test based on the feed and filtrate concentrations of the challenge particulate for that module. The individual LRVs for each module are used to determine the overall removal efficiency of the membrane product. If fewer than twenty modules are tested, the overall removal efficiency is assigned a value equal to the lowest of the representative LRVs for the various modules tested. If twenty or more modules are tested, then the overall removal efficiency is assigned a value equal to the 10th percentile of the representative LRVs for the various modules tested.

• As part of the challenge test, a quality control release value (QCRV) must be established for a non-destructive performance test (*e.g.*, bubble point test, diffusive airflow test, pressure/vacuum decay test) that demonstrates the Cryptosporidium removal capability of the membrane module. The non-destructive performance test must be applied to each membrane module a PWS uses in order to verify Cryptosporidium removal capability. Membrane modules that do not meet the established QCRV are not eligible for the Cryptosporidium removal credit demonstrated during challenge testing.

If a previously tested membrane product is modified in a manner that could change the removal efficiency of the membrane or the applicability of non-destructive performance test and associated QCRV, the modified membrane filter must be challenge tested to establish the removal efficiency and QCRV. If approved by the State, data from challenge testing conducted prior to promulgation of today's rule may be considered in lieu of additional testing. However, the prior testing must have been conducted in a manner that demonstrates a removal efficiency for Cryptosporidium commensurate with the treatment credit awarded to the filter.

Membrane Direct Integrity Testing

In order to receive Cryptosporidium treatment credit for a membrane filtration process, PWSs must conduct direct integrity testing in a manner that demonstrates a removal efficiency equal to or greater than the removal credit awarded to the membrane filtration process. A direct integrity test is defined as a physical test applied to a membrane unit in order to identify and isolate integrity breaches (*i.e.*, one or more leaks that could result in contamination of the filtrate).

Each membrane unit must be independently direct integrity tested, where a membrane unit is defined as a group of membrane modules that share common valving which allows the unit to be isolated from the rest of the system for the purpose of integrity testing or other maintenance. The direct integrity test must be applied to the physical elements of the entire membrane unit including membranes, seals, potting material, associated valving and piping, and all other components which under compromised conditions could result in contamination of the filtrate.

Common direct integrity tests include those that apply pressure or vacuum (such as the pressure decay test and diffusive airflow test) and those that measure the rejection of a particulate or molecular marker (such as spiked particle monitoring). Today's final rule does not stipulate the use of a particular direct integrity test. Instead, the direct integrity test must meet performance criteria for resolution, sensitivity, and frequency.

''Resolution'' is defined as the smallest leak that contributes to the response from a direct integrity test. Any direct integrity test applied to meet the requirements of this rule must have a resolution of 3 micrometers or less. The manner in which resolution is determined will depend on the type of direct integrity test used (*i.e.*, pressure-based versus marker-based tests).

''Sensitivity'' is defined as the maximum LRV that can be reliably verified by the direct integrity test. The sensitivity of the direct integrity test applied to a membrane filtration process to meet the Cryptosporidium treatment requirements of this rule must be equal to or greater than the removal credit awarded to the membrane filtration process. Furthermore, the increased concentration of suspended solids that occurs on the high pressure side of the membrane in some module designs must be considered in the sensitivity determination (*i.e.*, the scouring action of some membrane designs keeps the accumulated solids in suspension where they may pass through an integrity breach). Specifically, the sensitivity of the direct integrity test is reduced by a factor that quantifies the increased concentration of suspended solids relative to the feed concentration.

The ''frequency'' of direct integrity testing specifies how often the test is performed over an established time interval. Direct integrity tests available at the time of promulgation are applied periodically and must be conducted on each membrane unit at a frequency of not less than once per day that the unit is in operation, unless the State determines that less frequent testing is acceptable. If continuous direct integrity test methods become available that also meet the sensitivity and resolution criteria described earlier, such a continuous test may be used in lieu of periodic testing.

PWSs must establish a direct integrity test control limit that is indicative of an integral membrane unit capable of meeting the Cryptosporidium removal credit awarded to the membrane. If the control limit for the direct integrity test is exceeded, the membrane unit must be taken off-line for diagnostic testing and repair. The membrane unit may only be returned to service after the repair has been completed and confirmed through the application of a direct integrity test. A monthly report must be submitted to the State summarizing all direct integrity test results above the control limit and the corrective action that was taken in each case.

Continuous Indirect Integrity Monitoring

Available direct integrity test methods are applied periodically since the membrane unit must be taken out of service to conduct the test. In order to provide some measure of process performance between direct integrity testing events, PWSs must perform continuous indirect integrity monitoring on each membrane unit. Continuous indirect integrity monitoring is defined as monitoring some aspect of filtrate water quality that is indicative of the removal of particulate matter at a frequency of at least once every 15 minutes. If a continuous direct integrity test is implemented that meets the resolution and sensitivity criteria described previously in this section, continuous indirect integrity monitoring is not required.

Unless the State approves an alternative parameter, continuous indirect integrity monitoring must include continuous filtrate turbidity monitoring. If the filtrate turbidity readings are above 0.15 NTU for a period greater than 15 minutes, the PWS must perform direct integrity testing on the associated membrane unit.

If the State approves an alternate parameter for continuous indirect integrity monitoring, the State must approve a control limit for that parameter. If the parameter exceeds the control limit for a period greater than 15 minutes, the PWS must perform direct integrity testing on the associated membrane unit.

PWSs must submit a monthly report to the State summarizing all continuous indirect integrity monitoring results triggering direct integrity testing and the corrective action that was taken in each case.

EPA has developed the Membrane Filtration Guidance Manual to assist

systems with implementation of these requirements. This guidance may be requested from EPA's Safe Drinking Water Hotline, which may be contacted as described under **FOR FURTHER INFORMATION CONTACT** in the beginning of this notice.

b. Background and Analysis

In the August 11, 2003 proposed LT2ESWTR, EPA proposed to establish criteria for awarding credit to membrane filtration processes for removal of Cryptosporidium (USEPA 2003g). The Agency based these criteria on data demonstrating the Cryptosporidium removal efficiency of membrane filtration processes, a critical evaluation of available integrity monitoring techniques, and study of State approaches to the regulation of membrane filtration for pathogen removal. This information is summarized in the report Low-Pressure Membrane Filtration for Pathogen Removal: Application, Implementation, and Regulatory Issues (USEPA 2001g).

As summarized in this report, a number of studies demonstrate the ability of membrane filtration processes to remove pathogens, including Cryptosporidium, to below detection levels (USEPA 2001g). In some studies that used Cryptosporidium seeding, measured removal efficiencies were as high as 7-log (Jacangelo, et al., 1997; Hagen, 1998; Kachalsky and Masterson, 1993). In other studies, removal efficiencies ranged from 4.4- to 6.5-log and were only limited by the seeded concentration of Cryptosporidium oocysts (Dwyer, et al. 1995, Jacangelo et al. 1989, Trussel, et al. 1998, NSF 2000a–g, Olivieri 1989). Collectively, these results demonstrate that an integral membrane module (i.e., a membrane module without any leaks or defects, with an exclusion characteristic smaller than Cryptosporidium) is capable of removing this pathogen to below detection in the filtrate, independent of the influent concentration.

The 2003 proposal included a provision for challenge testing membranes to demonstrate the removal efficiency of Cryptosporidium. EPA believes this requirement is necessary due to the proprietary nature of these products and the lack of any uniform design criteria for establishing the exclusion characteristic of a membrane. Guidance on the design and conduct of a challenge test to meet the requirements of this rule is presented in the Membrane Filtration Guidance Manual.

Challenge testing is required on a product-specific basis, rather than a site-specific basis; thus, modules used in full-scale facilities will generally not be directly challenge tested. The removal capability of production membrane modules is verified through the application of a non-destructive performance test, such as a bubble point test. A quality control release value (QCRV) for the non-destructive performance test can be related to the results of the challenge test and used to demonstrate the ability of production modules to achieve the Cryptosporidium removal efficiency demonstrated during challenge testing. Most membrane manufacturers have adapted some form of non-destructive testing for the purpose of product quality control and have established a QCRV that is indicative of an acceptable product. It may be possible to apply these existing practices to meet the requirements of today's final rule.

While challenge testing demonstrates the removal efficiency of an integral membrane module, defects or leaks in the membrane or other system components can result in contamination of the filtrate unless they are identified, isolated, and repaired. In order to verify continued performance of a membrane system, today's final rule requires direct integrity testing of membrane filtration processes used to meet the Cryptosporidium treatment requirements of this rule.

An evaluation of available direct integrity tests indicates that pressure-based tests are widely applied and sufficiently sensitive to provide verification of removal efficiencies in excess of 4-log. Marker-based direct integrity tests are also available, and new direct integrity tests may be developed that present an improvement over existing tests. Rather than specify a particular direct integrity test, today's final rule defines performance criteria for direct integrity testing. These criteria are resolution, sensitivity, and frequency, as previously described. EPA believes that this approach will provide flexibility for the development and implementation of future innovations in direct integrity testing while ensuring that any test applied to meet the requirements of this rule will achieve the required level of performance.

Since available direct integrity tests require taking the membrane unit out of service to conduct the test, today's rule establishes a minimum test frequency for direct integrity testing. Currently, there is no standard frequency for direct integrity testing that has been adopted by all States and membrane treatment facilities. In a 2000 survey, the required frequency of integrity testing was found to vary from once every four hours to once per week; however, the most common frequency for conducting a direct integrity test was once every 24 hours (USEPA 2001g). Specifically, 10 out of 14 States that require periodic direct integrity testing specify a frequency of once per day. Furthermore, many membrane manufacturers of systems with automated integrity test systems set up the membrane units to automatically perform a direct integrity test once per day.

EPA believes that daily direct integrity testing is appropriate for most membrane filtration installations, but under some circumstances, less frequent testing may be adequate. Thus, EPA is allowing States to approve less frequent direct integrity testing on the basis of demonstrated process reliability, use of multiple barriers effective for Cryptosporidium, or reliable process safeguards.

Due to the periodic nature of direct integrity testing, today's rule includes a provision for continuous indirect integrity monitoring. While indirect monitoring is not as sensitive as direct testing, it provides an indication of process performance to ensure that a major failure has not occurred between application of direct integrity tests.

c. Summary of Major Comments

In response to the 2003 proposal, the Agency received significant comments on the following issues related to membrane filtration: the frequency of direct integrity testing; the procedure necessary to determine removal credit for membrane filtration; and the requirement for continuous indirect integrity monitoring.

The 2003 proposal requested comment on the proposed minimum direct integrity test frequency of once per day. Some commenters supported the daily frequency and commented that many states have already adopted this standard. Others commented that direct integrity testing once per day is too frequent, citing the lack of data in the proposal documenting the rate of membrane failure, as well as the loss in production that occurs when the membrane unit is taken off-line for testing.

While EPA recognizes these concerns, a critical factor in establishing a testing frequency is the amount of time that water from a compromised membrane unit is supplied to the public before the integrity breach is detected. EPA believes that this factor is most important to public health protection and that daily direct integrity testing is appropriate for the majority of membrane systems. However, EPA also acknowledges that there may be

circumstances under which less frequent testing may provide adequate public health protection, and has revised the rule to allow States to permit less frequent direct integrity testing based on demonstrated process reliability, use of multiple barriers effective for Cryptosporidium, or reliable process safeguards.

Several commenters expressed concern with the process needed to determine appropriate removal credit for membrane filtration. However, many commenters also supported the flexibility provided to States in determining the appropriate removal credit for membrane filtration based on the criteria defined in the 2003 proposal. EPA believes that the proposed approach for awarding Cryptosporidium removal credit to membrane filtration is supported by the available data and analysis, and will allow higher removal credits to be considered on a scientifically sound basis. EPA recognizes that the flexibility provided in the regulation does increase the complexity of determining removal credits for membrane filtration. To address this issue, EPA has developed extensive guidance to support the implementation of requirements for membrane filtration.

EPA received comment that continuous indirect integrity monitoring is unnecessary due to the poor sensitivity of currently available methods. EPA acknowledges that currently available indirect monitoring methods are less sensitive than available direct integrity tests. However, EPA believes that continuous indirect integrity monitoring is necessary to protect public health. Specifically, continuous monitoring may alert a system of potentially severe integrity breaches that could result in bypass of unfiltered water around the membrane filtration process and pose a risk to public health. Furthermore, EPA has provided States with the flexibility to permit use of more sensitive continuous indirect monitoring methods and/or to establish lower control limits. Also, implementation of continuous direct integrity testing would preclude the need to implement any form of indirect integrity monitoring.

12. Second Stage Filtration

a. Today's Rule

PWSs may receive 0.5-log credit towards the Cryptosporidium treatment requirements of today's rule for a second filtration stage. To be eligible for this credit, the second-stage filtration must meet the following criteria:

- The filter must be a separate second stage of granular media filtration, such as sand, dual media, or granular activated carbon (GAC), that follows a first stage of granular media filtration (e.g., follows a conventional treatment or direct filtration plant).
- The first filtration stage must be preceded by a coagulation process.
- Both filtration stages must treat 100 percent of the treatment plant flow.
- The State must approve the treatment credit based on an assessment of the design characteristics of the filtration process.

This microbial toolbox option does not apply to bag filters, cartridge filters, membranes, or slow sand filters, which are addressed separately in the microbial toolbox. Further, this options does not apply to roughing filters, which are pretreatment processes that typically consist of coarse media and are not preceded by coagulation. States may consider awarding treatment credit to roughing filters under a demonstration of performance.

PWSs may not receive additional treatment credit for both second-stage filtration and lower filter effluent turbidity (*i.e.*, combined or individual filter performance) that is based on turbidity levels following the second filtration stage. PWSs may receive credit for both options based on turbidity following the first filtration stage.

b. Background and Analysis

The Stage 2 M–DBP Advisory Committee recommended a 0.5-log Cryptosporidium treatment credit for a roughing filter with the stipulation that EPA identify the design and operational conditions under which such credit is appropriate. After reviewing available data, however, EPA was unable to determine conditions under which a roughing filter is likely to achieve at least 0.5-log removal of Cryptosporidium. Roughing filters consist of coarse media like gravel and usually are not preceded by coagulation. They are used to remove sediment and large particulate matter from raw water prior to the primary treatment processes. EPA identified no studies indicating that roughing filters would be effective for removal of Cryptosporidium (USEPA 2003a).

In contrast, numerous studies have demonstrated that granular media filtration can be effective for removing Cryptosporidium when preceded by coagulation (Patania et al. 1995, Nieminski and Ongerth 1995, Ongerth and Pecoraro 1995, LeChevallier and Norton 1992, LeChevallier et al. 1991, Dugan et al. 2001, Nieminski and Bellamy 2000, McTigue et al. 1998, Patania et al. 1999, Huck et al. 2000, Emelko et al. 2000). PWSs may implement a second granular media filtration stage to achieve various water quality objectives, such as increased removal of organic material in biologically active filters or removal of inorganic contaminants. Consequently, EPA believes that consideration of additional Cryptosporidium treatment credit for a second granular media filtration stage is appropriate.

The August 11, 2003 LT2ESWTR proposal included an additional 0.5-log Cryptosporidium treatment credit for PWSs that use a second separate filtration stage consisting of rapid sand, dual media, GAC, or other fine grain media. A cap, such as GAC, on a single stage of filtration did not qualify. In addition, the proposal required the first stage of filtration to be preceded by a coagulation step and both stages had to treat 100 percent of the plant flow. Today's final rule establishes this treatment credit with minimal changes from the proposal. The basis for this credit and for changes from the proposed rule are summarized in the following discussion.

While the studies of Cryptosporidium removal by granular media filtration cited previously evaluated only a single stage of filtration, the same removal mechanisms will be operative in a second stage of granular media filtration. Secondary filters may remove Cryptosporidium that were destabilized but not trapped in primary filters or that were trapped but subsequently detached from primary filters prior to backwash. Thus, EPA believes these studies are supportive of additional removal credit for a second filtration stage.

An important finding of these studies is that coagulation is necessary to achieve significant Cryptosporidium removal by granular media filtration (does not apply to slow sand filtration, which is addressed in the next section). Consequently, today's rule requires that the first filtration stage be preceded by coagulation for a PWS to receive treatment credit for second-stage filtration. This requirement is necessary to ensure that both filtration stages are effective for Cryptosporidium removal. PWSs will already comply with this requirement where a second filtration stage is applied after conventional treatment or direct filtration.

In the proposal, EPA also reviewed data provided by a PWS on the removal of aerobic spores through GAC filters (i.e., contactors) following conventional treatment. As discussed earlier, studies have demonstrated that aerobic spores can serve as an indicator of Cryptosporidium removal by granular

media filtration (Dugan et al. 2001, Emelko et al. 1999 and 2000, Yates et al. 1998, Mazounie et al. 2000). Over a two year period, the mean removal of aerobic spores across the GAC filters exceeded 0.5-log. These results support the finding that a second stage of granular media filtration can reduce Cryptosporidium levels by 0.5-log or greater.

Today's rule does not establish design criteria such as filter depth or media size for second-stage filters to be eligible for treatment credit. While filter design will influence Cryptosporidium removal efficiency, EPA recognizes that appropriate filter designs will vary depending on the application. States have traditionally provided oversight for treatment process designs in PWSs. Accordingly, today's rule requires State review and approval of second-stage filter design as a condition for PWSs to receive additional treatment credit for this process. The Microbial Toolbox Guidance Manual addresses second-stage filtration for Cryptosporidium treatment credit.

c. Summary of Major Comments

Public comment on the August 11, 2003 LT2ESWTR proposal generally supported additional treatment credit for second-stage filtration. Commenters raised specific concerns with EPA establishing design requirements for filtration, the sufficiency of data to support prescribed treatment credit, and the expansion of this credit to include other filtration technologies. These comments and EPA's responses are summarized as follows.

In the proposal, EPA requested comment on whether a minimum filter depth should be required for PWSs to receive treatment credit for a second filtration stage. All commenters opposed EPA setting regulatory design standards for filters on the basis that PWSs and States need the flexibility to determine appropriate treatment designs. In response, EPA agrees that effective filter designs will vary depending on the application. Consequently, EPA is not establishing filter design criteria in today's rule, but is requiring that States approve designs for PWSs to receive treatment credit for second-stage filtration.

Many commenters stated that available data support the prescribed 0.5-log Cryptosporidium treatment credit for second-stage filtration. Some commenters provided additional data on the removal of aerobic spores through GAC filters following conventional treatment that showed a mean reduction greater than 1-log. In contrast, other commenters were concerned about the lack of data to support increased removal through a second filtration stage. These commenters recommended that treatment credit for second-stage filtration should be awarded only on a site-specific basis through a demonstration of performance.

EPA has concluded that available data are sufficient to support the prescribed 0.5-log treatment credit for second-stage filtration. Studies of granular media filtration demonstrate high levels of Cryptosporidium removal and one study has shown greater than 1.0-log removal through secondary GAC filters. Secondary filters can remove Cryptosporidium that pass through or detach from the primary filters. This added removal will help to stabilize finished water quality by providing a barrier during periods of the filtration cycle when the primary filters are not performing optimally. Therefore, EPA is establishing this credit in today's rule.

Several commenters recommended that EPA expand the second-stage filtration option to include membranes, bag filters, and DE filtration. EPA notes that today's rule establishes prescribed treatment credits specifically for bag and cartridge filters and membranes as microbial toolbox options, and prescribed credit for DE filtration is addressed in section IV.B. PWSs may seek treatment credit for other filtration technologies through a demonstration of performance under today's rule.

13. Slow Sand Filtration

a. Today's Rule

PWSs may receive a 2.5-log credit towards the Cryptosporidium treatment requirements in today's rule for implementing slow sand filtration as a secondary filtration stage following a primary filtration process. To be eligible for this credit, the slow sand filtration must meet the following criteria:

- The slow sand filter must be a separate second stage of filtration that follows a first stage of filtration like conventional treatment or direct filtration;
- There must be no disinfectant residual in the influent water to the slow sand filtration process;
- Both filtration stages must treat 100 percent of the treatment plant flow from a surface water or GWUDI source; and
- The State must approve the treatment credit based on an assessment of the design characteristics of the filtration process.

Slow sand filtration used as a primary filtration process receives a prescribed 3-log Cryptosporidium treatment credit, as described in section IV.B.

b. Background and Analysis

Slow sand filtration is a process involving passage of raw water through a bed of sand at low velocity (generally less than 0.4 m/h), resulting in substantial particulate removal. Several studies have demonstrated that slow sand filtration can achieve significant Cryptosporidium removal (Schuler and Ghosh, 1991, Timms et al. 1995, Hall et al. 1994). Slow sand filtration is typically used as a primary filtration process, usually in small systems, rather than as a secondary filtration stage following conventional treatment or another primary filtration process. EPA expects, however, that slow sand filtration would be effective for Cryptosporidium removal in such an application, which warrants consideration of treatment credit under today's rule.

