

Summary of Questions and Answers from EPA /PWB Conference Call – July 28, 2009

[Draft not finalized; Marie Jennings' (EPA Region 10) comments underlined in red]

On July 28, 2009, Portland Water Bureau and their consultants, Clancy Environmental Consultants (CEC), held a follow-up conference call with EPA Region 10 and EPA Headquarters to resolve PWB's remaining questions from the call held on July 9, 2009, regarding statements made by EPA in their May 7, 2009 correspondence. The following summarizes Portland's understanding of EPA's responses to Portland's questions and assumptions.

Q1. What are the target acceptance criteria for Portland's method modification? Request that EPA confirm that the acceptance criteria are the same as for EPA Method 1623.

Background: Portland plans to collect a very large number of 200-L samples, using the Pall Gelman Envirochek HV filter, during an intensive year-long sampling period in order to determine if the raw source water at PWB's intake sample is below the target of 0.075 oocysts/1000-L as stated in LT2 in order to be considered for a variance to the treatment requirement of LT2, under the Safe Drinking Water Act. The December 2005 version of EPA Method 1623 states that interlaboratory validation studies have been performed to demonstrate the equivalency of modified versions of the method using the Envirochek HV filter (pg v) and section 6.2.2 states that the versions of the method using this filter was validated using 50-L sample volumes and "*Alternate sample volumes may be used, provided the laboratory demonstrates acceptable performance on initial and ongoing spiked reagent water and source water samples.*" Portland wishes to validate 200-L sample volumes in order to more feasibly achieve the extremely large volume of water that would be required to determine whether the raw water is below the target of 0.075 oocysts/1000-L

Answer:

Portland must follow the acceptance criteria for method modifications as written in the December 2005 version of EPA Method 1623. Specifically, according to section 9.1.2.1.1, "*the laboratory must, at a minimum, validate the modification according to Tier 1 of EPA's performance based measurement system (PBMS) (Table 2) to demonstrate that the modification produces results equivalent or superior to results produced by this method as written...IPR results must meet the acceptance criteria in Tables 3 and 4 in Section 21.0, and should be comparable to previous results using the unmodified procedure.*" EPA Method 1623 goes on to state "*Although not required, the laboratory also should perform a matrix spike/matrix spike duplicate (MS/MSD) test to demonstrate the performance of the modified method in at least one real world matrix before analyzing field samples using the modified method.*"

~~However, EPA is holding PWB to a higher standard because this study is for a SDWA variance.~~
[Marie Jennings: I remember PWB coming to this conclusion; but I don't think EPA provided this as a definitive reason. Can follow-up if needed.] In addition to the above, PWB must collect repeated (200-L) matrix spike samples for the method modification. The exact number for this expanded study will be determined via statistical analysis but is on the order of 10 samples. The results of these new matrix spikes will be compared to results produced by this method as written.

Portland has two options:

- 1) Portland can compare the new MS samples to their previous results by this method as written, i.e. 10-L or 50-L MS samples. Or,
- 2) Portland can compare the new MS recoveries to a value of "about 40%." EPA explained that the national average for MS recoveries is now around 40% with a very

wide distribution. However, EPA indicated that they are not sure where the hard data can be found. If Portland took this option, Portland and their contractors, Clancy Environmental Consultants, would need to access to this data from which the average is calculated in order to generate distribution statistics.

EPA is comfortable with either option. Both are valid and the first 1 which was called option A during the call follows the method. PWB agreed to put together options on how to do the matrix spike comparisons and include why EPA should consider 50L instead of 10L.

Follow-up from Method Modification Discussion – Need clarification on the 4 phrases used in the 2nd recommendation (in the May 7th letter) regarding the number of observations necessary for the experiments...

Q2. “for the experiments” – Is this referring to the expanded Matrix Spike study or the actual Bull Run monitoring?

Q3. “the number of observations” – Is this the number of observations for the Matrix Spike study or is it the number of observations for the source water monitoring plan?

Q4. “the number of observations necessary for the study” – It is not clear how the variability in the matrix spike samples is applicable to any designs of a field monitoring program.

