

spreadsheet).

- For each segment, log inactivation =  $(\frac{CT_{calc}}{CT_{99.9}}) \times 3.0$ .

- Sum the log inactivation values for each segment to get the log inactivation for the day (or week).

For calculating the virus log inactivation, systems should use the procedures approved by States under the IESWTR or LT1ESWTR.

Log inactivation benchmark is calculated as follows:

(1) Determine the calendar month with the lowest log inactivation.

(2) The lowest month becomes the critical period for that year.

(3) If acceptable data from multiple years are available, the average of critical periods for each year becomes the benchmark.

(4) If only one year of data is available, the critical period for that year is the benchmark.

c. *State review.* If a system that is required to produce a disinfection profile proposes to make a significant change in disinfection practice, it must calculate *Giardia lamblia* and virus inactivation benchmarks and must consult with notify the State before implementing such a change. Significant changes in disinfection practice are defined as: (1) moving the point of disinfection (this is not intended to include routine seasonal changes already approved by the State), (2) changing the type of disinfectant, (3) changing the disinfection process, or (4) making other modifications designated as significant by the State. Supporting materials for such consultation with When notifying the State, the system must include provide a description of the proposed change, the disinfection profiles and inactivation benchmarks for *Giardia lamblia* and viruses, and an

analysis of how the proposed change will affect the current inactivation benchmarks. In addition, the system should have disinfection profiles and, if applicable, inactivation benchmarking documentation, available for the State to review as part of its periodic sanitary survey.

EPA developed for the IESWTR, with stakeholder input, the *Disinfection Profiling and Benchmarking Guidance Manual* (USEPA 1999<sup>ed</sup>). This manual provides guidance to systems and States on the development of disinfection profiles, identification and evaluation of significant changes in disinfection practices, and considerations for setting an alternative benchmark. If necessary, EPA will produce an addendum to reflect changes in the profiling and benchmarking requirements necessary to comply with LT2ESWTR.

## 2. How was this proposal developed?

A fundamental premise in the development of the M-DBP rules is the concept of balancing risks between DBPs and microbial pathogens. Disinfection profiling and benchmarking were established under the IESWTR and LT1ESWTR, based on a recommendation by the Stage 1 M-DBP Federal Advisory Committee, to assureensure that systems maintained adequate control of pathogen risk as they reduced risk from DBPs. Today's proposal would extend disinfection benchmarking requirements to the LT2ESWTR.

EPA believes this extension is necessary because some systems will make significant changes in their current disinfection practice to meet more stringent limits on TTHM and HAA5 levels under the Stage 2 DBPR and additional *Cryptosporidium* treatment requirements under the LT2ESWTR. In order to assureensure that these

systems continue to provide adequate protection against the full spectrum of microbial pathogens, it is appropriate for systems and States to evaluate the effects of such treatment changes on microbial drinking water quality. The disinfection benchmark serves as a tool for making such evaluations.

EPA projects that to comply with the Stage 2 DBPR, systems will make changes to their disinfection practice, including switching from free chlorine to chloramines and, to a lesser extent, installing technologies like ozone, membranes, and UV. Similarly, to provide additional treatment for *Cryptosporidium*, some systems will install technologies like UV, ozone, and microfiltration. While these processes are all effective disinfectants, chloramines are a weaker disinfectant than free chlorine for *Giardia lamblia*. Ozone, UV, and membranes can provide highly effective treatment for *Giardia lamblia*, but they, as well as chloramines, are less efficient for treating viruses than free chlorine, relative to their efficacy for *Giardia lamblia*. Because of this, a system switching from free chlorine to one of these alternative disinfection technologies could experience a reduction in the level of virus and/or *Giardia lamblia* (for chloramines) treatment it is achieving. Consequently, EPA believes that systems ~~that make~~ making significant changes in their disinfection practice under the Stage 2 M-DBP rules should assess the impact of these changes with disinfection benchmarks for *Giardia lamblia* and viruses.

Changes in the proposed benchmarking requirements under the LT2ESWTR in comparison to IESWTR requirements include decreasing the frequency of calculating CT values for the disinfection profile from daily to weekly and requiring all systems to prepare a profile for viruses as well as *Giardia lamblia*. The proposal of a weekly frequency for CT calculations was made to accommodate existing profiles from small

systems, which are required to make weekly CT calculations for profiling under the LT1ESWTR. As described earlier, EPA would like for systems ~~which~~that have prepared a disinfection profile under the IESWTR or LT1ESWTR and ~~which~~ have not subsequently made significant changes in disinfection practice to be able to grandfather this profile for the LT2ESWTR. Allowing weekly calculation of CT values under the LT2ESWTR will make this possible.

The IESWTR and LT1ESWTR required virus inactivation profiling only for systems using ozone or chloramine as their primary disinfectant. However, as noted earlier, EPA has projected that under the Stage 2 DBPR and LT2ESWTR, systems will switch from free chlorine to disinfection processes like chloramines, UV, ozone, and microfiltration. The efficiency of these processes for virus treatment relative to protozoa treatment is lower in comparison to free chlorine. As a result, a disinfection benchmark for *Giardia lamblia* would not necessarily provide an indication of the level or adequacy of treatment for viruses. Consequently, EPA believes it is appropriate for systems to develop profiles for both *Giardia lamblia* and viruses. Moreover, developing a profile for viruses involves a minimal increase in effort and no additional data collection for those systems that have disinfection profiles for *Giardia lamblia*. Systems ~~would~~will use the same calculated CT values for viruses as would be used for the *Giardia lamblia* profile.

The strategy of disinfection profiling and benchmarking stemmed from data provided to the Stage1 M-DBP Advisory Committee, in which the baseline of microbial inactivation (expressed as logs of *Giardia lamblia* inactivation) demonstrated high variability. Inactivation varied by several ~~log~~logs (i.e., orders of magnitude) on a day-to-day basis at ~~any~~ particular treatment plants s and by as much as tens of logs over

a year due to changes in water temperature, flow rate, seasonal changes, pH, and disinfectant demand. There were also differences between years at individual plants. To address these variations, M-DBP stakeholders developed the procedure of profiling a plant's inactivation levels over a period of at least one year, and then establishing a benchmark of minimum inactivation as a way to characterize disinfection practice.

Benchmarking of inactivation levels, an assessment of the impact of proposed changes on the level of microbial inactivation of *Giardia lamblia* and viruses, and State review prior to approval of substantial changes in treatment are important steps in avoiding conditions that present an increase in microbial risk. In its assessment of the microbial risk associated with the proposed changes, States could consider site-specific knowledge of the watershed and hydrologic factors as well as variability, flexibility and reliability of treatment to ~~assure~~ensure that treatment for both protozoan and viral pathogens is appropriate.

EPA emphasizes that benchmarking is not intended to function as a regulatory standard. Rather, the objective of the disinfection benchmark is to facilitate interactions between the States and systems for the purpose of assessing the impact on microbial risk of proposed significant changes to current disinfection practices. Final decisions regarding levels of disinfection for *Giardia lamblia* and viruses beyond those required by the SWTR that are necessary to protect public health will continue to be left to the States. For this reason EPA has not mandated specific evaluation protocols or decision matrices for analyzing changes in disinfection practice. EPA, however, will provide support to the States in making these analyses through the issuance of guidance.

### 3. Request for comments

EPA requests comment on the proposed provisions of the inactivation profiling and benchmarking requirement.

*E. Additional Treatment Technique Requirements for Systems with Uncovered Finished Water ~~Reservoirs~~ Storage Facilities*

1. What is EPA proposing today?

EPA is proposing requirements for systems with uncovered finished water ~~reservoirs~~ storage facilities. The proposed rule requires that systems with uncovered finished water ~~reservoirs~~ storage facilities must: (1) cover the uncovered finished water ~~reservoir~~ storage facility, or (2) treat ~~reservoir~~ storage facility discharge to the distribution system to achieve a 4 log virus inactivation, unless (3) the ~~State determines that existing risk mitigation is adequate and the~~ system ~~has~~ implements a State-approved risk mitigation plan.

~~Systems that exercise the third option (i.e., do not cover the reservoir or treat the effluent) are required to implement risk mitigation plans. These plans must address that addresses physical access and site security, surface water runoff, animal and bird waste, and on-going water quality assessment, and ~~must~~ include a schedule for plan implementation. Where applicable, the plans should account for cultural uses by Indian Tribes.~~

Systems must notify the State if they use uncovered finished water storage facilities no later than 2 years following LT2ESWTR promulgation. Systems must cover or treat uncovered finished ~~reservoirs~~ facilities or have a State-approved risk mitigation plan within 3 years following LT2ESWTR promulgation, with the possibility of a two year extension granted by States for systems making capital improvements. Systems

seeking approval for a risk mitigation plan must submit the plan to the State within 2 years following LT2ESWTR promulgation.

These provisions apply to uncovered tanks, reservoirs, or other facilities where water is stored after it has undergone treatment to satisfy microbial treatment technique requirements for *Giardia lamblia*, *Cryptosporidium*, and viruses. In most cases, this refers to storage of water following all filtration steps, where required, and primary disinfection.

## 2. How was this proposal developed?

Today's proposal is intended to mitigate the water quality degradation and increased health risks that can result from uncovered finished water reservoirs storage facilities. In addition, these proposed requirements for uncovered finished water reservoirs storage facilities are consistent with recommendations of the Stage 2 M-DBP Advisory Committee in the Agreement in Principle (USEPA 2000a).

The use of uncovered finished water reservoirs storage facilities has been questioned since 1930 due to their susceptibility to contamination and subsequent threats to public health (LeChevallier et al. 1997). Many potential sources of contamination can lead to the degradation of water quality in uncovered finished water reservoirs storage facilities. These include surface water runoff, algal growth, insects and fish, bird and animal waste, airborne deposition, and human activity.

Algal blooms are the most common problem in open reservoirs and can become a public health risk, as they increase the presence of bacteria in the water. Algae growth also leads to the formation of disinfection byproducts and causes taste and odor problems. Some algae produce toxins that can induce headache, fever, diarrhea,

abdominal pain, nausea, and vomiting. Bird and animal wastes are also common and significant sources of contamination. These wastes may carry microbial contaminants such as coliform bacteria, viruses, and human pathogens, including *Vibrio cholera*, *Salmonella*, *Mycobacteria*, *Typhoid*, *Giardia lamblia*, and *Cryptosporidium* (USEPA 1999de). Microbial pathogens are found in surface water runoff, along with agricultural chemicals, automotive wastes, turbidity, metals, and organic matter (USEPA 1999de, LeChevallier et al. 1997).

In an effort to minimize contamination, systems have implemented various controls such as reservoir covers and liners, regular draining and washing, security and monitoring, bird and insect control programs, and drainage design to prevent surface runoff from entering the facility (USEPA 1999de).

A number of studies have evaluated the degradation of water quality in uncovered finished water reservoir storage facilities. LeChevallier et al. (1997) compared influent and effluent samples from six uncovered finished water storage reservoirs in New Jersey for a one year period. There were significant increases in the turbidity, particle count, total coliform, fecal coliform, and heterotrophic plate count bacteria in the effluent relative to the influent. Of particular concern were fecal coliforms, which were detected in 18 percent of effluent samples (no influent samples were positive for coliforms). Fecal coliforms are used as an indicator of the potential for contamination by pathogens. *Giardia* and/or *Cryptosporidium* were detected in 15% of inlet samples and 25% of effluent samples, demonstrating a significant increase in the effluent. There was a significant decrease in the chlorine residual concentration in some effluent samples.

Increases in algal cells, heterotrophic plate count (HPC) bacteria, turbidity, color, particle counts, and biomass, and decreases in residual chlorine levels, have been reported in other studies of uncovered finished water reservoirs as well (Pluntze 1974; AWWA Committee Report 1983; Silverman et al. 1993). Researchers have shown that small mammals, birds, fish, and algal growth contribute to the microbial degradation of an open finished water reservoir (Graczyk et al. 1996; Geldreich 1990; Fayer and Ungar 1986; Current 1986).

As described in section II, the IESWTR and LT1ESWTR require water systems to cover all new reservoirs, holding tanks, or other storage facilities for finished water. However, these rules do not require systems to cover existing finished water reservoirs storage facilities. EPA stated in the preamble to the final IESWTR (63 FR 69494, Dec. December 16, 1998) (USEPA 1998a) that with respect to requirements for existing reservoirs uncovered finished water storage facilities, the Agency needed more time to collect and analyze additional information to evaluate regulatory impact. The IESWTR preamble affirmed that EPA would consider whether to require the covering of existing reservoirs storage facilities during the development of subsequent microbial regulations when additional data to estimate national costs were available.

Since promulgation of the IESWTR, EPA has collected sufficient data to estimate national cost implications of regulatory control strategies for uncovered finished water reservoirs storage facilities. Based on information provided by States, EPA estimates that there are approximately 138 uncovered finished water reservoirs storage facilities in the United States and territories, not including reservoirs that systems currently plan to cover or take off-line. Costs for covering these reservoirs storage facilities or treating the

effluent, consistent with today's proposed requirements, are presented in section VI of this preamble and in the Economic Analysis for the LT2ESWTR (USEPA 20023a).

Briefly, total capital costs were estimated as \$64.4 million, resulting in annualized present value costs of \$5.4 million at a three percent discount rate and \$6.4 million at a seven percent discount rate.

Based on the findings of studies cited in this section, EPA continues to be concerned about contamination occurring in uncovered finished water reservoirs storage facilities. Therefore, as recommended by the Advisory Committee, EPA is proposing control measures for all systems with uncovered finished water reservoirs storage facilities. This proposal is intended to represent a balanced approach, recognizing both the potentially significant but uncertain risks associated with uncovered finished water reservoirs storage facilities and the substantial costs of either covering them or building alternative storage. Today's proposal allows systems to treat the reservoir storage facility effluent instead of providing a cover. Alternatively, States may determine that existing risk mitigation is adequate, provided a system implements a risk mitigation plan as described in this section.

### 3. Request for comments

EPA requests comment on the proposed requirements pertaining to the uncovered finished water reservoirs storage facilities. Specifically, the Agency would like comment on the following issues, and requests that comments include available supporting data or other technical information:

- Is it appropriate to allow systems with uncovered finished water reservoirs storage facilities to implement a risk management plan or treat the effluent to inactivate

viruses instead of covering the reservoir facility?

- If systems treat the effluent of an uncovered finished water reservoir storage facility instead of covering it, should systems be required to inactivate *Cryptosporidium* and *Giardia lamblia*, since these protozoa have been found to increase in uncovered reservoirs?

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storage facilities?

- Additional information on contamination or health risks that may be associated with uncovered finished water storage facilities.
- Additional data on how climatological conditions affect water quality, including daily fluctuations in the stability of the water related to corrosion control.

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The definition of an uncovered finished water reservoir storage facility in 40 CFR 141.2 is a tank, reservoir, or other facility used to store water that will undergo no further treatment except residual disinfection and is open to the atmosphere. There is a concern that this definition may not include certain systems using what would generally be considered an uncovered finished water reservoir storage facility. An example is a system that applies a corrosion inhibitor compound to the effluent of an uncovered reservoir storage facility where water is stored after filtration and primary disinfection. In this case, the system may claim that the corrosion inhibitor constitutes additional treatment and, consequently, the reservoir does not meet EPA's definition of an

uncovered finished water reservoir storage facility. EPA requests comment on whether the definition of an uncovered finished water reservoir storage facility should be revised to specifically include systems that apply a treatment such as corrosion control to water stored in an uncovered reservoir after the water has undergone filtration, where required, and primary disinfection.

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~~to water stored in an uncovered reservoir after the water has undergone filtration, where required, and primary disinfection.~~

#### *F. Compliance Schedules*

Today's proposal includes deadlines for public water systems to comply with the proposed monitoring, reporting, and treatment requirements. These deadlines stem from the microbial framework approach of the proposed LT2ESWTR, which involves a system-specific risk characterization through monitoring to determine the need for additional treatment.

##### 1. What is EPA proposing today?

###### *a. Source water monitoring.*

i. Filtered systems. Under today's proposal, filtered systems conduct source water *Cryptosporidium* monitoring for the purpose of being classified in one of four risk bins that determine the extent of any additional treatment requirements. Small filtered systems first monitor for *E. coli* as a screening analysis and are only required to monitor for *Cryptosporidium* if the mean *E. coli* level exceeds specified trigger values. Note that systems that currently provide or will provide a total of at least 5.5 log of treatment for *Cryptosporidium* are exempt from monitoring requirements.

Large surface water systems (\$serving at least 10,000 served people) that filter must sample at least monthly for *Cryptosporidium*, *E. coli*, and turbidity in their source water for 24 months, beginning 6 months after promulgation of the LT2ESWTR. Large systems must submit a sampling schedule to their primacy agency (in this case, EPA) no later than 3 months after promulgation of the LT2ESWTR.

Small surface water systems (<fewer than 10,000 people served) that filter must conduct biweekly *E. coli* sampling in their source water for 1 year, beginning 30 months after LT2ESWTR promulgation. States may designate an alternate indicator monitoring strategy based on EPA guidance, but compliance schedules will not change. Small systems that exceed the indicator trigger value (i.e., mean *E. coli* > 10/100 mL for lake/reservoir sources or > 50/100 mL for flowing stream sources) must conduct source water *Cryptosporidium* sampling twice-per-month for 1 year, beginning 48 months after LT2ESWTR promulgation (i.e., beginning 6 months following the completion of *E. coli* sampling). Small systems must submit an *E. coli* sampling schedule to their ir primacy agency no later than 27 months after LT2ESWTR promulgation. If *Cryptosporidium* monitoring is required, small systems must submit a *Cryptosporidium* sampling schedule no later than 45 months after LT2ESWTR promulgation.

