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Guidance on Generation and Submission of Grandfathered *Cryptosporidium* Data for Bin Classification Under the Long Term 2 Enhanced Surface Water Treatment Rule

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Guidance on Generation and Submission of Grandfathered *Cryptosporidium* Data for Bin Classification Under the Long Term 2 Enhanced Surface Water Treatment Rule

1.0 Purpose

The purpose of this guidance is to assist public water systems (PWSs) that elect to monitor for *Cryptosporidium* prior to finalization of the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR). The U.S. Environmental Protection Agency (EPA) is developing the LT2ESWTR to address risk from *Cryptosporidium* in drinking water. This guidance reflects recommendations by the Stage 2 Microbial and Disinfection Byproducts Advisory Committee (the Committee) to the EPA Administrator for the LT2ESWTR. The Committee's recommendations are set forth in an Agreement in Principle (Agreement) (65 FR 83015, December 29, 2000).

The Agreement recommends that under the LT2ESWTR, PWSs using surface water conduct source water *Cryptosporidium* monitoring for a specified period. The monitoring results would determine a risk bin classification, which would dictate what, if any, additional *Cryptosporidium* treatment would be required. Under the Agreement, PWSs could use previously collected (i.e., grandfathered) *Cryptosporidium* monitoring results to determine their LT2ESWTR bin classification in lieu of additional monitoring under the rule. However, to be used for bin classification, previously collected data should be equivalent in sample number, frequency, and data quality to data that would be collected during LT2ESWTR implementation.

This guidance describes how PWSs can perform grandfathered *Cryptosporidium* monitoring such that the results should be equivalent to data generated under the LT2ESWTR and, therefore, acceptable for use in bin classification. This guidance does not address the potential use under the LT2ESWTR of previously collected *Cryptosporidium* data that are determined not to be equivalent to the data generated under the LT2ESWTR; EPA plans to solicit comment on this issue in the proposed rule.

This document constitutes EPA's guidance for PWSs that choose to monitor for *Cryptosporidium* prior to EPA's issuance of the final LT2ESWTR and seek to have the data accepted for use ("grandfathered") when the LT2ESWTR is promulgated. This document does not substitute for the Safe Drinking Water Act or EPA regulations, nor is it a regulation itself. This guidance cannot impose legally binding requirements on the EPA, States, authorized tribes, or the regulated community, and might not apply to a particular situation based on the circumstances. As with all guidance, EPA may change this guidance in the future to reflect new information.

This guidance addresses the following topics:

2.0 Background

"Grandfathered" *Cryptosporidium* data are results generated before monitoring under the LT2ESWTR starts and that a PWS intends to use in determining its bin classification under the rule (for an initial discussion of bin classification, see http://www.epa.gov/safewater/lt2/st2eswtr.html). Under the Agreement, grandfathered data may be used in lieu of, or in addition to, results generated during LT2ESWTR implementation.

EPA plans to establish detailed, standardized requirements for *Cryptosporidium* sample collection, analysis, laboratory performance, and data reporting under the final LT2ESWTR to ensure that data will be of satisfactory quality for bin classification. These requirements will be published in the proposed LT2ESWTR and will be subject to public comment. Related information and guidance will be provided through laboratory and utility guidance manuals for the rule, the *Cryptosporidium* Laboratory Quality Assurance Evaluation Program, EPA Methods 1622 and 1623, and the LT2 Data Collection System.

Grandfathered *Cryptosporidium* data will be generated before LT2ESWTR requirements are established. The purpose of these guidelines is to assist PWSs in producing grandfathered data that should be equivalent to the data collected during LT2ESWTR implementation and, therefore, eligible for use in bin classification. The final LT2ESWTR will establish requirements for reporting and acceptance of grandfathered monitoring results.

