Is this correct?

2. Although EPA did not provide any assumptions for Options 2 & 3, is there a minimum total sampling volume (or number of samples) associated with Option 3? If so, what is that number and is that number tied to an assumed average matrix spike recovery? *Mike: There must be some minimum sample volume. I'd recommend at least the volume for which having found zero oocysts, one would conclude with 90% confidence that the concentration is at most 0.000225 (to be consistent with option 1) or at most 0.000075 (to be consistent with option 2). I updated the wiki page to address this question. If our concern is that a concentration of 0.000225/L should lead to treatment with probability 0.9, then it looks like 10,250 L or more should be assayed (with zero oocysts detected). If our concern is that a concentration of 0.000075/L should lead to treatment with probability 0.9, then at least 30,750 L should be assayed. Here's a link to the wiki page for option 3, (which I updated a bit to address the question here). These volumes are not tied to the average spike recovery. Average recovery doesn't enter into the calculation for systems that filter, so it doesn't seem appropriate to require recovery adjustment here. I think it is very important for Portland to demonstrate that their measurement system is maintained in a state of acceptable control - that ongoing QC (not just data from 2002 through early 2009) show good performance. **Stephanie: This appears to be a direct policy question and as a Regional scientist, I hesitate to suggest policy. [Marie : will work with Mike F. and Stephanie to follow-upon.]***

I'm not sure I understand Mike's answer. But it sounds like one option is to sample approximately 10,250 liters of water (which is consistent with option 1, likely our preferred option) and that all of the samples need to have zero oocysts. It also sounds like average recovery is not a factor in determining this volume of water (10,250L), although mean on-going matrix spike recoveries should meet the acceptance criteria (13-111%) and ORPs should meet the acceptance criteria (11-100%). Please confirm that this is correct.

3. Given Portland's historical 50 liter matrix spike data, if Portland chooses to pursue option 3 using 50 liter samples, what is the total sampling volume required by EPA and would Portland be able to begin sampling without additional experimentation? *Mike: I'd want to see their recent recovery data, as they'd be more relevant than recovery data from the past. Volume would depend on EPA's objectives (see 2, above). **Stephanie: They wouldn't be allowed to utilize any data that didn't meet the MS/MSD and OPR requirements for the method. Another question to ask; what is the average OPR recovery for the laboratory they are using?***

There is no new recent matrix spike data for 50 liter samples. The best estimates of performance that we have is the historical matrix spike data shown above. The recent data that we have (10 liter and 150 liter) is multiple samples from a short time period. This data shows very low recoveries, similar to our August 2007 recoveries above. I do not think that the recent data represents all of our water better than our historical data which includes multiple seasons and years. We are currently working with multiple labs to figure out how to improve recoveries during this time period.

I am checking on the lab's average ORP recovery and will get that to you.

Two addition questions I would like to discuss:

A. If Portland chooses to use equipment and volumes already approved in Method 1623 (with no modifications) (for example Envirochek HV 50L per Method 1623), is anything other than a single matrix spike required prior to

the start of sampling?

B. Would it be acceptable to switch from using equipment approved in Method 1623 to other equipment approved in Method 1623 once our sampling has begun? For example, to switch from Envirochek HV to FiltaMax or a continuous-flow centrifuge? Or would we have to stick with the same equipment for the duration of our variance sampling program?

Thank you for considering these questions.

Yone

S. Marie Jennings
Manager, Drinking Water Unit
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