Large systems must begin carry out a second round of source water monitoring beginning 108 months after LT2ESWTR promulgation, which is 6 years after initial bin classification. Similarly, small systems must begin conduct a second round of indicator monitoring (*E. coli* or other as designated by the State) beginning 138 months after LT2ESWTR promulgation, which is 6 years after their initial bin classification. Small systems that exceed the indicator trigger value in the second round of indicator

monitoring must conduct a second round of *Cryptosporidium* monitoring, beginning 156 months after LT2ESWTR promulgation.

Compliance dates for filtered systems are summarized in Table IV-283.

**Table IV-283-- Summary of Compliance Dates for Filtered Systems**

System Type	Requirement	Compliance Date
<b>Large Subpart H Systems</b> (serve \$10,000 people)	Submit sampling schedule <sup>1,2</sup>	No later than 3 months after promulgation.
	Source water <i>Cryptosporidium</i> , <i>E. coli</i> and turbidity monitoring	Begin monthly monitoring 6 months after promulgation for 24 months.
	Comply with additional <i>Cryptosporidium</i> treatment requirements	No later than 72 months after promulgation. <sup>3</sup>
	Second round of source water <i>Cryptosporidium</i> , <i>E. coli</i> , and turbidity monitoring <sup>2</sup>	Begin monthly monitoring 108 months after promulgation for 24 months.
<b>Small Subpart H Systems</b> (serve < 10,000 people)	Submit <i>E. coli</i> sampling schedule <sup>2</sup>	No later than 27 months after promulgation.
	Source water <i>E. coli</i> monitoring	Begin biweekly monitoring 30 months after promulgation for 1 year.
	Second round of source water <i>E. coli</i> monitoring <sup>2</sup>	Begin biweekly monitoring 138 months after promulgation for 1 year.
	<b>Additional requirements if indicator (e.g., <i>E. coli</i>) trigger level is exceeded<sup>4</sup></b>	
	Submit <i>Cryptosporidium</i> sampling schedule <sup>1,2</sup>	No later than 45 months after promulgation.
	Source water <i>Cryptosporidium</i> monitoring	Begin twice-per-month monitoring no later than 48 months after promulgation for 1 year
	Comply with additional <i>Cryptosporidium</i> treatment requirements	No later than 102 months after promulgation. <sup>3,5</sup>
	Second round of source water <i>Cryptosporidium</i> monitoring	Begin twice-per-month monitoring no later than 156 months after promulgation for 1 year.

<sup>1</sup>Systems may be eligible to use historical previously collected (grandfathered) data to meet LT2ESWTR requirements if specified quality control criteria are met (described in section IV.A.1.d).

<sup>2</sup>Systems are not required to monitor if they will provide at least 5.5 log *Cryptosporidium* treatment and notify EPA or the State

<sup>3</sup>States may grant up to an additional two years for systems making capital improvements

<sup>4</sup>If the *E. coli* annual mean concentration exceeds 10/100 mL for systems using lakes/reservoir sources or exceeds 50/100 mL for systems using flowing stream sources, *Cryptosporidium* monitoring is required.

<sup>5</sup>Systems that do not exceed the *E. coli* trigger level are classified in Bin 1 and are not required to provide *Cryptosporidium* treatment beyond LT1ESWTR levels.

ii. Unfiltered systems. Surface water systems that do not filter and meet the criteria for avoidance of filtration (40 CFR 141.71) (i.e., unfiltered systems) are required to conduct source water *Cryptosporidium* monitoring to determine if their mean source water ~~ooocyst~~*Cryptosporidium* level exceeds 0.01 oocysts/L. There is no *E. coli* screening analysis available to small unfiltered systems. However, both large and small unfiltered systems conduct *Cryptosporidium* monitoring on the same schedule as filtered systems of the same size. Note that unfiltered systems that currently provide or will provide a total of at least 3 log *Cryptosporidium* inactivation are exempt from monitoring requirements.

Large unfiltered systems (serving at least 10,000 people) must conduct at least monthly *Cryptosporidium* sampling for 24 months, beginning 6 months after LT2ESWTR promulgation. Small unfiltered systems (serving fewer than 10,000 people) must conduct at least twice-per-month *Cryptosporidium* sampling for 12 months, beginning 48 months after LT2ESWTR promulgation. Large systems must submit a *Cryptosporidium* sampling schedule to EPA no later than 3 months after LT2ESWTR promulgation, and small systems must submit a sampling schedule to their State no later than 45 months after LT2ESWTR promulgation.

Unfiltered systems are required to conduct a second round of *Cryptosporidium* monitoring on the same schedule as filtered systems of the same size. Large systems must carry out a second round of *Cryptosporidium* monitoring, beginning 108 months

after LT2ESWTR promulgation. Small systems must perform a second round of *Cryptosporidium* monitoring, beginning 156 months after LT2ESWTR promulgation.

Compliance dates for unfiltered systems are summarized in Table IV-294.

**Table IV-294.-- Summary of Compliance Dates for Unfiltered Systems**

System Type	Requirement	Compliance Date
<b>Large Subpart H Systems</b> (serve \$10,000 people)	Submit sampling schedule <sup>1</sup>	No later than 3 months after promulgation.
	Source water <i>Cryptosporidium</i> monitoring	Begin monthly monitoring [6 months after promulgation for 24 months.
	Comply with <i>Cryptosporidium</i> inactivation requirements	No later than 72 months after promulgation. <sup>2</sup>
	Second round of source water <i>Cryptosporidium</i> monitoring	Begin monthly monitoring 108 months after promulgation for 24 months.
<b>Small Subpart H Systems</b> (serve < 10,000 people)	Submit sampling schedule <sup>1</sup>	No later than 45 months after promulgation.
	Source water <i>Cryptosporidium</i> monitoring	Begin twice-per-month monitoring no later than 48 months after promulgation for 1 year.
	Comply with <i>Cryptosporidium</i> inactivation requirements	No later than 102 months after promulgation. <sup>2</sup>
	Second round of source water <i>Cryptosporidium</i> monitoring	Begin twice-per-month monitoring no later than 156 months after promulgation for 1 year.

<sup>1</sup>Systems may be eligible to use historical previously collected (grandfathered) data to meet LT2ESWTR requirements if specified quality control criteria are met (described in section IV.A.1.d).

<sup>2</sup>States may grant up to an additional two years for systems making capital improvements

*b. Treatment requirements.* Filtered systems must determine their bin classification and unfiltered systems must determine their mean source water *Cryptosporidium* level within 6 months of the scheduled month for collection of their final *Cryptosporidium* sample in the first round of monitoring. This 6 month period provides time for systems to receive all sample analysis results from the laboratory, analyze the

data, and work with their primacy agency.

Filtered systems have 3 years following initial bin classification to meet any additional *Cryptosporidium* treatment requirements. This equates to compliance dates of 72 months after LT2ESWTR promulgation for large systems and 102 months after LT2ESWTR promulgation for small systems (see dates noted in Table IV-283).

Unfiltered systems must comply with *Cryptosporidium* treatment requirements on the same schedule as filtered systems of the same size (see dates in Table IV-294). The State may grant systems an additional two years to comply when capital investments are necessary, as specified in the Safe Drinking Water Act (section 1412(b)(10)).

Systems with uncovered finished water reservoirs storage facilities are required to comply with the provisions described in section IV.E by 36 months following LT2ESWTR promulgation, with the possibility of a 2 year extension granted by the State for systems making capital improvements. Systems seeking approval for a risk mitigation plan must submit the plan to the State within 24 months following LT2ESWTR promulgation.

Systems will must comply with additional *Cryptosporidium* treatment requirements by implementing one or more treatment processes or control strategies from the microbial toolbox. Most of the toolbox components require submission of documentation to the State demonstrating compliance with design and/or implementation criteria required to receive credit. Compliance dates for reporting requirements associated with microbial toolbox components are presented in detail in section IV.J, Reporting and Recordkeeping Requirements.

c. *Disinfection benchmarks for Giardia lamblia and viruses.* Today's proposed LT2ESWTR includes disinfection profiling and benchmarking requirements consisting.

which consist of three major components: applicability determination, characterization of disinfection practice, and State review of proposed changes in disinfection practice.

Each of these components is discussed in detail in section IV.D. Compliance deadlines associated with each of these components, including associated reporting requirements, are stated in section IV.J, Reporting and Recordkeeping Requirements.

## 2. How was this proposal developed?

The compliance dates in today's proposal reflects the risk-targeted approach of the proposed LT2ESWTR, wherein additional treatment requirements are based on a system specific risk characterization as determined through source water monitoring. Additionally, they are designed to allow for systems to simultaneously comply with the LT2ESWTR and Stage 2 DBPR in order to balance risks in the control of microbial pathogens and DBPs. These dates are consistent with recommendations from the Stage 2 M-DBP Federal Advisory Committee.

Under the LT2ESWTR, large systems will sample for *Cryptosporidium* for a period of two years in order to characterize source water pathogen levels and capture a degree of annual variability. To expedite the date by which systems will provide additional treatment where high risk source waters are identified, large system *Cryptosporidium* monitoring will begin six months after promulgation of the LT2ESWTR. Upon completion of *Cryptosporidium* monitoring, systems will have six months to work with their primacy agency to determine their bin classification. Beginning at this point, which is three years following LT2ESWTR promulgation, large systems will have three years to implement the treatment processes or control strategies necessary to comply with any additional treatment requirements stemming from bin classification.

Other large system compliance dates in areas like approval of grandfathered monitoring data, disinfection profiling and benchmarking, and reporting deadlines associated with microbial toolbox components all stem from the *Cryptosporidium* monitoring and treatment compliance schedule.

With respect to small systems under the LT2ESWTR, EPA is proposing that small systems first monitor for *E. coli* as a screening analysis in order to reduce the number of small systems that incur the cost of *Cryptosporidium* monitoring. However, due to limitations in available data, the Agency has determined that it is necessary to use data generated by large systems under the LT2ESWTR to confirm or refine the *E. coli* indicator criteria that will trigger small system *Cryptosporidium* monitoring. Consequently, small system indicator monitoring will begin at the conclusion of large system monitoring. This approach ~~is consistent with recommendations of~~ was recommended by the Advisory Committee.

Accordingly, small systems will monitor for *E. coli* for one year, beginning 30 months after LT2ESWTR promulgation. Following this, small systems will have six months to determine if they are required to monitor for *Cryptosporidium* and, if so, contract with an approved analytical laboratory. *Cryptosporidium* monitoring by small systems will be conducted for one year, which, when added to the one year of *E. coli* monitoring, equals two years of source water monitoring. This is equivalent to the time period large systems spend in source water monitoring.

The time periods associated with bin assignment and compliance with additional treatment requirements for small systems are the same as those proposed for large systems. Specifically, ~~States~~ small systems will have six months to work with their

States to determine ~~the appropriate~~their bin classification ~~for each small system~~ following the conclusion of *Cryptosporidium* sampling. From this point, which is 5.5 years after LT2ESWTR promulgation, small systems have three years to meet any additional treatment requirements resulting from bin classification. States can grant additional time to small systems for compliance with treatment technique requirements through granting exemptions (see SDWA section 1416).

### 3. Request for comments

EPA requests comments on the treatment technique compliance schedules for large and small systems in today's proposal: including the following issues:

#### Time window between large and small system monitoring

Under the current proposal, small filtered system *E. coli* monitoring begins in the month following the end of large system *Cryptosporidium*, *E. coli*, and turbidity monitoring. EPA plans to evaluate large system monitoring results on an ongoing basis as the data are reported to determine if any refinements to the *E. coli* levels that trigger small system *Cryptosporidium* monitoring are necessary. If such refinements were deemed appropriate, EPA would issue guidance to States, which can establish alternative trigger values for small system monitoring under the LT2ESWTR.

This implementation schedule does not leave any time between the end of large system monitoring and the initiation of small system monitoring. Consequently, if it is necessary to provide guidance on alternative trigger values prior to when small system monitoring begins, such guidance would be based on less than the full set of large system results (e.g., first 18 months of large system data). EPA requests comment on whether an additional time window between the end of large system monitoring and the

beginning of small system monitoring is appropriate and, if so, how long such a window should be.

Implementation schedule for consecutive systems

The Stage 2 M-DBP Agreement in Principle (65 FR 83015, December 29, 2000) (USEPA 2000a) continues the principle of simultaneous compliance to address microbial pathogens and disinfection byproducts. Systems are generally expected to address LT2ESTWR requirements concurrently with those of the Stage 2 DBPR (as noted earlier, the Stage 2 DBPR is scheduled to be proposed later this year and to be promulgated at the same time as the LT2ESWTR).

As with the LT2ESWTR, small water systems (< 10,000 served) generally begin monitoring and must be in compliance with the Stage 2 DBPR at a date later than that for large systems. However, the Advisory Committee recommended that small systems that buy/receive from or sell/deliver finished water to a large system (that is, they are part of the same “combined distribution system”) comply with Stage 2 DBPR requirements on the same schedule as the largest system in the combined distribution system. This approach is intended to ensure that systems consider impacts throughout the combined distribution system when making compliance decisions (e.g. selecting new technologies or making operational modifications) and to facilitate all systems meeting the compliance deadlines for the rule.

The issue of combined distribution systems associated with systems buying and selling water is expected to be of less significance for the LT2ESWTR. The requirements of the LT2ESWTR apply to systems treating raw surface water and generally will not involve compliance steps when systems purchase treated water.

Consequently, the compliance schedule for today's proposal does not address combined distribution systems. However, this proposed approach raises the possibility that a small system treating surface water and selling it to a large system could be required to take compliance steps at an earlier date under the Stage 2 DBPR than under the LT2ESWTR. While a small system in this situation could chose to comply with the LT2ESWTR on an earlier schedule, the two rules would not require simultaneous compliance. EPA requests comment on how this scenario should be addressed in the LT2ESWTR.

#### *G. Public Notice Requirements*

##### 1. What is EPA proposing today?

EPA is proposing that under the LT2ESWTR, a Tier 2 public notice will be required for violations of additional treatment requirements and a Tier 3 public notice will be required for violations of monitoring and testing requirements. Where systems violate LT2ESWTR treatment requirements, today's proposal requires the use of the existing health effects language for microbiological contaminant treatment technique violations, as stated in 40 CFR 141 Subpart Q, Appendix B.

##### 2. How was this proposal developed?

In 2000, EPA published the Public Notification Rule (65 FR 25982, May 4, 2000) (USEPA 2000d), which revised the general public notification regulations for public water systems in order to implement the public notification requirements of the 1996 SDWA amendments. This regulation established the requirements that public water systems must follow regarding the form, manner, frequency, and content of a public notice. Public notification of violations is an integral part of the public health protection

and consumer right-to-know provisions of the 1996 SDWA Amendments.

Owners and operators of public water systems are required to notify persons served when they fail to comply with the requirements of a NPDWR, have a variance or exemption from the drinking water regulations, or are facing other situations posing a risk to public health. The public notification requirements divide violations into three categories (Tier 1, Tier 2 and Tier 3) based on the seriousness of the violations, with each tier having different public notification requirements.

EPA has limited its list of violations and situations routinely requiring a Tier 1 notice to those with a significant potential for serious adverse health effects from short term exposure. Tier 1 violations contain language specified by EPA that concisely and in non-technical terms conveys to the public the adverse health effects that may occur as a result of the violation. States and water utilities may add additional information to each notice, as deemed appropriate for specific situations. A State may elevate to Tier 1 other violations and situations with significant potential to have serious adverse health effects from short-term exposure, as determined by the State.

Tier 2 public notices address other violations with potential to have serious adverse health effects on human health. Tier 2 notices are required for the following situations:

- All violations of the MCL, maximum residual disinfectant level (MRDL) and treatment technique requirements, except where a Tier 1 notice is required or where the State determines that a Tier 1 notice is required; and
- Failure to comply with the terms and conditions of any existing variance or exemption.

Tier 3 public notices include all other violations and situations requiring public notice, including the following situations:

- A monitoring or testing procedure violation, except where a Tier 1 or 2 notice is already required or where the State has elevated the notice to Tier 1 or 2; and
- Operation under a variance or exemption.

The State, at its discretion, may elevate the notice requirement for specific monitoring or testing procedures from a Tier 3 to a Tier 2 notice, taking into account the potential health impacts and persistence of the violation.

As part of the IESWTR, EPA established health effects language for violations of treatment technique requirements for microbiological contaminants. EPA believes this language, which was developed with consideration of *Cryptosporidium* health effects, is appropriate for violations of additional *Cryptosporidium* treatment requirements under the LT2ESWTR.

### 3. Request for comment

EPA requests comment on whether the violations of additional treatment requirements for *Cryptosporidium* under the LT2ESWTR should require a Tier 2 public notice and whether the proposed health effects language is appropriate.

#### *H. Variances and Exemptions*

SDWA section 1415 allows States to grant variances from national primary drinking water regulations under certain conditions; section 1416 establishes the conditions under which States may grant exemptions to MCL or treatment technique requirements. For the reasons presented in the following discussion, EPA has determined that systems will not be eligible for variances or exemptions to the

requirements of the LT2ESWTR.

## 1. Variances

Section 1415 specifies two provisions under which general variances to treatment technique requirements may be granted:

(1) A State ~~which~~that has primacy may grant a variance to a system from any requirement to use a specified treatment technique for a contaminant if the system demonstrates to the satisfaction of the State that the treatment technique is not necessary to protect public health because of the nature of the system's raw water source. EPA may prescribe monitoring and other requirements as conditions of the variance (section 1415(a)(1)(B)).