Answer to Q2, Q3, and Q4:

All of these statements only refer to the Matrix Spike study for the method modification as described in Q1 above, and none of these statements refer to the actual field monitoring program for the Bull Run source water.

Follow-up on the target threshold of 0.075 oocysts / 1000-L (0.000075 oocysts/L)

Q5. Is the target for Bull Run monitoring a mean of 0.000075 oocysts/L 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/L (e.g., a one sided 90% confidence interval)?

Stated differently, is our threshold a point estimate of less than 0.000075 oocysts/L or does Portland have to demonstrate that their mean concentration is statistically significantly below 0.000075 oocysts/L?

Note: This point is crucial to the study design for the field monitoring program for the Bull Run source water. Portland cannot complete their sampling proposal until this question is answered. CEC noted that safety factors were already applied when EPA determined the threshold of 0.000075 oocysts/L.

Answer:

EPA could not give an answer on 7/28/2009. EPA needs to discuss this internally. Marie Jennings will follow up with Mike Finn to respond to Portland as soon as possible.

Portland Assumptions Regarding the LT2 Variance Process

Assumption 1. A one-year long sample plan is acceptable to EPA as the timeline for sampling for a variance.

Answer: EPA agrees that one year is acceptable.

Assumption 2. EPA will accept Portland's historical data from December 2002 through April 2009. (This would be monthly data based on a smaller volume (50-L) but would extend the temporal range of the data significantly.)

Answer: EPA will accept Portland's historical data, however EPA believes that if any historical data is to be submitted, all historical data should be submitted. (If PWB wanted to submit a technical reason why other data is not comparable, EPA would look at it.) The historical data will be considered as part of the variance package but will not be incorporated into the calculation to determine whether Portland meets the threshold of less than 0.075 oocysts/1000-L. PWB will decide whether or not to submit historical data.

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

Assumption 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-L has been met. (This assumption is related to #3 above).

Answer to Assumptions 3 and 4: EPA agrees; data from potential hotspots in the watershed will be considered only as part of the variance package and will not be incorporated into the calculation to determine whether Portland meets the threshold of less than 0.075 oocysts/1000-L. The sampling unit for this threshold is only the water at the Bull Run intake.

Assumption 5. EPA Method 1623 is a valid laboratory method for sample for *Cryptosporidium* in the attempt to gain a variance from LT2. And if so, then a modification of it that meets the requirements of the method should also be acceptable.

Answer: EPA agrees with this assumption, however, see answer to Q1 – the EPA will require Portland to conduct an expanded matrix spike study in addition to the text in Method 1623.

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

Answer: EPA agrees with this statement.

Follow-up from 7/23/09 call with Jeff Rosen (CEC) and Mike Messner (EPA), included Marie Jennings and PWB

1. **Are we looking at the mean of the 90th percentile and can we assume a normal distribution of the data?**

Answer: Refer to Q1 on the matrix spike study. A normal distribution can be assumed for the matrix spike data only.

2. **Monitoring program – what are we going to use for the distribution? Log normal or normal?**

Answer: Although further discussion will occur, the monitoring program data will likely be fitted to a binomial distribution. The pending answer to Q5 is crucial.

- 3. When PWB samples, do they need to demonstrate a mean below a confidence level below 0.000075 oocysts/ L? Safety factors have already been introduced.**

Answer: this is the same question as Q5; the EPA answer is pending. EPA will get back to Portland with by the next check-in call. EPA needs to be clear about what was intended when the rule was written.

- 4. What are the acceptance criteria? (13 – 111%). Is the lower limit of 13 an absolute number or is it surrounded by a confidence interval?**

Answer: this is the same question as Q1; for the matrix spike study Portland must compare to data from the existing Method 1623.

Time Line: EPA asked everyone to look at the dates and provide comments. PWB stated that they can get back to EPA with better dates after they get responses regarding how to demonstrate that the endpoint has been met.

EPA will answer the question regarding the extension of the treatment deadline if PWB doesn't receive a variance.