The Stage 2 M–DBP Advisory Committee recommended that slow sand filtration receive 2.5-log or greater Cryptosporidium treatment credit when used in addition to existing treatment that achieves compliance with the IESWTR or LT1ESWTR. The August 11, 2003 LT2ESWTR proposal included 2.5-log treatment credit for slow sand as a secondary filtration process, with the only associated condition being no disinfectant residual in the water influent to the filter. In today's rule, EPA is establishing this treatment credit with minimal changes from the proposal. The following discussion summarizes the basis for this credit and for changes from the proposal.

Removal of microbial pathogens in slow sand filters is complex and is believed to occur through a combination of physical, chemical, and biological mechanisms, both on the surface and in the interior of the filter bed. In particular, biological activity in the upper layers of the filter is believed to promote microbial removal. Based on previously cited studies demonstrating greater than 4-log removal of Cryptosporidium through slow sand filtration, today's rule awards a prescribed 3-log Cryptosporidium removal credit to slow sand filtration as a primary filtration process.

The effectiveness of slow sand as a secondary filtration process is more uncertain. In general, EPA expects that the same microbial removal mechanisms will be operative. However, due to the quality of treated water following a primary filtration process, filter ripening and development of the biologically active layer in a secondary slow sand filter may be inhibited. One study that evaluated Cryptosporidium removal by slow sand filtration alone

and slow sand filtration preceded by a rapid sand filter observed similar removal levels in the two treatment trains (Hall et al. 1994). Because of the uncertainty regarding the performance of slow sand as a secondary filtration step and in consideration of the Advisory Committee recommendation, today's rule establishes a 2.5-log additional Cryptosporidium treatment credit for this application.

Due to the importance of biological activity to slow sand filter performance, PWSs may not receive the prescribed treatment credit if the influent water to the slow sand filter contains a disinfectant residual. EPA is not establishing design standards for slow sand filters in today's rule. Studies have shown, however, that design deficiencies in slow sand filters may lead to poor Cryptosporidium removal (Fogel et al. 1993). Consequently, States must approve slow sand filter designs as a secondary filtration stage for PWSs to receive treatment credit under today's rule.

c. Summary of Major Comments

Public comment on the August 11, 2003 proposal focused on the question of whether the 2.5-log Cryptosporidium treatment credit for slow sand as a secondary filtration process is appropriate. Many commenters supported the proposed treatment credit. These commenters cited studies demonstrating greater than 4-log Cryptosporidium removal by slow sand filtration and concluded that the data justify a 2.5-log treatment credit for slow sand filtration added to a clarification and filtration treatment train.

Several commenters, however, stated that this treatment credit is not justified due to the lack of data on the performance of slow sand as a secondary filtration step. Available studies on slow sand filter performance for Cryptosporidium removal have mostly been conducted on raw (i.e., unfiltered) water. These commenters were concerned that if slow sand filtration is applied following a primary filtration process, the filter ripening period and other factors will be significantly affected. As a result, the slow sand filtration may provide only limited removal over a long ripening period.

In response, EPA recognizes that little testing has been conducted on the performance of slow sand filtration specifically as a second filtration stage in a treatment train. However, available data do not indicate that slow sand filtration would be substantially less effective when used in this capacity. Slow sand filtration is recommended only for higher quality source waters, and water quality following a primary filtration process would be well within recommended design limits for slow sand filtration (USEPA 1991a). EPA agrees that filter ripening is critical to slow sand filtration achieving its full performance level, and this process may require more time when slow sand filtration follows a primary filtration process. However, this effect may be counterbalanced by very long filter run times between cleaning the filter due to the high quality influent water. Consequently, EPA believes that 2.5-log Cryptosporidium treatment credit for slow sand as a secondary filtration process is warranted.

14. Ozone and Chlorine Dioxide

a. Today's Rule

PWSs may use ozone and chlorine dioxide to meet Cryptosporidium treatment requirements under today's rule. To receive treatment credit, PWSs must measure the water temperature, disinfectant contact time, and residual disinfectant concentration at least once each day and determine the log inactivation credit using the tables in this section. Specific criteria are as follows:

- The temperature of the disinfected water must be measured at least once per day at each residual disinfectant concentration sampling point.
- The disinfectant contact time(s) (''t'') must be determined for each day during peak hourly flow.
- The residual disinfectant concentration(s) (''C'') of the water before or at the first customer must be measured each day during peak hourly flow.
- Tables IV.D–3 or IV.D–4 must be used to determine Cryptosporidium log inactivation credit for ozone or chlorine dioxide, respectively, based on the water temperature and the product of disinfectant concentration and contact time (CT).

TABLE IV.D–3.—CT VALUES FOR CRYPTOSPORIDIUM INACTIVATION BY OZONE [1] (MG/L × MIN)

Log credit	Water temperature, °C										
	≤0.5	1	2	3	5	7	10	15	20	25	30
0.25	6.0	5.8	5.2	4.8	4.0	3.3	2.5	1.6	1.0	0.6	0.39
0.5	12	12	10	9.5	7.9	6.5	4.9	3.1	2.0	1.2	0.78
1.0	24	23	21	19	16	13	9.9	6.2	3.9	2.5	1.6
1.5	36	35	31	29	24	20	15	9.3	5.9	3.7	2.4
2.0	48	46	42	38	32	26	20	12	7.8	4.9	3.1
2.5	60	58	52	48	40	33	25	16	9.8	6.2	3.9
3.0	72	69	63	57	47	39	30	19	12	7.4	4.7

[1] PWSs may use this equation to determine log credit between the indicated values: Log credit = $(0.0397 \times (1.09757)^{Temp}) \times CT$.

TABLE IV.D–4.—CT VALUES FOR CRYPTOSPORIDIUM INACTIVATION BY CHLORINE DIOXIDE [1] (MG/L × MIN)

Log credit	Water temperature, °C										
	≤0.5	1	2	3	5	7	10	15	20	25	30
0.25	159	153	140	128	107	90	69	45	29	19	12
0.5	319	305	279	256	214	180	138	89	58	38	24
1.0	637	610	558	511	429	360	277	179	116	75	49
1.5	956	915	838	767	643	539	415	268	174	113	73
2.0	1275	1220	1117	1023	858	719	553	357	232	150	98
2.5	1594	1525	1396	1278	1072	899	691	447	289	188	122
3.0	1912	1830	1675	1534	1286	1079	830	536	347	226	147

[1] PWSs may use this equation to determine log credit between the indicated values: Log credit = $(0.001506 \times (1.09116)^{Temp}) \times CT$.

PWSs may have several disinfection segments in sequence along the treatment train, where a disinfectant segment is defined as a treatment unit process with a measurable disinfectant residual level and a liquid volume. In determining the total log inactivation, the PWS may calculate the CT for each disinfection segment and use the sum of these values to determine the log inactivation achieved through the plant. The Toolbox Guidance Manual provides information on recommended methodologies for determining CT values for different disinfection reactor designs and operations.

Alternatively, the State may approve alternative CT values to those specified in Tables IV.D–3 or IV.D–4 based on a site-specific study a PWSs conducts following a State-approved protocol. The Toolbox Guidance Manual describes recommended approaches for making such demonstrations.

b. Background and Analysis

Ozone and chlorine dioxide are chemical disinfectants that have been shown to be effective for inactivating Cryptosporidium. The Stage 2 M–DBP Advisory Committee recommended that EPA develop criteria for PWSs to achieve Cryptosporidium inactivation credit with these disinfectants. The August 11, 2003 LT2ESWTR proposal included CT values for 0.5- to 3-log Cryptosporidium inactivation credit by ozone or chlorine dioxide at temperatures ranging from less than 0.5 C to 25 C, along with daily required monitoring (USEPA 2003a). Today's final rule establishes these criteria with no changes from the proposed rule, but expands the CT tables down to 0.25-log inactivation and up to a water temperature of 30 C. The following discussion summarizes the basis for these criteria.

The requirements for at least daily monitoring of the water temperature, residual disinfectant concentration, and contact time during peak hourly flow to determine a daily inactivation level reflect existing requirements for Giardia inactivation by chemical disinfection in 40 CFR 141.74. EPA expects that in practice, many PWSs using ozone or chlorine dioxide will monitor more frequently and for multiple disinfectant segments. In the Toolbox Guidance Manual, EPA provides information on recommended approaches for monitoring and calculating CT values for ozone and chlorine dioxide reactors.

The CT values for both ozone and chlorine dioxide are based on analyses by Clark *et al.* (2002a,b), with additional procedures to assess confidence bounds. Clark *et al.* (2002a,b) developed predictive equations for Cryptosporidium inactivation through evaluating studies on ozone by Rennecker *et al.* (1999), Li *et al.* (2001), Owens *et al.* (2000), and Oppenheimer *et al.* (2000) and on chlorine dioxide by Li *et al.* (2001), Owens *et al.* (1999) and Ruffell *et al.* (2000). EPA applied confidence bounds to these predictive equations to ensure that PWSs operating at a given CT value are likely to achieve at least the corresponding log inactivation level in the CT table.

In identifying confidence bounds for CT values, EPA was primarily concerned with uncertainty in the estimations by Clark *et al.* (2002a,b) of the linear relationship between log inactivation and CT (*i.e.*, uncertainty in the regression) and with real variability in the inactivation rate. Such real variability could be associated with different populations of oocysts and different water matrices. In contrast, variability associated with experimental error, such as the assays used to measure loss of infectivity, was a lessor concern. The purpose of the CT tables is to ensure a given level of inactivation and not to predict the measured result of an individual experiment.

For developing earlier CT values, EPA has used bounds for confidence in prediction, which account for both real variability and experimental error. EPA believes that this approach was appropriate due to limited inactivation data and uncertainty in the sources of variability in the data. However, the high doses of ozone and chlorine dioxide necessary to inactivate Cryptosporidium create an offsetting concern with the formation of DBPs (*e.g.*, bromate and chlorite). In consideration of this concern, EPA has employed a less conservative method to calculate confidence bounds for the ozone and chlorine dioxide CT values in today's rule; specifically, EPA has attempted to exclude experimental error from the confidence bounds.

In order to estimate confidence bounds that exclude experimental error, EPA assessed the relative contribution of experimental error to the variance observed in the Cryptosporidium inactivation data sets. This assessment was done by comparing variance among data points with consistent experimental conditions, which was attributed to experimental error, with the total variance in a data set. By this analysis, EPA estimated that 87.5 and 62 percent of the variance in the Cryptosporidium inactivation data for ozone and chlorine dioxide, respectively, could be ascribed to experimental error (Sivaganesan 2003, Messner 2003). EPA then applied these estimates to the predictive equations developed by Clark *et al.* (2002a,b) using a modified form of a formula for calculating a 90 percent confidence bound (Messner 2003).

This analysis produced the CT values shown in tables IV.D–3 and IV.D–4 for ozone and chlorine dioxide, respectively. CT values are provided for inactivation as low as 0.25-log. Such a low inactivation level may be used by PWSs applying ozone in combination with other disinfectants. Available data do not support the determination of conditions for inactivation greater than 3-log, so the CT values in today's rule do not go beyond this level. The temperature range of CT values in today's rule goes to 30 C (86 F), which will accommodate most natural waters. If the water temperature is higher than 30 C, temperature should be set to 30 C for the log inactivation calculation. PWSs may use the equations provided as footnotes to tables IV.D–3 and IV.D–4 to interpolate between CT values.

EPA recognizes that inactivation rates may be sensitive to water quality and operational conditions at individual PWSs. To reflect this potential, PWSs are allowed to perform a site-specific inactivation study to determine CT requirements. The State must approve the protocols or other information used to derive alternative CT values. EPA has provided guidance for such studies in the Toolbox Guidance Manual.

c. Summary of Major Comments

Public comment on the August 11, 2003 LT2ESWTR proposal supported the inclusion of ozone and chlorine dioxide in the microbial toolbox for Cryptosporidium inactivation. Commenters stated concerns with the required criteria for achieving Cryptosporidium treatment credit, including the conservatism EPA applied in developing the CT tables, the ability of PWSs with different types of source waters to use these disinfectants, and the range of conditions covered by the CT tables. Commenters also made recommendations for guidance. These comments and EPA's responses are summarized as follows.

Some commenters supported the proposed CT tables, but others stated that the statistical approach used to calculate the confidence bounds from which the CT values are derived is overly conservative. These commenters were concerned that this approach will increase capital and operating costs and lead to higher byproduct levels.

In response, EPA believes that the confidence bounds used for the ozone and chlorine dioxide CT tables in today's rule are appropriate and

necessary to ensure that PWSs achieve intended levels of Cryptosporidium inactivation. They account only for uncertainty in the regression of inactivation data and for variability in inactivation data that cannot be attributed to experimental error. This approach is significantly less conservative than the approaches used in CT tables for earlier rules. EPA employed this less conservative approach in recognition of the high disinfectant doses necessary for Cryptosporidium inactivation and concern with byproducts.

Commenters were concerned that due to the relatively high ozone and chlorine dioxide doses necessary for Cryptosporidium inactivation, some PWSs will be unable to use these disinfectants to achieve required levels of Cryptosporidium treatment. In particular, using ozone for high Cryptosporidium inactivation levels will be difficult in areas where cold water temperatures would necessitate especially high doses or where high source water bromide levels would cause problems with bromate formation. The use of chlorine dioxide for Cryptosporidium inactivation may be difficult due to chlorite formation.

EPA recognizes that the use of ozone and chlorine dioxide to achieve Cryptosporidium inactivation will depend on source water factors and will not be feasible for all PWSs. Due to the availability of UV, which EPA has determined to be a feasible technology for Cryptosporidium inactivation by all PWS sizes, the feasibility of today's rule does not depend on the widespread use of ozone or chlorine dioxide for compliance. In assessing the impact of today's rule on PWSs, EPA used ICR survey data to estimate the fraction of PWSs that could use ozone or chlorine dioxide to achieve different levels of Cryptosporidium inactivation without exceeding DBP MCLs (see Economic Analysis for the LT2ESWTR). While EPA expects that some PWSs will use these disinfectants, the microbial toolbox provides many other options for PWSs to comply with the Cryptosporidium treatment requirements of today's rule.

Commenters recommended that EPA expand the range of conditions encompassed in the CT tables. Specifically, commenters asked that CT tables include values for water temperatures above 25 C and supported this request by providing data showing temperature profiles for water sources with maximum temperatures near 30 C. Commenters also requested CT values for Cryptosporidium inactivation levels below 0.5-log for PWSs that will use multiple disinfectants to meet the treatment requirements in today's rule. In addition, commenters suggested that EPA provide equations that PWSs can use to interpolate between the listed CT values.

EPA has addressed these recommendations in today's final rule. The CT tables for ozone and chlorine dioxide include values for a water temperature of 30 C and for 0.25-log inactivation. Footnotes to these tables contain equations that PWSs can use to calculate log inactivation credit for conditions between those provided in the tables. PWSs may use these equations in their process control systems.

Commenters made recommendations for guidance on the use of ozone and chlorine dioxide to comply with today's rule. These recommendations concern topics like monitoring disinfection reactors, procedures for calculating disinfectant concentration and contact time, site specific studies, and synergistic effects of multiple disinfectants. EPA has addressed these topics in the Toolbox Guidance Manual.

15. Ultraviolet Light

a. Today's Rule

PWSs may use ultraviolet (UV) light to comply with Cryptosporidium treatment requirements in today's rule, as well as Giardia lamblia and virus treatment requirements in existing regulations. To receive treatment credit, PWSs must operate UV reactors validated to achieve the required UV dose, as shown in the table in this section, and monitor their UV reactors to demonstrate operation within validated conditions. Specific criteria are as follows:

Required UV Doses

• UV dose (fluence) is the product of the UV intensity over a surface area (fluence rate) and the exposure time. PWSs must use validation testing to demonstrate that a UV reactor achieves the UV doses shown in Table IV.D–5 in order to receive the associated inactivation credit.

TABLE IV.D–5.—UV DOSE REQUIREMENTS FOR CRYPTOSPORIDIUM, GIARDIA LAMBLIA, AND VIRUS INACTIVATION CREDIT

Log credit	Cryptosporidium UV dose (mJ/cm^2)	Giardia lamblia UV dose (mJ/cm^2)	Virus UV dose (mJ/cm^2)
0.5	1.6	1.5	39
1.0	2.5	2.1	58
1.5	3.9	3.0	79
2.0	5.8	5.2	100
2.5	8.5	7.7	121
3.0	12	11	143
3.5	15	15	163
4.0	22	22	186

• The dose values in Table IV.D–5 are for UV light at a wavelength of 254 nm as delivered by a low pressure mercury vapor lamp. However, PWSs may use this table to determine treatment credits for other lamp types through validation testing, as described in the UV Disinfection Guidance Manual. The dose values in Table IV.D–5 apply to post-filter applications of UV in filtration plants and to PWSs that meet all applicable filtration avoidance criteria.

UV Reactor Validation Testing

• The validation test may be reactor-specific or site-specific. Unless the State approves an alternative approach, this testing must involve the following: (1) Full scale testing of a reactor that conforms uniformly to the UV reactors used by the PWS, and (2) inactivation of a test microorganism whose dose response characteristics have been quantified with a low pressure mercury vapor lamp.

• Validation testing must identify ranges for parameters the PWS can monitor to ensure that the required UV dose is delivered during operation. These parameters must include flow rate, UV intensity as measured by UV sensors, and UV lamp status.

• The operating parameters determined by validation testing must

account for the following factors: (1) UV absorbance of the water, (2) lamp fouling and aging, (3) measurement uncertainty of UV sensors, (4) dose distributions arising from the flow velocity profiles through the reactor, (5) failure of UV lamps or other critical system components, and (6) inlet and outlet piping or channel configurations of the UV reactor. In the UV Disinfection Guidance Manual, EPA describes recommended approaches for reactor validation that address these factors.

UV Reactor Monitoring

- PWSs must monitor for the parameters necessary to demonstrate operation within the validated conditions of the required UV dose. These parameters must include flow rate, UV intensity as measured by UV sensors, and UV lamp status. PWSs must check the calibration of UV sensors and recalibrate in accordance with a protocol approved by the State.
- For PWSs using UV light to meet microbial treatment requirements, at least 95 percent of the water delivered to the public every month must be treated by UV reactors operating within validated conditions for the required UV dose.

b. Background and Analysis

Numerous studies have demonstrated that UV light is effective for inactivating Cryptosporidium, Giardia lamblia, and other microbial pathogens at relatively low doses (Clancy et al. 1998, 2000, 2002, Bukhari et al. 1999, Craik et al. 2000, 2001, Landis et al. 2000, Sommer et al. 2001, Shin et al. 2001, and Oppenheimer et al. 2002). EPA has determined that UV light is a feasible technology for PWSs of all sizes to inactivate Cryptosporidium. Accordingly, EPA expects that UV is one of the primary technologies PWSs will use to comply with Cryptosporidium treatment requirements in today's rule.

The Stage 2 M–DBP Advisory Committee recommended that EPA establish standards for the use of UV to comply with drinking water treatment requirements. These standards include the UV doses necessary for different levels of Cryptosporidium, Giardia lamblia, and virus inactivation and a protocol for validating the disinfection performance of UV reactors. The Committee also directed EPA to develop a UV disinfection guidance manual to familiarize States and PWSs with important design and operational issues for UV installations.

The August 11, 2003 LT2ESWTR proposal included UV doses for PWSs to achieve treatment credit of up to 3-log for Cryptosporidium and Giardia lamblia and up to 4-log for viruses, along with associated reactor validation and monitoring requirements. The proposal also required unfiltered PWSs using UV to achieve the UV dose for the required level of Cryptosporidium inactivation in at least 95 percent of the water delivered to the public every month (USEPA 2003a).

Today's final rule establishes these criteria with no changes from the proposed rule. However, EPA has expanded the UV dose table to include 4-log inactivation of Cryptosporidium and Giardia lamblia and has expanded the 95 percent compliance requirement to include filtered PWSs and to cover Giardia lamblia and virus inactivation. The following discussion summarizes the basis for these criteria.

The UV dose values in Table IV.D–5 are based on meta-analyses of UV inactivation studies with Cryptosporidium parvum, Giardia lamblia, Giardia muris, and adenovirus (Qian et al. 2004, USEPA 2003a). EPA has expanded the dose values for Cryptosporidium and Giardia lamblia from 3- to 4-log inactivation because available data support criteria for this level of treatment. Neither today's rule nor any existing regulations require PWSs to provide Cryptosporidium inactivation above this level, so EPA has not expanded the UV dose tables further. While today's rule requires up to 5.5-log Cryptosporidium treatment by filtered PWSs, at least 2.0-log of this treatment must be achieved by physical removal.