(2) EPA may grant a variance from any treatment technique requirement upon a showing by any person that an alternative treatment technique not included in such requirement is at least as efficient in lowering the level of the contaminant (section 1415(a)(3)).

EPA does not believe the first provision for granting a variance is applicable to the LT2ESWTR because *Cryptosporidium* treatment technique requirements under this rule account for the degree of source water contamination. Systems initially comply with the LT2ESWTR by conducting source water monitoring for *Cryptosporidium*. Filtered systems are required to provide additional treatment for *Cryptosporidium* only if the source water concentration exceeds a level where current treatment does not provide sufficient protection. All unfiltered systems are required to provide a baseline of 2 log inactivation of *Cryptosporidium* to achieve finished water risk levels comparable to filtered systems; however, unfiltered systems are required to achieve 3 log inactivation

only if the source water level exceeds 0.01 oocysts/L.-

The second provision for granting a variance is not applicable to the LT2ESWTR because the treatment technique requirements of this rule specify the degree to which systems must lower their source water *Cryptosporidium* level (e.g., 4, 5, and 5.5 log reduction in Bins 2,3, and 4, respectively). The LT2ESWTR provides broad flexibility in how systems achieve the required level of *Cryptosporidium* reduction, as shown in the discussion of the microbial toolbox in section VI.C. Moreover, the microbial toolbox contains an option for Demonstration of Performance, under which States can award treatment credit based on the demonstrated efficiency of a treatment process in reducing *Cryptosporidium* levels. Thus, there is no need for this type of variance under the LT2ESWTR.

SDWA section 1415(e) describes small system variances, but these cannot be granted for a treatment technique for a microbial contaminant. Hence, small system variances are not allowed for the LT2ESWTR.

## 2. Exemptions

Under SDWA section 1416(a), a State may exempt any public water system from a treatment technique requirement upon a finding that: (1) due to compelling factors (which may include economic factors such as qualification of the system as serving a disadvantaged community), the system is unable to comply with the requirement or implement measures to develop an alternative source of water supply; (2) the system was in operation on the effective date of the treatment technique requirement, or for a system that was not in operation by that date, no reasonable alternative source of drinking water is available to the new system; (3) the exemption will not result in an

unreasonable risk to health; and (4) management or restructuring changes (or both) cannot reasonably result in compliance with the Act or improve the quality of drinking water.

If EPA or the State grants an exemption to a public water system, it must at the same time prescribe a schedule for compliance (including increments of progress or measures to develop an alternative source of water supply) and implementation of appropriate control measures that the State requires the system to meet while the exemption is in effect. Under section 1416(b)(2)(A), the schedule shall require compliance as expeditiously as practicable (to be determined by the State), but no later than three years after the otherwise applicable compliance date for the regulations established pursuant to section 1412(b)(10). For public water systems that do not serve more than a population of 3,300 and ~~which~~that need financial assistance for the necessary improvements, EPA or the State may renew an exemption for one or more additional two-year periods, but not to exceed a total of six years.

A public water system shall not be granted an exemption unless it can establish that: (1) the system cannot meet the standard without capital improvements that cannot be completed prior to the date established pursuant to section 1412(b)(10); or (2) in the case of a system that needs financial assistance for the necessary implementation, the system has entered into an agreement to obtain financial assistance pursuant to section 1452 or any other Federal or state program; or (3) the system has entered into an enforceable agreement to become part of a regional public water system.

EPA believes that granting an exemption to the *Cryptosporidium* treatment requirements of the LT2ESWTR would result in an unreasonable ~~risk to~~risk to health ~~risk~~. As

described in section II.C, *Cryptosporidium* causes acute health effects, which may be severe in sensitive subpopulations and include risk of mortality. Moreover, the additional *Cryptosporidium* treatment requirements of the LT2ESWTR are targeted to systems with the highest degree of risk. Due to these factors, EPA ~~has concluded that delaying the application of additional treatment in the higher risk systems targeted by the LT2ESWTR would present an unacceptable~~ is not proposing to allow exemptions under the LT2ESWTR.

### 3. Request for comment

a. Variances. EPA requests comment on the determination that the provisions for granting variances are not applicable to the proposed LT2ESWTR, specifically including *Cryptosporidium* inactivation requirements for unfiltered systems.

In theory it would be possible for an unfiltered system to demonstrate raw water *Cryptosporidium* levels that were 3 log lower than the cutoff for bin 1 for filtered systems and, thus, that it may be providing comparable public health protection without additional inactivation. However, EPA has determined that in practice it is not currently economically or technologically feasible for systems to ascertain the level of *Cryptosporidium* at this concentration. This is due to the extremely large number and volume of samples that would be necessary to make this demonstration with sufficient confidence. Based on this determination and the *Cryptosporidium* occurrence data described in section III.C, EPA is not proposing to allow unfiltered systems to demonstrate raw water *Cryptosporidium* levels low enough to avoid inactivation requirements. EPA requests comment on this approach.

b. Exemptions. EPA requests comment on the determination that granting an

exemption to the *Cryptosporidium* treatment requirements of the LT2ESWTR would result in an unreasonable risk to health.

#### *I. Requirements for Systems to Use Qualified Operators*

The SWTR established a requirement that each public water system using a surface water source or a ground water source under the direct influence of surface water must be operated by qualified personnel who meet the requirements specified by the State (40 CFR 141.70). The Stage 1 DBPR extended this requirement to include all systems affected by that rule, and required that States maintain a register of qualified operators (40 CFR 141.130(c)). While the proposed LT2ESWTR establishes no new requirements regarding the operation of systems by qualified personnel, the Agency would like to emphasize the important role that qualified operators play in delivering safe drinking water to the public. EPA encourages States that do not already have operator certification programs in effect to develop such programs. States should also review and modify, as required, their qualification standards to take into account new technologies (e.g., ultraviolet disinfection) and new compliance requirements.

#### *J. System Reporting and Recordkeeping Requirements*

##### 1. Overview

Today's proposal includes reporting and recordkeeping requirements associated with proposed monitoring and treatment requirements. ~~The proposed LT2ESWTR requires public water~~ As described earlier, systems ~~to~~ must conduct source water monitoring to determine a treatment bin classification for filtered systems or a mean *Cryptosporidium* level for unfiltered systems. Systems with ~~historical~~ previously collected monitoring data may be able to use (i.e., grandfathered) ~~monitoring data that~~

~~meet specified criteria may be able to use~~ those data in lieu of conducting new monitoring. Following ~~bin classification~~source water monitoring, systems will be required to comply with any additional *Cryptosporidium* treatment requirements by implementing treatment and control strategies from a microbial toolbox of options.

Systems must conduct a second round of source water monitoring six years after bin classification.

In addition, systems using uncovered finished water storage facilities must cover the facility or provide treatment unless the system implements a State-approved risk management strategy. Certain systems will be required to conduct disinfection profiling and benchmarking. ~~Reporting requirements associated with these activities are summarized in Tables IV-30 to IV-33. Further details are provided in the following discussion.~~

The proposed rule requires public water systems to submit schedules for ~~both *Cryptosporidium* and *E. coli*~~ and turbidity sampling at least 3 months before monitoring must begin. ~~Monitoring results are required to be reported within 2 months~~Source water sample analysis results must be reported not later than ten days after the end of first month following the month ~~in which~~when the sample is collected. As described later, large systems (~~\$10~~at least 10,000 people served) will report monitoring results from the initial round of monitoring directly to EPA through an electronic data system. Small systems will report monitoring results to the ~~primacy agency~~State. Both small and large systems will report monitoring results from the second round of monitoring to the State.

Systems must report a bin classification (filtered systems) or mean *Cryptosporidium* level (unfiltered systems) within six months following the month when

the last sample in a particular round of monitoring is scheduled to be collected. If systems are required to provide additional treatment for *Cryptosporidium*, they must report regarding the use of microbial toolbox components. Systems must notify the State within 24 months following promulgation of the rule if they use uncovered finished water storage facilities. Systems must also make reports related to disinfection profiling and benchmarking. Reporting requirements associated with these activities are summarized in Tables IV-25 to IV-28.

**Table IV-3025.-- Summary of Initial Large Filtered System Reporting Requirements**

YOU MUST REPORT THE FOLLOWING ITEMS	ON THE FOLLOWING SCHEDULE
Sampling schedule for <i>Cryptosporidium</i> , <i>E. coli</i> , and turbidity monitoring	No later than 3 months after promulgation.
Results of <i>Cryptosporidium</i> , <i>E. coli</i> , and turbidity analyses	No later than 10 days after the end of the first month following the month in which the sample is collected.
Bin determination	No later than 36 months after promulgation.
Demonstration of compliance with additional treatment requirements	<del>No later than</del> <u>Beginning</u> 72 months after promulgation <sup>1</sup> (See table <del>IV-42</del> <u>IV-34</u> ).
Disinfection <del>benchmarking</del> <u>profiling</u> component reports	See Table <del>IV-43</del> <u>IV-35</u>

<sup>1</sup>States may ~~allow~~ grant an additional two years for systems making capital improvements.

**Table IV-3126.-- Summary of Initial Small Filtered System Reporting Requirements**

YOU MUST REPORT THE FOLLOWING ITEMS	ON THE FOLLOWING SCHEDULE
Sampling schedule for <i>E. coli</i> monitoring	No later than 27 months after promulgation.
Results of <i>E. coli</i> analyses (unless State approves a different indicator)	No later than 10 days after the end of the first month following the month in which the sample was collected.
Mean <i>E. coli</i> concentration (unless State approves a different indicator)	No later than 45 months after promulgation.
Disinfection <del>benchmarking</del> <u>profiling</u> component reports	See Table <del>IV-44</del> <u>IV-36</u> .

Additional requirements if <i>E. coli</i> trigger level is exceeded <sup>1</sup>	
Sampling schedule for <i>Cryptosporidium</i> monitoring	No later than 45 months after promulgation.
Results of <i>Cryptosporidium</i> analyses	No later than <u>210 days after the end of the first months</u> following the month in which the sample <u>was</u> collected.
Bin determination	No later than 66 months after promulgation.
Demonstration of compliance with additional treatment requirements	<del>No later than</del> <u>Beginning</u> 102 months after promulgation <sup>2</sup> (See Table <del>IV-42</del> <u>IV-34</u> ).

<sup>1</sup>If the *E. coli* annual mean concentration exceeds 10/100 mL for systems using lakes/reservoirs or exceeds 50/100 mL for systems using flowing streams, then systems must conduct *Cryptosporidium* monitoring. States may approve alternative indicator criteria to trigger *Cryptosporidium* monitoring.

<sup>2</sup>States may allow grant an additional time two years for systems making capital improvements.

**Table ~~IV-32~~ IV-27.-- Summary of Initial Large Unfiltered System Reporting**

### Requirements

YOU MUST REPORT THE FOLLOWING ITEMS	ON THE FOLLOWING SCHEDULE
<i>Cryptosporidium</i> sampling schedule	No later than 3 months after promulgation.
Results of <i>Cryptosporidium</i> analyses	No later than 10 days after the end of the first month following the month in which the sample was collected
Determination of mean <i>Cryptosporidium</i> concentration	No later than 36 months after promulgation.
Disinfection <u>benchmarking</u> <u>profiling</u> component reports	See Table <del>IV-43</del> <u>IV-35</u> .
Demonstration of compliance with <i>Cryptosporidium</i> inactivation requirements	Beginning 72 months after promulgation <sup>1</sup> (see Table <del>IV-42</del> <u>IV-34</u> ).

<sup>1</sup>States may grant an additional two years for systems making capital improvements.

**Table IV-~~33~~ 28.-- Summary of Initial Small Unfiltered System Reporting**

### Requirements

YOU MUST REPORT THE FOLLOWING ITEMS	ON THE FOLLOWING SCHEDULE
<i>Cryptosporidium</i> sampling schedule	No later than 45 months after promulgation.

Results of <i>Cryptosporidium</i> analyses	No later than 10 days after the end of the first month following the month in which the sample was collected.
Determination of mean <i>Cryptosporidium</i> concentration	No later than 66 months after promulgation.
Disinfection <del>benchmarking</del> <u>profiling</u> component reports	See Table <del>IV-43</del> <u>IV-35</u> .
Demonstration of compliance with <i>Cryptosporidium</i> inactivation requirements	Beginning 102 months after promulgation <sup>1</sup> (see Table <del>IV-42</del> <u>IV-34</u> ).

<sup>1</sup>States may grant an additional two years for systems making capital improvements

## 2. Reporting requirements for source water monitoring

*a. Data elements to be reported.* Proposed reporting requirements for LT2ESWTR monitoring stem from proposed analytical method requirements ~~and data quality objectives~~. As stated in sections IV.K and IV.L, systems must have *Cryptosporidium* analyses conducted by EPA-approved laboratories using Methods 1622 or 1623. *E. coli* analyses must be performed by State-approved laboratories using the *E. coli* methods proposed for approval in section IV.K. Systems are required to report the data elements specified in Table IV-~~34~~ 29 for each *Cryptosporidium* analysis. To comply with LT2ESWTR requirements, only the sample volume filtered and the number of oocysts counted must be reported for samples in which at least 10 L is filtered and all of the sample volume is analyzed. Additional information is required for samples where the laboratory analyzes less than 10 L or less than the full sample volume collected. Table IV-~~35~~ 0 presents the data elements that systems must report for *E. coli* analyses.

As described in the following section, EPA is developing a data system to manage and analyze the microbial monitoring data that will be reported by large systems under the LT2ESWTR. EPA is exploring approaches for application of this

data system to support small system data reporting as well. Systems, or laboratories acting as the systems' agents, must keep Method ~~1622 and 1623~~1622/1623 bench sheets and slide examination report forms until 36 months after an equivalent round of source water monitoring has been completed (e.g., second round of *Cryptosporidium* monitoring).

**Table IV-~~34~~29-- Proposed *Cryptosporidium* Data Elements to be Reported**

Data element	Reason for Data Element
<b>Identifying information</b>	
• PWSID	Needed to associate plant with public water system
• Facility ID	Needed to associate sample result with facility
• Sample collection point	Needed to associate sample result with sampling point
• Sample collection date	Needed to determine that utilities are collecting samples at the frequency required
• Sample type (field or matrix spike) <sup>1</sup>	Needed to distinguish field samples from matrix samples for recovery calculations
<b>Sample results</b>	
• Sample volume filtered (L), to nearest ¼ L <sup>2</sup>	Needed to verify compliance with sample volume requirements
• Was 100% of filtered volume examined? <sup>3</sup>	Needed to calculate the final concentration of oocysts/L and determine if volume analyzed requirements are met
• Number of oocysts counted	Needed to calculate the final concentration of oocysts/L

<sup>1</sup>For matrix spike samples, sample volume spiked and estimated number of oocysts spiked ~~would~~must be ~~entered~~reported. These data ~~will~~are not ~~be~~ required for field samples.

<sup>2</sup>For samples in which <10 L is filtered or <100% of the sample volume is examined, the number of filters used and the packed pellet volume ~~would~~must also be ~~entered~~reported to verify compliance with LT2ESWTR sample volume analysis requirements. These data ~~will~~are not ~~be~~ required for most samples.

<sup>3</sup>For samples in which <100% of sample is examined, the volume of resuspended concentrate and volume of this resuspension processed through IMS ~~will be required to~~must be reported to calculate the sample volume examined. These data will not be required for most samples.

**Table IV-~~35~~0-- Proposed *E. coli* Data Elements to be Reported**

Data element	Reason for Collecting Data Element
<b>Identifying Information</b>	
PWS ID	Needed to associate analytical result with public water system
Facility ID	Needed to associate plant with public water system
Sample collection point	Needed to associate sample result with sampling point
Sample collection date	Needed to determine that utilities are collecting samples at the frequency required
Analytical method number	Needed to associate analytical result with analytical method
Method Type	Needed to verify that an approved method was used and call up correct web entry form

Source water type	Needed to <del>reassess microbial index</del> <u>assess <i>Cryptosporidium</i> indicator relationships</u>
<i>E. coli</i> /100 mL	Sample result (although not required, the laboratory also will have the option of entering primary measurements for a sample into the LT2ESWTR internet-based database to have the database automatically calculate the sample result)
<b>Turbidity Information</b>	
Turbidity result	Needed to assess <i>Cryptosporidium</i> indicator relationships

b. *Data system.* Because source water monitoring by large systems (serving at least 10,000 people) will begin 6 months following promulgation of the LT2ESWTR, EPA expects to act as the primacy agency with oversight responsibility for large system sampling, analysis, and data reporting. To facilitate collection and analysis of large system monitoring data, EPA is developing an Internet-based electronic data collection and management system. This approach is similar to that used under the Unregulated Contaminants Monitoring Rule (UCMR) (64 FR 50556, September 17, 1999) (USEPA 1999c).

Analytical results for *Cryptosporidium*, *E. coli*, and turbidity analyses will be reported directly to this database using web forms and software that can be downloaded free of charge. ~~EPA will make large system monitoring data available to States when States assume primacy for the LT2ESWTR or earlier under State agreements with EPA.~~

———The data system will perform logic checks on data entered and calculate final results from primary data (where necessary). This is intended to reduce reporting errors and limit the time involved in investigating, checking, and correcting errors at all levels. EPA will make large system monitoring data available to States when States assume primacy for the LT2ESWTR or earlier under State agreements with EPA.

