

Questions and Action Items from PWB and EPA Conference Call July 9th, 2009 Portland Water Bureau Variance Sampling Approach

In the letter dated May 7, 2009 to David G. Shaff, Administrator, Portland Water Bureau from Marie Jennings the following two items were included on page 2 in the section that specified the additional work that is needed for the agency to have a high level of confidence in the quality of data and information collected and submitted in support of the variance.

“1. Portland should provide statistically valid data to demonstrate the efficacy of the proposed method before initiation of sampling. The information provided under the proposed protocol is limited and is not sufficient to demonstrate the efficacy of the modified method with a high degree of confidence. The degree of variability is substantial for Method 1622/1623 even when experimental conditions are held as constant as possible. Statistics are necessary to describe the variability of the method when analyzing for *Cryptosporidium* in raw source water.

2. The number of observations necessary for the experiments should be calculated using the variation in repeated matrix spike tests. Standard statistical practices for estimating measurement uncertainties should be incorporated, including the approach for determining the number of observations. A 90% confidence interval based on matrix spike samples should be used to determine the number of observations necessary for the study. The confidence interval will estimate the reliability of the method to detect oocysts.”

Please address the following questions:

First Bullet

Item number 1 seems to be addressing two separate issues.

First: “Portland should provide statistically valid data to demonstrate the efficacy of the proposed method before initiation of sampling.”

This is asking for validation of the method. The method was validated using a Tier 1 validation which is formally specified in USEPA Method 1623: *Cryptosporidium* and *Giardia* in Water by Filtration/IMS/FA. USEPA Office of Water, Washington, DC (EPA-815-R-05-002) and reiterated in Clancy, J.L et al. 2003. Implementing PBMS improvements to USEPA’s *Cryptosporidium* and *Giardia* Methods. JAWWA, 95:9:80. Clancy et al (2003. Recovery of *Cryptosporidium* oocysts from high volume water samples. AwwaRF and AWWA) demonstrated that 1000L samples of treated water can be sampled and analyzed using Method 1623, with a variation in the elution buffer needed to maintain recoveries that fall within the method acceptance criteria for Method 1623. This method has been used successfully in Paul Rochelle’s AwwaRF study 3021 - Detection of Infectious *Cryptosporidium* in Filtered Drinking Water.

EPA’s response (PWB/CEC notes, 7/9/09):

A Variance is a different case and the method that needs to be applied for a variance is very different. The method and approach for LT2 is meant to be a national method and therefore needed more flexibility. The method for the variance needs to focus on validation specifically for Bull Run and at much lower concentrations than were expected for LT2 monitoring. EPA is looking for additional matrix spike samples to make sure that the proposed changes in the method will result in recovery rates that are in the range of acceptance criteria.

Carrie Miller also said that EPA felt it was critical for the matrix spikes to be done over the entire volume of the sampling. They had specific concerns about filtering a large volume

(e.g. 190 liters) and then spiking and filtering a smaller volume (e.g. 10 liters). Intuitively they felt (and would also like lab verification) that it would be better to spike with the small volume up front and then filter the larger volume through the already spiked filter. Best case would be that the spiking is done over the entire volume that is being used.

PWB expressed the concern over bringing crypto into the watershed so that it can be spiked in the field versus filtering a large volume in the field and then returning the filter and a smaller volume to the laboratory where the spiking can be done without risk of introducing *Cryptosporidium* in the environment.

EPA would like to see a demonstration that the way the spiking is done has no effect on the recovery efficiencies. Once this is demonstrated EPA is looking for an enhanced matrix spiking program that will result in a 90% confidence that the mean recovery rate from spiking studies falls firmly in the range of the acceptance criteria which is 13-111 % with a precision as maximum relative percent difference of 61% (or less) (see table 3, pg 59, of method 1623).

At first, Carrie Miller said that they could not tell us the acceptance criteria until after they saw the data. PWB countered that we could not design the matrix spike studies without knowing the acceptance criteria so that we can plan for sufficient samples to meet a 90% confidence interval if the new method performs as well as the 10 or 50 liter methods.

Action Item #1 - EPA agreed that they need to confirm that the target acceptance criteria for this method modification are the same as in the method.

(PWB / CEC Notes, 7/9/09) - This doesn't make sense since the method is the method regardless of how it is being applied. Method 1623 was not developed for LT2; it was developed for Crypto and for Giardia and should be applicable no matter the purpose of the analyses. If the method is valid then the acceptance criteria should remain the same. PWB said that if EPA is going to come up with different criteria then these need to be justified and based on *something*, not just picking numbers out of the air.)

Second question about the first bullet: "Statistics are necessary to describe the variability of the method when analyzing for *Cryptosporidium* in raw Source Water". This seems to be a different topic. Specifically, what is the variability of the modified method when analyzing for *Cryptosporidium* in raw water? This would include many different components of variability, including, sampling, filtering, elution, staining and counting.

EPA's Response (PWB/CEC notes, 7/9/09):

EPA stated that this is meant as the same question, specifically how does the modified method perform in the specific matrix that is being tested – Bull Run. This will be resolved through an expanded matrix spike trial that includes enough samples to demonstrate that the mean recovery efficiency meets the acceptance criteria when considering the 90% confidence interval.

Second Bullet

The words in Item Two are ambiguous and lead to the following requests for clarification:

“2. The number of observations necessary for the experiments should be calculated using the variation in repeated matrix spike tests. Standard statistical practices for estimating measurement uncertainties should be incorporated, including the approach for determining the number of observations. A 90% confidence interval based on matrix spike samples should be used to determine the number of observations necessary for the study. The confidence interval will estimate the reliability of the method to detect oocysts.”