The required UV doses for inactivation of viruses are based on the dose-response of adenovirus because among waterborne pathogenic viruses that have been studied, it appears to be the most UV resistant. As summarized in Embrey (1999), adenoviruses have been identified as the second most important agent of gastroenteritis in children and can cause significant adverse health effects, including death, in persons with compromised immune systems. They are associated with fecal contamination in water and have been implicated in waterborne disease outbreaks.

EPA used data from studies performed with low pressure mercury vapor lamps on water with turbidity representative of filtered water to derive the UV dose values in Table IV.D–5. Studies with low pressure mercury vapor lamps were selected because they allow the UV dose to be accurately quantified (see USEPA 2003a for specific studies). The UV dose values in Table IV.D–5 can be applied to medium pressure mercury vapor lamps and other lamp types through UV reactor validation testing, as described in the UV Disinfection Guidance Manual. Due to the potential for particulate matter to interfere with UV disinfection, the application of these dose values is limited to post-filtration in filtered PWSs and to unfiltered PWSs.

Flow-through UV reactors deliver a distribution of doses due to variations in light intensity and particle flow path through the reactor. To best account for the dose distribution, the validation test must use a challenge microorganism to determine the degree of inactivation achieved by the UV reactor. This level of performance must then be associated to the UV dose requirements in Table IV.D–5 through known dose-response relationships for the challenge microorganism and target pathogen in order to assign disinfection credit to the UV reactor. States may approve an alternative basis for awarding UV disinfection credit.

Today's rule requires full-scale testing of UV reactors to validate the operating conditions under which the reactors can deliver a required UV dose. EPA believes this testing is necessary due to the uncertainty associated with predicting reactor disinfection performance entirely through modeling or through reduced-scale testing. Under today's rule, EPA intends UV reactor validation testing to be reactor-specific and not site-specific. This means that once a UV reactor has been validated for a range of operating conditions, the validation test results can be applied by all PWSs that will operate within those conditions without the need for retesting at each individual site.

Validation testing must account for factors that will influence the dose delivered by UV reactors during routine operation. These factors include UV absorbance, lamp fouling, lamp aging, the performance of UV intensity sensors, hydraulic flow path and residence time distributions, UV lamp failure, and reactor inlet and outlet hydraulics. The successful outcome of validation testing is the determination of acceptable operating ranges for parameters the PWSs can monitor to ensure delivery of the required UV dose during treatment. The specific parameters will vary depending on the reactor control strategy. In all cases, however, PWSs must monitor UV intensity within the reactor as measured by UV sensors, the flow rate, and the status of lamps. EPA believes that any effective UV reactor control strategy will involve monitoring for these parameters.

Today's rule requires all PWSs using UV for disinfection compliance to treat

at least 95 percent of the water distributed to the public each month with UV reactors operating within validated conditions for the required UV dose. EPA views this 95 percent limit as a feasible minimum level of performance for PWSs to achieve, while ensuring the desired level of health protection is provided. For purposes of design and operation, PWSs should strive to deliver the required UV dose at all times during treatment.

EPA developed these requirements and the associated UV Disinfection Guidance Manual solely for public water systems using UV light to meet drinking water disinfection standards established under SDWA. EPA has not addressed and did not consider the extension of these requirements and guidance to other applications, including point of entry or point of use devices for residential water treatment that are not operated by public water systems to meet SDWA disinfection standards.

c. Summary of Major Comments

Public comment on the August 11, 2003 LT2ESWTR proposal supported the inclusion of UV light in the microbial toolbox for Cryptosporidium inactivation. EPA received significant comment on the UV dose tables, the use of adenovirus as the basis for virus UV dose requirements, UV compliance standards for filtered systems, and safety factors associated with draft guidance. These comments and EPA's responses are summarized as follows.

Commenters generally supported the proposed UV dose values for Cryptosporidium and Giardia lamblia inactivation and recommended that EPA incorporate these values into the final rule. Several commenters requested that EPA provide values for 3.5-, 4.0- or higher log inactivation of Cryptosporidium and Giardia lamblia because available dose-response data include this range. Due to factors like tailing and censoring in the underlying dose-response data, some commenters stated that the proposed UV dose values are conservative and advised EPA to consider this conservatism when recommending additional safety factors in guidance.

In response, EPA has extended the UV dose table in today's rule to cover 3.5- and 4.0-log Cryptosporidium and Giardia lamblia inactivation. None of EPA's regulations require inactivation of Cryptosporidium or Giardia lamblia above these levels, so EPA has not established UV dose requirements for inactivation above 4-log. EPA believes that the statistical analysis used to determine the required UV doses appropriately accounts for variability, tailing, and censoring in the underlying dose-response data. However, the required UV dose values do not account for bias and uncertainty associated with UV reactor validation and monitoring, which are addressed in guidance.

Several commenters were concerned with the use of adenovirus to set UV dose requirements for virus inactivation because the resulting dose values are several times higher than typical UV doses for drinking water disinfection. These high dose values impact the feasibility of PWSs using UV to fully meet virus treatment requirements, which will hinder the use of UV to reduce DBPs and for point-of-entry treatment. Commenters requested that EPA consider waterborne viruses that are more UV-sensitive, such as rotavirus or hepatitus, when setting UV dose requirements. Commenters noted that adenovirus commonly causes infections of the lung or eye, which are not transmitted through water consumption, and that no drinking water outbreaks associated with adenovirus have been reported in the United States.

EPA recognizes that the UV doses for virus inactivation in today's rule are relatively high and that this will limit the degree to which PWSs can use UV for virus treatment. Based on occurrence and health effects, however, EPA continues to believe that UV dose requirements should be protective for adenovirus. The existing requirement for 4-log virus treatment, as established under the SWTR, applies to all waterborne viruses of public health concern in PWSs. Adenovirus is consistently found in water subject to fecal contamination and can be transmitted through consumption of or exposure to contaminated water. It is a common cause of diarrheal illness, particularly in children, and fecal shedding is prevalent in asymptomatic adults. While illness from adenovirus is typically self-limiting, severe health effects, including death, can occur. Consequently, EPA regards adenovirus as a potential health concern in PWSs and has established UV dose requirements to address it.

Many commenters recommended that EPA establish a compliance standard for the operation of UV reactors within validated conditions by filtered PWSs, similar to the 95 percent standard proposed for unfiltered PWSs. Commenters were concerned that without a clear compliance standard in the rule, filtered PWSs would be held to inconsistent and unclear standards, which would impede the design and implementation of UV systems. Some commenters recommended that filtered PWSs by held to the same 95 percent standard as unfiltered PWSs, while others recommended a lower 90 percent standard on the basis that filtered PWSs have more barriers of protection.

EPA agrees that establishing a clear compliance standard for the use of UV to meet inactivation requirements is appropriate. For filtered PWSs using UV to meet microbial treatment requirements, today's final rule requires at least 95 percent of the water distributed to consumers to be treated by UV reactors operating within validated conditions. This is the same standard that applies to unfiltered PWSs. EPA believes that a 95th percentile standard is feasible for all PWSs and represents the minimum level of performance that should be achieved. During routine operation, PWSs should endeavor to maintain UV reactors within validated conditions for the required UV dose at all times.

E. Disinfection Benchmarking for Giardia lamblia and Viruses

1. Today's Rule

The purpose of disinfection benchmarking under today's rule is to ensure that PWSs maintain protection against microbial pathogens as they implement the Stage 2 DBPR and LT2ESWTR. If a PWS proposes to make a significant change in disinfection practice, the PWS must perform the following:

- Develop a disinfection profile for Giardia lamblia and viruses. A disinfection profile consists of documenting Giardia lamblia and virus log inactivation levels at least weekly over a period of at least one year. PWSs that operate for less than one year must profile only during the period of operation. The calculated log inactivation levels must include the entire treatment plant and must be based on operational and water quality data, such as disinfectant residual concentration(s), contact time(s), temperature(s), and, where necessary, pH. PWSs may create profiles by conducting new weekly (or more frequent) monitoring and/or by using previously collected data. A PWS that created a Giardia lamblia disinfection profile under the IESWTR or LT1ESWTR may use the operational data collected for the Giardia lamblia profile to create a virus disinfection profile.
- Calculate a disinfection benchmark, using the following procedure: (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.

- Notify the State before implementing the significant change in disinfection practice. The notification to the State must include 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.

For the purpose of these requirements, 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. The Disinfection Profiling and Benchmarking Guidance Manual provides information to PWSs and States on the development of disinfection profiles, identification and evaluation of significant changes in disinfection practices, and considerations for setting an alternative benchmark (USEPA 1999d).

2. Background and Analysis

A goal in the development of rules to control microbial pathogens and disinfection byproducts (DBPs) is the balancing risks between these two classes of contaminants. EPA established disinfection profiling and benchmarking under the IESWTR and LT1ESWTR, based on a recommendation by the Stage 1 M–DBP Advisory Committee, to ensure that PWSs maintained adequate protection against pathogens as they reduced risk from DBPs. EPA is extending profiling and benchmarking requirements to the LT2ESWTR for the same objective.

Some PWSs will make significant changes in their current disinfection practice to meet TTHM and HAA5 requirements under the Stage 2 DBPR and to provide additional treatment for Cryptosporidium under the LT2ESWTR. To ensure that these PWSs maintain disinfection that is effective against a broad spectrum of microbial pathogens, EPA believes that PWSs and States should evaluate the effects of significant changes in disinfection practice on current microbial treatment levels. Disinfection profiling and benchmarking serves as a tool for making such evaluations.

The August 11, 2003 LT2ESWTR proposal included disinfection profiling and benchmarking requirements. Under the proposal, profiling for Giardia lamblia and viruses was required if a PWS was required to monitor for Cryptosporidium or, in the case of small PWSs, exceeded 80 percent of the TTHM or HAA5 MCL based on a locational running annual average. Under this approach, most large PWSs and a significant fraction of small PWSs were required to develop profiles. The proposal also included a schedule for disinfection profile development. Those PWSs that developed profiles were then required to calculate a disinfection benchmark and notify the State if they proposed to make a significant change in disinfection practice.

In today's final rule, EPA has significantly modified the applicability requirements for disinfection profiling. PWSs are only required to develop a disinfection profile if they propose to make a significant change in disinfection practice after completing the first round of source water monitoring. EPA has made this change from the proposal because under the LT2ESWTR and Stage 2 DBPR, most PWSs will not be required to make significant changes to their disinfection practice. Consequently, most PWSs will not need a disinfection profile. EPA believes that disinfection profiling requirements should be targeted to those PWSs that will make significant disinfection changes.

EPA has also eliminated the scheduling requirements for development of the disinfection profile in order to provide more flexibility to PWSs and States. Today's rule only requires that PWSs notify States prior to making a significant change in their disinfection practice and that this notification include the disinfection profiles and benchmarks, along with an analysis of how the proposed change will affect the current benchmarks. EPA believes that PWSs should collect the operational data needed to develop disinfection profiles, such as disinfectant residual, water temperature, and flow rate, as part of routine practice. PWSs that do not have current disinfection profiles should record this operational information at least weekly for one year so that they can use it to develop disinfection profiles if required.

Today's rule retains the proposed requirement that when disinfection profiling is required, PWSs must develop profiles for both Giardia lamblia and viruses. EPA believes that profiling for both target pathogens is appropriate because the types of treatment changes that PWSs will make to comply with the Stage 2 DBPR or LT2ESWTR could lead to a significant change in the inactivation level for one pathogen but not the other. For example, a PWS that switches from chlorine to UV light to meet Giardia lamblia inactivation requirements is likely to maintain a high level of treatment for this pathogen. The level of treatment for viruses, however, may be significantly reduced. In general, viruses are much more sensitive to chlorine than Giardia but are more resistant to UV. The situation for a PWS switching to microfiltration is similar. The same operational data are used to develop disinfection profiles for both Giardia lamblia and viruses.

As was the case with the IESWTR and LT1ESWTR, the disinfection benchmark under today's rule is not intended to function as a regulatory standard. Rather, the objective of these provisions is to facilitate interactions between the States and PWSs to assess the impact on microbial risk of proposed changes to disinfection practice. Final decisions regarding levels of disinfection for Giardia lamblia and viruses beyond the minimum required by regulation will continue to be left to the States and PWSs. To ensure that the level of treatment for both protozoan and viral pathogens is appropriate, States and PWSs should consider site-specific factors such as source water contamination levels and the reliability of treatment processes.

3. Summary of Major Comments

EPA received significant public comment on disinfection profiling and benchmarking requirements in the August 11, 2003 proposal. A few commenters supported the proposed requirements but most raised concerns with the burden and usefulness of disinfection profiling and requested greater flexibility. These comments and EPA's responses are summarized as follows.

Commenters stated that disinfection profiling diverts PWS and State resources from other public health protection activities and presents an incomplete picture of the information that should be considered when evaluating disinfection changes. Further, some States can only require the level of treatment specified in regulations (e.g., the SWTR, IESWTR, LT1ESWTR) and cannot use a disinfection benchmark to enforce a higher treatment standard. Some commenters also disagreed with requiring a disinfection profile for viruses, since current disinfection practices targeting Giardia lamblia typically achieve much greater virus inactivation than required.

To address these concerns, commenters requested that profiling only be required for PWSs prior to switching disinfectants or that States be allowed to grant waivers from disinfection profiling requirements. Commenters also recommended that States be given flexibility to determine the appropriate time for PWSs to develop disinfection profiles, if necessary. In regard to virus profiling, some commenters suggested that it only be required for PWSs that have not developed profiles for Giardia lamblia or that are switching disinfectants to UV.

In response, EPA has modified the proposed requirements for disinfection profiling and benchmarking from the proposal to significantly reduce the burden on PWSs and States. In today's final rule, profiling is only required for PWSs that propose to make a significant change in disinfection practice. EPA projects that most PWSs will not be required to make treatment changes to comply with the LT2ESWTR and Stage 2 DBPR and, as a result, will not be required to develop disinfection profiles. Further, today's rule gives PWSs and States flexibility to determine the timing for developing disinfection profiles and only requires that the profiles and benchmarks be included in a notification to the State before a PWS implements a significant change in disinfection practice. For PWSs that have not developed disinfection profiles, EPA recommends recording the necessary operational data at least weekly over one year so that a profile can be prepared if needed.

For PWSs that propose to make a significant change in disinfection practice, today's rule maintains the proposed requirement for a disinfection profile for viruses. EPA recognizes that current disinfection practices with chlorine typically achieve far more virus inactivation than required. However, the types of treatment changes that PWSs will make to comply with the Stage 2 DBPR or LT2ESWTR, such as implementing UV or microfiltration, are likely to maintain high levels of treatment for Giardia lamblia but may result in a significant decrease in treatment for viruses. Consequently, EPA believes that States and PWSs should consider whether such a decrease in virus treatment will occur when evaluating proposed treatment changes.

Moreover, developing a virus disinfection profile does not require the collection of operational data beyond that necessary to develop a Giardia lamblia disinfection profile. Therefore, today's rule allows PWSs to use previously developed Giardia lamblia disinfection profiles and allows the operational data that underlie the Giardia lamblia profile to be used for a virus disinfection profile.

F. Requirements for Systems With Uncovered Finished Water Storage Facilities

1. Today's Rule

Today's rule requires PWSs that store treated water in an open reservoir (i.e., use uncovered finished water storage facilities) to do either of the following:

- Cover the finished water storage facility; or
- Treat the discharge of the uncovered finished water storage facility that is distributed to consumers to achieve inactivation and/or removal of 4-log virus, 3-log Giardia lamblia, and 2-log Cryptosporidium.

PWSs must notify the State if they use uncovered finished water storage facilities no later than April 1, 2008. PWSs must either meet the requirements of today's rule for covering or treating each facility or be in compliance with a State-approved schedule for meeting these requirements no later than April 1, 2009.

Today's rule revises the definition of an uncovered finished water storage facility as follows: uncovered finished water storage facility is a tank, reservoir, or other facility used to store water that will undergo no further treatment to reduce microbial pathogens except residual disinfection and is directly open to the atmosphere.

2. Background and Analysis

The requirements in today's rule for PWSs that use uncovered finished water storage facilities (open reservoirs) are based on an assessment of the types and sources of contaminants in open reservoirs, the efficacy and feasibility of regulatory approaches to reduce risks from this contamination, and comments on the August 11, 2003 proposal. The following discussion summarizes this assessment.

a. *Types and sources of contaminants in open reservoirs.* The storage of treated drinking water in open reservoirs can lead to significant water quality degradation and health risks to consumers (USEPA 1999e). Examples of such water quality degradation include increases in algal cells, coliform bacteria, heterotrophic plate count bacteria, turbidity, particulates, DBPs, metals, taste and odor, insect larvae, Giardia, Cryptosporidium, and nitrate (USEPA 1999e). Contamination of open reservoirs occurs through surface water runoff, bird and animal wastes, human activity, algal growth, insects and fish, and airborne deposition. Additional information on these sources of contamination follows.

If a reservoir receives surface water runoff, the SWTR requires that it be treated as raw water storage, rather than a finished water reservoir (40 CFR 141.70(a)). Nevertheless, many uncovered finished water reservoirs have been found to be affected by surface water runoff, which may include agricultural fertilizers, pesticides, microbial pathogens, automotive fluids and residues, sediment, nutrients, natural organic matter, and metals (USEPA 1999e, LeChevallier et al. 1997).

Birds are a significant cause of contamination in open reservoirs, and bird feces may contain coliform bacteria, viruses, and other human pathogens, including vibrio cholera, Salmonella, Mycobacteria, Typhoid, Giardia, and Cryptosporidium (Geldreich and Shaw 1993). Birds can ingest pathogens at landfills or wastewater treatment plants prior to visiting a reservoir and have been shown to carry and pass infectious Cryptosporidium parvum (Graczyk et al. 1996). Five to twenty percent of birds are estimated to be periodically infected with human pathogens like Salmonella (USEPA 1999e). A 1993 Salmonella outbreak in Gideon, MO that resulted in seven deaths was traced to pigeons roosting in a finished water storage tank.

Animals that are either known or suspected to contaminate open reservoirs include dogs, cats, deer, rats, mice, opossums, squirrels, muskrats, raccoons, beavers, rabbits, and frogs. Some animals are infected with human pathogens like Cryptosporidium, which can be discharged to the reservoirs in feces or transmitted by direct contact between animals and the water (Fayer and Unger 1986, Current 1986, USEPA 1999e).

Open reservoirs are exposed to contamination through human activities. Pesticides and fertilizers can enter open reservoirs through runoff and airborne drifts from spray applications. Swimming in reservoirs can result in pathogens being passed from the feces, shedded skin, and mucus membranes of infected persons. PWSs routinely find a great variety of items that have been thrown into open reservoirs, despite the use of high fences and set-back distances. Such items include baby carriages, beer bottles, bicycles, bullets, dead animals, dog waste bags, fireworks, garbage cans, a pay phone, shoes, and shovels (USEPA 1999e). These items are a potential source of pathogens and toxic substances and clearly indicate the

susceptibility of open reservoirs to intentional contamination.

Algal growth is common in open reservoirs and can lead to aesthetic problems like color, taste, and odor, and may generate cyanobacterial toxins, which cause headaches, fever, diarrhea, abdominal pain, nausea, and vomiting. In addition, algae can increase other contaminants like DBPs by increasing biomass within reservoirs, and corrosion products like lead, through causing significant pH fluctuations. Algae have been shown to shield bacteria from the effects of disinfection (Geldreich and Shaw 1993).

Open reservoirs may be infested with the larvae of insects such as midge flies, water fleas, and gnats, which can be carried through the distribution system from the reservoir (USEPA 1999e). Chlorination is ineffective against midge fly larvae. Fly outbreaks may increase the presence of insect-eating birds, which present another source of contamination as described earlier. Some open finished water reservoirs have been found to support fish populations.

Open reservoirs also are subject to airborne deposition of contaminants, such as industrial pollutants, automobile emissions, pollen, dust, particulate matter, and bacteria. Deposition occurs during all types of weather conditions, but is likely to be accelerated during precipitation events as air pollutants are transported from the air column above the reservoir by rain or snow.

b. *Regulatory approaches to reduce risk from contamination in open reservoirs.* For many decades, public health agencies and professional associations like the American Public Health Association, the U.S. Public Health Service, and the American Water Works Association have recommended that all finished water reservoirs be covered (USEPA 1999e). In the IESWTR and LT1ESWTR, EPA prohibited the construction of new uncovered finished water reservoirs (40 CFR 141.170(c) and 141.511). These regulations did not address existing uncovered finished water reservoirs, however. In the preamble to the IESWTR, EPA stated that a requirement to cover existing reservoirs would be considered when data to develop national cost estimates were available.

EPA has now collected the necessary data to estimate costs associated with regulatory control strategies for uncovered finished water reservoirs. The August 11, 2003 LT2ESWTR proposal included three options for PWSs with uncovered finished water reservoirs to reduce risk: (1) cover the reservoir, (2) treat the discharge to achieve 4-log virus inactivation, or (3) implement a State-approved risk mitigation plan (USEPA 2003a). These options reflected recommendations from the Stage 2 M–DBP Advisory Committee (USEPA 2000a). Today's final rule includes the first option to cover, modifies the second option to also require 3-log Giardia and 2-log Cryptosporidium treatment, and does not establish an option for a risk mitigation plan. The following discussion describes the basis for these changes.