Large systems ~~will~~ should instruct their laboratories to electronically enter

monitoring results into the EPA data system using web-based manual entry forms or by uploading XML files from laboratory information management systems (LIMS). After data are submitted by a laboratory, systems may review the results on-line. If a system believes that a result was entered into the data system erroneously, the system may notify the laboratory to rectify the entry. In addition, if a system believes that a result is incorrect, the system may ~~electronically mark (flag)~~submit the result as a contested result and petition EPA or the State to invalidate the sample. If a system contests a sample result, the system must submit a rationale to the primacy agency, including a supporting statement from the laboratory, providing a justification. Systems may arrange with laboratories to review their sample results prior to the results being entered into the EPA data system.

———If Also, if a system determines that its laboratory does not have the capability to report data electronically, the system can submit a request to EPA to use an alternate reporting format.

Regardless of the reporting process used, systems are required to report an analytical monitoring result to the primacy agency no later than 10 days after the end of the first month following the month when the sample was collected. ~~As described in cases where~~section IV.A.1, if a system ~~fails~~is unable to report a valid *Cryptosporidium* ~~analysis~~analytical result for a ~~required~~scheduled sampling date, ~~the system must collect a make-up sample no later than 14 days after learning that a result for the required date will not be reported. Factors that could lead to failure to report a valid analysis result include violation of method~~ due to failure to comply with the analytical method requirements (e.g., violation of quality control requirements ~~like holding time and loss of~~

~~sample in transit to the laboratory~~), the system must collect a replacement sample within 14 days of being notified by the laboratory or the State that a result cannot be reported for that date and must submit an explanation for the replacement sample with the analytical results. A system will not incur a monitoring violation if the ~~primacy agency~~State determines that the failure to report a valid analysis result was due to circumstances beyond the control of the system. However, in all cases the system must collect a replacement sample.

The data elements to be collected by the electronic data system will enhance the reliability of the microbial data generated under the LT2ESWTR, while reducing the burden on the analytical laboratories and public water systems. Tables IV-36 to 1 and IV-382 summarize the system's data analysis functions ~~that the LT2ESWTR data system will perform on~~for *Cryptosporidium* ~~and~~ *E. coli* measurements.

**Table IV-361.-- LT2ESWTR Data System Functions for *Cryptosporidium* Data**

Value Calculated	Formula	Applicability to Sample Types	
		Field	Matrix Spike
Calculation of sample volume analyzed	(Volume filtered) * (resuspended concentrate volume transferred to IMS / resuspended concentrate volume)	Yes	Yes
Pellet volume analyzed	(pellet volume)*(resuspended concentrate volume transferred to IMS/resuspended concentrate volume)	Yes	Yes
Calculation of oocysts/L	(Number of oocysts counted)/(sample volume analyzed)	Yes	Yes
Calculation of estimated number of oocysts spiked/L	(Number of oocysts spiked)/(sample volume spiked)	No	Yes
Calculation of percent recoveries for IMS samples	((Calculated # of oocysts/L for the MS sample) - (Calculated # of oocysts/L in the associated field sample)) / (Estimated number of oocysts spiked/L) * 100%	No	Yes

**Table IV-372.-- LT2ESWTR Data System Functions for *Cryptosporidium* Compliance Checks**

LT2 Requirements	Description
Sample volume analysis	<p>Specifies that the LT2 requirements for sample volume analyzed were met when:</p> <ul style="list-style-type: none"> <li>• volume analyzed is &gt; 10 L</li> <li>• volume analyzed is &lt; 10 L and pellet volume analyzed is at least 2 mL</li> <li>• volume analyzed &lt; 10 L and pellet volume analyzed &lt; 2 mL and 100% of filtered volume examined= Y and two filters were used</li> </ul> <p>Specifies that the LT2 requirements for sample volume analyzed were not met when:</p> <ul style="list-style-type: none"> <li>• volume analyzed &lt; 10 L and pellet volume analyzed is &lt; 2 mL and 100% of filtered volume examined= N</li> <li>• volume analyzed is &lt; 10 L and pellet volume analyzed &lt; 2 mL and only 1 filter used</li> </ul>
Schedule met	Specifies that the predetermined sampling schedule is met when the sample collection data is within ± 2 days of the scheduled date.

**Table IV-38.-- LT2ESWTR Data System Functions for *E. coli* Compliance Checks**  
**LT2 Requirements Description** Collection date same as *Cryptosporidium* collection data Specifies that the *E. coli* sample was collected on the same date as the *Cryptosporidium* sample with the same sample number



c. ~~Previously collected monitoring~~ data. Table IV-39~~3~~ provides a summary of the items that systems must report to EPA for consideration of ~~historical~~previously collected (grandfathered) monitoring data under the LT2ESWTR. For each field and matrix spike (MS) sample, systems must ~~submit~~report the data elements specified in Table IV-~~34~~29. ~~Systems also must submit a signed letter from~~In addition, the laboratory that analyzed the samples must submit a letter certifying that all Method 1622 and 1623 quality control (~~QC~~) requirements (including ongoing precision and recovery (OPR) and method blank (MB) results, holding times, and positive and negative staining controls) were performed at the required frequency and were acceptable. Alternatively, the ~~system~~laboratory may ~~submit~~provide for each field, MS, OPR, and MB sample a copy of the laboratory bench sheet and sample examination report form (Method 1622 and 1623 bench sheets are shown in USEPA 200~~2e3h~~). ~~In addition, the system~~

Systems must ~~provide a letter certifying that~~report all routine source water *Cryptosporidium* monitoring results collected during the ~~sampling~~ period covered by the previously collected data that have been submitted.

~~Systems seeking approval of historical data under LT2ESWTR should submit a general information sheet (Table IV-40) and should provide a summary table with their analysis results as shown in Table IV-41. This applies to all samples that were collected from the sampling location used for monitoring, not spiked, and analyzed using the laboratory's routine process for Method 1622 or 1623 analyses, including analytical technique and QA/QC.~~ Other requirements associated with ~~the~~ use of ~~historical~~previously collected data are specified in section IV.A.1.d. Where applicable, systems must provide 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. Review of the submitted information, along with the results of the quality assurance audits of the laboratory that produced the data, will be used to determine whether the data meet the requirements for grandfathering.

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**Table IV-393.-- Items that Must Be Reported for Consideration of Grandfathered Monitoring Data**

THE FOLLOWING ITEMS MUST BE REPORTED <sup>1</sup>	ON THE FOLLOWING SCHEDULE <sup>1</sup>
Data elements listed in Table IV-3429 for each field and MS sample	No later than 2 months after promulgation if the system does not intend to conduct new monitoring under the LT2ESWTR.
Letter from laboratory certifying that method-specified QC was performed at required frequency and was acceptable	
OR	No later than 8 months after promulgation if the system intends to conduct new monitoring under the LT2ESWTR.
Method 4622 and 4623 1622/1623 bench sheet and sample examination report form for each field, MS, OPR, and method blank sample	
Letter from PWS system certifying (1) that all source water data collected during <u>sampling period has been submitted the time period covered by the previously collected data have been submitted and (2) that the data represent the plant's current source water</u>	
General information sheet (Table IV-40) Results summary table (Table IV-41) <u>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</u>	

<sup>1</sup>See section IV.A.1.d for details

**Table IV-40.-- General Information to be Reported by Utilities Requesting Use of Historical Data Under the LT2ESWTR**

Utility Information PWSID: Plant ID: Address: City: State: Zip: Protozoa Laboratory  
 Information Laboratory Name: \_\_\_\_\_ Laboratory  
 Number: Address: City: State: Zip: Is the laboratory that analyzed your plant's data  
 currently participating in the USEPA Laboratory QA Program Program for Analysis of  
*Cryptosporidium* in Water? \_\_\_\_\_ 9 Yes 9 No Total number of  
 samples your plant  
 is submitting for grandfathering: Number of samples your plant  
 anticipates collecting under LT2: Date first historical sample  
 was collected: Date last historical sample

~~was collected: Were all samples collected from the same sampling location? For utilities that do not intend to collect additional data under the LT2ESWTR<sup>1</sup> What calculation was used to estimate your plant's bin classification? Based on this estimate, which bin does your plant fall into?<sup>†</sup> Systems must conduct monitoring under the LT2ESWTR until notified in writing by EPA that they have at least 2 years of acceptable data~~

~~Table IV-41.-- Historical *Cryptosporidium* Monitoring Results Summary Table<sup>†</sup>~~

~~Data element~~Sample

~~1~~Sample

~~2~~Sample

~~3~~Sample

~~4~~Sample

~~5~~Sample

~~6~~Sample

~~7~~Sample

~~8~~Sample

~~9~~Sample

~~10~~Sample

~~11~~Sample

~~12~~Sample collection date (dd/mm/yyyy)Laboratory nameMethod usedSample volume analyzed (to nearest 1/4 L)Number of oocysts counted under FA<sup>†</sup>Systems with more than 1 year of historical data should complete this table for each year

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### 3. Compliance with additional treatment requirements

Under the proposed LT2ESWTR, systems may choose from a “toolbox” of management and treatment options to meet their additional *Cryptosporidium* treatment requirements. In order to receive credit for toolbox components, systems must initially demonstrate that they comply with any required design and implementation criteria, including performance validation testing. Additionally, systems must provide monthly verification of compliance with any required operational criteria, as shown through ongoing monitoring. Required design, implementation, operational, and monitoring criteria for toolbox components are described in section IV.C. Proposed reporting requirements associated with these criteria are shown in Table [IV-42](#)[IV-34](#) for both large and small systems.

**Table [IV-42](#)[IV-34](#)-- Toolbox Reporting Requirements**

Toolbox Option (Potential <i>Cryptosporidium</i> reduction log credit)	You must submit the following items	On the following schedule <sup>1</sup> (Systems serving \$10,000 people)	On the following schedule <sup>1</sup> (Systems serving < 10,000 people)
<b>Watershed Control Program (WCP) (0.5 log)</b>	Notify State of intention to develop WCP	No later than 48 months after promulgation	No later 78 months after promulgation
	Submit initial WCP plan to State	No later than 60 months after promulgation	No later than 90 months after promulgation
	Annual program status report and State-approved watershed survey report	By a date determined by the State, every 12 months, beginning 84 months after promulgation	By a date determined by the State, every 12 months, beginning 114 months after promulgation
	Request for re-approval and report on the previous approval period	No later than 6 months prior to the end of the current approval period or by a date previously determined by the State	No later than 6 months prior to the end of the current approval period or by a date previously determined by the State

Toolbox Option (Potential <i>Cryptosporidium</i> reduction log credit)	You must submit the following items	On the following schedule <sup>1</sup> (Systems serving \$10,000 people)	On the following schedule <sup>1</sup> (Systems serving < 10,000 people)
<b>Pre-sedimentation (0.5 log) (new basins)</b>	Monthly verification of: <ul style="list-style-type: none"> <li>• Continuous basin operation</li> <li>• Treatment of 100% of the flow</li> <li>• Continuous addition of a coagulant</li> <li>• At least 0.5 log removal of influent turbidity based on the monthly mean of daily turbidity readings for 11 of the 12 previous months</li> </ul>	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning 72 months after promulgation	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning 102 months after promulgation
<b>Two-Stage Lime Softening (0.5 log)</b>	Monthly verification of: <ul style="list-style-type: none"> <li>• Continuous operation of a second clarification step between the primary clarifier and filter</li> <li>• Presence of coagulant (may be lime) in first and second stage clarifiers</li> <li>• Both clarifiers treat 100% of the plant flow</li> </ul>	No later than 72 months after promulgation	No later than 102 months after promulgation
<b>Bank filtration (0.5 or 1.0 log) (new)</b>	Initial demonstration of: <ul style="list-style-type: none"> <li>• Unconsolidated, predominantly sandy aquifer</li> <li>• Setback distance of at least 25 ft. (0.5 log) or 50 ft. (1.0 log)</li> </ul>	Initial demonstration no later than 72 months after promulgation	Initial demonstration no later than 102 months after promulgation
	If monthly average of daily max turbidity is greater than 1 NTU then system must report result and submit an assessment of the cause.	Report within 30 days following the month in which the monitoring was conducted, beginning 72 months after promulgation	Report within 30 days following the month in which the monitoring was conducted, beginning 102 months after promulgation
<b>Combined filter performance (0.5 log)</b>	Monthly verification of: <ul style="list-style-type: none"> <li>• Combined filter effluent (CFE) turbidity levels less than or equal to 0.15 NTU in at least 95 percent of the 4 hour CFE measurements taken each month</li> </ul>	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on 72 months after promulgation	Monthly reporting: within 10 days following the month in which the monitoring was conducted, beginning on 102 months after promulgation
<b>Membranes (MF, UF, NF, RO) (2.5 log or greater based on verification/integrity testing)</b>	Initial demonstration of: <ul style="list-style-type: none"> <li>• Removal efficiency through challenge studies</li> <li>• Methods of challenge studies meet rule criteria</li> <li>• Integrity test results and baseline</li> </ul>	No later than 72 months after promulgation	No later than 102 months after promulgation

Toolbox Option (Potential <i>Cryptosporidium</i> reduction log credit)	You must submit the following items	On the following schedule <sup>1</sup> (Systems serving \$10,000 people)	On the following schedule <sup>1</sup> (Systems serving < 10,000 people)
	Monthly report summarizing: <ul style="list-style-type: none"> <li>• All direct integrity test results above the control limit and the corrective action that was taken</li> <li>• All indirect integrity monitoring results triggering direct integrity testing and the corrective action that was taken</li> </ul>	Within 10 days following the month in which monitoring was conducted, beginning 72 months after promulgation	Within 10 days following the month in which monitoring was conducted, beginning 102 months after promulgation
<b>Bag filters (1.0 log) and Cartridge filters (2.0 log)</b>	Initial demonstration that the following criteria are met: <ul style="list-style-type: none"> <li>• Process meets the basic definition of bag or cartridge filtration;</li> <li>• Removal efficiency established through challenge testing that meets rule criteria</li> <li>• Challenge test shows at least 2 and 3 log removal for bag and cartridge filters, respectively</li> </ul>	No later than 72 months after promulgation	No later than 102 months after promulgation
<b>Chlorine dioxide (log credit based on CT)</b>	Summary of CT values for each day and log inactivation based on tables in section IV.C.14.	Within 10 days following the month in which monitoring was conducted, beginning 72 months after promulgation	Within 10 days following the month in which monitoring was conducted, beginning 102 months after promulgation
<b>Ozone (log credit based on CT)</b>	Summary of CT values for each day and log inactivation based on tables in section IV.C.15 <sup>4</sup>	Within 10 days following the month in which monitoring was conducted, beginning 72 months after promulgation	Within 10 days following the month in which monitoring was conducted, beginning 102 months after promulgation
<b>UV (log credit based UV dose and operating within validated conditions)</b>	Results from reactor validation testing demonstrating operating conditions that achieve required UV dose	No later than 72 months after promulgation	No later than 102 months after promulgation
	Monthly report summarizing the percentage of water entering the distribution system that was not treated by UV reactors operating within validated conditions for the required UV dose <a href="#">in section IV.C.15.</a>	Within 10 days following the month in which monitoring was conducted, beginning 72 months after promulgation	Within 10 days following the month in which monitoring was conducted, beginning 102 months after promulgation

Toolbox Option (Potential <i>Cryptosporidium</i> reduction log credit)	You must submit the following items	On the following schedule <sup>1</sup> (Systems serving \$10,000 people)	On the following schedule <sup>1</sup> (Systems serving < 10,000 people)
<b>Individual filter performance (1.0 log)</b>	Monthly verification of the following, based on continuous monitoring of turbidity for each individual filter: <ul style="list-style-type: none"> <li>• Filtered water turbidity less than 0.1 NTU in at least 95 percent of the daily maximum values from individual filters (excluding 15 minute period following start up after backwashes)</li> <li>• No individual filter with a measured turbidity greater than 0.3 NTU in two consecutive measurements taken 15 minutes apart.</li> </ul>	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on 72 months after promulgation	Monthly reporting: within 10 days following the month in which the monitoring was conducted, beginning 102 months after promulgation
<b>Demonstration of Performance</b>	Results from testing following State approved protocol.	No later than 72 months after promulgation	No later than 102 months after promulgation
	Monthly verification of operation within State-approved conditions for demonstration of performance credit	Within 10 days following the month in which monitoring was conducted, beginning 72 months after promulgation	Within 10 days following the month in which monitoring was conducted, beginning 102 months after promulgation

<sup>1</sup>States may allow an additional two years for systems making capital improvements.

Reporting requirements associated with disinfection profiling and benchmarking are summarized in Table IV-43~~IV-35~~ for large systems and in Table IV-44~~36~~ for small systems.-

**Table IV-43IV-35.-- Disinfection Benchmarking Reporting Requirements for Large Systems**

System Type	Benchmark Component	Submit the following items	On the following schedule
Systems Required to Conduct <i>Cryptosporidium</i> Monitoring	Characterization of Disinfection Practices	<i>Giardia lamblia</i> and virus inactivation profiles must be on file for State review during sanitary survey	No later than 36 months after promulgation
	State Review of Proposed Changes to Disinfection Practices	Inactivation profiles and benchmark determinations	Prior to significant modification of disinfection practice
Systems Not Required to Conduct <i>Cryptosporidium</i> Monitoring <sup>1</sup>	Applicability	None	None
	Characterization of Disinfection Practices	None	None
	State Review of Proposed Changes to Disinfection Practices	None	None

<sup>1</sup> Systems that provide at least 5.5 log of *Cryptosporidium* treatment consistent with a Bin 4 treatment implication are not required to conduct *Cryptosporidium* monitoring.