3.0 General Guidelines for Generating *Cryptosporidium* Data

Under the Agreement, a PWSs' grandfathered *Cryptosporidium* data package should meet the following general conditions:

- Samples were collected from the appropriate location(s) (see details below)
- Samples were representative of a plant's source water(s) and the source water(s) have not changed
- Samples were collected no less frequently than each calendar month on a regular schedule, beginning no earlier than January 1999 (when EPA Method 1622 was first released as an interlaboratory-validated method)
- Samples were collected in equal intervals of time over the entire collection period (e.g., weekly, twice-per-month, monthly)
- The data set includes all source water *Cryptosporidium* monitoring results generated during the grandfathered data monitoring period (see details below—data from monitoring not directed towards LT2ESWTR binning will not be a component of the binning data set)
- Sample volumes of at least 10 L were analyzed or, in cases where 10 L were not analyzed, at least 2 mL of packed pellet volume were analyzed (additional details below)
- The data were generated using the validated versions of EPA Methods 1622 or 1623

- The data are fully compliant with the QA/QC criteria specified in the version of Method 1622 or Method 1623 used to generate the data, including analysis of matrix spike (MS) samples at a frequency of at least 5% (1 MS sample for every 20 monitoring samples)

The following sections discuss these recommendations in more detail.

3.1 Sample Collection Location

Under the Agreement, LT2ESWTR monitoring is intended to assess the mean *Cryptosporidium* level in the influent to drinking water plants that treat surface water or ground water under the direct influence (GWUDI) of surface water. Generally, monitoring should be performed for each plant that treats a surface water or GWUDI source. However, where multiple plants receive all of their water from the same influent (e.g., multiple plants draw water from the same pipe), the same set of monitoring results may be applicable to each plant.

Cryptosporidium samples intended for grandfathering under the LT2ESWTR should be collected at a location that is representative of the treatment plant influent and prior to any treatment (with exceptions noted below). Additional information for specific situations is provided as follows:

3.1.1 Plants That Do Not Have a Sampling Tap Located Prior to Any Treatment

Plants in this situation should pursue one of the following options:

- Establish a sampling location prior to treatment
- Discontinue chemical addition for a period of 6 to 12 hours (or when determined by the plant to be chemical-free as indicated by appropriate analytical methods for the chemical additive) before sample collection
- Manually collect source water samples as close to the intake as is feasible, at a similar depth and distance from shore

3.1.2 Plants That Use Different Water Sources at the Same Time

This includes multiple surface water sources and blended surface water and groundwater sources. Plants in this situation should pursue one of the following options:

- If there is a sampling tap where the sources are combined prior to treatment, the sample should be collected from the tap.
- If the sampling tap is located after treatment, discontinue chemical addition for a period of 6 to 12 hours (or when determined by the plant to be chemical-free) before sample collection.
- Samples can be manually collected at each source near the intake on the same day and composited into one sample. The volume of sample from each source should be weighted according to the proportion of that source used by the plant. For example, if a plant has two sources and 75% of the drinking water is from Source A and 25% is from Source B, then for a 10 L sample, 7.5 L would be collected from Source A and combined with 2.5 L collected from Source B. Compositing of samples should reflect plant operation at the time the sample is collected and may change during the monitoring period.

3.1.3 Plants That Use Presedimentation

PWSs with plants using a presedimentation basin should take source water samples after the presedimentation basin but before any other treatment. Use of presedimentation basins during monitoring should be consistent with routine operational practice and should be documented.

3.1.4 Plants That Use Raw Water Off-Stream Storage

PWSs with plants using an off-stream raw water storage reservoir should take source water samples after the off-stream storage reservoir but before any other treatment. Use of off-stream storage during monitoring should be consistent with routine operational practice and should be documented.

3.1.5 Plants That Use Bank Filtration

The correct sampling location for PWSs with plants using bank filtration differs depending on whether the bank filtered water is treated by subsequent filtration for compliance with the Surface Water Treatment Rule (SWTR) (i.e., compliance with 40 CFR 141.73).