As described earlier, studies have shown that small mammals and birds that live near water may be infected with Cryptosporidium and Giardia and may shed infectious oocysts and cysts into the water (Graczyk et al. 1996, Fayer and Unger 1986, Current 1986). LeChevallier et al. (1997) evaluated Cryptosporidium and Giardia levels in six uncovered finished water reservoirs. The geometric mean concentration of Cryptosporidium was 1.2 oocysts/100 L in the inlet samples and 8.1 oocysts/100 L in the effluent samples (i.e., 600 percent increase in the reservoir). For Giardia, the geometric mean concentrations in the inlet and effluent samples were 1.9 and 6.1 cysts/100 L, respectively (i.e., 200 percent increase in reservoir).

Most, if not all, PWSs would treat to achieve 4-log virus inactivation with chlorine. Based on EPA guidance, the dose of chlorine necessary for 4-log virus inactivation would not achieve even 0.5-log Giardia inactivation and would produce no inactivation of Cryptosporidium (USEPA 1991b). Consequently, PWSs treating for viruses in open reservoirs, as proposed, would provide very little protection against contamination by Giardia and Cryptosporidium.

Due to the demonstrated potential for contamination by Giardia and Cryptosporidium in open reservoirs and the ineffectiveness of virus treatment against these pathogens, today's rule requires PWSs to treat for Giardia and Cryptosporidium in addition to viruses if they do not cover their finished water reservoirs. Specifically, today's rule specifies the same baseline treatment as required for a raw unfiltered source, which is 4-log virus, 3-log Giardia, and 2-log Cryptosporidium reduction.

EPA believes that requiring treatment for viruses, Giardia, and Cryptosporidium in uncovered finished water reservoirs is consistent with SDWA section 1412(b)(7)(A), which authorizes the use of a treatment technique to prevent adverse health effects to the extent feasible if measuring the contaminant is not feasible. Monitoring for these pathogens at the very low levels that would cause public health concern and at the frequency necessary to detect contamination events is not feasible with available analytical methods. EPA has determined that with the availability of technologies like UV, treating for Giardia, Cryptosporidium, and viruses is feasible for all PWS sizes.

Today's rule does not allow PWSs to implement a risk mitigation plan as an alternative to covering a reservoir or treating the discharge because EPA does not believe that a risk mitigation plan would provide equivalent public health protection. Consequently, a risk mitigation plan would not meet the statutory provision for a treatment technique to prevent adverse health effects from pathogens like Giardia and Cryptosporidium to the extent feasible (SDWA section 1412(b)(7)(A)).

As discussed earlier, open reservoirs are subject to contamination from many sources, including runoff, birds, animals, humans, algae, insects, and airborne deposition. Control measures can provide a degree of protection against some of these sources (e.g., bird deterrent wires, security fences with setback distances). All PWSs are significantly constrained, however, in the degree to which they can implement such measures with existing open reservoirs due to factors like the size of the reservoir, the location of the reservoir (e.g., within residential communities or parks), and the existing infrastructure. For example, many open finished water reservoirs are impacted by runoff, despite the fact that this has been prohibited for many years under existing regulations (USEPA 1999e). EPA has concluded that implementing control measures that would be highly effective against all sources of contamination of open reservoirs would not be feasible for PWSs. Accordingly, today's rule does not allow this option.

c. *Definition of uncovered finished water storage facility.* The IESWTR established the following definition for an uncovered finished water storage facility: uncovered finished water storage facility 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.

In the August 11, 2003, proposed LT2ESWTR, EPA requested comment on whether this definition should be revised. EPA was concerned that it would not include certain cases in which water is stored in an open reservoir after a PWS completes treatment to reduce microbial

pathogens. Such a case would be a PWS that applies a corrosion inhibitor to the effluent of an open reservoir where water is stored after filtration and primary disinfection. In this case, the PWS could claim that the corrosion inhibitor constitutes additional treatment and, consequently, the open reservoir does not meet EPA's definition of an uncovered finished water storage facility. However, the water stored in the open reservoir would be subject to microbial contamination from the sources described in this section and would undergo no further treatment for this contamination.

Today's rule revises the definition of an uncovered finished water storage facility in two ways: (1) The phrase ''to reduce microbial pathogens'' is inserted following the word ''treatment;'' and (2) the word ''directly'' is inserted prior to ''open to the atmosphere.'' The first change ensures that an open reservoir where water is stored after a PWS has completed filtration (where required) and primary disinfection will be appropriately classified as an uncovered finished water storage facility. Whether a PWS applies corrosion control or other treatment to maintain water quality in the distribution system will not affect this determination.

The second change clarifies that covered reservoirs with air vents or overflow lines are not uncovered finished water storage facilities. Such air vents and overflow lines are open to the atmosphere but are usually hooded or screened to prevent contamination of the water. Consequently, these reservoirs are not directly open to the atmosphere and are not subject to the requirements of today's rule for uncovered finished water storage facilities.

3. Summary of Major Comments

EPA received significant public comment on requirements for uncovered finished water storage facilities in the August 11, 2003 proposal. Major issues raised by commenters include whether to require all reservoirs to be covered, requiring treatment for Giardia and Cryptosporidium, support for the proposed options, and revising the definition of an uncovered finished water storage facilities. A summary of these comments and EPA's responses follows.

Several commenters recommended that EPA require all finished water reservoirs to be covered. These commenters stated that making an uncovered reservoir equal in quality to a covered reservoir is not possible—open reservoirs will always be contaminated by fecal material from birds and small mammals, as well as increased DBPs due to algae and other aquatic organisms, airborne contaminants, and sediment stirred up by wind. Commenters were also concerned that uncovered reservoirs are a major vulnerability for PWS security (i.e., intentional contamination). Some commenters cited the fact that there are hundreds of thousands of covered finished water reservoirs in comparison to approximately 100 uncovered finished water reservoirs as evidence that the public health risks of open reservoirs are widely recognized.

EPA agrees that storing treated water in open reservoirs presents a risk to public health. With today's final rule, EPA expects that many PWSs will cover or eliminate uncovered finished water reservoirs. For reservoirs where covering is not feasible, EPA believes that treating the water for Giardia, Cryptosporidium, and viruses will provide protection against the range of pathogens likely to contaminate the reservoir.

Many commenters supported requiring treatment for Giardia and Cryptosporidium for PWSs that treat the reservoir discharge. Commenters stated that reservoirs should either be covered or treated as unfiltered sources (meaning 3-log Giardia, 2-log Cryptosporidium, and 4-log virus treatment). The LeChevallier et al. (1997) study was cited as demonstrating increases in Giardia and Cryptosporidium in uncovered finished water reservoirs, and commenters noted that treatment for viruses would not be effective against these protozoa. EPA agrees with these comments and today's rule requires treatment for Giardia and Cryptosporidium, as well as viruses, by PWSs that do not cover their reservoirs.

Some commenters expressed support for the proposed options, including allowing risk mitigation plans as an adequate remedy for an uncovered reservoir. These commenters characterized the proposal as providing reasonable alternatives to the substantial costs involved in covering reservoirs or providing alternative storage. Commenters stated that strategies included in a risk management plan could address the range of microorganisms for which treatment is necessary, depending on site-specific circumstances.

EPA recognizes that covering or finding alternative storage for uncovered finished water reservoirs can be costly. While EPA believes that covering finished water reservoirs is the most effective approach to protecting public health, today's rule allows PWSs to provide treatment for Giardia, Cryptosporidium, and viruses as a feasible alternative. As described earlier, EPA does not believe that providing treatment only for viruses, as proposed, would be protective against the range of pathogens that contaminate open reservoirs. Further, EPA has concluded that implementing a risk mitigation plan that would provide equivalent protection to covering or treating a reservoir is not feasible. This is due to the many potential sources of contamination and the significant limitations that all PWSs have in the control measures they can implement for existing open reservoirs.

Commenters supported revising the definition of uncovered finished water storage facilities to include situations where PWSs apply a treatment like corrosion control to water stored in an open reservoir after the water has undergone filtration, where required, and primary disinfection. In addition, commenters recommended that EPA clarify that ''open to the atmosphere'' in the definition does not include vents and overflow lines in covered reservoirs. EPA agrees with these comments and today's rule is consistent with them.

G. Compliance Schedules

1. Today's Rule

This section specifies compliance dates for the monitoring and treatment technique requirements in today's rule. As described in sections IV.A through IV.F of this preamble, today's rule requires PWSs to carry out the following activities:

- Conduct initial source water monitoring on a reported schedule. PWSs may grandfather previously collected monitoring results and may elect to provide the maximum Cryptosporidium treatment level of 5.5-log for filtered PWSs or 3.0-log for unfiltered PWSs instead of monitoring.
- Determine a treatment bin classification (or mean Cryptosporidium level for unfiltered PWSs) based on monitoring results.
- For filtered PWSs in Bins 2–4 and all unfiltered PWSs, provide additional treatment for Cryptosporidium by selecting technologies from the microbial toolbox.
- Report disinfection profiles and benchmarks prior to making a significant change in disinfection practice.
- Report the use of uncovered finished water storage facilities and cover or treat the discharge of such reservoirs on a State-approved schedule.

• Conduct a second round of source water monitoring approximately six years after initial bin classification.

Compliance dates for these activities vary by PWS size. Tables IV.G–1 and IV.G–2 specify source water monitoring and treatment compliance dates for large and small PWSs, respectively. Table IV.G–3 shows compliance dates for PWSs using uncovered finished water storage facilities. Wholesale PWSs must comply with the requirements of today's rule based on the population of the largest PWS in the combined distribution system.

TABLE IV.G–1.—MONITORING AND TREATMENT COMPLIANCE DATES FOR PWSS SERVING AT LEAST 10,000 PEOPLE

Requirement	Compliance dates by PWS Size		
	PWSs serving at least 100,000 people	PWSs serving at least 50,000 but less than 100,000 people	PWSs serving at least 10,000 but less than 50,000 people
Report sampling schedule and sampling location description for initial source water monitoring for Cryptosporidium (plus E. coli and turbidity at filtered PWSs) [1, 2].	No later than July 1, 2006.	No later than January 1, 2007.	No later than January 1, 2008.
Report notice of intent to grandfather previously collected Cryptosporidium data, if applicable.			
Report intent to provide the maximum Cryptosporidium treatment level in lieu of monitoring, if applicable [1].			
Begin initial source water monitoring for Cryptosporidium (plus E. coli and turbidity at filtered PWSs) [1,2].	No later than the month beginning October 1, 2006.	No later than the month beginning April 1, 2007.	No later than the month beginning April 1, 2008.
Submit previously collected Cryptosporidium data and required documentation for grandfathering, if applicable.	No later than December 1, 2006.	No later than June 1, 2007..	No later than June 1, 2008.
Report Cryptosporidium treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) and supporting data for approval.	No later than the month beginning April 1, 2009.	No later than the month beginning October 1, 2009.	No later than the month beginning October 1, 2010.
Report disinfection profiles and benchmarks, if applicable.	Prior to making a significant change in disinfection practice.		
Comply with additional Cryptosporidium treatment requirements based on treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) [3].	No later than April 1, 2012 [3].	No later than October 1, 2013 [3].	No later than October 1, 2012 [3].
Report sampling schedule and sampling location description for second round of source water monitoring for Cryptosporidium (plus E. coli and turbidity at filtered PWSs) [1].	No later than January 1, 2015.	No later than July 1, 2015.	No later than July 1, 2016.
Report intent to provide maximum Cryptosporidium treatment level in lieu of monitoring, if applicable [1].			
Begin second round of source water monitoring for Cryptosporidium (plus E. coli and turbidity at filtered PWSs) [1].	No later than the month beginning April 1, 2015.	No later than the month beginning October 1, 2015.	No later than the month beginning October 1, 2016.
Report Cryptosporidium treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) and supporting data from second round of monitoring for approval.	No later than the month beginning October 1, 2017.	No later than the month beginning April 1, 2018.	No later than the month beginning April 1, 2019.
Comply with additional Cryptosporidium treatment requirements if bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) changes based on second round of monitoring.	On a schedule the State approves.		

[1] PWS are not required to conduct source water monitoring if they submit a notice of intent to provide the maximum Cryptosporidium treatment level: 5.5-log for filtered PWSs or 3.0-log for unfiltered PWSs.

[2] Not required if PWS grandfathers at least 2 years of Cryptosporidium data.

[3] States may grant up to an additional 2 years for systems making capital improvements.

TABLE IV.G–2.—MONITORING AND TREATMENT COMPLIANCE DATES FOR PWSS SERVING FEWER THAN 10,000 PEOPLE

Requirement	Compliance dates
Indicator (E. coli) Monitoring Requirements for Filtered PWSs Only	
Report sampling schedule and sampling location description for initial source water monitoring for E. coli or alternative State-approved indicator [1 2].	No later than July 1, 2008.
Report notice intent to grandfather previously collected E. coli data, if applicable.	
Report intent to provide the maximum Cryptosporidium treatment level in lieu of monitoring, if applicable [1].	
Begin initial source water monitoring for E. coli [1 2]	No later than the month beginning October 1, 2008.
Report E. coli data for grandfathering, if applicable	No later than December 1, 2008.

TABLE IV.G–2.—MONITORING AND TREATMENT COMPLIANCE DATES FOR PWSS SERVING FEWER THAN 10,000 PEOPLE—Continued

Requirement	Compliance dates	
Report sampling schedule and sampling location description for second round of source water monitoring for E. coli [1].	No later than July 1, 2017.	
Report intent to provide the maximum Cryptosporidium treatment level in lieu of monitoring, if applicable [1].		
Begin second round of source water monitoring for E. coli [1].	No later than the month beginning October 1, 2017.	
Requirement	Compliance dates by monitoring option	
	PWSs monitoring twice-per-month for 1 year	PWSs monitoring monthly for 2 years
Cryptosporidium Monitoring Requirements for Filtered PWSs That Exceed Indicator (E. coli) Trigger Concentration [3] and All Unfiltered PWSs		
Report sampling schedule and sampling location description (if not reported previously) for initial source water monitoring for Cryptosporidium [1 4].	No later than January 1, 2010.	
Report notice of intent to grandfather previously collected Cryptosporidium data, if applicable.		
Begin initial source water monitoring for Cryptosporidium [1 4]	No later than the month beginning April 1, 2010.	
Submit previously collected Cryptosporidium data and required documentation for grandfathering, if applicable.	No later than June 1, 2010.	
Report Cryptosporidium treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) and supporting data for approval.	No later than the month beginning October 1, 2011.	No later than the month beginning October 1, 2012.
Report disinfection profiles and benchmarks, if applicable	Prior to making a significant change in disinfection practice.	
Comply with additional Cryptosporidium treatment requirements based on treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) [5].	No later than October 1, 2014 [5].	
Report sampling schedule sampling location description (if not reported previously) for second round of source water Cryptosporidium monitoring [1].	No later than than January 1, 2019.	
Begin second round of source water monitoring for Cryptosporidium [1].	No later than the month beginning April 1, 2019.	
Report Cryptosporidium treatment bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) and supporting data from second round of monitoring for approval.	No later than the month beginning October 1, 2020.	No later than the month beginning October 1, 2021.
Comply with additional Cryptosporidium treatment requirements if bin classification (or mean Cryptosporidium concentration for unfiltered PWSs) changes based on second round of monitoring.	On a schedule the State approves.	

[1] PWS are not required to conduct source water monitoring if they submit a notice of intent to provide the maximum Cryptosporidium treatment level: 5.5-log for filtered PWSs or 3.0-log for unfiltered PWSs.
[2] Not required if PWS grandfathers at least 1 year of E. coli data.
[3] Filtered PWSs must conduct Cryptosporidium monitoring if the E. coli annual mean concentration exceeds 10/100 mL for PWSs using lake or reservoir sources or exceeds 50/100 mL for PWSs using flowing stream sources or a trigger value for an alternative State-approved indicator is exceeded.
[4] Not required if PWS grandfathers at least 1 year of twice-per-month or 2 years of monthly Cryptosporidium data.
[5] States may grant up to an additional 2 years for PWSs making capital improvements.

TABLE IV.G–3.—COMPLIANCE DATES FOR PWSS USING UNCOVERED FINISHED WATER STORAGE FACILITIES

Report the use of uncovered finished water storage facilities, if applicable.	No later than April 1, 2008.
Either comply with requirement to cover or treat uncovered finished water storage facilities or comply with State-approved schedule to meet this requirement.	No later than April 1, 2009.

2. Background and Analysis

The compliance schedule in today's final rule stems from its risk-targeted approach, wherein PWSs initially conduct monitoring to determine additional treatment requirements. A primary objective of this schedule is to ensure that PWSs provide additional treatment without delay for higher risk sources. This is especially important with a risk-targeted rule, given the significant time required for initial monitoring. However, the compliance schedule balances this objective with the need to provide PWSs and States with time to prepare for implementation activities.

SDWA section 1412(b)(10) states that a drinking water regulation shall take effect 3 years from the promulgation date unless the Administrator determines that an earlier date is practicable. Today's rule requires PWSs to begin monitoring prior to 3 years from the promulgation date. Based on EPA's assessment and recommendations of the Advisory Committee, as described in this section, EPA has determined that these monitoring start dates are practicable and appropriate.

In general, PWSs serving at least 10,000 people conduct two years of source water monitoring for Cryptosporidium (as well as E. coli and turbidity in filtered PWSs). At the conclusion of this monitoring, these PWSs have six months to analyze monitoring results and report their treatment bin classification to the State for approval. Where required, PWSs must provide the necessary level of additional Cryptosporidium treatment within three years of bin classification, though States may allow an additional two years for PWSs making capital improvements. A second round of source water monitoring must be initiated six years after initial bin classification.

For PWSs serving at least 10,000 people, the timing of monitoring and treatment activities in today's rule partially reflects recommendations by the Stage 2 M–DBP Advisory Committee and the schedule in the August 11, 2003 proposed LT2ESWTR. EPA has modified the proposed compliance schedule to stagger monitoring start dates for PWSs serving 10,000 to 99,999 people. The following discussion addresses these changes from the proposal.

The proposed rule required all PWSs serving at least 10,000 people to begin source water monitoring six months after the rule was established, as recommended by the Advisory Committee. Under today's final rule, PWSs serving at least 100,000 people maintain this schedule. The monitoring start date for PWSs serving 50,000 to 99,999 people is staggered by six months and begins 12 months after the rule is effective. For PWSs serving 10,000 to 49,999, the monitoring start date is staggered by 18 months and begins 24 months after the rule is effective. Dates to comply with additional treatment requirements are staggered accordingly.

This staggering of monitoring start dates for PWSs serving 10,000 to 99,999 people is advantageous in several respects:

- Provides more time for PWSs that have not monitored for Cryptosporidium previously to prepare for monitoring (PWSs serving at least 100,000 people monitored for Cryptosporidium under the ICR). PWSs can use this time to develop budgets, establish contracts with Cryptosporidium laboratories, identify appropriate sampling locations, and learn sampling procedures.
- Provides more time for Cryptosporidium analytical laboratories to build capacity as needed to accommodate the sample analysis needs of PWSs.
- Spreads out the transactional demand for regulatory oversight. EPA anticipates that the period of greatest transactional demand for States and EPA that oversee monitoring will be when PWSs begin monitoring. The staggered schedule will allow States and EPA to provide more assistance to individual PWSs.
- Eliminates the gap between the end of large PWS monitoring and the start of small PWS monitoring (under the proposed rule schedule, a gap of 18 months existed between the time that large PWSs completed and small PWSs started Cryptosporidium monitoring). Such a gap could create difficulties with maintaining Cryptosporidium sampling and laboratory analysis expertise to support monitoring by small PWSs.

The timing of monitoring and treatment activities in today's rule for PWSs serving fewer than 10,000 people is nearly identical to the schedule in the August 11, 2003 proposed LT2ESWTR and reflects recommendations by the Advisory Committee. The only change is allowing these PWSs the option to spread their Cryptosporidium monitoring over two years in order to facilitate budgeting for this monitoring. However, this change does not affect the treatment compliance dates for these PWSs.

Specifically, filtered PWSs serving fewer than 10,000 people initially conduct one year of source water monitoring for E. coli or an alternative indicator if approved by the State, beginning 30 months after the rule is effective. At the conclusion of this monitoring, these PWSs have six months to prepare for Cryptosporidium monitoring, if required based on their indicator monitoring results. Filtered PWSs that exceed the indicator trigger value and all unfiltered PWSs serving fewer than 10,000 people must begin Cryptosporidium monitoring 48 months after the rule is effective. This Cryptosporidium monitoring may consist of sampling twice-per-month for one year or once-per-month for two years. PWSs must report their bin classification to the State for approval within six months of the scheduled completion of Cryptosporidium monitoring.