**Table IV-4436.-- Disinfection Benchmarking Reporting Requirements for Small Systems**

System Type	Benchmark Component	Submit the following items	On the following schedule
Systems required to conduct <i>Cryptosporidium</i> monitoring	Characterization of Disinfection Practices	<i>Giardia lamblia</i> and virus inactivation profiles must be on file for State review during sanitary survey	No later than 66 months after promulgation
	State Review of Proposed Changes to Disinfection Practices	Inactivation profiles and benchmark determinations	Prior to significant modification of disinfection practice
Systems not required to conduct <i>Cryptosporidium</i> monitoring and that exceed DBP triggers <sup>1,2,3</sup>	Applicability Period	Notify State that profiling is required based on DBP levels	No later than 42 months after promulgation
	Characterization of Disinfection Practices	<i>Giardia lamblia</i> and virus inactivation profiles must be on file for State review during sanitary survey	No later than 54 months after promulgation
	State Review of Proposed Changes to Disinfection Practices	Inactivation profiles and benchmark determinations	Prior to significant modification of disinfection practice

Systems not required to conduct <i>Cryptosporidium</i> monitoring and that do not exceed DBP triggers <sup>2,3</sup>	Applicability Period	Notify State that profiling is not required based on DBP levels	No later than 42 months after promulgation
	Characterization of Disinfection Practices	None	None
	State Review of Proposed Changes to Disinfection Practices	None	None

<sup>1</sup> Systems that provide at least 5.5 log of *Cryptosporidium* treatment consistent with a Bin 4 treatment implication are not required to conduct *Cryptosporidium* monitoring.

<sup>2</sup> If the *E. coli* annual mean concentration is # 10/100 mL for systems using lakes/reservoirs or # 50/100 mL for systems using flowing streams, the system is not required to conduct *Cryptosporidium* monitoring and will only be required to characterize disinfection practices if DBP triggers are exceeded.

<sup>3</sup> If the system is a CWS or NTNCWSs and TTHM or HAA5 levels in the distribution system are at least 0.064 mg/L or 0.048 mg/L, respectively, calculated as an LRAA at any Stage 1 DBPR sampling site, then the system is triggered into disinfection profiling.

#### 4. Request for comment

EPA requests comment on the reporting and recordkeeping requirements proposed for the LT2ESWTR.

Specifically, the Agency requests comment on the proposed requirement that systems report monthly on the use of microbial toolbox components to demonstrate compliance with their *Cryptosporidium* treatment requirements. An alternative may be for systems to keep records on site for State review instead of reporting the data.

#### K. Analytical Methods

EPA is proposing to require public water systems to conduct LT2ESWTR monitoring using approved methods for *Cryptosporidium*, *E. coli*, and turbidity analyses. This includes meeting quality control (QC) criteria stipulated by the approved methods and additional method-specific requirements, as stated later in this section. Related requirements on the use of approved laboratories are proposed discussed in section IV.L, and proposed requirements for reporting of data were stated previously in section IV.J. EPA has developed draft guidance for sampling and analyses under the

LT2ESWTR (see USEPA 2002e3g and 2002j3h). This guidance is available in draft form in the docket for today's proposal (<http://www.epa.gov/edocket/>).

## 1. *Cryptosporidium*

a. *What is EPA proposing today?* Method 1622: “*Cryptosporidium* in Water by Filtration/IMS/FA” (EPA-821-R-01-026, April 2001) (USEPA 2001e) and Method 1623: “*Cryptosporidium* and *Giardia* in Water by Filtration/IMS/FA” (EPA 821-R-01-025, April 2001) (USEPA 2001f) are proposed for *Cryptosporidium* analysis under this rule.

Methods 1622 and 1623 require filtration, immunomagnetic separation (IMS) of the oocysts from the captured material, and ~~immunofluorescence assay (IFA), vital dye staining using 4',6-diamidino-2-phenylindole (DAPI) examination based on IFA, DAPI staining results,~~ and differential interference contrast (DIC) microscopy for determination of oocyst concentrations.

### ~~LT2ESWTR-specific m~~Method requirements

For each *Cryptosporidium* sample under this proposal, all systems must analyze at least a 10-L sample volume. Systems may collect and analyze greater than a ~~10-L sample volume as long as the system consistently attempts to analyze the larger sample volume throughout the monitoring period.~~

———10-L sample volume. If a sample is very turbid, it may generate a large packed pellet volume upon centrifugation (a packed pellet refers to the concentrated sample after centrifugation has been performed in EPA Methods 1622 and 1623). Based on IMS purification limitations, samples resulting in large packed pellets will require that the sample concentrate be aliquoted into multiple “subsamples” for independent processing through IMS, staining, and examination. Because of the expense of the

IMS beads reagents and analyst time to examine multiple slides per sample, systems are not required to analyze more than 2 mL of packed pellet volume per sample.

In cases where it is not feasible for a system to process a 10-L sample for *Cryptosporidium* analysis (e.g., filter clogs prior to filtration of 10 L) the system must analyze as much sample volume as can be filtered by 2 filters, up to a packed pellet volume of 2 mL. This condition applies only to filters that have been approved by EPA for nationwide use with Methods 1622 and 1623—the Pall Gelman Envirochek™ and Envirochek™ HV filters, the IDEXX Filta-Max™ foam filter, and the Whatman CrypTest™ cartridge filter.

Methods 1622 and 1623 include fluorescein isothiocyanate (FITC) as the primary antibody stain for *Cryptosporidium* detection, DAPI staining to detect nuclei, and DIC to detect internal structures. For purposes of the LT2ESWTR, systems must report total *Cryptosporidium* oocysts as detected by FITC as determined by the color (apple green or alternative stain color approved for the laboratory under the Lab QA Program described in section VI.L), size (4-6 µm) and shape (round to oval). This total includes all of the oocysts identified as described here, less atypical organisms identified by FITC, DIC, or DAPI (e.g., possessing spikes, stalks, appendages, pores, one or two large nuclei filling the cell, red fluorescing chloroplasts, crystals, spores, etc.).

#### *Matrix spike samples*

As required by Method 1622 and 1623, systems must have 1 matrix spike (MS) sample analyzed for each 20 source water samples. ~~Matrix spike samples must be spiked and filtered in the laboratory.~~ The ~~sample~~ volume of the ~~matrix spike~~ MS sample must be equal to within ten percent of the volume of the unspiked sample that is

collected at the same time, and the samples must be collected by splitting the sample stream or collecting the samples sequentially. The ~~matrix spike~~MS sample and the associated unspiked sample must be analyzed by the same procedure. MS samples must be spiked and filtered in the laboratory. However, 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. In this case, the laboratory must spike the remaining 10 L of water and filter it through the filter used to collect the balance of the sample in the field.

EPA is proposing to require the use of flow cytometer-counted spiking suspensions for spiked QC samples during the LT2ESWTR. This provision is based on the improved precision expected for spiking suspensions counted with a flow cytometer, as compared to those counted using well slides or hemacytometers. During the Information Collection Rule Supplemental Surveys, the mean relative standard deviation (RSD) across 25 batches of flow cytometer-sorted *Cryptosporidium* spiking suspensions was 1.8%, with a median of 1.7% (USEPA Connell et al. 2004). In EPA Performance Evaluation (PE) studies (~~USEPA 1999e and 2000a~~), the mean RSD for flow cytometer sorted *Cryptosporidium* spiking suspensions was 3.4%. In comparison, the mean RSD for *Cryptosporidium* spiking suspensions enumerated manually by 20 laboratories using well slides or hemacytometers was 17% across 108 rounds of 10-replicate counts (DynCorp, 2001).

#### Quality control criteria

~~Quality control (QC)~~ requirements in Methods 1622 and 1623 must be followedmet by laboratories analyzing *Cryptosporidium* samples under the LT2ESWTR.

The QC acceptance criteria are the same as stipulated in the method. For the initial precision and recovery (IPR) test, the mean *Cryptosporidium* recovery must be 24% to 100% with maximum relative standard deviation (i.e., precision) of 55%. For each ongoing precision and recovery (OPR) sample, recovery must be in the range of 11% to 100%. For each method blank, oocysts must be undetected.

~~Major deviations require separate quality control verification~~

Methods 1622 and 1623 are performance-based methods and, therefore, allow multiple options to perform the sample processing steps in the methods if a laboratory can meet applicable QC criteria and uses the same determinative technique. If a laboratory uses the same procedures for all samples, then all field samples and QC samples must be analyzed in that same manner. However, if a laboratory uses more than one set of procedures for *Cryptosporidium* analyses under LT2ESWTR then the laboratory must analyze separate QC samples for each option to verify compliance with the QC criteria. For example, if the laboratory analyzes samples using both the Envirochek™ and Filta-Max™ 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 ~~assure~~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 [matrix spike 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 [matrix spikes](#) [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.

~~If systems are collecting samples larger than 10 L (e.g., 50 L), EPA requests comment on whether the entire matrix spike grab sample should be required to be shipped to the laboratory, or if all but 10 L could be filtered on site and a sequential 10 L grab sample shipped to the laboratory for spiking and filtration through the same filter.~~

~~Frequency of matrix spike sample analyses~~

~~Approval of updated versions of EPA Methods 1622 and 1623, which are proposed for Cryptosporidium analyses under the LT2ESWTR, require one matrix spike analysis to be performed per 20 field samples. Matrix spike analyses indicate analytical method recovery.~~

~~As proposed, the LT2ESWTR requires systems to follow EPA Method 1622 or 1623 quality control procedures, including the analysis of one matrix spike sample per 20 field samples. This will typically result in systems analyzing one to two matrix spike samples per year, depending on sampling frequency. Consistent with the Agreement in Principle, EPA is proposing that systems not adjust Cryptosporidium analysis results for analytical method recovery when determining their LT2ESWTR bin classification.~~

~~Rather, EPA accounted for an expected mean analytical method recovery of 40% when proposing the Cryptosporidium concentrations that bound LT2ESWTR bins (see section IV.A.2.c). This mean recovery estimate is based on Cryptosporidium method recoveries reported during the ICRSS.~~

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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 ~~systems should be required to analyze matrix spike samples at a higher frequency~~these revised versions should be approved for monitoring under the LT2ESWTR. ~~Specifically, should systems analyze one matrix spike sample with every field sample? As discussed in section 3.C, the recovery of~~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.

(7) Addition of an approved method modification using the Pall Gelman Envirochek HV filter. This approval was based on an interlaboratory validation

study demonstrating that three laboratories, each analyzing reagent water and a different source water, met all method acceptance criteria for *Cryptosporidium*. EPA issued a letter (dated March 21, 2002) under the Alternative Test Procedures program approving the procedure as an acceptable version of Method 1623 for *Cryptosporidium* (but not for *Giardia*). EPA also noted in the letter that the procedure was considered to be an acceptable modification of EPA Method 1622.

(8) Incorporation of detailed procedures for concentrating samples using an IDEXX Filta-Max™ foam filter. A method modification using this filter already is approved by EPA in the April 2001 versions of the methods.

(9) Addition of BTF EasySeed™ irradiated oocysts and cysts as acceptable materials for spiking routine QC samples. EPA approved the use of EasySeed™ based on side-by-side comparison tests of method recoveries using EasySeed™ and live, untreated organisms. EPA issued a letter (dated August 1, 2002) approving EasySeed™ for use in routine QC samples for EPA Methods 1622 and 1623 ~~has been observed to be highly variable. Analyzing a matrix spike sample with every field sample would provide the ability to assess data quality on a sample-by-sample basis. This would potentially allow for a more accurate classification of systems in LT2ESWTR bins. The primary downside to more frequent analysis of matrix spike samples is the additional expense for systems, with each sample estimated to cost \$530.~~

~~In addition, EPA is in the process of evaluating a commercially available, attenuated, colored *Cryptosporidium* that potentially could be added as an internal~~

~~surrogate to all samples analyzed by~~ and for demonstrating comparability of method modifications in a single laboratory.

(10) Removal of the Whatman Nuclepore CrypTest™ cartridge filter. Although a method modification using this filter was approved by EPA in the April 2001 versions of the methods, the filter is no longer available from the manufacturer, and so is no longer an option for sample filtration.

The changes in the June 2003 draft revisions of EPA Methods 1622 and 1623—  
~~The colored~~ reflect method-related clarifications, modifications, and additions that EPA believes should be addressed for LT2ESWTR ~~Cryptosporidium is intended to allow differentiation from uncolored, native species. If the colored~~ Cryptosporidium is approved as a spiking reagent, should EPA require that all samples be spiked to determine recoveries?

monitoring. Alternatively, these issues could be addressed through regulatory requirements in the final LT2ESWTR (for required changes and additions) and through guidance (for recommended changes and clarifications). However, EPA believes that addressing these issues through a single source in updated versions of EPA Methods 1622 and 1623 (which could be approved in the final LT2ESWTR) may be more straightforward and easier for systems and laboratories to follow than addressing them in multiple sources (i.e., existing methods, the final rule, and laboratory guidance).

## 2. *E. coli*

a. *What is EPA proposing today?* For enumerating source water *E. coli* density under the LT2ESWTR, EPA is proposing to approve the same methods that were proposed by EPA 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](#)). These methods are summarized in Table IV-4537. Methods are listed within the general categories of most probable number tests and membrane filtration tests, and Method identification numbers are provided for applicable standards published by EPA and voluntary consensus standards bodies (VCSB) including Standard Methods, American Society of Testing Materials (ASTM), and the Association of Analytical Chemists (AOAC).

**Table IV-4537.-- Proposed Methods for *E. coli* Enumeration<sup>1</sup>**

Technique	Method <sup>1</sup>	EPA	VCSB Methods			Commercial Example
			Standard Methods <sup>2</sup>	ASTM <sup>3</sup>	AOAC <sup>4</sup>	
Most Probable Number (MPN)	LTB, EC-MUG		9221B.1/ 9221F			
	ONPG-MUG		9223B		991.15	Colilert® <sup>5</sup>
	ONPG-MUG		9223B			Colilert-18® <sup>5,7</sup>
Membrane Filter (MF)	mFCy NA-MUG		9222D/ 9222G			
	<del>ENDOf NA-MUG</del> <del>mENDOf or</del> <del>LES-ENDOf NA-</del> <del>MUG</del>		9222B/ 9222G			
	mTEC agar	1103.1	9213D	D5392 - 93		
	Modified mTEC agar	1603				
	MI agar medium	1604				
	m-ColiBlue24 broth					m-ColiBlue24® <sup>6</sup>

<sup>1</sup>Tests must be conducted in a format that provides organism enumeration.

<sup>2</sup>*Standard Methods for the Examination of Water and Wastewater*. American Public Health Association. 20<sup>th</sup>, 19<sup>th</sup>, and 18<sup>th</sup> Editions. Amer. Publ. Hlth. Assoc., Washington, DC.

<sup>3</sup>Annual Book of ASTM Standards - Water and Environmental Technology. Section 11.02. ASTM. 100 Barr Harbor Drive, West Conshohocken, PA 19428.

<sup>4</sup>Official Methods of Analysis of AOAC International, 16<sup>th</sup> Edition, Volume I, Chapter 17. AOAC International. 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877-2417.

<sup>5</sup>Manufactured by IDEXX Laboratories, Inc., One IDEXX Drive, Westbrook, Main 04092.

<sup>6</sup>Manufactured by Hach Company, 100 Dayton Ave., Ames, IA 50010.

<sup>7</sup>Acceptable version of method approved as a drinking water ATP alternative test procedure.

EPA is proposing to allow a holding time of 24 hours for *E. coli* samples. The holding time refers to the time between sample collection and initiation of analysis. Currently, 40 CFR 141.74(a) limits the holding time for source water coliform samples to 8 hours and requires that samples be kept below 10°C during transit. EPA believes that new studies, described later in this section, demonstrate that *E. coli* analysis results for samples held for 24 hours will be comparable to samples held for 8 hours, provided ~~that~~ the samples are ~~maintained between 0°C~~ held below 10°C and ~~40°C~~ are not allowed to freeze. This proposed increase in holding time is significant for the LT2ESWTR because typically it is not feasible for systems to meet an ~~8-~~hour holding time when samples cannot be analyzed on-site. Many small systems that will conduct *E. coli* monitoring under the LT2ESWTR lack ~~an~~ a certified on-site laboratory for *E. coli* analyses and ~~may have~~ will be required to ship samples to a certified laboratory. EPA believes that it is feasible for these systems to comply with a 24 hour holding time for *E. coli* samples through using overnight delivery services.

*b. How was this proposal developed?* As noted, EPA recently proposed methods for ambient water *E. coli* analysis 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). These proposed methods were selected based on data generated by EPA laboratories, submissions to

the alternate test procedures (ATP) program and voluntary consensus standards bodies, published peer reviewed journal articles, and publicly available study reports.

The source water analysis for *E. coli* that will be conducted under the LT2ESWTR is similar to the type of ambient water analyses for which these methods were previously proposed (66 FR 45811, August 30, 2001) ([USEPA 2001i](#)). EPA continues to support the findings of this earlier proposal and believes that these methods have the necessary sensitivity and specificity to meet the data quality objectives of the LT2ESWTR.

#### *New information on E. coli sample holding time*

It is generally not feasible for systems that must ship *E. coli* samples to an off-site laboratory to comply with an 8-hour holding time requirement. During the ICRSS, 100% of the systems that shipped samples off-site for *E. coli* analysis exceeded the 8 hour holding time; 12% of these samples had holding times in excess of 30 hours. Most large systems that will be required to monitor for *E. coli* under the LT2ESWTR could conduct these analyses on-site, but many small systems will need to ship samples off-site to a certified contract laboratory.