- PWSs using bank filtered water that is treated by subsequent filtration for compliance with the SWTR should collect source water samples from the well (i.e., after bank filtration) but before any other treatment. Use of bank filtration during monitoring should be consistent with routine operational practice and should be documented.
- PWSs using bank filtered water without additional filtration (e.g., PWSs complying with the SWTR using an alternative filtration demonstration under 40 CFR 141.73(d)) should take source water samples in the surface water source (e.g., the river). Use of bank filtration during monitoring should be consistent with routine operational practice and should be documented.

If the PWS does not collect samples as recommended in this section, the data may not be acceptable for grandfathering.

3.2 Sample Collection Schedule

The Agreement recommends that during LT2ESWTR monitoring, PWSs should collect samples at least monthly and in accordance with a schedule established by the PWS prior to initiation of monitoring. PWSs may collect samples more frequently (e.g., twice-per-month, weekly) provided the same frequency is maintained throughout the monitoring period. Sampling for grandfathered data should follow these same criteria.

EPA recommends that prior to initiation of grandfathered monitoring, PWSs develop a schedule listing the calendar date on which each *Cryptosporidium* sample will be collected and include this schedule when submitting the grandfathered data package to EPA. PWSs that have begun grandfathered monitoring without establishing a sampling schedule should develop a schedule for the collection of remaining samples. PWSs should collect samples within 2 days before or after the dates indicated in their sampling schedules. Exceptions to the sampling schedule are noted as follows:

- If extreme conditions or situations exist that may pose danger to the sampler, or which are unforeseen or cannot be avoided and which cause the system to be unable to sample in the required time frame, the PWS should sample as close to the scheduled date as feasible and submit an explanation for the alternative sampling date with the analytical results.
- PWSs that are unable to report a valid *Cryptosporidium* analytical result for a scheduled sampling date due to failure to comply with the analytical method quality control standards (e.g., sample is lost or contaminated; laboratory exceeds an analytical method holding time) should collect a replacement sample within 14 days of being notified by the laboratory that a result cannot be reported for that date. PWSs should submit an explanation for the replacement sample with the analytical results.

Alternative sample collection dates should be timed so as not to coincide with another scheduled *Cryptosporidium* sample collection date. Documentation of alternate sample collection, including the reason, should be provided with the grandfathered data package.

Water treatment plants that use surface water or GWUDI but are operated only seasonally (e.g., during times of high-water demand) should monitor at least monthly during the period when the plant is in

operation. EPA plans to solicit comment in the LT2ESWTR proposal on whether a minimum number of samples should be required for seasonally operated plants.

The Agreement recommends that if PWSs collect a total of at least 48 samples (regardless of whether all of the samples were collected before LT2ESWTR promulgation or some were collected before and some after rule promulgation), the *Cryptosporidium* bin concentration will be equal to the arithmetic mean of all sample concentrations. For PWSs that serve at least 10,000 people and collect a total of at least 24 samples, but not more than 47 samples, the *Cryptosporidium* bin concentration will be equal to the highest arithmetic mean of all sample concentrations in any 12 consecutive months during which *Cryptosporidium* samples were collected.

3.3 *Cryptosporidium* Analytical Methods for Grandfathered Data

The Agreement recommends that Methods 1622 or 1623 be used for *Cryptosporidium* analyses for the LT2ESWTR. The following are EPA validated versions of Methods 1622 and 1623:

- *Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA.* U.S. Environmental Protection Agency, Office of Water. 2001. EPA-821-R-01-025
- *Method 1622: Cryptosporidium in Water by Filtration/IMS/FA.* U.S. Environmental Protection Agency, Office of Water. 2001. EPA-821-R-01-026
- *Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA.* U.S. Environmental Protection Agency, Office of Water. 1999. EPA-821-R-99-006 *(**Note:** The 2001 version of the method should be used to generate data after January 1, 2002.)*
- *Method 1622: Cryptosporidium in Water by Filtration/IMS/FA.* U.S. Environmental Protection Agency, Office of Water. 1999. EPA-821-R-99-001 *(**Note:** The 2001 version of the method should be used to generate data after January 1, 2002.)*

Notable differences between the 1999 and 2001 versions of EPA Method 1622/1623 include the following:

- Nationwide approval of modified versions of the methods using the following components:
  - Whatman Nuclepore CrypTest™ filter
  - IDEXX Filta-Max™ filter
  - Waterborne Aqua-Glo™ G/C Direct FL antibody stain
  - Waterborne Crypt-a-Glo™ and Giardi-a-Glo™ antibody stains
- Clarified sample acceptance criteria
- Modified capsule filter elution procedure
- Modified concentrate aspiration procedure
- Modified IMS acid dissociation procedure
- Updated QC acceptance criteria for IPR and OPR tests
- Addition of a troubleshooting section for QC failures
- Modified holding times
- Inclusion of flow cytometry–sorted spiking suspensions (required for spiked samples analyzed during LT2 monitoring)

Since release of the 2001 versions of Methods 1622/1623, EPA also has approved a modified version of the methods using the Pall Gelman Envirochek™ HV filter and has approved the use of irradiated, flow cytometer–sorted spiking suspensions for routine QC sample spiking.

Laboratories that analyze *Cryptosporidium* samples using other modified procedures, as allowed under the performance criteria of Methods 1622/1623, should be approved to use the modified procedures under the Lab QA Program discussed in section 3.4.

3.3.1 Minimum Sample Volume and Subsampling Analysis

The Agreement recommends a sample volume of at least 10 L for *Cryptosporidium* analyses and, in addition, recommends that EPA provide guidelines for those cases where it is not possible to process a 10 L sample. The following are guidelines for minimum sample and subsample volume for *Cryptosporidium* analyses under the LT2ESWTR.

- 10 L of sample, *or*
- 2 mL of packed pellet volume, *or*
- As much volume as two filters can accommodate before clogging (this condition applies only to filters that have been approved by EPA for nationwide use with Methods 1622/1623—the Pall Gelman Envirochek™ and Envirochek™ HV filters, the IDEXX FiltaMax™ foam filter, and the Whatman CrypTest™ cartridge filter).

The Agreement would allow PWSs to analyze larger volumes. EPA recommends that PWSs analyze similar sample volumes throughout the monitoring period. However, data sets including different samples volumes would be acceptable under the Agreement, provided the PWS analyzes at least the minimum sample volume, as given in this section, for each sample.

3.3.2 Analysis of Matrix Spike Samples

Method 1622 and 1623 require matrix spike (MS) samples to be analyzed at a frequency of 1 MS sample for every 20 monitoring samples from each plant. The MS sample and the associated unspiked sample must be analyzed by the same procedure and the MS sample must be the same volume as the associated monitoring sample. If the volume of the MS sample is greater than 10 L, the system is permitted to filter all but 10 L of the MS sample in the field, and ship the filtered sample and the remaining 10 L of source water to the laboratory to have the laboratory spike the remaining 10 L of water and filter it through the filter used to collect the balance of the sample in the field.

Utilities collecting and shipping bulk water samples for filtration and analysis at the laboratory should split their sample stream and collect the monitoring sample volume and MS sample volume simultaneously.

- The sample stream should be split using flow controllers on both sides of the split to regulate the pressure difference between the side being subjected to filtration (resulting in higher pressure) and the side flowing into a bulk sample container. A mixing chamber (filter housing without filter) can be added immediately upstream from the Y to aid in equalizing the distribution of sample particulates to either side.
- If splitting the sample stream is not practical, the utility should collect the MS sample immediately before or after the monitoring sample.

Under the Agreement, MS sample results would not be used to adjust *Cryptosporidium* recoveries at any individual source water; but MS results would be used collectively to assess overall recovery and variability for EPA Method 1622/1623 in source water. No resampling would be necessary for MS samples that do not meet Method 1622/1623 recovery guidelines.