Regardless of the Cryptosporidium sampling frequency, PWSs serving fewer than 10,000 people must comply with any additional Cryptosporidium treatment requirements within 102 months (8.5 years) after the rule is effective. States may allow an additional two years for PWSs making capital improvements. PWSs must begin a second round of source water monitoring for E. coli or an alternative State-approved indicator within 11.5 years (138 months) after the rule is effective (six years after the bin classification date for PWSs that sampled for Cryptosporidium twice-per-month during initial source water monitoring).

In summary, the compliance schedule for today's rule maintains the earliest compliance dates recommended by the Advisory Committee for PWSs serving at least 100,000 people. These PWSs serve the majority of people that consume water from surface sources. The schedule also maintains the latest compliance dates the Advisory Committee recommended, which apply to PWSs serving fewer than 10,000 people. EPA has staggered compliance schedules for PWSs between these two size categories in order to facilitate implementation of the rule.

3. Summary of Major Comments

EPA received significant public comment on the compliance schedule in the August 11, 2003 proposal. Major issues raised by commenters include providing more time for PWSs to prepare for monitoring, giving States more time to oversee monitoring, ensuring that laboratory capacity can accommodate the compliance schedule, and establishing consistent schedules for consecutive PWSs. A summary of these comments and EPA's responses follows.

Commenters were concerned that some PWSs, in particular PWSs serving 10,000 to 50,000 people, would need more than the three months allowed under the proposed rule to report sampling schedules for monitoring. In order to develop sampling schedules, PWSs must establish contracts with laboratories, which may involve using municipal procurement procedures. For smaller PWSs, budgeting for this expense may require substantial time and planning.

EPA recognizes this concern and today's final rule provides significantly more time for many PWSs to submit sampling schedules. Specifically, PWSs serving 50,000 to 99,999 people and those serving 10,000 to 49,999 people must submit sampling schedules 9 and 21 months after the rule is effective, respectively. EPA believes that these PWSs will have sufficient time to develop sampling schedules with these compliance dates. Today's rule still requires PWSs serving at least 100,000 people to submit sampling schedules 3 months after the rule is effective. Because these PWSs have monitored for Cryptosporidium previously, however,

EPA believes that this compliance date is feasible for these PWSs.

Several commenters recommended that States, rather than EPA, oversee monitoring due to States' existing relationships with and knowledge of their PWSs. Commenters were concerned that some States will not participate in early implementation activities and indicated that States would prefer monitoring to begin 24 months after rule promulgation. States need sufficient time to become familiar with the rule, train their staff, prepare primacy packages, and train PWSs.

In general, EPA would prefer that States oversee monitoring by their PWSs and will work with States to facilitate their involvement with rule implementation. Where States are unable to implement today's rule, however, EPA is prepared to oversee implementation. Moreover, EPA believes that the staggered compliance schedule in today's final rule will enhance States' ability to implement the rule.

While EPA does not consider waiting until 24 months after rule promulgation to start monitoring for all PWSs to be appropriate, most PWSs will not begin monitoring until this time or later under today's rule. Among large PWSs (*i.e.*, those serving at least 10,000 people), the majority are in the 10,000 to 49,999 person size category and these PWSs do not begin monitoring until 24 months after rule promulgation. Further, all PWSs serving fewer than 10,000 people do not begin monitoring until 30 months after rule promulgation. These smaller PWSs are likely to need the most assistance from States. By staggering monitoring start dates, today's rule also reduces the number of PWSs that will begin monitoring at any one time, when the most assistance from regulatory agencies will be required.

Many commenters were concerned that the capacity at Cryptosporidium analytical laboratories would not be sufficient for the proposed implementation schedule. Commenters noted that the proposed rule schedule had a break of 18 months between the end of large PWS Cryptosporidium monitoring and the start of small PWS Cryptosporidium monitoring and thought that this break would discourage laboratories from making investments to improve capacity. Other commenters stated that excess laboratory capacity exists and that upon indication that a final rule is imminent, commercial laboratories will hire staff to handle the expected number of samples. Laboratories will, however, need time to train analysts.

EPA recognizes the concern with ensuring that capacity at Cryptosporidium laboratories will be sufficient. Through EPA's laboratory approval program (described in section IV.K), the Agency has evaluated capacity at Cryptosporidium laboratories. Based on information provided by laboratories, EPA believes that current capacity at Cryptosporidium laboratories will be sufficient for the monitoring that PWSs serving at least 100,000 people will begin six months after the rule is effective. EPA expects that commercial laboratories will increase capacity as needed to serve the demand of smaller PWSs that begin monitoring later. Approximately six months are required to train Cryptosporidium analysts. Consequently, the staggered compliance schedule should allow time for laboratories to hire and train staff as necessary. In addition, with the compliance schedule in today's final rule, no break exists between the time that large PWSs end and small PWSs begin Cryptosporidium monitoring. Thus, EPA has eliminated this potential disincentive to laboratories investing in capacity.

However, EPA will continue to monitor laboratory capacity and the ability of PWSs to contract with laboratories to meet their monitoring requirements under the LT2ESWTR. The Agency will assist with implementation of the rule to help maximize the use of available laboratory capacity by PWSs. If evidence emerges during implementation of the rule that PWSs are experiencing problems with insufficient laboratory capacity, the Agency will undertake appropriate action at that time.

In regard to consecutive PWSs (*i.e.*, PWSs that buy and sell treated water), commenters recommended that compliance schedules in the Stage 2 DBPR and LT2ESWTR should be consistent. Some commenters also suggested that where a small PWS sells water to a large PWS, the small PWS should comply on the large PWS schedule. In response, today's final rule requires PWSs that sell treated drinking water to other PWSs to comply according to the schedule that applies to the largest PWS in the combined distribution system. This approach will ensure that PWSs have the same compliance schedule under both the LT2ESWTR and Stage 2 DBPR.

H. Public Notice Requirements

1. Today's Rule

Today's rule establishes the following public notice requirements:

- For violations of treatment technique requirements, which today's rule establishes for Cryptosporidium treatment and for covering or treating uncovered finished water reservoirs, PWSs must issue a Tier 2 public notice and must use existing health effects language (except as provided below) for microbiological contaminant treatment technique violations, as stated in 40 CFR 141 Subpart Q, Appendix B.
- For violations of monitoring and testing procedure requirements, including the failure to collect one or two source water Cryptosporidium samples, PWSs must issue a Tier 3 public notice. If the State determines that a PWS has failed to collect three or more Cryptosporidium samples, the PWS must provide a Tier 2 special public notice. Violations for failing to monitor continue until the State determines that the PWS has begun sampling on a revised schedule that includes dates for collection of missed samples. This schedule may also include a revised bin determination date where necessary.
- PWSs must report their bin classification no later than six months after the end of the scheduled monitoring period (specific dates in section IV.G.). Failure by a PWS to collect the required number of Cryptosporidium samples to report its bin classification by the compliance date is a treatment technique violation and the PWS must provide a Tier 2 public notice. The treatment technique violation persists until the State determines that the PWS is implementing a State-approved monitoring plan to allow bin classification or will install the highest level of treatment required under the rule. If the PWS has already provided a Tier 2 special public notice for missing 3 sampling dates and is successfully meeting a State-approved schedule for sampling and bin determination, it need not provide a second Tier 2 notice for missing the bin determination deadline in today's rule.

2. Background and Aalysis

In 2000, EPA published the Public Notification Rule (65 FR 25982, May 4, 2000) (USEPA 2000b), which revised the general public notification regulations for PWSs in order to implement the public notification requirements of the 1996 SDWA amendments. This regulation established the requirements that PWSs 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 PWSs 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 some Cryptosporidium treatment requirements under the LT2ESWTR. However, for persistent monitoring violations and missing the deadline for bin determination, EPA is promulgating alternative language that better informs consumers of the nature and potential health consequences of the violation.

As described in section IV.C, EPA proposed automatically classifying PWSs in the highest treatment bin (Bin 4) if they fail to complete required monitoring. For today's final rule, EPA has determined that providing more flexibility to States in dealing with PWSs that fail to monitor is appropriate. EPA also believes, however, that responses to monitoring failures must reasonably ensure that PWSs complete monitoring as required to determine a bin classification within the compliance date, or as soon thereafter as possible. Moreover, consistent with the public health protection and consumer right-to-know provisions of the 1996 SDWA Amendments, consumers should be informed of these monitoring failures.

Instead of the proposed automatic Bin 4 classification for monitoring failures under today's rule, PWSs must provide a Tier 3 public notice for monitoring violations including up to two missed Cryptosporidium samples. If a PWS misses three or more Cryptosporidium samples (other than the specifically exempted situations described in section IV.A.1.c), this persistent violation requires a Tier 2 public notice. This elevated public notice level reflects significant concern that persistent failure to collect required samples will result in the PWS being unable to determine its Cryptosporidium treatment bin classification and the corresponding required treatment level by the compliance date.

Further, if a PWS is unable to determine a bin classification by the compliance date due to failure to collect the required number of Cryptosporidium samples, this is a treatment technique violation that also requires a Tier 2 public notice, unless the system is already complying with an alternate State-approved schedule for monitoring and bin determination. A PWS that does not determine its bin classification by the required date may not be able to comply with the Cryptosporidium treatment technique requirements of today's rule by the required date and provide the appropriate level of public health protection.

3. Summary of Major Comments

In the August 11, 2003, proposal, EPA requested comment on whether violations of the treatment requirements for Cryptosporidium under the LT2ESWTR should require a Tier 2 public notice and whether the proposed health effects language is appropriate (USEPA 2003a). Most commenters supported requiring a Tier 2 public notice for violations of Cryptosporidium treatment requirements under the LT2ESWTR and agreed that no new health effects language is needed for this notification. One commenter stated that a failure to meet Cryptosporidium removal requirements under LT2ESWTR should require Tier 1 public notice.

Today's final rule reflects the views of most commenters and is consistent with existing regulations in requiring a Tier 2 public notice for Cryptosporidium treatment technique violations. A State may elevate a violation to Tier 1 if the State determines that the violation creates significant potential for serious adverse health effects from short-term exposure.

Another commenter agreed that Tier 2 notice was appropriate but recommended that the LT2ESWTR and any associated guidance be more explicit as to when a treatment technique violation occurs with the use of microbial toolbox options. As described in section IV.D, EPA has stated in today's final rule that failure by a PWS in any month to demonstrate treatment credit with microbial toolbox options equal to or greater than its Cryptosporidium treatment requirements is a treatment technique violation. This violation lasts until the PWS demonstrates that it is meeting criteria for sufficient treatment credit to satisfy its Cryptosporidium treatment requirements.

I. Reporting Source Water Monitoring Results

This section presents specific reporting requirements that apply to source water monitoring under today's rule, including EPA's data system for reporting and reviewing monitoring results. For related requirements, see section IV.A for monitoring parameters frequency, section IV.J for required analytical methods, and section IV.K for approved laboratories. General reporting requirements under today's rule and associated compliance dates are shown in section IV.G.

1. Today's Rule

PWSs must report results from the required source water monitoring

described in section IV.A no later than 10 days after the end of the first month following the month when the sample is collected. For Cryptosporidium analyses, PWSs must report the data elements specified in Table IV.I–1. For samples in which at least 10 L is filtered and all of the sample volume is analyzed, only the sample volume filtered and the number of oocysts counted must be reported. Table IV.I–2 presents the data elements that PWSs must report for E. coli and turbidity analyses. PWSs, or approved laboratories acting as the PWSs' agents, must retain results from Cryptosporidium and E. coli monitoring until 36 months after bin determination for the particular round of monitoring.

TABLE IV.I–1.—CRYPTOSPORIDIUM DATA ELEMENTS TO BE REPORTED

Data element	Reason for data element
Identifying information:	
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) [1]	Needed to distinguish field samples from matrix samples for recovery calculations.
Sample results:	
Sample volume filtered (L), to nearest ¼ L [2]	Needed to verify compliance with sample volume requirements.
Was 100% of filtered volume examined? [3]	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.

[1] For matrix spike samples, sample volume spiked and estimated number of oocysts spiked must be reported. These data are not required for field samples.

[2] 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 must also be reported to verify compliance with LT2ESWTR sample volume analysis requirements. These data are not required for most samples.

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

TABLE IV.I–2.—E. COLI AND TURBIDITY DATA ELEMENTS TO BE REPORTED

Data element	Reason for collecting data element
Identifying Information:	
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 assess Cryptosporidium indicator relationships.
E. coli/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).
Turbidity Information:	
Turbidity result	Needed to assess Cryptosporidium indicator relationships.

PWSs serving at least 10,000 people must submit sampling schedules (described in section IV.A) and monitoring results for the initial source water monitoring to EPA electronically at the following Internet site: *https://intranet.epa.gov/lt2/*. These PWSs should instruct their laboratories to electronically enter results at this site using web-based manual entry forms or by uploading XML files (extensible markup language files—a standard format that enables information exchange between different systems) from laboratory information management systems (LIMS). After laboratories enter sample results, PWSs must review the results on-line at this site. The State may approve an alternative approach for reporting source water monitoring schedules and sample results if, for example, a PWS or laboratory does not have the capability to report data electronically.

If a PWS believes that its laboratory entered a sample result into the data system erroneously, the PWS may notify the laboratory to rectify the entry. In addition, if a PWS believes that a result is incorrect, the PWS may electronically mark the result as contested and petition the State to invalidate the sample. If a PWS contests a sample result, the PWS should submit a rationale to the State, including a supporting statement from the laboratory, providing a justification. PWSs may arrange with laboratories to review their sample results prior to the results being entered into the EPA data system.

PWSs serving fewer than 10,000 people must submit sampling schedules and monitoring results for the initial round of source water monitoring to the State. Further, all PWSs must submit sampling schedules and monitoring results for the second round of

monitoring to the State. Regardless of the reporting process used, PWSs must report an analytical monitoring result to the State no later than 10 days after the end of the first month following the month when the sample was collected.

2. Background and Analysis

The reporting requirements for source water monitoring in today's final rule reflect those in the August 11, 2003 proposed LT2ESWTR (USEPA 2003a). The data elements that PWSs must report for Cryptosporidium and E. coli analyses are the minimum necessary to identify the sample, determine the sample concentration, and verify that the PWS complied with rule requirements like minimum sample volume and approved analytical methods. PWSs or laboratories must keep bench sheets and slide reports for Cryptosporidium analyses for three years after bin determination for the particular round of monitoring, at which time PWSs must be in compliance with any additional Cryptosporidium treatment requirements based on the monitoring results.

Due to the early implementation schedule, EPA expects to partner with States to implement initial source water monitoring by large PWSs under today's rule. EPA has developed an Internet-based data system to allow electronic reporting and review of source water monitoring results by laboratories, PWSs, States, and EPA. States may use this data system to oversee monitoring by their PWSs. Where States are unable to provide this oversight, the data system will allow EPA to implement today's rule. Accordingly, PWSs serving at least 10,000 people must use this data system to report sampling schedules and sample results for the initial round of source water monitoring unless the State approves an alternative method for reporting.

EPA expects laboratories to report analytical results for Cryptosporidium, E. coli, and turbidity analyses directly to the data system using web forms and software that are available free of charge. The data system will perform logic checks on data entered and will calculate 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. The LT2ESWTR proposal describes the analysis functions of the data system in more detail (USEPA 2003a).

In general, EPA expects that States will implement the initial source water monitoring by small PWSs and the second round of monitoring by all PWSs. Thus, PWSs must submit sampling schedules and monitoring results for this monitoring to the State. Note that where States do not assume primacy for the rule, however, EPA will act as the State.

3. Summary of Major Comments

EPA received significant public comment on the following aspects of reporting requirements for source water monitoring in the August 11, 2003 proposed LT2ESWTR: the deadline for reporting sample results, EPA's electronic data system, and reporting results to EPA rather than the State. A summary of these comments and EPA's responses follows.

Some commenters were concerned with requiring PWSs to report sample results no later than the 10th of the second month after the month when the sample is collected. Commenters stated that this will cause most PWSs to sample in the first part of the month, which will exacerbate laboratory capacity problems. As an alternative, commenters recommended that PWSs be required to report sample results 72 days after collection. This approach would give all PWSs the same time period to report sample results regardless of the collection date and would facilitate PWSs and laboratories scheduling sample collection dates more uniformly throughout the month.

In response, EPA believes that requiring PWSs to report monitoring results by the 10th of the second month after sample collection is appropriate. This will maintain consistency with existing drinking water regulations, which typically require monitoring results to be reported by the 10th of the following month. Thus, specifying this reporting date under today's rule will avoid causing PWSs and States to develop different reporting dates for different regulations. Due to the time required for laboratories to analyze Cryptosporidium samples, today's rule gives PWSs an extra month to report monitoring results; i.e., the minimum time PWSs have to report results is approximately 40 days (one month plus 10 days). This time frame, however, is greater than what is necessary for laboratories to analyze samples and for PWSs to review results. Consequently, EPA does not believe that PWSs will benefit by collecting a sample at the start of a month in comparison to the end of a month.

Many commenters expressed concern with the readiness of the electronic data system for reporting and reviewing monitoring results under today's rule. Commenters stated that PWSs have experienced significant problems with data systems that supported earlier rules, such as the Information Collection Rule and the Unregulated Contaminant Monitoring Rule. Commenters recommended that the data system be in place and fully tested prior to finalization of the rule and that EPA provide training for users. If the data system is not available when the rule is finalized, commenters asked that the monitoring be delayed as specified in the Agreement in Principle (USEPA 2000a).

EPA has ensured that the LT2 data system has been fully tested and deployed prior to finalizing the rule. During development of the data system, EPA has involved stakeholders in a joint requirements workgroup, which has made recommendations for data system characteristics and has participated in data system testing. EPA has developed guidance and other training materials for PWSs, States, and laboratories on how to use the data system and will provide technical assistance on a ongoing basis to data system users. EPA believes these steps will help to avoid problems that stakeholders experienced with data systems for earlier rules.

Some commenters expressed concerns about large PWSs reporting monitoring results to EPA. Commenters stated that implementation of the rule should be administered by States, due to the existing relationships States have with the PWSs they regulate. For States that will implement the rule, commenters recommended allowing PWSs to report to States, rather than EPA. Commenters also requested that EPA provide copies of all monitoring data and PWS correspondence to States when they assume primacy.

EPA will work with States to implement today's rule and to help States assume as much responsibility for implementation as they can. Through the LT2ESWTR data system, States will have full access to monitoring results reported by their PWSs. Today's rule also allows States to direct their PWSs to report monitoring results directly to them, rather than EPA. Further, States may require PWSs to submit descriptions of monitoring locations for approval. In general, EPA will seek to involve States in any communications with and decisions for their PWSs and will allow States to take responsibility for these activities if they choose to do so. However, because monitoring for the largest systems begins before States will have had time to assume primacy, EPA must be prepared to oversee monitoring for these PWSs where States are unable to do so.

J. Analytical Methods

1. Analytical Methods Overview

Today's final rule requires public water systems to conduct LT2ESWTR source water monitoring using approved methods for Cryptosporidium, E. coli, and turbidity analyses. PWSs must meet the quality control criteria stipulated by the approved methods and additional method-specific requirements, as stated in this section. Related requirements for reporting source water monitoring results and using approved laboratories are discussed in sections IV.I and IV.K, respectively.

EPA has developed guidance for sampling and analyses under the LT2ESWTR. The Source Water Monitoring Guidance Manual for Public Water Systems under the LT2ESWTR provides recommendations on activities like collecting samples and setting up contracts with laboratories. The Microbial Laboratory Manual for the LT2ESWTR provides information for laboratories that conduct analyses. These guidance documents may be requested from EPA's Safe Drinking Water Hotline, which may be contacted as described in the **FOR FURTHER INFORMATION CONTACT** section in the beginning of this notice, and are available on the Internet at *www.epa.gov/safewater/disinfection/lt2.*

2. Cryptosporidium Methods

a. Today's Rule

Cryptosporidium analysis for source water monitoring under today's rule must be conducted using either Method 1622: Cryptosporidium in Water by Filtration/IMS/FA (EPA 815–R–05–001, USEPA 2005c) or Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA (EPA 815–R–05–002, USEPA 2005d). Additional method requirements for today's rule include the following:

- For each Cryptosporidium sample, at least a 10–L sample volume must be analyzed unless a PWS meets one of the two exceptions stated in this section. PWSs may collect and analyze greater than a 10–L sample volume.
- The first exception to the sample volume requirement stems from sample turbidity. 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). Samples resulting in large packed pellets must have the sample concentrate aliquoted into multiple ''subsamples'' for independent processing through IMS, staining, and examination. PWSs are not required to analyze more than 2 mL of packed pellet volume per sample.
- The second exception to the sample volume requirement stems from filter clogging. In cases where the filter clogs prior to filtration of 10 L, the PWS 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. Under today's rule, PWSs 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 IV.K), size (4–6 micrometers) and shape (round to oval). This total includes all of the oocysts identified as described here, less any 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.).
- As required by Method 1622 and 1623, PWSs must have 1 matrix spike (MS) sample analyzed for each 20 source water samples. The volume of the MS sample must be 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 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 PWS 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 that was used to collect the balance of the sample in the field.
- Laboratories must use flow cytometer-counted spiking suspensions for spiked QC samples.

b. Background and Analysis

The M–DBP Advisory Committee recommended the use of Methods 1622 or 1623 and a minimum sample volume of 10 L for source water Cryptosporidium analyses under the LT2ESWTR. The August 11, 2003 proposed rule reflected these recommendations, with associated QC requirements and exceptions to the minimum sample volume for samples that are highly turbid or cause significant filter clogging (USEPA 2003a). Today's final rule is unchanged from the proposal in these respects.