EPA participated in three phases of studies to assess the effect of increased sample holding time on *E. coli* analysis results. These are summarized as follows, and are described in detail in Pope et al. ([20023](#)).

- Phase 1—EPA, the Wisconsin State Laboratory of Hygiene (WSLH), and DynCorp conducted a study to evaluate *E. coli* sample concentrations from four sites at 8, 24, 30, and 48 hours after sample collection for samples stored at 4°C, 10°C, 20°C, and 35°C. Temperature was varied to assess the effect of different

shipping conditions. Samples were analyzed in triplicate by membrane filtration (mFC followed by transfer to NA-MUG) and Colilert (Quanti-Tray 2000) (Pope et al. 2002~~3~~).

- Phase 2—EPA conducted a study to evaluate *E. coli* sample concentrations from seven sites at 8, 24, 30, and 48 hours after sample collection for samples stored in coolers containing wet ice or Utek ice packs (to assess real-world storage conditions). Samples were analyzed in triplicate by membrane filtration (mFC followed by transfer to NA-MUG); and Colilert (Quanti-Tray 2000); ~~and Colisure~~ (Pope et al. 2002~~3~~).
- Phase 3—EPA, through cooperation with AWWA, obtained *E. coli* holding time data from ten drinking water utilities that evaluated samples from 12 source waters. Each utility used an *E. coli* method of its choice (Colilert, mTEC, mEndo to NA-MUG, or mFC to NA-MUG). Samples were stored in coolers with wet ice, Utek ice packs, or Blue ice (Pope et al. 2002~~3~~).

Phase 1 results indicated that *E. coli* concentrations were not significantly different after 24 hours at most sites when samples were stored at lower temperatures. Results from Phase 2, which evaluated actual sample storage practices, verified the Phase 1 observations at most sites. Similar results were observed during Phase 3, which evaluated a wider variety of surface waters from different regions throughout the U.S. During Phase 3, *E. coli* concentrations were not significantly different after 24 hours at most sites when samples were maintained below 10°C and ~~when samples~~ did not freeze during storage. At longer holding times (e.g., 48 hours), larger differences were observed.

Based on these studies, EPA has concluded that *E. coli* samples can be held for up to 24 hours prior to analysis without compromising the data quality objectives of LT2ESWTR *E. coli* monitoring. Further, EPA believes that it is feasible for systems that must ship *E. coli* samples to an off-site laboratory for analysis to meet a 24 hour holding time. EPA is developing guidance for systems on packing and shipping *E. coli* samples so that sample ~~temperature is~~ are maintained ~~between 0°C below 10°C~~ and ~~10°C not~~ allowed to freeze (USEPA 2002j3g). This guidance is available in draft ~~from~~ in the docket for today's proposal (<http://www.epa.gov/edocket/>).

*c. Request for comment.* EPA requests comment on whether the *E. coli* methods proposed for approval under the LT2ESWTR are appropriate, and whether there are additional methods not proposed that should be considered. Comments concerning method approval should be accompanied by supporting data where possible.

EPA also requests comment on ~~extending the proposal to extend~~ the holding time for *E. coli* source water sample analyses to 24 hours, including any data or other information that would support, modify, or repudiate such an extension. Should EPA limit the extended holding time to only those *E. coli*- analytical methods that were evaluated in the holding time studies noted in this section? The results in Pope et al. (2002j3) indicate that most *E. coli*- samples analyzed using ONPG-MUG (see methods in Table IV-37) incurred no significant degradation after a 30 ~~to 48~~ hour holding time. ~~As a result, should EPA increase the source water *E. coli*- holding time to 30 hours to facilitate compliance by systems that must ship samples off-site for analysis? or 48 hours for samples evaluated by ONPG-MUG, and retain a 24-hour holding time for~~

samples analyzed by other methods? EPA also requests comment on the cost and availability of overnight delivery services for E. coli samples, especially in rural areas.

### 3. Turbidity

a. *What is EPA proposing today?* For turbidity analyses that will be conducted under the LT2ESWTR, EPA is proposing to require systems to use the analytical methods that have been previously approved by EPA for analysis of turbidity in drinking water, as listed in 40 CFR Part 141.74. These are Method 2130B as published in *Standard Methods for the Examination of Water and Wastewater* (APHA, 1992); EPA Method 180.1 (USEPA 1993); and Great Lakes Instrument Method 2 (Great Lakes Instruments, 1992).

~~In addition, under a separate rulemaking, *Unregulated Contaminant Monitoring Regulation: Approval of Analytical Method for Aeromonas*; *National Primary and Secondary Drinking Water Regulations: Approval of Analytical Methods for Chemical and Microbiological Contaminants* (67 FR 10532, March 7, 2002), EPA has proposed to approve Hach Filter Trak (Method 10133) for NPDWR compliance monitoring of turbidity below 1.0 NTU. If this method is approved under this rulemaking, EPA is proposing that it be approved for finished water turbidity monitoring under the LT2ESWTR.~~

and Hach FilterTrak Method 10133.

EPA method 180.1 and Standard Method 2130B are both nephelometric methods and are based upon a comparison of the intensity of light scattered by the sample under defined conditions with the intensity of light scattered by a standard

reference suspension. Great Lakes Instruments Method 2 is ~~an instrument specific,~~ a modulated four beam infrared method using a ratiometric algorithm to calculate the turbidity value from the four readings that are produced. Hach Filter Trak (Method 10133) ~~“Determination of Turbidity by Laser Nephelometry” is an additional industry developed method that employs a laser nephelometer~~ is a laser-based nephelometric method used to determine the turbidity of finished drinking waters.

~~Turbidity is a method-defined parameter. Turbidity therefore is not a candidate for, and will not be subject to, the performance-based measurements system.~~

#### *Turbidimeters*

Systems are required to use turbidimeters ~~consistent with~~ described in EPA- ~~approved methods for measuring turbidity. For regulatory reporting purposes, either an on-line or a bench top turbidimeter can be used. If a system chooses to use on-line units for monitoring, the system must validate the continuous measurements for accuracy on a regular basis using a protocol approved by the State.~~

*b. How was this proposal developed?* EPA believes the currently approved ~~and proposed~~ methods for analysis of turbidity in drinking water are appropriate for turbidity analyses that will be conducted under the LT2ESWTR.

*c. Request for comment.* EPA requests comment on whether the turbidity methods proposed today for the LT2ESWTR should be approved, and whether there are additional methods not proposed that should be approved. ~~EPA requests that any comments on method approval include supporting data where available.~~

#### *L. Laboratory Approval*

Given the potentially significant implications in terms of both cost and public

health protection of microbial monitoring under the LT2ESWTR, laboratory analyses for *Cryptosporidium*, *E. coli*, and turbidity must be accurate and reliable within the limits of approved methods. Therefore, EPA proposes to require public water systems to use laboratories that have been approved to conduct analyses for these parameters by EPA or the State. The following criteria are proposed for laboratory approval under the LT2ESWTR:

- For *Cryptosporidium* analyses under the LT2ESWTR, EPA proposes to approve laboratories that have passed a quality assurance evaluation under EPA's Laboratory Quality Assurance Evaluation Program (Lab QA Program) for Analysis of *Cryptosporidium* in Water (described in 67 FR 9731, March 4, 2002) (USEPA 2002c). If States adopt an equivalent approval process under State laboratory certification programs, then systems can use laboratories approved by the State.
- For *E. coli* analyses, EPA proposes to approve laboratories that have been certified by ~~the State or EPA to conduct analyses for total coliforms and fecal coliforms in drinking~~ EPA, the National Environmental Laboratory Accreditation Conference, or the State for total coliform or fecal coliform analysis in source water under 40 CFR 141.74. The laboratory must use the same analytical technique for *E. coli* that the laboratory uses for total coliform or fecal coliform analysis under 40 CFR 141.74.
- Turbidity analyses must be conducted by a person approved by the State for analysis of turbidity in drinking water under 40 CFR 141.74.

These criteria are further described in the following paragraphs.

## 1. *Cryptosporidium* laboratory approval

Because States do not currently approve laboratories for *Cryptosporidium* analyses and LT2ESWTR monitoring will begin 6 months after rule promulgation, EPA will initially assume responsibility for *Cryptosporidium* laboratory approval. EPA expects, however, that States will include *Cryptosporidium* analysis in their State laboratory certification programs in the future. EPA has established the Lab QA Program for *Cryptosporidium* analysis to identify laboratories that can meet LT2ESWTR data quality objectives. This is a voluntary program open to laboratories involved in analyzing *Cryptosporidium* in water. Under this program, EPA assesses the ability of laboratories to reliably measure *Cryptosporidium* occurrence with EPA Methods 1622 and 1623, using both performance testing samples and an on-site evaluation.

EPA initiated the Lab QA Program for *Cryptosporidium* analysis prior to promulgation of the LT2ESWTR to ~~assure~~ensure that adequate sample analysis capacity will be available at qualified laboratories to support the required monitoring. The Agency ~~tracks laboratory~~is monitoring sample analysis capacity at approved laboratories through the Lab QA Program, and does not plan to ~~finalize the~~implement LT2ESWTR monitoring until the Agency determines that there is adequate laboratory capacity ~~has been established~~. In addition, utilities that choose to conduct *Cryptosporidium* monitoring prior to LT2ESWTR promulgation with the intent of grandfathering the data may elect to use laboratories that have passed the EPA quality assurance evaluation.

Laboratories seeking to participate in the EPA Lab QA Program for *Cryptosporidium* analysis must submit an interest application to EPA, successfully

analyze a set of initial performance testing samples, and undergo an on-site evaluation. The on-site evaluation includes two separate but concurrent assessments: (1) assessment of the laboratory's sample processing and analysis procedures, including microscopic examination, and (2) evaluation of the laboratory's personnel qualifications, quality assurance/quality control program, equipment, and recordkeeping procedures.

Laboratories that pass the quality assurance evaluation will be eligible for approval for *Cryptosporidium* analysis under the LT2ESWTR. The Lab QA Program is described in detail in a Federal Register Notice (67 FR 9731, March 4, 2002) ([USEPA 2002c](#)) and additional information can be found online at: [www.epa.gov/safewater/lt2/cla\\_int.html](http://www.epa.gov/safewater/lt2/cla_int.html).

Laboratories in the Lab QA Program will receive a set of three ongoing proficiency testing (OPT) samples approximately every four months. EPA [plans to will](#) evaluate the precision and recovery data for OPT samples to determine if the laboratory continues to meet the performance criteria of the Laboratory QA Program.

## 2. *E. coli* laboratory approval

Public water systems are required to have samples analyzed for *E. coli* by laboratories certified under the State drinking water certification program to perform total coliform and fecal coliform analyses under 40 CFR 141.74. EPA is proposing that the general analytical techniques the laboratory is certified to use under the drinking water certification program (e.g., membrane filtration, multiple-well, multiple-tube) will be the methods the laboratory can use to conduct *E. coli* source water analyses under the LT2ESWTR.

## 3. Turbidity analyst approval

Measurements of turbidity must be conducted by a party approved by the State. This is consistent with current requirements for turbidity measurements in drinking water (40 CFR 141.74).

#### 4. Request for comment

EPA requests comment on the laboratory approval requirements proposed today, including the following specific issues:

##### *Analyst experience criteria*

The Lab QA Program, which EPA will use to approve laboratories for *Cryptosporidium* analyses under the LT2ESWTR, includes criteria for analyst experience. Principal analyst/supervisors (minimum of one per laboratory) should have a minimum of one year of continuous bench experience with *Cryptosporidium* and immunofluorescent assay (IFA) microscopy, a minimum of six months experience using EPA Method 1622 and/or 1623, and a minimum of 100 samples analyzed using EPA Method 1622 and/or 1623 (minimum 50 samples if the person was an analyst approved to conduct analysis for the Information Collection Rule Protozoan Method) for the specific analytical procedure they will be using.

Under the Lab QA Program, other analysts (no minimum number of analysts per laboratory) should have a minimum of six months of continuous bench experience with *Cryptosporidium* and IFA microscopy, a minimum of three months experience using EPA Method 1622 and/or 1623, and a minimum of 50 samples analyzed using EPA Method 1622 and/or 1623 (minimum 25 samples if the person was an analyst approved to conduct analysis for the Information Collection Rule Protozoan Method) for the specific analytical procedures they will be using.

The Lab QA Program criteria for principal analyst/supervisor experience are more rigorous than those in Methods 1622 and 1623, which are as follows: the analyst must have at least 2 years of college lecture and laboratory course work in microbiology or a closely related field. The analyst also must have at least 6 months of continuous bench experience with environmental protozoa detection techniques and IFA microscopy, and must have successfully analyzed at least 50 water and/or wastewater samples for *Cryptosporidium*. Six months of additional experience in the above areas may be substituted for two years of college.

In seeking approval for an Information Collection Request, EPA requested comment on the Lab QA Program (67 FR 9731, March 4, 2002) (USEPA 2002c). A number of commenters stated that the analyst qualification criteria are restrictive and could make it difficult for laboratories to maintain adequate analyst staffing (and, hence, sample analysis capacity) in the event of staff turnover or competing priorities. Some commenters suggested that laboratories and analysts should be evaluated based on proficiency testing, and that analyst experience standards should be reduced or eliminated. (Comments are available in Office of Water docket, number W-01-17).

Another aspect of the analyst experience criteria is that systems may generate *Cryptosporidium* data for grandfathering under the LT2ESWTR using laboratories that meet the analyst experience requirement of Methods 1622 or 1623; but not the more rigorous principal analyst/supervisor experience requirement of the Lab QA Program.

EPA requests comment on whether the criteria for analyst experience in the Lab QA Program are necessary, whether systems are experiencing difficulty in finding laboratories that have passed the Lab QA Program to conduct *Cryptosporidium*

analysis, and whether any of the Lab QA Program criteria should be revised to improve the LT2ESWTR lab approval process.

State programs to approve laboratories for *Cryptosporidium* analysis

Under today's proposal, systems must have *Cryptosporidium* samples analyzed by a laboratory approved under EPA's Lab QA Program, or an equivalent State laboratory approval program. Because States do not currently approve laboratories for *Cryptosporidium* analyses, EPA will initially assume responsibility for *Cryptosporidium* laboratory approval. EPA expects, however, that States will adopt equivalent approval programs for *Cryptosporidium* analysis under State laboratory certification programs. EPA requests comment on how to establish that a State approval program for *Cryptosporidium* analysis is equivalent to the Lab QA Program.

Specifically, should EPA evaluate State Approval programs to determine if they are equivalent to the Lab QA Program? EPA also requests comment on the elements that would constitute an equivalent State approval program for *Cryptosporidium* analyses, including the following: (1) successful analysis of initial and ongoing blind proficiency testing samples prepared using flow cytometry, including a matrix and meeting EPA's pass/fail criteria (described in USEPA 2002c); (2) an on-site evaluation of the laboratory's sample processing and analysis procedures, including microscopic examination skills, by auditors who meet the qualifications of a principal analyst as set forth in the Lab QA Program (described in USEPA 2002c); (3) an on-site evaluation of the laboratory's personnel qualifications, quality assurance/quality control program, equipment, and recordkeeping procedures; (4) a data audit of the laboratories' QC data and monitoring data; and (5) use of the audit checklist used in the Lab QA Program or

equivalent.

### *M. Requirements for Sanitary Surveys Conducted by EPA*

#### 1. Overview

In today's proposal, EPA is ~~taking~~requesting comment on establishing requirements for public water systems with significant deficiencies as identified in a sanitary survey conducted by EPA under SDWA section 1445. These requirements would apply to surface water systems for which EPA is responsible for directly implementing national primary drinking water regulations (i.e., systems not regulated by States with primacy). As described in this section, these requirements would ensure that systems in non-primacy States, currently Wyoming, and systems not regulated by States, such as Tribal systems, ~~meet the same~~are subject to standards for sanitary surveys as similar to those that apply to systems regulated by States with primacy.

#### 2. Background

As established by the IESWTR in 40 CFR 142.16(b)(3), primacy States must conduct sanitary surveys for all surface water systems no less frequently than every three years for community water systems and no less frequently than every five years for noncommunity water systems. The sanitary survey is an onsite review and must address the following eight components: (1) source, (2) treatment, (3) distribution system, (4) finished water storage, (5) pumps, pump facilities, and controls, (6) monitoring, reporting, and data verification, (7) system management and operation, and (8) operator compliance with State requirements.

Under the IESWTR, primacy States are required to have the appropriate rules or other authority to assure that systems respond in writing to significant deficiencies

outlined in sanitary survey reports no later than 45 days after receipt of the report, indicating how and on what schedule the system will address significant deficiencies noted in the survey (40 CFR 142.16(b)(1)(ii)). Further, primacy States must have the authority to assure that systems take necessary steps to address significant deficiencies identified in sanitary survey reports if such deficiencies are within the control of the system and its governing body (40 CFR 142.16(b)(1)(iii)). The IESWTR did not define a significant deficiency, but required that primacy States describe in their primacy applications how they will decide whether a deficiency identified during a sanitary survey is significant for the purposes of the requirements stated in this paragraph (40 CFR 142.16(b)(3)(v)).

EPA conducts sanitary surveys under SDWA section 1445 for public water systems not regulated by primacy States (e.g., Tribal systems, Wyoming). However, EPA does not have the authority required of primacy States under 40 CFR 142 to ensure that systems address significant deficiencies identified during sanitary surveys. Consequently, the sanitary survey requirements established by the IESWTR create an unequal standard. Systems regulated by primacy States are subject to the ~~requirement to correct~~ States' authority to require correction of significant deficiencies noted in sanitary survey reports, while systems for which EPA has direct implementation authority do not have to meet an equivalent requirement.