3.4 *Cryptosporidium* Laboratories for Grandfathered Data

EPA has established the Laboratory Quality Assurance Evaluation Program for the Analysis of *Cryptosporidium* in Water (Lab QA Program) to approve laboratories to perform *Cryptosporidium* analyses under the LT2ESWTR (see http://www.epa.gov/safewater/lt2/cla_final.html). EPA recognizes that some

PWSs could begin generating grandfathered *Cryptosporidium* data prior to when the Lab QA Program is fully implemented (e.g., before EPA is able to evaluate all laboratories that will participate in the program). Consequently, PWSs should ensure that their grandfathered *Cryptosporidium* samples are analyzed by laboratories that will be evaluated under the Lab QA Program before the data are submitted to EPA. Note that PWSs will not submit grandfathered data packages until after the LT2ESWTR is final, currently scheduled for mid- or late 2004. Samples analyzed by laboratories that do not meet the criteria for approval under the LT2ESWTR may not be accepted for grandfathering.

Laboratories should also participate in the EPA Protozoa PT Program. EPA does not expect there to be restrictions on the number of laboratories involved in the generation of a PWS's grandfathered data.

3.5 *E. coli* and Turbidity Measurements

The Agreement recommends that PWSs serving at least 10,000 people should collect *E. coli* and turbidity samples along with *Cryptosporidium* samples when monitoring under the LT2ESWTR. EPA recommends that PWSs conducting early (i.e., grandfathered) monitoring collect and analyze *E. coli* samples with each *Cryptosporidium* sample and measure turbidity during each sampling event. However, the Agreement would not exclude the use of previously collected *Cryptosporidium* data if *E. coli* and turbidity samples are not collected.

4.0 Reporting Grandfathered Data

The final LT2ESWTR will establish reporting requirements for grandfathered data. The following recommendations are intended to give PWSs an indication of potential reporting requirements for consideration when establishing their grandfathered data monitoring programs.

For consideration of grandfathered data, PWSs should submit to EPA a complete data package as described below.

4.1 Data Package Contents

The grandfathered data package should include the following:

1. A signed cover letter from the PWS certifying that the data represent the plant's current source water and that all source water *Cryptosporidium* monitoring results collected during the LT2ESWTR monitoring period (defined below) are included in the package
2. Sample collection schedule established before beginning monitoring
3. Where applicable, documentation addressing the dates and reason(s) for re-sampling, as well as the use of presedimentation, off stream storage, or bank filtration during monitoring
4. A list of the field and MS samples submitted in the data package (see Section 4.1.1, below, for details), identified by sample ID and collection date
5. Sample results for all field and MS samples (see Section 4.1.2, below, for details) and
6. Documentation that all method-required quality control requirements were acceptable for every field and MS sample submitted with the package (see Section 4.1.3, below, for details).

4.1.1 Sample Results to be Reported

PWSs that conduct monitoring for grandfathering should submit results for all source water *Cryptosporidium* samples analyzed during the LT2ESWTR monitoring period, as defined below. This will include all samples that were:

- Collected from the sampling location used for LT2ESWTR monitoring,
- Not spiked, and
- Analyzed using the laboratory's routine process for Method 1622/1623 analyses, including analytical technique and QA/QC.

EPA plans that the LT2ESWTR monitoring period for a specific PWS will begin with the collection of the first sample submitted for LT2ESWTR binning and end with the collection of the final sample submitted for LT2ESWTR binning (as long as a minimum of 2 years of acceptable data have been submitted). With the use of grandfathered data, the final sample may be collected before the end of the LT2ESWTR implementation schedule. Sample results generated after the last sample result in the PWS's data package would be considered outside the PWS's LT2ESWTR monitoring period and would not need to be submitted to EPA for LT2ESWTR binning purposes. However, these results may be subject to reporting requirements under other federal or State regulations.

4.1.2 Data Elements to be Reported for Each Sample Result

The following data elements, at a minimum, should be submitted for each *Cryptosporidium* monitoring sample and MS sample:

- PWS ID
- Facility ID
- Sample collection point
- Sample collection date
- Sample type (field or MS)
- Sample volume filtered (L), to nearest ¼ L
- Number of oocysts counted
- For samples in which less than 10 L is filtered or less than 100% of the sample volume is examined, PWSs should also report the number of filters used and the packed pellet volume.
- For samples in which less than 100% of sample volume is examined, PWSs should also report the volume of resuspended concentrate and volume of this resuspension processed through immunomagnetic separation.
- For matrix spike samples, PWSs should also report the sample volume spiked and estimated number of oocysts spiked. These data are not applicable to monitoring samples.