Today's rule requires the use of methods 1622 or 1623 because they are the best available methods that have undergone full validation testing. As described in section III.E, these methods were used during the ICRSS, where MS samples indicated a mean recovery and relative standard deviation of 43 and 47 percent, respectively (Connell et al. 2000). EPA expects that PWSs will achieve comparable performance with these methods during source water monitoring under today's rule. With the minimum sample volume and QC requirements in today's rule, this level of performance will be sufficient to assign PWSs to Cryptosporidium treatment bins and realize the public health goals intended by EPA and the Advisory Committee for the LT2ESWTR. EPA has also approved these methods for ambient water monitoring under a separate rulemaking (68 FR 43272, July 21, 2003) (USEPA 2003b).

The proposed LT2ESWTR required the use of April 2001 versions of Methods 1622 or 1623 and requested comment on approving revised versions of these methods in the final rule (USEPA 2003a). The revised methods were included in the proposal as draft June 2003 versions. The revisions in these versions included increased flexibility in some QC requirements, clarification of certain method procedures, an increase in the allowable sample storage temperature to 10°C, the addition of several approved analysis modifications, and other refinements (see the proposed rule for details)(USEPA 2003a).

Today's rule requires the use of the revised versions of Methods 1622 and 1623. In the versions of these methods finalized with today's rule, the upper temperature limit for sample receipt has been increased to 20°C. This change responds to public comment and recent publications (Ware and Schafer 2005, Francy et al. 2004, Nichols et al. 2004). As described in section IV.A, PWSs may grandfather data generated with earlier approved versions of these methods (i.e., 1999 or 2001 versions).

c. Summary of Major Comments

Public comment on the August 11, 2003 proposed LT2ESWTR supported approval of the revised versions of Methods 1622 and 1623, which today's rule establishes for source water Cryptosporidium monitoring. EPA also received comment regarding the lack of viability and infectivity information with these methods and requirements for analyzing QC samples.

Several commenters were concerned that Methods 1622 and 1623 do not indicate whether a Cryptosporidium oocyst is viable and infectious. While EPA recognizes that these methods do not provide information on Cryptosporidium infectivity, EPA's analysis indicates that they can perform effectively for identifying those PWSs that should provide additional Cryptosporidium treatment (USEPA 2005a). This analysis is based on the actual performance of these methods in the ICRSS. Further, EPA and the M–DBP Advisory Committee, which recommended Methods 1622 and 1623, accounted for this lack of information on infectivity when designing the Cryptosporidium treatment bins in today's rule. EPA has not identified any feasible methods for quantifying Cryptosporidium infectivity in a national monitoring program.

Several commenters suggested that laboratories should only be required to perform one OPR test per day instead of one for every 20 samples, as Methods 1622 and 1623 require. EPA believes, however, that the frequency of one OPR test per 20 samples is appropriate for identifying and correcting problems. For example, if an OPR test is performed once per day for a laboratory that processes 60 samples per day, a problem that occurs at sample 10 will be continued through the next 50 samples. If an OPR test is performed once per 20 samples, a problem that occurs at sample 10 would only affect 10 additional samples. Consequently, EPA is maintaining the current QC criteria in Methods 1622 and 1623.

3. E. coli Methods

a. Today's Rule

For enumerating source water E. coli density under the LT2ESWTR, EPA is approving the same methods that are currently approved for ambient water monitoring under 40 CFR 136.3. EPA established these methods through the rulemaking ''Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water'' (USEPA 2003b). Table IV.J–1 summarizes these methods. Method identification numbers are provided for applicable standards published by EPA and voluntary consensus standards bodies including Standard Methods, American Society of Testing Materials (ASTM), and the Association of Analytical Chemists (AOAC).

TABLE IV.J–1.—LIST OF APPROVED ANALYTICAL METHODS FOR E. COLI [1]

Method	EPA	Standard Methods 18th, 19th, 20th Ed.	ASTM	AOAC	Other
MPN [2 3 4], multiple tube		9221B.1/9221F [5 6 7].			
Multiple tube/multiple well		9223B [5 8]		991.15 [9]	Colilert® [8 10], Colilert-18® [8 10 11].
MF [2 3 12 13 14] two step, or	1103.1 [16]	9222B/9222G [5 15] 9213D [5]	D5392–93 [17].		
Single step	1603 [18], 1604 [19].				mColiBlue 24 [20].

[1] Recommended for enumeration of E. coli in ambient water only, number per 100 ml.

[2] Tests must be conducted to provide organism enumeration (density). Select the appropriate configuration of tubes/filtrations and dilutions/volumes to account for the quality, character, consistency, and anticipated organism density of the water sample.

[3] To assess the comparability of results obtained with individual methods, it is suggested that side-by-side tests be conducted across seasons of the year with the water samples routinely tested in accordance with the most current Standard Methods for the Examination of Water and Wastewater or EPA alternate test procedure (ATP) guidelines.

[4] Samples shall be enumerated by the multiple-tube or multiple-well procedure. Using multiple-tube procedures, employ an appropriate tube and dilution configuration of the sample as needed and report the Most Probable Number (MPN). Samples tested with Colilert® may be enumerated with the multiple-well procedures, Quanti-tray®, or Quanti-tray® 2000, and the MPN calculated from the table provided by the manufacturer.

[5] APHA. 1998, 1995, 1992. Standard Methods for the Examination of Water and Wastewater. American Public Health Association. 20th, 19th, and 18th Editions. Amer. Publ. Hlth. Assoc., Washington, DC.

[6] The multiple-tube fermentation test is used in 9221.B.1. Lactose broth may be used in lieu of lauryl tryptose broth (LTB), if at least 25 parallel tests are conducted between this broth and LTB using the water samples normally tested, and this comparison demonstrates that the false-positive rate and false-negative rate for total coliform using lactose broth is less than 10 percent. No requirement exists to run the completed phase on 10 percent of all total coliform-positive tubes on a seasonal basis.

[7] After prior enrichment in a presumptive medium for total coliform using 9221B.1, all presumptive tubes or bottles showing any amount of gas, growth or acidity within 48± 3 h of incubation shall be submitted to 9221F. Commercially available EC–MUG media or EC media supplemented in the laboratory with 50 μg/ml of MUG may be used.

[8] These tests are collectively known as defined enzyme substrate tests, where, for example, a substrate is used to detect the enzyme glucuronidase produced by E. coli.

[9] AOAC. 1995. Official Methods of Analysis of AOAC International, 16th Edition, Volume 1, Chapter 17. Association of Official Analytical Chemists International. 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877–2417.

[10] Descriptions of the Colilert®, Colilert-18®, Quanti-Tray® and Quanti-Tray® 2000 may be obtained from IDEXX Laboratories, Inc., One IDEXX Drive, Westbrook, Maine 04092.

[11] Colilert-18® is an optimized formulation of the Colilert® for the determination of total coliforms and E. coli that provides results within 18 h of incubation at 35 °C rather than the 24 h required for the Colilert® test and is recommended for marine samples.

[12] A 0.45 μm membrane filter (MF) or other pore size certified by the manufacturer to fully retain organisms to be cultivated and to be free of extractables which could interfere with their growth.

[13] Because the MF technique usually yields low and variable recovery from chlorinated wastewaters, the Most Probable Number method will be required to resolve any controversies.

[14] When the MF method has not been used previously to test ambient water with high turbidity, large number of noncoliform bacteria, or samples that may contain organisms stressed by chlorine, a parallel test should be conducted with a multiple-tube technique to demonstrate applicability and comparability of results.

[15] Subject total coliform positive samples as determined by 9222B or other membrane filter procedure to 9222G using NA–MUG media.

[16] USEPA. 2002c. Method 1103.1: Escherichia coli (E. coli) In Water By Membrane Filtration Using membrane-Thermotolerant Escherichia coli Agar (mTEC). U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA–821–R–02–020.

[17] ASTM. 2000, 1999, 1996. Annual Book of ASTM Standards—Water and Environmental Technology. Section 11.02. American Society for Testing and Materials. 100 Barr Harbor Drive, West Conshohocken, PA 19428.

[18] USEPA. 2002. Method 1610: Escherichia coli (E. coli) In Water By Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (modified mTEC). U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA–821–R–02–023.

[19] Preparation and use of MI agar with a standard membrane filter procedure is set forth in the article, Brenner et al. 1993. ''New Medium for the Simultaneous Detection of Total Coliform and Escherichia coli in Water.'' Appl. Environ. Microbiol. 59:3534–3544 and in USEPA. 2002. Method 1604: Total Coliforms and Escherichia coli (E. coli) in Water by Membrane Filtration by Using a Simultaneous Detection Technique (MI Medium). U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA–821–R–02–024.

[20] A description of the mColiBlue24 test, Total Coliforms and E. coli, is available from Hach Company, 100 Dayton Ave., Ames, IA 50010.

For most PWSs, the time from sample collection to initiation of analysis (i.e., the holding time) for source water E. coli samples may not exceed 30 hours for all approved E. coli methods. However, if the State determines on a case-by-case basis that analyzing an E. coli sample within 30 hours is not feasible, the State may approve the holding of an E. coli sample for up to 48 hours between collection and initiation of analysis. E. coli samples held between 30 to 48 hours must be analyzed by the Colilert reagent version of Standard Method 9223B as listed in 40 CFR 136.3. All E. coli samples must be maintained below 10° C and not allowed to freeze.

The E. coli sample holding time established for source water monitoring under the LT2ESWTR does not apply to E. coli sample holding time requirements that have been established under other programs and regulations.

b. Background and Analysis

In the August 11, 2003 proposed LT2ESWTR, EPA planned to approve the same E. coli methods that the Agency had proposed for ambient water monitoring in an earlier rulemaking, ''Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water'' (USEPA 2001h). EPA selected these methods based on data generated by EPA laboratories, submissions to the EPA alternate test procedures program and voluntary consensus standards bodies, peer reviewed journal articles, and publicly available study reports.

On July 21, 2003, EPA finalized ''Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water'' (USEPA 2003b). The only method from the proposal of this rule that was not included in the final rule was Colisure, which was excluded due to insufficient data on its performance with surface water. For the other methods, EPA revised certain titles and added method numbers to be consistent with other microbiological methods, but the technical content of these methods in the final rule did not change from the versions included in the proposed rule.

EPA is approving these same E. coli methods for analyses under the LT2ESWTR. The source water E. coli analyses that PWSs will conduct under the LT2ESWTR are similar to the ambient water analyses for which EPA approved E. coli methods under ''Guidelines Establishing Test Procedures for the Analysis of Pollutants; Analytical Methods for Biological Pollutants in Ambient Water'' (USEPA 2003b). EPA continues to support the findings of this rule and believes that the E. coli methods approved therein have the necessary sensitivity and specificity to meet the data quality objectives of the LT2ESWTR.

An important aspect of monitoring for E. coli is the allowable sample holding time (i.e., the time between sample collection and initiation of analysis). Existing regulations, such as 40 CFR 141.74, limit the holding time for E. coli samples to 8 hours. However, for PWSs that must ship E. coli samples to an off-site laboratory for analysis, meeting an 8 hour holding time is generally not feasible. For example, during the ICRSS, all of the PWSs that shipped samples off-site for E. coli analysis exceeded an 8 hour holding time, and 12 percent of these samples had holding times in excess of 30 hours.

While most large PWSs that will monitor for E. coli under the LT2ESWTR will conduct these analyses on-site, most small PWSs must ship samples off-site to an approved laboratory. To address the concern that PWSs using off-site laboratories cannot meet an 8-hour holding time, EPA participated in studies to assess the effect of increased sample holding time on E. coli analysis results. These studies are summarized in the proposed rule (USEPA 2003a) and are described in detail in Pope et al. (2003). Based on these studies, EPA has concluded that the holding time for E. coli samples can be extended beyond 8 hours prior to analysis without compromising the data quality objectives of LT2ESWTR monitoring.

In the proposed LT2ESWTR, EPA required analysis of E. coli samples to be initiated within 24 hours of sample collection and required that samples be kept below 10° C and not allowed to freeze (USEPA 2003a). These proposed requirements were based on data showing that most samples maintained within these temperature conditions were not significantly different at 24 hours than at the standard holding time of 8 hours. The proposal also noted that data indicated no significant sample degradation after longer time periods, such as 30 or 48 hours, for certain methods. Accordingly, EPA requested comment on establishing a longer E. coli holding time in the final rule.

For today's final rule, EPA is establishing a holding time of 30 hours for all approved E. coli methods. After reviewing public comment on this issue, which is summarized in the following section, and reassessing the studies described in the proposed rule, EPA has concluded that a 30 hour holding time limit for E. coli samples is appropriate and consistent with the data quality objectives of LT2ESWTR source water monitoring. Further, EPA believes that meeting a 30 hour holding time is feasible for most PWSs that must ship E. coli samples to an off-site laboratory for analysis. This longer holding time, however, does not apply to E. coli monitoring conducted under other programs and regulations.

EPA recognizes that in rare cases, having an E. coli sample analyzed within 30 hours may not be feasible for a PWS due to distance to an approved laboratory and limited transportation options. In these cases, today's rule allows the State to approve up to a 48 hour holding time for E. coli samples. Samples held between 30 to 48 hours must be analyzed by the Colilert reagent version of Standard Method 9223B. This is the only method evaluated in Pope et al. (2003) where no significant sample degradation occurred at 48 hours.

PWSs must maintain samples below 10°C and not allow them to freeze. EPA has developing guidance for PWSs on packing and shipping E. coli samples to maintain these temperature conditions. See the overview at the beginning of this section for information on how to access this guidance.

c. Summary of Major Comments

In the August 11, 2003 LT2ESWTR proposal, EPA requested 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. EPA also requested comment on the proposal to extend the holding time for E. coli

samples to 24 hours; whether EPA should limit the extended holding time to only those E. coli analytical methods that were evaluated in the holding time studies described in the proposal; and whether EPA should increase the source water E. coli holding time to 30 or 48 hours for samples evaluated by one method, ONPG–MUG, and retain a 24-hour holding time for samples analyzed by other methods.

Most commenters stated that the proposed E. coli analytical methods are appropriate. Commenters also agreed with the proposal to extend the holding time for source water E. coli samples, but recommendations about the maximum holding time and the methods to which the extended holding time should apply differed among commenters. Some suggested that EPA increase the holding time to 30 hours for the ONPG–MUG method, but retain a 24-hour holding time for the other methods. Other commenters recommended a 48-hour holding time for some or all methods. Several commenters advised that holding times for all methods should be the same to limit confusion. Some commenters were concerned that a 30-hour holding time would not be sufficient for small PWSs in remote areas to ship samples to distant laboratories.

After consideration of the comments received, as well as the holding time study data presented in the proposed rule and the time required to ship samples off-site for analysis as evidenced in the ICRSS, EPA has concluded that allowing a 30-hour holding time for all E. coli methods approved under today's final rule is appropriate. Data indicate that a 30-hour holding time for E. coli samples will not adversely impact the data quality objectives of LT2ESWTR monitoring. Further, establishing the same holding time for all methods will limit confusion, and a 30-hour holding time will allow most PWSs that ship samples off site for analysis to meet the holding time requirements. Today's rule also allows the State to authorize a 48-hour holding time for rare cases where a 30-hour holding time is not feasible.

4. Turbidity Methods

a. Today's Rule

Today's rule requires PWSs to use the analytical methods that have been previously approved by EPA for analysis of turbidity in drinking water, as listed in 40 CFR 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), Great Lakes Instruments Method 2 (Great Lakes Instruments 1992), and Hach FilterTrak Method 10133.

b. Background and Analysis

As stated in section IV.A, today's rule requires filtered PWSs serving at least 10,000 people to monitor for turbidity when they conduct source water monitoring. EPA may use these data to modify the indicator criteria that trigger Cryptosporidium monitoring by small filtered PWSs, as recommended by the M–DBP Advisory Committee (USEPA 2000a). In addition, PWSs using conventional or direct filtration may achieve additional Cryptosporidium treatment credit by demonstrating very low turbidity in the combined filter effluent, as described in section IV.D.7, or the individual filter effluent, as described in section IV.D.8.

The August 11, 2003 proposed LT2ESWTR required PWSs to use turbidity methods that EPA had previously approved under 40 CFR 141.74 for analyzing drinking water (USEPA 2003a). These are EPA Method 180.1 and Standard Method 2130B, which are based on a comparison of the intensity of light scattered by the sample with the intensity of light scattered by a standard reference suspension; Great Lakes Instruments Method 2, which is a modulated four beam infrared method using a ratiometric algorithm to calculate the turbidity value from the four readings that are produced; and Hach FilterTrak (Method 10133), which is a laser-based method used to analyze finished drinking water.

Today's final rule is unchanged from the proposal in regard to analytical methods for turbidity. Hence, PWSs must use methods currently approved in 40 CFR 141.74 for turbidity analysis. EPA believes the currently approved methods are appropriate for turbidity analyses that will be conducted under the LT2ESWTR. PWSs must use turbidimeter instruments as described in the EPA-approved methods, which may be either on-line or bench top instruments. If a PWS chooses to use on-line instruments for monitoring turbidity, the PWS must validate the continuous measurements for accuracy on a regular basis using a protocol approved by the State, as required in 40 CFR 141.74.

c. Summary of Major Comments

EPA received public comment on the turbidity methods required in the August 11, 2003 proposed LT2ESWTR. While commenters, in general, agreed that currently approved turbidity methods are adequate to meet the requirements of the rule, several commenters were concerned with turbidity measurement variation among different instruments. One commenter suggested voluntary third party testing, while another recommended more rigorous calibration and verification processes.

As described in section IV.D.7, EPA has reviewed studies of low level turbidity measurements, as well as standard test methods for measurement of turbidity below 5 NTU. After reviewing this information, EPA concluded that currently available monitoring equipment can reliably measure turbidity at levels of 0.15 NTU and lower. However, EPA agrees that rigorous calibration and maintenance of turbidity monitoring equipment is necessary for PWSs pursuing the low filtered water turbidity performance options in the microbial toolbox. EPA has developed guidance on proper calibration, operation, and maintenance of turbidimeters (USEPA 1999c).

A few commenters stated that the LT2ESTWR does not recognize advancements in turbidity measurement and newly developed turbidity measurement technologies. In response, EPA has not received information that supports approval of analytical methods for turbidity in addition to those currently approved under 40 CFR 141.74, which are also approved for turbidity monitoring under today's rule. If other turbidity methods are approved and added to 40 CFR 141.74 in the future, these methods will also be approved under the LT2ESWTR.

One commenter requested that the LT2ESWTR specifically address turbidity measurements in plants that practice lime softening. EPA notes that additional treatment credit for combined filter effluent turbidity is based on measurements collected under 40 CFR 141.173 or 40 CFR 141.551 (the IESWTR or LT1ESWTR). These regulations allow PWSs that use lime softening to acidify samples prior to analysis in order to address the effects of lime softening on turbidity measurements. In regard to treatment credit based on individual filter effluent turbidity, EPA does not believe that acidifying samples while measuring turbidity every 15 minutes at each individual filter, as the IESWTR and LT1ESWTR require, is feasible. However, PWSs that practice lime softening could use the demonstration of performance toolbox option to demonstrate that a plant is achieving removal efficiencies equivalent to the additional credit allowed for individual filter performance.

K. Laboratory Approval

Given the potentially significant implications for PWSs and drinking water consumers of microbial monitoring under the LT2ESWTR, laboratory analyses for Cryptosporidium, E. coli, and turbidity should be accurate and reliable within the limits of approved methods. Therefore, today's final rule requires PWSs to use laboratories that have been approved to conduct analyses for these parameters by EPA or the State.

