

option to verify compliance with the QC criteria. For example, if the laboratory analyzes samples using both the Envirochek™ and Filtamax™ filters, a separate set of IPR, OPR, method blank, and MS samples must be analyzed for each filtration option.

b. *How was this proposal developed?* EPA is proposing EPA Methods 1622 and 1623 for *Cryptosporidium* analyses under the LT2ESWTR because these are the best available methods that have undergone full validation testing. In addition, these methods have been used successfully in a national source water monitoring program as part of the Information Collection Rule Supplemental Surveys (ICRSS). The minimum sample volume and other quality control requirements are intended to ensure that data are of sufficient quality to assign systems to LT2ESWTR risk bins. Further, the proposed method requirements for analysis of *Cryptosporidium* are consistent with recommendations by the Stage 2 M-DBP Advisory Committee. In the Agreement in Principle, the Committee recommended that source water *Cryptosporidium* monitoring under the LT2ESWTR be conducted using EPA Methods 1622 and 1623 with no less than 10 L samples. EPA also has proposed these methods for approval for ambient water monitoring under Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water (66 FR 45811, August 30, 2001) (USEPA 2001i).

When considering the method performance that could be achieved for analysis of *Cryptosporidium* under the LT2ESWTR, EPA and the Advisory Committee evaluated the *Cryptosporidium* recoveries reported for Methods 1622 and 1623 in the ICRSS. As described in section III.C, the ICRSS was a national monitoring program that involved 87 utilities sampling twice per month over 1 year for *Cryptosporidium* and other microorganisms and water quality parameters. During the ICRSS, the mean recovery and relative standard deviation associated with enumeration of MS samples for total oocysts by Methods 1622 and 1623 were 43% and 47%, respectively (Connell *et al.* 2000).

EPA believes that with provisions like the Laboratory QA Program for *Cryptosporidium* laboratories (see section IV.L), comparable performance to that observed in the ICRSS can be achieved in LT2ESWTR monitoring with the use of Methods 1622 and 1623, and that this level of performance will be sufficient to realize the public health goals intended by EPA and the Advisory Committee for the LT2ESWTR. Other

methods would need to achieve comparable performance to be considered for use under the LT2ESWTR. For example, EPA does not expect the Information Collection Rule Method, which resulted in 12% mean recovery for MS samples during the Information Collection Rule Laboratory Spiking Program (Scheller, 2002), to meet LT2ESWTR data quality objectives.

For systems collecting samples larger than 10 L, EPA is proposing the approach of allowing systems to filter all but 10 L of the corresponding MS sample in the field, and ship the filtered sample and the remaining 10 L of source water to the laboratory for spiking and analysis. The Agency has determined that the added costs associated with shipping entire high-volume (e.g. 50-L) samples to a laboratory for spiking and analysis are not merited by improved data quality relative to the use of *Cryptosporidium* MS data under the LT2ESWTR. EPA estimates that the average cost for shipping a 50-L bulk water sample is \$350 more than the cost of shipping a 10-L sample and a filter. A study comparing these two approaches (*i.e.*, spiking and filtering 50 L vs. field filtering 40 L and spiking 10 L) indicated that spiking the 10-L sample produced somewhat higher recoveries (USEPA 2003i). However, the differences were not significant enough to offset the greatly increased shipping costs, given the limited use of MS data in LT2ESWTR monitoring.

c. *Request for comment.* EPA requests comment on the proposed method requirements for *Cryptosporidium* analysis, including the following specific issues:

#### Minimum Sample Volume

It is the intent of EPA that LT2ESWTR sampling provide representative annual mean source water concentrations. If systems were unable to analyze an entire sample volume during certain periods of the year due to elevated turbidity or other water quality factors, this could result in systems analyzing different volumes in different samples. Today's proposal requires systems to analyze at least 10 L of sample or the maximum amount of sample that can be filtered through two filters, up to a packed pellet volume of 2 mL. EPA requests comment on whether these requirements are appropriate for systems with source waters that are difficult to filter or that generate a large packed pellet volume. Alternatively, systems could be required to filter and analyze at least 10 L of sample with no exceptions.

#### Approval of Updated Versions of EPA Methods 1622 and 1623

EPA has developed draft revised versions of EPA Methods 1622 and 1623 in order to consolidate several method-related changes EPA believes may be necessary to address LT2ESWTR monitoring requirements (see USEPA 2003j and USEPA 2003k). EPA is requesting comment on whether these revised versions should be approved for monitoring under the LT2ESWTR, rather than the April 2001 versions proposed in today's rule. If the revised versions were approved, previously collected data generated using the earlier versions of the methods would still be acceptable for grandfathering, provided the other criteria described in section IV.A.1.d were met. Drafts of the updated methods are provided in the docket for today's rule, and differences between these versions and the April 2001 versions of the methods are clearly indicated for evaluation and comment. Changes to the methods include the following:

(1) Increased flexibility in matrix spike (MS) and initial precision and recovery (IPR) requirements—the requirement that the laboratory must analyze an MS sample on the first sampling event for a new PWS would be changed to a recommendation; the revised method would allow the IPR test to be performed across four different days, rather than restrict analyses to 1 day;

(2) Clarification of some method procedures, including the spiking suspension vortexing procedure and the buffer volumes used during immunomagnetic separation (IMS); requiring (rather than recommending) that laboratories purchase HCl and NaOH standards at the normality specified in the method; and clarification that the use of methanol during slide staining in section 14.2 of the method is as per manufacturer's instructions;

(3) Additional recommendations for minimizing carry-over of debris onto microscope slides after IMS and information on microscope cleaning;

(4) Clarification in the method of the actions to take in the event of QC failures, such as that any positive sample in a batch associated with an unacceptable method blank is unacceptable and that any sample in a batch associated with an unacceptable ongoing precision and recovery (OPR) sample is unacceptable;

(5) Changes to the sample storage and shipping temperature to “less than 10°C and not frozen”, and additional guidance on sample storage and shipping procedures that addresses time of collection, and includes suggestions for monitoring sample temperature during shipment and upon receipt at the laboratory.

(6) Additional analyst verification procedures—adding examination using differential interference contrast (DIC) microscopy to the analyst verification requirements.