### 3. Request for comment

In order to ensure that systems for which EPA has direct implementation authority address significant deficiencies identified during sanitary surveys, EPA requests comment on establishing either or both of the following requirements under 40

CFR 141 as part of the NPDWR established in the final LT2ESWTR:

——— (1) For sanitary surveys conducted by EPA under SDWA section 1445, systems ~~must~~would be required to respond in writing to significant deficiencies outlined in sanitary survey reports no later than 45 days after receipt of the report, indicating how and on what schedule the system will address significant deficiencies noted in the survey.

(2) Systems ~~must address~~would be required to correct significant deficiencies identified in sanitary survey reports if such deficiencies are within the control of the system and its governing body.

For the purposes of ~~this paragraph~~these requirements, a sanitary survey, as conducted by EPA, ~~includes but is not limited to~~is an onsite review of the water source (identifying sources of contamination by using results of source water assessments where available), facilities, equipment, operation, maintenance, and monitoring compliance of a public water system to evaluate the adequacy of the system, its sources and operations, and the distribution of safe drinking water. A significant deficiency includes a defect in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that EPA determines to be causing, or has the potential for causing the introduction of contamination into the water delivered to consumers.

## **V. State Implementation**

This section describes the regulations and other procedures and policies States will be required to adopt to implement the LT2ESWTR, if finalized as proposed today.

States must continue to meet all other conditions of primacy in 40 CFR Part 142.

The Safe Drinking Water Act (Act) establishes requirements that a State or eligible Indian Tribe must meet to assume and maintain primary enforcement responsibility (primacy) for its public water systems. These requirements include: (1) adopting drinking water regulations that are no less stringent than Federal drinking water regulations, (2) adopting and implementing adequate procedures for enforcement, (3) keeping records and making reports available on activities that EPA requires by regulation, (4) issuing variances and exemptions (if allowed by the State), under conditions no less stringent than allowed under the Act, and (5) adopting and being capable of implementing an adequate plan for the provisions of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the public water supply supervision program as authorized under section 1413 of the Act. In addition to adopting basic primacy requirements specified in 40 CFR Part 142, States may be required to adopt special primacy provisions pertaining to specific regulations where implementation of the rule involves activities beyond general primacy provisions. States must include these regulation specific provisions in an application for approval of their program revision. Primacy requirements for today's proposal are discussed below.

To implement the proposed LT2ESWTR, States will be required to adopt revisions to:

§141.2 - Definitions

§141.71 - Criteria for avoiding filtration

§141.153 - Content of the reports

§141.170 - Enhanced filtration and disinfection

Subpart Q - Public Notification

New Subpart W - Additional treatment technique requirements for *Cryptosporidium*

§142.14 - Records kept by States

§142.15 - Reports by States

§142.16 - Special primacy requirements

*A. Special State Primacy Requirements*

To ensure that a State program includes all the elements necessary for an effective and enforceable program under today's rule, a State primacy application must include a description of how the State will perform the following:

- (1) Approve watershed control programs for the 0.5 log watershed control program credit in the microbial toolbox (see section IV.C.2);
- (2) Assess significant changes in the watershed and source water as part of the sanitary survey process and determine appropriate follow-up action (see section IV.A);
- (3) Determine that a system with an uncovered finished water reservoir storage facility has a risk mitigation plan that is adequate for purposes of waiving the requirement to cover the reservoir storage facility or treat the ~~reservoir~~ effluent (see section IV.E); ~~and~~
- (4) Approve protocols for removal credits under the Demonstration of Performance toolbox options option (see section IV.C.17) and for site specific chlorine dioxide and ozone CT tables (see section IV.C.184); ~~and~~
- (5) Approve laboratories to analyze for *Cryptosporidium*.

————— Note that a State program can be more, but not less, stringent than

Federal regulations. As such, some of the elements listed here may not be applicable to a specific State program. For example, if a State chooses to require all finished water storage facilities to be covered or provide treatment and not to allow a risk mitigation plan to substitute for this requirement, then the description for item (3) would be inapplicable.

#### B. State Recordkeeping Requirements

The current regulations in §142.14 require States with primacy to keep various records, including the following: analytical results to determine compliance with MCLs, MRDLs, and treatment technique requirements; system inventories; State approvals; enforcement actions; and the issuance of variances and exemptions. The proposed LT2ESWTR will require States to keep additional records of the following, including all supporting information and an explanation of the technical basis for each decision:

- 
- Results of source water *E. coli* and *Cryptosporidium* monitoring;
  - *Cryptosporidium* ~~risk~~ bin classification for each filtered system, including any changes to initial bin classification based on review of the watershed during sanitary surveys or the second round of monitoring;
  - Determination of whether each unfiltered system has a mean source water *Cryptosporidium* level above 0.01 oocysts/L;
  - The treatment processes or control measures that each system employs to meet ~~LT2ESWTR~~ *Cryptosporidium* treatment ~~technique~~ requirements under the LT2ESWTR; this includes documentation to demonstrate compliance with required design and implementation criteria for receiving credit for microbial

toolbox options, as specified in section IV.C;

- A list of systems required to cover or treat the effluent of an uncovered finished water reservoir storage facilities; and
- A list of systems for which the State has waived the requirement to cover or treat the effluent of an uncovered finished water reservoir storage facility, along with supporting documentation of the risk mitigation plan.

### C. State Reporting Requirements

EPA currently requires in § 142.15 that States report to EPA information such as violations, variance and exemption status, and enforcement actions. The LT2ESWTR, as proposed, will add additional reporting requirements in the following areas:

- ~~(1) Initial~~ The *Cryptosporidium* bin classification for each filtered system ~~and~~ including any changes into initial bin classifications due classification based on review of to the watershed assessment during sanitary surveys or the second round of monitoring;
- The determination of whether each unfiltered system has a mean source water *Cryptosporidium* monitoring;
- ~~(2) The technologies that filtered systems employ to meet their action bin requirements (level above 0.01 oocysts/L, including any changes in toolbox treatment technologies) and the disinfectants employed by unfiltered systems to meet inactivation requirements. The treatment processes and other control measures that systems employ to meet *Cryptosporidium* treatment technique requirements.~~ to this determination based on the second round of monitoring.

#### *D. Interim Primacy*

On April 28, 1998, EPA amended its State primacy regulations at 40 CFR 142.12 to incorporate the new process identified in the 1996 SDWA Amendments for granting primary enforcement authority to States while their applications to modify their primacy programs are under review (63 FR 23362, April 28, 1998) (USEPA 1998f). The new process grants interim primary enforcement authority for a new or revised regulation during the period in which EPA is making a determination with regard to primacy for that new or revised regulation. This interim enforcement authority begins on the date of the primacy application submission or the effective date of the new or revised State regulation, whichever is later, and ends when EPA makes a final determination. However, this interim primacy authority is only available to a State that has primacy (including interim primacy) for every existing NPDWR in effect when the new regulation is promulgated.

As a result, States that have primacy for every existing NPDWR already in effect may obtain interim primacy for this rule, beginning on the date that the State submits the application for this rule to USEPA, or the effective date of its revised regulations, whichever is later. In addition, a State that wishes to obtain interim primacy for future NPDWRs must obtain primacy for this rule. As described in Section IV.A, EPA expects to oversee the initial source water monitoring that will be conducted under the LT2ESWTR by systems serving at least 10,000 people, beginning 6 months following rule promulgation.

## **VI. Economic Analysis**

This section summarizes the economic analysis (EA) for the LT2ESWTR proposal. The EA is an assessment of the benefits, both health and non-health related, and costs to the regulated community of the proposed regulation, along with those of regulatory alternatives that the Agency considered. EPA developed this EA to meet the requirement of SDWA section 1412(b)(3)(C) for a Health Risk Reduction and Cost Analysis (HRRCA), as well as the requirements of Executive Order 12866, Regulatory Planning and Review, under which EPA must estimate the costs and benefits of the LT2ESWTR. The full EA is presented in *Economic Analysis for the Long Term 2 Enhanced Surface Water Treatment Rule* (USEPA 2002~~3~~<sup>3</sup>a), which is available in the docket for today's proposal ([www.epa.gov.edocket/](http://www.epa.gov.edocket/)).

Today's proposed LT2ESWTR is the second in a staged set of rules that address public health risks from microbial contamination of surface and GWUDI drinking water supplies and, more specifically, prevent *Cryptosporidium* from reaching consumers. As described in section I, the Agency promulgated the IESWTR and LT1ESWTR to provide a baseline of protection against *Cryptosporidium* in large and small drinking water systems, respectively. Today's proposed rule would achieve further reductions in *Cryptosporidium* exposure for systems with the highest risk vulnerability. ~~This economic analysis considers only the incremental reduction in exposure between from the two previously promulgated rules (IESWTR and LT1ESWTR) to the alternatives evaluated for the LT2ESWTR is included in this analysis.~~

Both benefits and costs are determined as annualized present values. The process allows comparison of cost and benefit streams that are variable over a given time period. The time frame used for both benefit and cost comparisons is 25 years;

approximately five years account for rule implementation and 20 years for the average useful life of the equipment used to comply with treatment technique requirements. The Agency uses social discount rates of both three percent and seven percent to calculate present values from the stream of benefits and costs and also to annualize the present value estimates ([see EPA's Guidelines for Preparing Economic Analyses \(USEPA 2000c\) for a discussion of social discount rates](#)). The LT2ESWTR EA (USEPA 2002~~3~~a) also shows the undiscounted stream of both benefits and costs over the 25 year time frame.

#### A. What Regulatory Alternatives Did the Agency Consider?

Regulatory alternatives considered by Agency for the LT2ESWTR were developed through the deliberations of the Stage 2 M-DBP Federal Advisory Committee (described in section II). The Committee considered several general approaches for reducing the risk from *Cryptosporidium* in drinking water. As discussed in section IV.A.2, these approaches included both additional treatment requirements for all systems and risk-targeted treatment requirements for systems with the highest vulnerability to *Cryptosporidium* following implementation of the IESWTR and LT1ESWTR. In addition, the Committee considered related factors such as surrogates for *Cryptosporidium* monitoring and alternative monitoring strategies to minimize costs to small drinking water systems.

After considering these general approaches, the Committee focused on four specific regulatory alternatives for filtered systems— ([see Table VI-1 summarizes these four alternatives](#)). With the exception of Alternative 1, which requires all systems to achieve an additional 2 log (99%) reduction in *Cryptosporidium* levels, these

alternatives incorporate a microbial framework approach. In this approach, systems are classified in different risk bins based on the results of source water monitoring. Additional treatment requirements are directly linked to the risk bin classification. Accordingly, these rule alternatives are differentiated by two criteria: (1) the *Cryptosporidium* concentrations that define the bin boundaries and (2) the degree of treatment required for each bin.

In assessing regulatory alternatives, EPA and the Advisory Committee were concerned with the following questions: (1) Do the treatment requirements adequately control *Cryptosporidium* concentrations in finished water? (2) How many systems will be required to add treatment?, (3) What is the likelihood that systems with high source water *Cryptosporidium* concentrations will not be required to provide additional treatment (i.e., be misclassified in a low risk bin)? and (4) What is the likelihood that systems with low source water *Cryptosporidium* concentrations will be required to provide unnecessary additional treatment (i.e., misclassified in a high risk bin)?

The Committee reached consensus regarding additional treatment requirements for unfiltered systems and uncovered finished water ~~reservoirs~~storage facilities without formally identifying regulatory alternatives.

Table VI-1 summarizes the four alternatives that were considered for filtered systems.

**Table VI-1.-- Summary of Regulatory Alternatives for Filtered ~~System's Action Bin~~  
Requirements by Rule Alternative~~Systems~~**

<u>Avg. Source Water <i>Cryptosporidium</i> Monitoring Results</u> (oocysts/L)	<u>Additional Treatment Requirements</u> <sup>1</sup>
<b>Alternative A1</b>	
2.0 log inactivation required for all systems	
<b>Alternative A2</b>	
< 0.03	No action
\$ 0.03 and < 0.1	0.5 log
\$ 0.1 and < 1.0	1.5 log
\$ 1.0	2.5 log
<b>Alternative A3 - Preferred Alternative</b>	
< 0.075	No action
\$ 0.075 and < 1.0	1 log
\$ 1.0 and < 3.0	2 log
\$ 3.0	2.5 log
<b>Alternative A4</b>	
< 0.1	No action
\$ 0.1 and < 1.0	0.5- log
\$1.0	1.0 log

Note: "Additional treatment requirements" are in addition to levels already required under existing rules (e.g., the IESWTR and LT1ESWTR). Source: Chapter 3 of the LT2ESWTR Economic Analysis (USEPA 2002a)

*B. What Analyses Support Selecting the Proposed Rule Option?*

EPA has quantified benefits and costs of each of the regulatory alternatives in Table VI-1. ~~The Agency analyzed data collected under the Information Collection Rule, the Information Collection Rule Supplemental Surveys for medium systems (ICRSSM), and the Information Collection Rule Supplemental Surveys for large systems (ICRSSL) to generate estimates of the national occurrence distribution of *Cryptosporidium* in surface water (described in section III.C). EPA then evaluated these distributions under different regulatory scenarios to assess benefits and costs. These data sets are used independently. In most cases, results from the ICRSSM data set are within the range~~

of results of the Information Collection Rule and ICRSSL data sets; therefore, ICRSSM results are not included in the preamble but are located in the appendices to the LT2ESWTR EA (USEPA 2002a).

To estimate changes, as well as for the proposed requirements for unfiltered systems. Quantified benefits stem from estimated reductions in the incidence of cryptosporidiosis ~~that would result~~resulting from this ~~rule~~regulation. To make these estimates, the Agency developed a two-dimensional Monte Carlo model that accounts for uncertainty and variability in key parameters like Cryptosporidium occurrence, infectivity, and treatment efficiency. ~~The analysis~~Analyses involved estimating the baseline (pre-LT2ESWTR) ~~level of exposure and~~ risk from *Cryptosporidium* in drinking water, and then projecting the reductions in exposure and risk resulting from the additional treatment requirements of the LT2ESWTR. Costs result largely from the installation of additional treatment, with lesser costs due to monitoring and other implementation activities. Results of these analyses are summarized in the following subsections, and details are shown in the LT2ESWTR EA (USEPA ~~2002a~~2003a).

Cryptosporidium occurrence significantly influences the estimated benefits and costs of regulatory alternatives. As discussed in section III.C, EPA analyzed data collected under the Information Collection Rule, the Information Collection Rule Supplemental Surveys of medium systems (ICRSSM), and the Information Collection Rule Supplemental Surveys of large systems (ICRSSL) to estimate the national occurrence distribution of Cryptosporidium in surface water. EPA evaluated these distributions independently when assessing benefits and costs for different regulatory alternatives. In most cases, results from the ICRSSM data set are within the range of

results of the Information Collection Rule and ICRSSL data sets.

EPA selected a Preferred Regulatory Alternative for the LT2ESWTR, consistent with the recommendations of the Advisory Committee. As described next, this selection was based on the estimated impacts and feasibility of the alternatives shown in Table VI-1.

Alternative A1 (across-the-board 2-log inactivation) was not selected because it was the highest cost option and imposed costs but provided few benefits to systems with high quality source water (i.e., relatively low *Cryptosporidium* risk). In addition, there were concerns about the feasibility of requiring almost every surface water treatment plant to install additional treatment processes (e.g., UV or ozone) for *Cryptosporidium*.

Alternatives A2 - A4 were evaluated based on several factors, including predictions of costs and benefits, feasibility performance of implementation analytical methods for classifying systems in the risk bins, and other specific impacts (e.g., impacts on small systems or sensitive subpopulations). Alternative A3 was recommended by the Advisory Committee and selected by EPA as the Preferred Regulatory Alternative because it provides significant health benefits in terms of avoided illnesses and deaths for an acceptable cost. In addition, the Agency believes this alternative is feasible with available analytical methods and treatment technologies.

Incremental costs and benefits of regulatory alternatives for the LT2ESWTR are shown in section VI.F, and the LT2ESWTR EA contains more detailed information about the benefits and costs of each regulatory option (USEPA 20023a).

### *C. What Are the Benefits of the Proposed LT2ESWTR?*

As ~~described~~discussed previously, the LT2ESWTR is expected to substantially reduce drinking water related exposure to *Cryptosporidium*, thereby reducing both illness and death associated with cryptosporidiosis. As described in section II, cryptosporidiosis is an infection caused by *Cryptosporidium* and is an acute, typically self-limiting, illness with symptoms that include diarrhea, abdominal cramping, nausea, vomiting, and fever (Juraneck, 1995). Cryptosporidiosis patients in sensitive subpopulations, such as infants, the elderly, and AIDS patients, are at risk for severe illness, including risk of ~~mortality~~death. While EPA has quantified and monetized the health benefits for reductions in endemic cryptosporidiosis that would result from the LT2ESWTR, the Agency was unable to quantify or monetize other health and non-health related benefits associated with this rule. These unquantified benefits are characterized next, followed by a summary of the quantified benefits.

#### 1. Non-quantifiable health and non-health related benefits

Although there are substantial monetized benefits that result from this rule due to reduced rates of endemic cryptosporidiosis, other potentially significant benefits of this rule remain unquantified and non-monetized. The unquantified benefits that result from this rule are summarized in Table VI-2 and are described in greater detail in the LT2ESWTR EA (USEPA 20023a).