1. Cryptosporidium Laboratory Approval

a. Today's Rule

Analysis of samples for Cryptosporidium under today's rule must be conducted by a laboratory that is approved 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 2002d). A list of laboratories that are approved under this program is available on the Internet at *www.epa.gov/safewater/disinfection/lt2*. If a State adopts an equivalent approval process under a State laboratory certification program, then PWSs can use laboratories approved by the State.

b. Background and Analysis

Because States do not currently approve laboratories for Cryptosporidium analyses, EPA has assumed initial responsibility for Cryptosporidium laboratory approval. EPA initiated the Cryptosporidium Lab QA Program prior to LT2ESWTR promulgation to ensure that adequate analytical capacity will be available at approved laboratories to support required monitoring, which begins 6 months after rule promulgation. The August 11, 2003 proposed LT2ESWTR required PWSs to have Cryptosporidium samples analyzed by laboratories approved under the EPA Lab QA Program. Today's final rule is unchanged from the proposal with respect to this requirement.

Laboratories seeking approval under 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. Laboratories that pass the quality assurance evaluation are approved for Cryptosporidium analysis under the LT2ESWTR. To maintain approval, laboratories must successfully analyze a set of three ongoing proficiency testing samples approximately every four months. The Lab QA Program is described in detail in USEPA (2002d) and additional information can be found on the Internet at *www.epa.gov/safewater/disinfection/lt2*.

EPA tracks the Cryptosporidium sample analysis capacity of approved laboratories through the Lab QA Program. Using information provided by laboratories, EPA expects that existing capacity should be sufficient to support initial source water monitoring by large PWSs under the LT2ESWTR. Further, the implementation schedule for today's rule, which is described in section IV.G, provides time for laboratories to increase capacity through steps like training new analysts as the demand for sample analysis grows.

c. Summary of Major Comments

In regard to approval of laboratories for Cryptosporidium analysis, major comments on the August 11, 2003 proposal addressed the following issues: laboratory capacity, State approval programs, and analyst experience criteria. Comments regarding Cryptosporidium laboratory capacity are summarized in section IV.G, while those on the other issues are summarized as follows.

EPA requested comment on States approving Cryptosporidium laboratories. Most commenters, however, recommended that EPA maintain the Lab QA Program, due to the specialized nature of the work. EPA intends to maintain the Lab QA Program, but today's rule does allow States to certify Cryptosporidium laboratories by setting up an equivalent program.

EPA also requested comment on the experience criteria that Methods 1622 and 1623 include for Cryptosporidium analysts. Some commenters recommended lowering analyst training and experience requirements, while others recommended no change or an increase in microscopy training. After evaluating these comments, EPA has concluded that the analyst criteria included in Methods 1622 and 1623 are reasonable for ensuring that analysts have the experience to evaluate source water samples under today's rule. Consequently, EPA has not altered these criteria from the approved methods.

2. E. coli Laboratory Approval

a. Today's Rule

PWSs must have E. coli samples analyzed by a laboratory that has been certified by EPA, the National Environmental Laboratory Accreditation Conference (NELAC) or the State for total coliform or fecal coliform analysis in drinking water under 40 CFR 141.74. The laboratory must use the same technique for E. coli analysis under today's rule that the laboratory is certified to use for drinking water under 40 CFR 141.74 (e.g., membrane filtration, multiple-well, multiple-tube).

b. Background and Analysis

The August 11, 2003 proposed LT2ESWTR required PWSs to have E. coli samples analyzed by laboratories that are certified to conduct total or fecal coliform analyses in drinking water (i.e., under 40 CFR 141.74) by EPA, NELAC or the State. The proposal required laboratories to use the same E. coli analytical technique that they are certified to use for coliform analyses in drinking water. Today's final rule is unchanged from the proposal in regard to these requirements. EPA believes that laboratories that are certified to conduct coliform analyses in drinking water have the expertise to conduct E. coli analyses under today's rule, provided they use the analytical technique for which they are certified.

c. Summary of Major Comments

Two commenters on the August 11, 2003 proposal suggested that laboratories should be certified specifically for quantitative analyses of total or fecal coliform in a source water matrix. However, the methods approved for source water E. coli analyses under today's rule are also approved under the drinking water certification program. EPA believes that analysts certified for these methods under the drinking water certification program have the capability to perform the same methods for a source water matrix, even though additional steps may be required (such as dilutions). EPA has revised the Laboratory Certification Manual to suggest Performance Evaluation (PE) samples for source water matrix analyses and States have the option to require PE samples as needed in their State laboratory certification programs.

3. Turbidity Analyst Approval

a. Today's Rule

Under today's rule, measurements of turbidity must be made by a party approved by the State.

b. Background and Analysis

The August 11, 2003 proposed LT2ESWTR required that measurements of turbidity be made by a party approved by the State. This reflects existing requirements in 40 CFR 141.74 for measurement of turbidity in drinking water. Today's final rule is unchanged from the proposal in this respect.

c. Summary of Major Comments

Commenters on requirements for turbidity analyst approval in the August 11, 2003 proposal agreed that turbidity analyses should be consistent with 40 CFR 141.74. Specifically, any person that is currently approved to conduct turbidity analysis under existing drinking water regulations should be approved to conduct turbidity analyses under the LT2ESWTR. EPA agrees with this comment and it is reflected in today's final rule.

L. Requirements for Sanitary Surveys Conducted by EPA

1. Today's Rule

Today's final rule establishes requirements for PWSs to respond to significant deficiencies identified in sanitary surveys that EPA conducts. These requirements give EPA authority equivalent to that exercised by States under existing regulations to ensure that PWSs address significant deficiencies.

- For sanitary surveys conducted by EPA under SDWA section 1445 or other authority, PWSs must 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 PWS will address significant deficiencies noted in the survey.
- PWSs must correct significant deficiencies identified in sanitary survey reports according to the schedule approved by EPA, or if there is no approved schedule, according to the schedule the PWS reported if such deficiencies are within the control of the PWS.
- A sanitary survey, as conducted by EPA, 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 PWS to evaluate the adequacy of the PWS, 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.

2. Background and Analysis

As established by the IESWTR in 40 CFR 142.16(b)(3), primacy States must conduct sanitary surveys for PWSs using surface water sources every three or five years. The sanitary survey is an onsite review of the following: (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 must have the authority to assure that PWSs respond in writing to significant deficiencies identified in sanitary survey reports no later than 45 days after receipt of the report, indicating how and on what schedule the system will address the deficiency (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)).

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

In the August 11, 2003 proposal, EPA requested comment on establishing requirements under 40 CFR 141 for PWSs to correct significant deficiencies identified in sanitary surveys conducted by EPA. The requirements in today's final rule follow closely on the language presented in the proposal. Today's rule ensures that PWSs in non-primacy States are subject to comparable requirements for sanitary surveys as PWS regulated by States with primacy.

3. Summary of Major Comments

Most public comment on the August 11, 2003 proposal supported requiring PWSs to correct significant deficiencies identified in sanitary surveys conducted by EPA. Commenters stated that requirements for sanitary surveys should be consistent for PWSs and should not depend on the primacy agency. EPA believes the requirements in today's final rule will establish this consistency.

One commenter requested that EPA include a process for PWSs to appeal a significant deficiency determination. EPA expects that PWSs will raise any concerns regarding significant deficiency determinations with the primacy agency, either the State or EPA, that conducts the sanitary survey. States or EPA may withdraw or amend their significant deficiency determinations as appropriate. The IESWTR did not establish a separate appeal process for sanitary surveys conducted by States, and EPA has not established such a process for sanitary surveys conducted by EPA under today's rule.

M. 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. These conditions and EPA's view on their applicability to the LT2ESWTR are summarized as follows:

1. Variances

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

(1) A State that has primacy may grant a variance to a PWS from any requirement to use a specified treatment technique for a contaminant if the PWS demonstrates to the satisfaction of the State that the treatment technique is not necessary to protect public health because of the nature of the PWS'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 that the first variance provision is applicable to filtered PWSs under today's rule. Filtered PWSs are required to implement additional treatment under the LT2ESWTR only when source water monitoring demonstrates higher levels of Cryptosporidium contamination. Thus, this treatment technique requirement accounts for the nature of the PWS's raw water source. Unfiltered PWS treatment requirements also account for the nature of a PWS's raw water source with respect to whether 2- or 3-log Cryptosporidium inactivation is required.

In theory, the first variance provision could be applied to the requirement that all unfiltered PWSs provide at least 2-

log Cryptosporidium inactivation. If an unfiltered PWS could show a raw water Cryptosporidium level 3-log lower than the Bin 1 cutoff for filtered PWSs (i.e., below 0.075 oocysts/1,000 L), this could demonstrate that no treatment for Cryptosporidium is necessary. The unfiltered PWS would already be achieving public health protection against Cryptosporidium equivalent to filtered PWSs due to the nature of the raw water source.

In practice, EPA has not identified an approach that is economically or technologically feasible for a PWS to demonstrate such a low level of Cryptosporidium to support granting a variance. This is due to the extremely large volume and number of samples that would be necessary to make such a demonstration with confidence. However, unfiltered PWSs may choose to pursue the development and implementation of monitoring programs to apply for a variance from Cryptosporidium inactivation requirements based on the nature of the raw water source. A sufficient monitoring program may be feasible in site-specific circumstances or with the use of innovative approaches.

The second provision for granting a variance is not applicable to the LT2ESWTR because the rule provides broad flexibility in how PWSs achieve the required level of Cryptosporidium reduction through the microbial toolbox. 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 PWS variances, but these cannot be granted for a treatment technique for a microbial contaminant. Hence, small PWS variances are not allowed for the LT2ESWTR.

2. Exemptions

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

EPA believes that granting an exemption to the Cryptosporidium treatment requirements of the LT2ESWTR would result in an unreasonable risk to health. As described in section III.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 PWSs with the highest degree of risk. Due to these factors, EPA does not support the granting exemptions from the LT2ESWTR.

V. State Implementation

A. Today's Rule

This section describes the regulations and other procedures and policies States must adopt to implement today's rule. States must continue to meet all other conditions of primacy in 40 CFR Part 142. To implement the LT2ESWTR, States must adopt revisions to the following sections:

§ 141.2—Definitions
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

1. 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:

- Approve an alternative to the E. coli levels that trigger Cryptosporidium monitoring by filtered systems serving fewer than 10,000 people (see section IV.A.1);
- Approve watershed control programs for the 0.5 log watershed control program credit in the microbial toolbox (see section IV.D.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); and
- Approve protocols for treatment credit under the Demonstration of Performance toolbox option (see section IV.D.9), for site specific chlorine dioxide and ozone CT tables (see section IV.D.14), and for alternative UV reactor validation testing (see section IV.D.15).

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.

2. State Recordkeeping Requirements

Today's rule requires 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 for not less than 1 year;
- Cryptosporidium treatment bin classification for each filtered PWS after the initial and after the second round of source water monitoring. Also, any change in treatment requirements for filtered systems due to watershed assessment during sanitary surveys;
- Determination of whether each unfiltered PWS has a mean source water Cryptosporidium level above 0.01 oocysts/L after the initial and after the second round of source water monitoring;
- The treatment processes or control measures that each PWS employs to meet Cryptosporidium treatment requirements under the LT2ESWTR, including measures that systems may use for only part of the year; and
- A list of PWSs required to cover or treat the effluent of an uncovered finished water storage facilities.

3. State Reporting Requirements

Today's rule requires States to report the following information:

- The Cryptosporidium treatment bin classification for each filtered PWS after the initial and after the second round of source water monitoring. Also, any change in treatment requirements for filtered systems due to watershed assessment during sanitary surveys; and
- The determination of whether each unfiltered PWS has a mean source water Cryptosporidium level above 0.01 oocysts/L after the initial and after the second round of source water monitoring.

4. Interim Primacy

States that have primacy (including interim 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. A State that wishes to obtain interim primacy

for future NPDWRs must obtain primacy for today's rule. As described in Section IV.A, EPA expects to work with States to oversee the initial source water monitoring that begins six months following rule promulgation.

B. Background and Analysis

SDWA establishes requirements that a State or eligible Indian Tribe must meet to assume and maintain primary enforcement responsibility (primacy) for its PWSs. These requirements include the following activities: (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 SDWA; 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 SDWA section 1413. 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.

The current regulations in 40 CFR 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; PWS inventories; State approvals; enforcement actions; and the issuance of variances and exemptions. Today's final rule requires States to keep additional records, including all supporting information and an explanation of the technical basis for decisions made by the State regarding today's rule requirements. EPA currently requires in 40 CFR 142.15 that States report to EPA information such as violations, variance and exemption status, and enforcement actions, and today's rule adds additional reporting requirements related to monitoring and treatment requirements.

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 1998c). 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. States that have primacy for every existing NPDWR already in effect may obtain interim primacy for this rule and a State that wishes to obtain interim primacy for future NPDWRs must obtain primacy for this rule.

C. Summary of Major Comments

Public comment generally supported the special primacy requirements in the August 11, 2003 proposal, and many commenters expressed appreciation for the flexibility the special primacy requirements provided to States. One commenter expressed concern that a State that adopted this rule by reference would lose the flexibility intended in the proposal. In response, EPA recognizes that some States may be limited by their statutes in applying the flexibility allowed under today's rule. However, EPA believes that providing flexibility for States to approve site-specific approaches that achieve the public health goals of the LT2ESWTR is appropriate and will benefit some States and PWSs.

A few commenters were concerned that the special primacy requirement to assess changes in watersheds as part of the sanitary survey process would be difficult to meet due to a lack of resources or large watersheds that overlap State boundaries. In response, EPA notes that States are required to evaluate PWS sources under the existing sanitary survey requirements (40 CFR 142.16(b)(3)). If a State determines during a sanitary survey that significant changes have occurred in the watershed that could lead to increased contamination of the source by Cryptosporidium, today's rule gives the State the authority to require the PWS to take actions to mitigate or treat the contamination. Because the treatment requirements in today's rule depend on the degree of source water contamination, EPA believes that this assessment of changes in a PWS's source water following initial bin classification is necessary.

EPA also received comments on State approval processes for laboratories analyzing for Cryptosporidium to meet LT2ESWTR requirements. Most commenters stated that EPA should maintain a national certification program for laboratories approved for Cryptosporidium analysis for LT2ESTWR compliance. Commenters indicated that requiring States to approve laboratories for Cryptosporidium analysis placed too great a demand on State resources. Today's rule does not include a State primacy requirement for laboratory certification for Cryptosporidium analysis.

Some commenters were concerned with the data tracking and review burden on States from the reporting requirements for the individual toolbox components. EPA agrees with commenters that, in some cases, allowing PWSs to report summaries or to self-certify that the PWS met the performance requirements for microbial toolbox treatment credit may be appropriate. Today's rule allow States to modify the level of reporting required for toolbox components and specifically, permit PWSs to self-certify to the State that a toolbox component has met its performance requirements.

VI. Economic Analysis

This section summarizes the economic analysis (EA) for the final LT2ESWTR. The EA is an assessment of the benefits, both health and nonhealth-related, and costs to the regulated community of the final regulation, along with those of regulatory alternatives that the Agency considered. EPA developed the 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 2005a), which includes additional details and discussion on the topics presented throughout this section of the preamble.

The 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 III, EPA promulgated the IESWTR and LT1ESWTR to provide a baseline of protection against Cryptosporidium in large and small PWSs, respectively. Today's final rule will achieve further reductions in Cryptosporidium exposure for PWSs with the highest vulnerability. This EA considers only the incremental reduction in exposure beyond the two previously promulgated rules (IESWTR and LT1ESWTR) from the alternatives evaluated for the LT2ESWTR.

A. What Regulatory Alternatives Did the Agency Consider?

Regulatory alternatives considered by the Agency for the LT2ESWTR were developed through the deliberations of the Stage 2 M–DBP Federal Advisory Committee (described in section III). The Advisory Committee considered several general approaches for reducing the risk from Cryptosporidium in drinking water. These approaches included both additional treatment requirements for all PWSs and risk-targeted treatment requirements for PWSs with the highest vulnerability to Cryptosporidium following implementation of the IESWTR and LT1ESWTR. In addition, the Advisory Committee considered related issues such as alternative monitoring strategies.

After considering these general approaches, the Advisory Committee focused on four regulatory alternatives for filtered PWSs (see Table VI.A–1). With the exception of Alternative 1, which requires all PWSs to provide additional treatment for Cryptosporidium, these alternatives incorporate a risk-targeting approach in which PWSs are classified in different treatment bins based on the results of source water monitoring. Additional Cryptosporidium treatment requirements are directly linked to the treatment 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.

The Advisory Committee reached consensus regarding additional treatment requirements for unfiltered PWSs without formally identifying regulatory alternatives other than requiring no treatment for Cryptosporidium (i.e., no new regulation).

TABLE VI.A–1.—SUMMARY OF REGULATORY ALTERNATIVES FOR FILTERED PWSS

Mean source water Cryptosporidium monitoring result (oocysts/L)	Additional treatment requirements [1]
Alternative A1	
2.0-log inactivation required for all PWSs	
Alternative A2	
< 0.03	No additional treatment.
≥ 0.03 and < 0.1	0.5-log.
≥ 0.1 and < 1.0	1.5-log.
≥ 1.0	2.5-log.
Alternative A3—Today's Final Rule	
< 0.075	No additional treatment.
≥ 0.075 and < 1.0	1-log.
≥ 1.0 and < 3.0	2-log.
≥ 3.0	2.5-log.
Alternative A4	
< 0.1	No additional treatment.
≥ 0.1 and < 1.0	0.5-log.
≥1.0	1.0-log.

[1] Note: ''Additional treatment requirements'' are in addition to levels already required under existing rules (e.g., the IESWTR and LT1ESWTR) for PWSs using conventional treatment or equivalent.

B. What Analyses Support Today's Final Rule?

EPA has quantified benefits and costs for each of the filtered PWS regulatory alternatives in Table VI.A–1 and for unfiltered PWS requirements. Quantified benefits stem from estimated reductions in the incidence of cryptosporidiosis resulting from the regulation. To make these estimates, the Agency employed Monte Carlo modeling to account for uncertainty and variability in key parameters like Cryptosporidium occurrence, infectivity, and treatment efficiency. Costs result largely from the installation of additional treatment, with lesser costs due to monitoring and other implementation activities.

Cryptosporidium occurrence significantly influences the estimated benefits and costs of regulatory alternatives. As discussed in section III.E, EPA analyzed data collected under the ICR, the ICR Supplemental Surveys of medium PWSs (ICRSSM), and the ICR Supplemental Surveys of large PWSs (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.

Another parameter that significantly influences estimated benefits is Cryptosporidium infectivity (i.e., the likelihood of infection after exposure to a given dose of Cryptosporidium). As discussed in section III.E, EPA considered results from human volunteer feeding studies and applied six different model forms to estimate dose-response relationships.

To address uncertainty in these estimates, benefits are presented for three different dose response models: A ''high'' estimate based on the model that showed the highest mean baseline risk, a ''medium'' estimate based on the model and data used at proposal, which is in the middle of the range of estimates produced by the six models, and a ''low'' estimate, based on the model that showed the lowest mean baseline risk. These estimates are not upper and lower bounds. For each model, a distribution of effects is estimated, and the ''high'' and ''low'' estimates show only the means of these distributions for two different model choices.

Both benefits and costs are determined as annualized present values, which allows comparison of cost and benefit streams that are variable over time. The time frame used for both benefit and cost comparisons is 25 years. The Agency uses social discount rates of both 3 percent and 7 percent to calculate present values from the stream of benefits and costs and also to annualize the present value estimates over 25 years (see EPA's Guidelines for Preparing Economic Analyses (USEPA 2000c) for a discussion of social discount rates).

Results of these analyses are summarized in this section of the preamble. Detailed results and descriptions of the supporting analyzes are shown in the LT2ESWTR EA (USEPA 2005a).

In evaluating the regulatory alternatives shown in Table VI.A–1, 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 PWSs will be required to add treatment? and (3) What is the likelihood that PWSs will be misclassified in higher or lower treatment bins through monitoring?

Consistent with the consensus recommendation of the Advisory Committee, EPA selected Alternative A3 for today's final rule. EPA has determined that this alternative will significantly reduce the incidence of cryptosporidiosis due to drinking water

in vulnerable PWSs and is feasible for PWSs to implement.

Alternative A1 (across-the-board 2-log inactivation) was not selected because it would impose costs but provide few benefits to PWSs with relatively low Cryptosporidium risk. EPA was also concerned about the feasibility of requiring every surface water treatment plant to install additional treatment processes (e.g., UV) for Cryptosporidium. With Alternative A2, EPA was concerned with the feasibility of accurately classifying PWSs in treatment bins at a Cryptosporidium concentration of 0.03 oocysts/L. EPA does not believe that Alternative A4 would reduce risks from Cryptosporidium in vulnerable PWSs to the extent feasible, as required under SDWA section 1412(b)(7)(A), because of the low levels of treatment required.

C. What Are the Benefits of the LT2ESWTR?

EPA has quantified and monetized health benefits for reductions in endemic cryptosporidiosis due to the LT2ESWTR. In addition, today's rule is expected to provide additional health and nonhealth-related benefits that EPA was unable to quantify. Table VI.C–1 summarizes these unquantified benefits.