EPA recommends that these data elements be reported by submitting a completed sample collection form, laboratory bench sheet, and *Cryptosporidium* report form for each sample. Example bench sheets and report forms can be found at http://www.epa.gov/microbes/bnchju01.pdf and http://www.epa.gov/microbes/cptoju01.pdf. Sample documentation forms that are different from these examples, but that contain the minimum required data elements listed above, may be acceptable.

4.1.3 Supporting Quality Control Information

The data package should include a signed letter from the laboratory certifying that all method-required quality control elements (including sample temperature upon receipt, ongoing precision and recovery and method blank results, holding times, and positive and negative staining controls) were performed at the required frequency, and were acceptable for every monitoring and MS sample submitted with the package. The letter should include a list of the applicable monitoring and MS samples, and the corresponding OPR and method blank sample ID for each.

Alternately, the PWS may include the bench sheet and *Cryptosporidium* report form (or comparable detailed data reporting forms) for each OPR and method blank sample associated with the field and MS samples in the grandfathered data package. If this option is selected, the letter from the laboratory still should certify that sample temperature upon receipt, holding times, and positive and negative staining controls were acceptable for all samples. (The letter is not necessary if detailed data reporting forms containing this information are submitted for the field and MS sample results.)

4.2 Schedule for Submission of Grandfathered Data

EPA's current intent is that PWSs with at least 2 years of grandfathered data at the time of LT2ESWTR promulgation and that intend to use these data in lieu of monitoring under the LT2ESWTR (*i.e.*, do NOT intend to conduct additional monitoring) should submit these data to EPA within 2 months following LT2ESWTR promulgation (currently planned for mid- or late 2004). EPA plans to notify these PWSs within 4 months following LT2ESWTR promulgation as to whether their data are sufficient for bin classification. PWSs with fewer than 2 years of grandfathered data at the time of LT2ESWTR promulgation, or that have at least 2 years of grandfathered data but intend to conduct monitoring under the LT2ESWTR, should submit these data to EPA within 8 months of LT2ESWTR promulgation. Under the Agreement, PWSs should conduct monitoring under the LT2ESWTR unless notified in writing by EPA that they have 2 years of acceptable data.

4.3 Procedures for Submission of Grandfathered Data

EPA does not intend to formally accept grandfathered *Cryptosporidium* data until the LT2ESWTR is finalized. The final rule will include procedures for submission of grandfathered data.

5.0 Contact Information

For general questions regarding the LT2ESWTR, please contact Dan Schmelling, EPA Office of Ground Water and Drinking Water, at schmelling.dan@epa.gov or (202) 564-5281. For specific questions regarding *Cryptosporidium* analytical methods, data QA/QC issues, and the *Cryptosporidium* Lab QA Program, please contact Mary Ann Feige, EPA Office of Ground Water and Drinking Water, Technical Support Center at feige.maryann@epa.gov or (513) 569-7944.

6.0 Checklists for Grandfathering *Cryptosporidium* Data

To help PWSs interested in monitoring for *Cryptosporidium* before LT2ESWTR apply the information provided in this guidance, two checklists have been developed and are provided below. The "Checklist for Beginning Grandfathered *Cryptosporidium* Monitoring" is designed to be used by PWSs to check their monitoring plans against the this guidance document before proceeding with monitoring. The "Checklist for Submitting Grandfathered *Cryptosporidium* Data" is designed to be used by PWSs to check their data package against the information in this guidance document before submitting the data package to EPA for review.