#### **Table VI-2.– Summary of Nonquantified Benefits**

Benefit Type	Potential Effect on Benefits	Comments
Reducing outbreak risks and response costs	Increase	Determining the precise reduction in outbreak risk and resulting benefits is not possible given current information; however, the positive benefits associated with a reduction in outbreak risk are expected to be significant. <u>Some outbreaks are caused by human or equipment failures that may occur even with the proposed new requirements; however, by adding barriers of protection for some systems, the rule will reduce the possibility of such failures leading to outbreaks.</u>
Reducing averting behavior (e.g., boiling tap water or purchasing bottled water)	Increase / No Change	Averting behavior is associated with both out-of-pocket costs (e.g., purchase of bottled water) and opportunity costs (e.g., time required to boil water) to the consumer. Reductions in averting behavior are expected to have a positive impact on benefits from the rule.
Improving aesthetic water quality	Increase	<u>Improved filtration, which systems will implement to increase the removal of Cryptosporidium, will also decrease levels of turbidity and particle associated contaminants in finished water. Some technologies installed for this rule (e.g., ozone) are likely to reduce taste and odor problems.</u>
Reducing risk from co-occurring and emerging pathogens	Increase	Although focused on removal of <i>Cryptosporidium</i> from drinking water, systems that change treatment processes will also increase removal of pathogens that the rule does not specifically regulate. Additional benefits will accrue.
Increased source water monitoring	Increase	The greater understanding of source water quality that results from monitoring may enhance the ability of plants to optimize treatment operations <u>in ways other than those addressed in this rule.</u>
<u>Reduced contamination due to covering all or treating finished water reservoirs storage facilities</u>	Increase	Although insufficient data were available to quantify benefits, the reduction of contaminants introduced through uncovered finished water <u>reservoirs storage facilities</u> would produce positive public health benefits.

Source: Chapter 5 of the LT2ESWTR Economic Analysis (USEPA 2002<sup>3a</sup>)

## 2. Quantifiable health benefits

EPA quantified benefits for the LT2ESWTR based on reductions in the risk of endemic cryptosporidiosis. ~~Table VI-3 summarizes the annual cases of cryptosporidiosis illness and associated deaths avoided due to the LT2ESWTR, with estimates for both the Information Collection Rule and ICRSSL data sets. The proposed rule, on average, is expected to reduce 244,871 to 1,016,852 illnesses and 36 to 141 deaths annually after full implementation (range based on the ICRSSL and Information Collection Rule data sets).~~

~~**Table VI-3.-- Summary of Annual Avoided Illness and Deaths**~~

~~Source: The *LT2ESWTR Economic Analysis* (USEPA 2002a)~~

~~Table VI-4 shows the monetized present value of the benefit for reductions in endemic cryptosporidiosis that would result from the LT2ESWTR. Values are given for both the Information Collection Rule and ICRSSL data sets. Using a three percent discount rate, the annual present value of the mean benefit estimate ranges from \$361 million to \$1.4 billion, with a 90 percent confidence bound of \$35 million to \$297 million at the lower 5<sup>th</sup> percentile and \$1.1 billion to \$3.5 billion at the upper 95<sup>th</sup> percentile. At a seven percent discount rate, the mean quantified benefit estimate ranges from \$308 million to \$1.2 billion, with a 90 percent confidence bound of \$30 million to \$252 million at the lower 5<sup>th</sup> percentile and \$900 million to \$3.0 billion at the upper 95<sup>th</sup> percentile. These values underestimate the total benefits of the rule because they do not include the unquantified and non-monetized Several categories of monetized benefits discussed previously.~~

~~**Table VI-4.-- Summary of Quantified Benefits (\$millions, 2000\$)**~~

~~Source: The *LT2ESWTR Economic Analysis* (USEPA 2002a)~~

~~In monetizing the benefit from the cases of cryptosporidiosis avoided, the Agency used different values for reduced morbidity and mortality rates. A value of statistical life (VSL) estimate was applied to the fraction of avoided cases attributed to the LT2ESWTR that would have resulted in mortality. To value mortalities, the Agency uses a distribution of VSL values that is based on 26 wage-risk studies. The mean VSL value from these studies is \$4.8 million in 1990 dollars and this estimate is updated in real terms to year 2000 dollars (\$6.3 million). A more detailed discussion of these studies and the VSL estimate can be found in EPA's *Guidelines for Preparing Economic Analyses* (USEPA 2000b).~~

~~were considered in this analysis.~~

~~First, EPA estimated the number of cases expected to result in premature mortality (primarily for members of sensitive subpopulations such as AIDS patients).~~ In order to estimate the benefits from deaths avoided as a result of the rule, EPA multiplied the estimates for number of illnesses avoided by a projected mortality rate. This mortality rate was developed using mortality data from the Milwaukee cryptosporidiosis outbreak of 1993 (described in section II), ~~with adjustments to account for the subsequent decrease in the mortality rate among people with AIDS and for the difference between the 1993 Milwaukee AIDS rate and the current national rate.~~ EPA estimated a mortality rate of 16.6 deaths per 100,000 illnesses for those served by unfiltered systems and a mortality rate of 10.6 deaths per 100,000 illnesses for those served by filtered systems. These different rates are associated with the incidence of AIDS in populations served by unfiltered and filtered systems. A complete discussion

on how EPA derived these rates can be found in subchapter 5.2 of the LT2ESWTR EA (USEPA 2002a).

~~The~~ 2003a.

Reductions in mortalities were monetized using EPA's standard methodology for monetizing mortality risk reduction. This methodology is based on a distribution of value of statistical life (VSL) estimates from 26 labor market and stated preference studies, with a mean VSL of \$6.3M in 2000, and a 5<sup>th</sup> to 95<sup>th</sup> percentile range of \$1.0 to \$14.5. A more detailed discussion of these studies and the VSL estimate can be found in EPA's Guidelines for Preparing Economic Analyses (USEPA 2000c). A real income growth factor was applied to these estimates of approximately 2.3% per year for the 20 year time span following implementation. Income elasticity for VSL was estimated as a triangular distribution that ranged from 0.08 to 1.00, with a mode of 0.40. VSL values for the 20 year span are shown in the LT2 EA in Exhibit C.13 (USEPA 2003a).

The substantial majority of cases are not expected to be fatal and the Agency separately estimated the value of non-fatal illnesses avoided that would result from the LT2ESWTR. The goal with this estimate was to provide as complete an accounting as possible of the social welfare impacts of the regulatory options under consideration. Based on the principles of welfare economics, the preferred approach for valuing reductions in the risk of cryptosporidiosis-related morbidity is to rely on estimates of For these, EPA first divided projected cases into three categories, mild, moderate, and severe, and then calculated a monetized value per case avoided for each severity level. These were then combined into a weighted average value per case based on the relative frequency of each severity level. According to a study conducted by Corso et

al. (2003), the majority of illness fall into the mild category (88 percent). Approximately 11 percent of illness fall into the moderate category, which is defined as those who seek medical treatment but are not hospitalized. The final one percent have severe symptoms that result in hospitalization. EPA estimated different medical expenses and time losses for each category.

Benefits for non-fatal cases were calculated using a cost-of-illness (COI) approach. Traditional COI valuations focus on medical costs and lost work time, and leave out significant categories of benefits, specifically the reduced utility from being sick (i.e., lost personal or non-work time, including activities such as child care, homemaking, community service, time spent with family, and recreation), although some COI studies also include an estimate for unpaid labor (household production) valued at an estimated wage rate designed to reflect the market value of such labor (e.g. median wage for household domestic labor). This reduced utility is variously referred to as lost leisure or a component of pain and suffering. Ideally, a comprehensive willingness to pay for these risk reductions (WTP) estimate would be used that includes all categories of loss in a single number. However, a review of the literature indicated that the available studies ~~address illnesses with significantly different effects from those associated with~~ were not suitable for valuing cryptosporidiosis; hence, estimates from this literature are inappropriate for use in this analysis. ~~This analysis instead estimated the value of averted morbidity risks based on the (1) avoided~~ Instead, EPA presents two COI estimates: a traditional approach that only includes valuation for medical costs and ~~(2) the value of averted time losses. The rationale for, and~~

limitations of, this approach are discussed in greater detail in the LT2ESWTR EA (USEPA 2002a)

The calculation of medical costs is relatively straightforward and includes the costs of medical services and medications received by ill individuals. The indirect costs usually include lost earnings due to missed market work time, and may also include costs associated with reduced productivity while at work and/or lost nonmarket work time (e.g., child care or housekeeping).

In the analysis of cryptosporidiosis-related morbidity, a more complete measure of the welfare effects of lost time is used. It considers the impact of time losses on (1) foregone market production, which affects the individual worker (e.g., in terms of lost income) as well as other members of society (who benefit from the availability of the goods or services produced as well as the taxes paid); (2) foregone nonmarket (household and volunteer) production, which affects the individual and other household members and often has impacts outside the home; (3) lost work time (including some portion of unpaid household production); and an enhanced approach that also factors in valuations for lost unpaid work time for employed people. reduced utility (or sense of well-being) associated with decreased enjoyment of time spent in both work and non-work activities; and (4) impacts on others, such as children who would be normally cared for by the ill individual or friends or family members who provide unpaid care.

In addition, the Agency considered three different severity levels of cryptosporidiosis: mild, moderate, and severe. According to a forthcoming study conducted by the CDC (Corso et al., 2002), the majority of illness fall into the mild category (88 percent). Approximately 11 percent of illness fall into the moderate

category, which is defined as those who sought medical treatment but were not hospitalized. The final one percent have severe symptoms that result in hospitalization. EPA estimated different medical expenses and time losses for each category. The lost productivity at work on days when workers are ill but go to work anyway.

Table VI-3 shows the various categories of loss and how they were valued for each estimate for a “typical” case (weighted average of these three estimates results in a cost of illness (COI) of \$736 per case. A complete discussion of the VSL and COI values and how they are calculated can be found in the severity level - see LT2ESWTR EA - Chapter 5 for more details (USEPA 2003a).

**Table VI-3.–Traditional and Enhanced COI for Cryptosporidiosis**

<u>Loss Category</u>	<u>Traditional COI</u>	<u>Enhanced COI</u>
<u>Direct Medical Costs</u>	<u>\$93.82</u>	<u>\$93.82</u>
<u>Lost Paid Work Days</u>	<u>\$109.88</u>	<u>\$109.88</u>
<u>Lost Unpaid Work Days<sup>1</sup></u>	<u>\$20.22</u>	<u>\$40.44</u>
<u>Lost Caregiver Days<sup>2</sup></u>	<u>\$20.70</u>	<u>\$54.31</u>
<u>Lost Leisure Time<sup>3</sup></u>	<u>not included</u>	<u>\$333.96</u>
<u>Lost Productivity at Work</u>	<u>not included</u>	<u>\$112.49</u>
<b><u>Total<sup>4</sup></u></b>	<b><u>\$244.62</u></b>	<b><u>\$744.89</u></b>

<sup>1</sup>Assigned to 38.2% of the population not engaged in market work; assumes 40 hr. unpaid work week, valued at \$5.46/hr in traditional COI and \$10.92/hr in enhanced COI. Does not include lost unpaid work for employed people and may not include all unpaid work for people outside the paid labor force.

<sup>2</sup>Values lost work or leisure time for people caring for the ill. Traditional approach does not include lost leisure time.

<sup>3</sup>Includes child care and homemaking (to the extent not covered in lost unpaid work days above), time with family, and recreation for people within and outside the paid labor force.

<sup>4</sup>Detail may not calculate to totals due to independent rounding.

Source: Appendix L in LT2ESWTR EA (USEPA 20023a)–

a. Filtered systems. Benefits to the approximately 161 million people served by filtered surface water and GWUDI systems range from 82,000 – 461,000 reduction in mean annual cases of endemic illness based on ICRSSL and ICR data sets

The various loss categories were calculated as follows: Medical costs are a weighted average across the three illness severity levels of actual costs for doctor and

emergency room visits, medication, and hospital stays. Lost paid work represents missed work time of paid employees, valued at the median pre-tax wage, plus benefits of \$18.47 hour. The average number of lost work hours per case is 5.95 (this assumes that 62 percent of the population is in the paid labor force and the loss is averaged over seven days). Medical costs and lost work days reflect market transactions. Medical costs are always included in COI estimates and lost work days are usually included in COI estimates.

In the traditional COI estimate, an equivalent amount of lost unpaid work time was assigned to the 38% of the population that are not in the paid labor force. This includes homemakers, students, children, retirees, and unemployed persons. EPA did not attempt to calculate what percent of cases falls in each of these five groups, or how many hours per week each group works, but rather assumed an across-the-board 40 hour unpaid work week. This time is valued at \$5.46 per hour, which is one half the median post-tax wage, (since work performed by these groups is not taxed). This is approximately the median wage for paid household domestic labor.

In the enhanced COI estimate, all time other than paid work and sleep (8 hours per day) is valued at the median after tax wage, or \$10.92 per hour. This includes lost unpaid work (e.g., household production) and leisure time for people within and outside the paid labor force. Implicit in this approach, is that people would pay the same amount not to be sick during their leisure time as they require to give up their leisure time to work (i.e., the after tax wage). In reality, people might be willing to pay either more than this amount (if they were very sick and suffering a lot) or less than this amount (if they were not very sick and still got some enjoyment out of activities such as

resting, reading and watching TV), not to be sick. Multiplying 16 hours by \$10.92 gives a value of about \$175.00 for a day of “lost” unpaid work and leisure (i.e., lost utility of being sick).

An estimate of lost unpaid work days for the enhanced approach was made by assigning the value of \$10.92 per hour to the same number of unpaid work hours valued in the traditional COI approach (i.e., 40 unpaid work hours per week for people outside the paid labor force). Lost unpaid work for employed people and any unpaid labor beyond 40 hours per week for those not in the labor market is shown as lost leisure time in Table VI-3 for the enhanced approach and is not included in the traditional approach. In addition, ~~deaths are expected to be reduced by an average of 9 –49 annually.~~

~~b. *Unfiltered systems.* The 12 million people served by unfiltered surface water or GWUDI systems will see a significant reduction in for days when an individual is well enough to work but still experiencing symptoms, such as diarrhea, the enhanced estimate also includes a 30% loss of work and leisure productivity, based on a study of giardiasis illness (Harrington et al. 1985) which is similar to cryptosporidiosis as a result of the rule. The LT2ESWTR is expected to reduce approximately 556,000 illness and 93 deaths annually in unfiltered systems based on the Information Collection Rule data set. Only the Information Collection Rule data set is used to directly calculate illness reduced because it is the only data set to included sufficient information on unfiltered systems. Illness reduction in unfiltered systems was estimated for the ICRSSL and ICRSSM data sets by multiplying the Information Collection Rule unfiltered system result by the ratio, for the quantity estimated, between filtered results from the~~

supplemental data set (SSM or SSL) and filtered results from the Information Collection Rule.

~~c. Sensitivity analysis of the value of non-fatal risk reductions.~~ In addition to developing best case estimates for non-fatal risk reductions, the Agency considered the uncertainty of two key parameters of the estimate: the dollar value of non-work time losses and the reduction in productivity attributable to illness. The LT2ESWTR EA contains a complete discussion and results of the sensitivity analysis (USEPA 2002a)

~~The valuation of non-work losses is subject to two major sources of uncertainty: (1) individuals may value these losses at a rate significantly higher than the post-tax median wage; and (2) the reported amount of time lost includes some time spent on activities that represent an incomplete loss of utility; e.g., some of this time may be spent reading rather than coping with a bout of diarrhea. For the first scenario, the Agency assumed that the value of non-work time is 150 percent of best case estimate. For the second scenario, EPA assumed that non-work losses will be valued at 50 percent less than the best case scenario. The rationale for these assumptions is discussed in appendix P of the EA for the LT2ESWTR (USEPA 2002a).~~

~~Another key valuation parameter, productivity loss due to illness, is also considered uncertain. However, the estimate of 30 percent does fall within a range of other estimates of productivity losses for other illnesses (USEPA 2002a). Due to the similarities, Appendix P in the EA describes similar productivity losses for other illnesses such as influenza (35% - 73% productivity losses). In the traditional COI analysis, productivity losses are not included for either work or non-work time.~~

The Agency believes that losses in productivity ~~losses for similar illnesses, the Agency chose a narrow sensitivity analysis range for this parameter. Therefore, the productivity loss parameter in the sensitivity analysis is varied between 20 and 40 percent.~~

and lost leisure time are unquestionably present and that these categories have positive value; consequently, the traditional COI estimate understates the true value of these loss categories. EPA notes that these estimates should not be regarded as upper and lower bounds. In particular, the enhanced COI estimate may not fully incorporate the value of pain and suffering, as people may be willing to pay more than \$201 to avoid a day of illness. The traditional COI estimate includes a valuation for a lost 40 hour work week for all persons not in the labor force, including children and retirees. This may be an overstatement of lost productivity for these groups, which would depend on the impact of such things as missed school work or volunteer activities that may be affected by illness.

As with the avoided mortality valuation, the real wages used in the COI estimates were increased by a real income growth factor that varies by year, but is the equivalent of about 2.3% over the 20 year period. This approach of adjusting for real income growth was recommended by the SAB (USEPA 2000e) because the median real wage is expected to grow each year (by approximately 2.3%) — the median real wage is projected to be \$38,902 in 2008 and \$59,749 in 2027. Correspondingly, the real income growth factor of the COI estimates increases by the equivalent of 2.3% per year (except for medical costs, which are not directly tied to wages). This approach gives a total COI valuation in 2008 of \$268.92 for the traditional COI estimate and \$931.06 for