PWB/CEC notes, 7/9/09: EPA agreed with the need to carefully explain each of the underlined terms above.

Action Item #2 – EPA has agreed to clarify what is meant by the words “**for the experiments**”. Is this referring to the expanded Matrix Spike study or the actual Bull Run monitoring?

Action Item #3 - EPA has agreed to explain what “**the number of observations**” refers to. Is this the number of observations for the Matrix Spike study or is it the number of observations for the source water monitoring plan?

Action Item #4 – EPA has agreed to explain what they meant by “**the number of observations necessary for the study**” –again, which study are they referring to?

(PWB / CEC notes, 7/9/09: It is not clear how the variability in the matrix spike samples is applicable to any designs of a field monitoring program.)

Action Item #5 – EPA has agreed to clearly define whether the target for the Bull Run Monitoring is a mean of 0.000075 oocysts/Liter or a specified % confidence interval around this value (e.g., two sided 90% confidence interval) or a specified % confidence that the mean monitored in Bull Run will not exceed the mean of 0.000075 oocysts/liter (e.g., a one sided 90% Confidence interval).

(PWB / CEC notes, 7/9/09: the LT2 rule includes a discussion of including a safety factor into the calculations when the original bin 1 boundary of 0.075 oocysts/L was developed. This is documented in the Economic analysis (Appendices to the Economic Analysis for the Final Long Term 2 Enhanced Surface Water Treatment Rule Volume I (A – G), EPA 815-R-06-001 December 2005). In PWB’s opinion, therefore, a demonstration of a mean value that meets the criteria should be more than adequate, especially given the number of samples that will be required. Again, Mike Finn was to verify this. Marie will make sure that we get clarification within the next couple of weeks.)

Portland Assumptions regarding the LT2 Variance Process

Portland has the following assumptions that EPA will verify:

1. A 1-year sampling plan is acceptable to EPA since EPA did not comment on this part of our proposal submitted April 10, 2009.

Action Item #6 - EPA agreed to evaluate whether or not a 1-year sampling plan is acceptable to EPA.

2. EPA will accept Portland’s historical data (12/02-4/09) since EPA did not comment on this part of our proposal submitted April 10, 2009.

Action Item #7 - EPA agreed to decide if they will accept Portland's historical data (12/02-4/09) This would be monthly data based on a smaller volume (50 Liters) but would extend the temporal range of the data significantly.

3. Data collected at potential hotspots in the watershed will not be combined with data collected from the intake,

and,

4. Samples collected at the intake will be the only samples used in calculations to determine whether or not the threshold of 0.075 oocysts/1000 liters has been met. (related to assumption #3)

PWB / CEC Notes, 7/9/09: These two questions will need to be addressed by Mike Finn. EPA has not considered this. Hot spot sampling will be used to feed the modeling fate and transport.

Marie will work with the EPA policy group to resolve this issue.

It is PWB’s belief that the water that needs to be characterized is the water that will be used as a drinking water source. Historically the sampling unit has been water at the intake since it is the only water that is relevant to the risk of ingesting *Cryptosporidium*. The hot spot sampling should be useful in helping to calibrate the model but including these data could bias the results in a way that will have no role in public health protection.

Action Item #8 – EPA has agreed to define what the sampling unit is. Is it the water at the intake or is it the water at various locations throughout Bull Run Watershed?

5. Method 1623 is a valid laboratory method for sampling for *Cryptosporidium* in the attempt to gain a variance from LT2.

PWB / CEC Notes, 7/9/09: PWB is modifying the method. 1623 is only valid if a recovery can be demonstrated. Carrie Miller wants to see that the modified method meets the current acceptance criteria. EPA (Carrie) will get back to us on the acceptance criteria and we will design to those numbers, both acceptance criteria and precision.

Action Item #9 – EPA has agreed to clarify whether Method 1623 is a valid laboratory method for sampling for Cryptosporidium in the attempt to gain a variance from LT2. If it is, then a modification of it that meets the requirements of the method should also be acceptable.

6. EPA understands that the pathogen budget model developed by Christobel Ferguson will require significant adaptations to be used in North America and specifically the Bull Run Watershed.

PWB /CEC Note (7/7/09): Does everyone understand that the model is going to be modified based on the existing model to conform to the realities and properties of the Bull Run Watershed? Marie Jennings indicated that she thinks this means a clear statement of the assumptions – which is part but not all of the issue. Some parameters in the model and some relationships between the parameters may be completely inappropriate for Bull Run. This is related to the assumptions but it may also be that there are parameters that are just not relevant that should be dropped from the model. Region 10 intends to be regularly involved in defining the assumptions - need to get agreement from Region 10 on all assumptions. Region 10 will be involved in applying the key assumptions that are the foundation of the model.

Action Item #10 - Does EPA understand that the pathogen budget model developed by Christobel Ferguson will require significant adaptations to be used in North America and specifically the Bull Run Watershed?

In addition to the above action items, EPA and PWB agreed on:

- A regular weekly check-in call between Marie Jennings and Yone Akagi (or designee)
- A summary of the 7/9/09 conference call by July 14, 2009.
- EPA will strive to provide answers to PWB's questions discussed during the 7/9/09 call in approximately 10 days.
- Another conference call to include Mike Finn, during the week of July 20th to discuss EPA's answers to Portland's questions.
- Marie Jennings will make a variance process timeline to send to everyone.