Checklist for Beginning Grandfathered *Cryptosporidium* Monitoring

- ☐ **Sampling location.** Does the intended sample collection location comply with the guidance provided in Section 3.1 of this guidance document?
- ☐ **Sampling schedule.** Is the sample collection schedule designed to monitor for *Cryptosporidium* at least monthly, and in accordance with the guidance provided in Section 3.2 of this guidance document?
- ☐ **Laboratory coordination.** Have you verified that your intended sample collection schedule can be accommodated by the *Cryptosporidium* laboratory (to avoid holding time problems)?
- ☐ **Matrix spikes.** Does the sampling schedule include collection of extra volume for matrix spike samples every 20 field samples?
- ☐ **Method version.** Will the April 2001 version of EPA Method 1622 or EPA Method 1623 be used to analyze samples?
- ☐ **Sample volume issues.** Have you consulted with your *Cryptosporidium* laboratory to determine whether your samples are likely to clog filters or require additional "subsample" analyses?
- ☐ ***Cryptosporidium* laboratory qualifications.** Is your *Cryptosporidium* sample analysis laboratory approved, or seeking approval, under EPA's Lab QA Program?
- ☐ ***E. coli* laboratory qualifications.** Is your utility laboratory certified under the drinking water certification program to perform the technique that the laboratory will be using to analyze *E. coli* samples during *Cryptosporidium* monitoring (techniques include multiple-well, membrane filtration, and multiple tube)? If the analyses will be performed by a commercial laboratory, is the commercial laboratory certified to perform the technique?
- ☐ **Turbidity measurements.** Will turbidity measurements be made for each sample?
- ☐ **Data reporting.** Will your *Cryptosporidium* laboratory be recording all data elements specified in Section 4.1.2 of this document?

Checklist for Submitting Grandfathered *Cryptosporidium* Data

- ☐ **Cover letter.** Does the data package include a signed cover letter certifying that the data represent the plant's current source water and that all source water *Cryptosporidium* monitoring results collected during the LT2ESWTR monitoring period are included in the package?
- ☐ **Sampling schedule.** Does the data package include a sample collection schedule established before beginning monitoring?
- ☐ **Additional documentation.** Have you included any additional documentation required regarding resampling, the use of presedimentation, and/or off stream storage during routine plant operation?
- ☐ **List of samples.** Does the data package include a list of the field and matrix spike (MS) samples submitted in the data package, identified by sample ID and collection date?
- ☐ **Number of field samples.** Does the data package include at least 24 field samples collected over 2 years?
- ☐ **Completeness of results.** Are all applicable field sample results from the monitoring period included?
- ☐ **MS sample results.** Is the number of MS results submitted equivalent to at least 5% of the number of field sample results?
- ☐ **Sample data.** Are the minimum data elements (specified in Section 4.1.2 of this document) provided for each field and MS sample?
- ☐ **Sample volumes.** Are the volume analyzed for all field samples at least 10 L? For samples in which less than 10 L was examined, were at least 2 mL of packed pellet volume analyzed or did two filters clog?
- ☐ **Quality control (QC) certification.** Does the data package include a letter from the laboratory certifying that all method-required QC requirements were acceptable for every field and MS sample submitted with the package?
- ☐ **Detailed quality control information.** If bench sheets and report forms with QC information are included, rather than a laboratory letter, are the following requirements met?
  - ☐ **Sample temperature requirements.** Was the temperature of all monitoring samples between 0°C and 8°C upon receipt?
  - ☐ **Ongoing precision and recovery (OPR) recovery.** Do All OPR sample results meet QC acceptance criteria of the method version used for the analysis?
  - ☐ **OPR frequency.** Is an acceptable OPR sample associated with every field sample?
  - ☐ **Method blank results.** Are all method blank sample results acceptable?
  - ☐ **Method blank frequency.** Is an acceptable method blank sample associated with every field sample?
  - ☐ **Spike levels.** Were spike levels of 500 oocysts or less used for all OPR and MS samples?
  - ☐ **Holding times.** Were all holding times met for all field and QC samples for composite samples (holding times start when collection of the first sample begins)?
  - ☐ **Staining control frequency.** Are positive and negative staining controls associated with all field and QC samples?
  - ☐ **Staining control results.** Were positive and negative staining controls acceptable for all

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