1. Nonquantified Benefits

TABLE VI.C–1.—SUMMARY OF NONQUANTIFIED BENEFITS

Benefit type	Potential effect on benefits	Comments
Reducing outbreak risks and response costs.	Increase	Some human or equipment failures may occur even with the requirements of today's rule; however, by adding barriers of protection for some PWSs, the rule will reduce the possibility of such failures leading to outbreaks.
Reducing averting behavior (e.g., boiling tap water or purchasing bottled water).	Increase/No Change	Consumers in PWSs that cease using uncovered finished water reservoirs (through covering or taking such reservoirs off-line) may have greater confidence in water quality. This may result in less averting behavior that reduces both out-of-pocket costs (e.g., purchase of bottled water) and opportunity costs (e.g., time to boil water).
Improving aesthetic water quality	Increase	Some technologies installed for this rule (e.g., ozone) are likely to reduce taste and odor problems.
Reducing risk from co-occurring and emerging pathogens.	Increase	Although focused on removal of Cryptosporidium from drinking water, PWSs that change treatment processes will also increase removal of pathogens that the rule does not specifically regulate.
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 in ways other than those addressed in this rule.
Reduced contamination due to covering or treating finished water storage facilities.	Increase	Contaminants introduced through uncovered finished water storage facilities will be reduced, which will produce positive public health benefits.
Change in the levels of disinfection byproducts.	Increase/Decrease	PWSs that install ozone to comply with the LT2ESWTR may experience an increase in certain DBPs. PWSs that install UV or microfiltration may reduce the use of chlorine and experience a decrease in DBPs.

Source: Chapter 5 of the LT2ESWTR Economic Analysis (USEPA 2005a).

2. Quantified Benefits

In quantifying benefits for the LT2ESWTR based on reductions in the risk of endemic cryptosporidiosis, EPA considered several categories of monetized benefits. First, EPA estimated the number of cases expected to result in premature mortality (primarily for members of sensitive subpopulations such as AIDS patients). The mortality estimate was developed using data from the Milwaukee cryptosporidiosis outbreak of 1993 (described in section III), with adjustments to account for the subsequent decrease in the mortality rate among people with AIDS and for the difference between the portion of people living with AIDS in 1993 in Milwaukee and the current and projected national levels. EPA estimated a mortality rate of 26.3 deaths per 100,000 illnesses for those served by unfiltered PWSs and a mortality rate of 16.7 deaths per 100,000 illnesses for those served by filtered PWSs. These different rates are associated with the incidence of AIDS in populations served by unfiltered and filtered PWSs. A complete discussion on how EPA derived these rates can be found in subchapter 5.2 of the LT2ESWTR EA (USEPA 2005a).

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. The mean VSL is $7.4 million in 2005 with a 5th to 95th percentile range of $1.2 to $16.9 million. 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 1.9 percent 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 LT2ESWTR EA in Exhibit 5.24 (USEPA 2005a).

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. 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 1 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 wages, 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, recreation, and pain and suffering), 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). Ideally, a comprehensive willingness to pay (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 were not suitable for valuing cryptosporidiosis; hence, estimates from this literature are inappropriate for use in this analysis. Instead, EPA presents two COI estimates: A traditional approach that only includes valuation for medical costs and 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 non-work activities, and lost productivity at work on days when paid workers are ill but go to work anyway.

Table VI.C–2 shows the various categories of loss and how they were valued for each estimate for a ''typical'' case in 2003 (weighted average based on severity level).

TABLE VI.C–2.—TRADITIONAL AND ENHANCED COI FOR CRYPTOSPORIDIOSIS, 2003$

[Weighted average cost per case]

Loss category	Traditional COI	Enhanced COI
Direct Medical Costs	$106.91	106.91
Lost Paid Work Days	120.13	120.13
Lost Unpaid Work Days [1]	24.32	48.64
Lost Leisure Time [2]	not included	217.79
Lost Caregiver Days [3]	22.98	61.50
Lost Leisure Productivity [4]	not included	162.98
Lost Productivity at Work	not included	126.29
Total	274.34	844.24

[1] Assigned to 39.7% of the population not engaged in market work; assumes 40 hr. unpaid work week, valued at $6.23/hr in traditional COI and $12.46/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.

[2] 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, on days when subject is too sick to work.

[3] Values lost work or leisure time for people caring for the ill. Traditional approach does not include lost leisure time. Detail may not calculate to totals due to independent rounding; Source: Appendix L in LT2ESWTR EA (USEPA 2005a)

[4] Analogous to lost productivity at work. Includes reduced productivity in unpaid work and reduced enjoyment of recreation on days when subject is sick but engages in unpaid work or leisure activities anyway.

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 $20.82 hour. The average number of lost work hours per illness day is 3.4 (this assumes that 60 percent of the population is in the paid labor force and the loss is averaged over 7 days). The weighted average number of lost work days per case is 1.7 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 40 percent of the population that are not in the paid labor force. This includes homemakers, students, children, retires, and unemployed persons. This estimate attempts to capture market-like work (e.g., homemaking, volunteer work) that is unpaid. 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. For this reason, it likely overstates the value of unpaid, market-like work, but EPA does not have data on this. This time is valued at $6.23 per hour, which is one half the median post-tax wage (since work performed by these groups is not taxed). This is also approximately the median wage for paid household domestic labor.

In the enhanced COI estimate, an estimate of lost unpaid work days for people outside the paid labor force was made by assigning the value of $12.46 per hour to the same number of unpaid work hours valued in the traditional COI approach (i.e., 40 unpaid work hours per week). 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.C–2 for the enhanced approach and is not included in the traditional approach.

In the enhanced approach, all time other than paid and market-like work and sleep (8 hours per work day and 16 hours per non-work day) is valued at the median after tax wage, or $12.46 per hour. This includes lost unpaid personal work (e.g., chores, errands, housework) and leisure time for people within and outside the paid labor force. The average number of unpaid work hours per illness day is 2.3 (40 hours per week averaged over 7 days $\times$ 40 percent of the population). 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 10.3 hours by $12.46 gives a value of about $128 for a day of ''lost'' unpaid personal work and leisure (i.e., lost utility of being sick). The weighted average number of lost leisure days per case is the same as the weighted average number of lost work days (1.7 days per case).

In addition, for days when an individual is well enough to work but is still experiencing symptoms, such as diarrhea, the enhanced estimate also includes a 30 percent loss of work and leisure productivity, based on a study of giardiasis illness (Harrington et al. 1985), which is similar to cryptosporidiosis. 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 nonwork time. The weighted average number of reduced productivity days per case, for both work and leisure, is 1.3 days.

EPA believes that losses in productivity 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 $228 (the sum of the valuation of lost work and leisure) to avoid a day of illness. The traditional COI estimate may not be a lower bound because it 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 1.9 percent over the 20 year period. This approach of adjusting for real income growth was recommended by the SAB (USEPA 2000d) because the median real wage is expected to grow each year (by approximately 1.9 percent). Correspondingly, the real income growth factor of the COI estimates increases by the equivalent of 1.9 percent per year (except for medical costs, which are not directly tied to wages). This approach gives a total COI valuation per case in 2010 of $306 (undiscounted) for the traditional COI estimate and $985 (undiscounted) for the enhanced COI estimate; the valuation in 2029 is $381 (undiscounted) for the traditional COI estimate and $1,316 (undiscounted) for the enhanced COI estimate. There is no difference in the methodology for calculating the COI over this 20 year period of implementation; the change in valuation is due to the underlying change in projected real wages.

Table VI.C–3 summarizes the annual cases of cryptosporidiosis illness and associated deaths avoided due to the LT2ESWTR proposal. Today's rule, on average, is expected to reduce 89,375 to 1,459,126 illnesses and 20 to 314 deaths annually after full implementation (range based on the ICRSSL, ICRSSM, and ICR data sets and model choice for Cryptosporidium infectivity).

Table VI.C-3.–Summary of Annual Avoided Illness and Deaths

Data Set	Annual Illnesses Avoided			Annual Deaths Avoided		
	Low	Medium	High	Low	Medium	High
Total after Full implementation						
ICR	358,732	964,360	1,459,126	76	207	314
ICRSSL	89,375	230,730	372,507	20	52	84
ICRSSM	177,101	455,170	711,123	39	100	156
Annual Average over 25 years						
ICR	264,980	712,732	1,078,796	57	154	232
ICRSSL	66,187	170,977	276,078	15	39	62
ICRSSM	130,918	336,652	438,203	29	74	116

Source: The LT2ESWTR Economic Analysis (USEPA 2005a)
Note: High, medium, and low estimates reflect the mean estimates for a range of dose-response modeling assumptions. See Appendix N of the LT2ESWTR Economic Analysis (USEPA, 2005a).

Tables VI.C–4a and VI.C–4b show the monetized present value of the benefit for reductions in endemic cryptosporidiosis estimated to result from the LT2ESWTR for the enhanced and traditional COI values, respectively. Estimates are given for the ICR, ICRSSL, and ICRSSM occurrence data sets and for the three infectivity models.

With the enhanced COI and a 3 percent discount rate, the annual present value of the mean benefit estimate ranges from $177 million to $2.8 billion; at a 7 percent discount rate, the mean estimate ranges from $144 million to $2.3 billion. With the traditional COI, the corresponding mean benefit estimate at a 3 percent discount rate ranges from $130 million to $2.0 billion; for a 7 percent discount rate, the mean estimate ranges from $105 million to $1.7 billion. None of these values include the unquantified and nonmonetized benefits listed in Table VI.C–1.

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Table VI.C-4a.–Summary of Quantified Benefits—Enhanced COI[1] ($millions, 2003$)

Data Set	Value of Benefits ($ Millions, 2003$)		
	Low	Medium	High
Annualized Value (at 3%, 25 Years)			
ICR	$ 687	$ 1,853	$ 2,822
ICRSSL	$ 177	$ 458	$ 744
ICRSSM	$ 344	$ 886	$ 1,393
Annualized Value (at 7%, 25 Years)			
ICR	$ 556	$ 1,501	$ 2,286
ICRSSL	$ 144	$ 371	$ 603
ICRSSM	$ 279	$ 718	$ 1,128

Table VI.C-4b.--Summary of Quantified Benefits—Traditional COI[1] ($Millions, 2003$)

Data Set	Value of Benefits ($ Millions, 2003$)		
	Low	Medium	High
Annualized Value (at 3%, 25 Years)			
ICR	$ 497	$ 1,341	$ 2,047
ICRSSL	$ 130	$ 335	$ 546
ICRSSM	$ 250	$ 644	$ 1,014
Annualized Value (at 7%, 25 Years)			
ICR	$ 403	$ 1,089	$ 1,662
ICRSSL	$ 105	$ 272	$ 443
ICRSSM	$ 203	$ 523	$ 824

[1]The traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production and other market like work). The enhanced COI also factors in valuations for lost personal time (non-worktime) such as child care and homemaking (to the extent not covered by the traditional COI), time with family, and recreation, and lost productivity in both work and leisure on days when workers are ill but go to work anyway. Source: The LT2ESWTR Economic Analysis (USEPA 2005a)

Note: High, medium, and low estimates reflect the mean estimates for a range of dose-response modeling assumptions. See Appendix N of the LT2ESWTR Economic Analysis (USEPA. 2005a)

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a. *Filtered PWSs.* Benefits to the approximately 168 million people served by filtered surface water and GWUDI PWSs range from 34,000 to 702,000 reduction in mean annual cases of endemic illness based on three infectivity models and ICRSSL, ICRSSM, and ICR data sets. In addition, premature mortality is expected to be reduced by an average of 6 to 116 deaths annually.

b. *Unfiltered PWSs.* The 10 million people served by unfiltered surface water or GWUDI PWSs will see a significant reduction in cryptosporidiosis as a result of the LT2ESWTR. In this population, the rule is expected to reduce approximately 55,000 to 758,000 cases of illness and 14 to 197 premature deaths annually.

For unfiltered PWSs, only the ICR data set is used to directly calculate illness reduction because it is the only data set that includes sufficient information on unfiltered PWSs. Illness reduction in unfiltered PWSs was estimated for the ICRSSL and ICRSSM

data sets by multiplying the ICR unfiltered PWS result by the ratio, for the quantity estimated, between filtered PWS results from the supplemental survey data set (SSM or SSL) and filtered PWS results from the ICR.

3. Timing of Benefits Accrual (latency)

In previous rulemakings, some commenters have argued that the Agency should consider an assumed time lag or latency period in its benefits calculations. The Agency has not conducted a latency analysis for this rule because cryptosporidiosis is an acute illness; therefore, very little time elapses between exposure, illness, and mortality. However, EPA does account for benefits and costs that occur in future years by converting these to present value estimates.

D. What Are the Costs of the LT2ESWTR?

In order to estimate the costs of today's rule, the Agency considered impacts on PWSs and on States (including territories and EPA implementation in non-primacy States). Summary information on these costs follows, with more detailed information in chapter 6 of the LT2ESWTR EA (USEPA 2005a). A detailed discussion of the requirements of today's rule is located in section IV of this preamble.

1. Total Annualized Present Value Costs

Tables VI.D–1 summarizes the annualized present value cost estimates for the LT2ESWTR at 3 percent and 7 percent discount rates. The mean annualized present value costs of the LT2ESWTR are estimated to range from approximately $93 to $133 million using a 3 percent discount rate and $107 to $150 million using a 7 percent discount rate. This range in mean cost estimates is associated with the different Cryptosporidium occurrence data sets. In addition to mean estimates of costs, the Agency calculated 90 percent confidence bounds by considering the uncertainty in Cryptosporidium occurrence estimates and the uncertainty around the mean unit technology costs (USEPA 2005a).

PWSs will incur approximately 99 percent of the rule's total annualized present value costs. States incur the remaining rule costs. Table VI.D–2 shows the undiscounted initial capital and one-time costs broken out by rule component. A comparison of annualized present value costs among the rule alternatives considered by the Agency is located in section VI.F of this preamble.

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Table VI.D-1.– Annualized Present Value Costs for the LT2ESWTR ($millions, 2003$)

	ICR			ICRSSL			ICRSSM		
		Confidence Bounds			Confidence Bounds			Confidence Bounds	
	Mean	5th %ile	95th %ile	Mean	5th %ile	95th %ile	Mean	5th %ile	95th %ile
	3%								
National	$ 133.42	$ 111.05	$ 160.00	$ 92.88	$ 72.11	$ 112.17	$ 105.90	$ 86.30	$ 125.74
System Total	$ 132.27	$ 109.91	$ 158.83	$ 91.78	$ 71.03	$ 111.07	$ 104.79	$ 85.20	$ 124.62
State Total	$ 1.15	$ 1.14	$ 1.17	$ 1.09	$ 1.08	$ 1.10	$ 1.11	$ 1.10	$ 1.12
	7%								
National	$ 150.48	$ 125.12	$ 180.61	$ 106.77	$ 83.21	$ 128.83	$ 120.93	$ 98.58	$ 143.61
System Total	$ 149.07	$ 123.72	$ 179.19	$ 105.42	$ 81.87	$ 127.47	$ 119.56	$ 97.22	$ 142.23
State Total	$ 1.41	$ 1.39	$ 1.42	$ 1.35	$ 1.34	$ 1.36	$ 1.37	$ 1.36	$ 1.38

Source: Chapter 6 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

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Table VI.D-2.–Initial Capital and One-time Costs for the LT2ESWTR ($millions, 2003$)

	Serving < 10,000 People			Serving ≥ 10,000 People			All Systems		
Type of Cost	ICR	ICRSSL	ICRSSM	ICR	ICRSSL	ICRSSM	ICR	ICRSSL	ICRSSM
Total									
National (System + State)							$2,104.32	$ 1,526.27	$ 1,719.41
System									
System Total	$ 214.30	$ 132.32	$ 157.93	$ 1,869.74	$ 1,373.81	$ 1,541.30	$2,084.04	$ 1,506.13	$ 1,699.23
Treatment	$ 140.74	$ 76.26	$ 94.75	$ 1,706.86	$ 1,208.24	$ 1,376.73	$1,847.60	$ 1,284.50	$ 1,471.48
Implementation	$ 1.19	$ 1.19	$ 1.19	$ 0.39	$ 0.39	$ 0.39	$ 1.59	$ 1.59	$ 1.59
Initial Monitoring	$ 38.03	$ 28.27	$ 32.07	$ 26.77	$ 26.77	$ 26.77	$ 64.80	$ 55.04	$ 58.84
Second Monitoring	$ 33.47	$ 26.05	$ 29.30	$ 18.01	$ 20.97	$ 19.86	$ 51.48	$ 47.02	$ 49.16
Benchmarking	$ 0.07	$ 0.04	$ 0.05	$ 0.08	$ 0.06	$ 0.07	$ 0.16	$ 0.10	$ 0.11
Tech Reporting	$ 0.65	$ 0.37	$ 0.43	$ 0.74	$ 0.49	$ 0.58	$ 1.39	$ 0.86	$ 1.01
Uncovered Reservoirs	$ 0.14	$ 0.14	$ 0.14	$ 116.88	$ 116.88	$ 116.88	$ 117.03	$ 117.03	$ 117.03
State									
State Total							$ 20.28	$ 20.15	$ 20.19
Implementation							$ 7.77	$ 7.77	$ 7.77
Initial Monitoring							$ 5.98	$ 5.98	$ 5.98
Second Monitoring							$ 6.18	$ 6.18	$ 6.18
Benchmarking							$ 0.09	$ 0.06	$ 0.07
Tech Reporting							$ 0.27	$ 0.17	$ 0.19
Uncovered Reservoirs							$ 0.00	$ 0.00	$ 0.00

Source: Chapter 6 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

2. PWS Costs

Table VI.D–3 shows the number of filtered and unfiltered PWSs that will incur costs by rule provision. All PWSs that treat surface water or GWUDI (*i.e.*, nonpurchased PWSs) will incur one-time costs that include time for staff training on rule requirements. PWSs will incur monitoring costs to assess source water Cryptosporidium levels, though monitoring requirements vary by PWS size (large vs. small) and PWS type (filtered vs. unfiltered). Some PWSs will incur costs for additional Cryptosporidium treatment, where required, and for covering or treating uncovered finished water reservoirs.

Table VI.D-3.– Number of Filtered and Unfiltered PWSs and Plants Expected to Incur Monitoring and Treatment Costs[1]

	Nonpurchased Systems and Plants							
			Source Water Monitoring - Plants					
Dataset	System Size (population served)	Systems Incurring Implementation Costs	Initial *E. Coli* Monitoring	Initial *Crypto* Monitoring	Future *E. coli* Monitoring	Future *Crypto* Monitoring	Plants Adding Treatment	Systems with Uncovered Reservoirs
		A	B	C	D	E	F	G
ICR	< 10,000	5,663	5,575	1,978	4,977	1,732	2,205	12
	≥ 10,000	1,493	1,733	1,762	1,184	1,184	677	69
	Total	7,156	7,308	3,741	6,161	2,916	2,882	81
ICRSSL	< 10,000	Same as ICR		1,285	5,237	1,171	1,428	
	≥ 10,000			1,762	1,379	1,379	440	Same as ICR
	Total			3,047	6,615	2,550	1,868	
ICRSSM	< 10,000	Same as ICR		1,555	5,181	1,409	1,729	
	≥ 10,000			1,762	1,306	1,306	531	Same as ICR
	Total			3,317	6,487	2,715	2,260	

[1]Numbers shown for plants monitoring include nonpurchased plants only. Numbers shown for plants adding treatment include both nonpurchased plants and a fraction of plants purchasing water that could not be linked to their wholesale plant. Source: Chapter 6 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

a. *Source water monitoring costs.* Source water monitoring costs are structured on a per-plant basis. There are three types of monitoring that plants may be required to conduct—turbidity, E. coli, and Cryptosporidium. Source water turbidity is a common water quality parameter used for plant operational control. Also, to meet SWTR, LT1ESWTR, and IESWTR requirements, most PWSs have turbidity analytical equipment in-house and operators are experienced with turbidity measurement. Thus, EPA assumes that the incremental turbidity monitoring burden associated with the LT2ESWTR is negligible.

Filtered plants in small PWSs initially will be required to conduct 1 year of biweekly E. coli source water monitoring. These plants will be required to monitor for Cryptosporidium if E. coli levels exceed 10 E. coli/100 mL for lakes and reservoir sources or 50 E. coli/100 mL for flowing stream sources. EPA estimated the percent of small plants that would be triggered into Cryptosporidium monitoring as being equal to the percent of large plants that would fall into any bin requiring additional treatment.

Estimates of laboratory fees, shipping costs, labor hours for sample collection, and hours for reporting results were used to predict PWS costs for initial source water monitoring under the LT2ESWTR. Table VI.D–4 summarizes the present value of monitoring costs for initial bin classification. Total present value monitoring costs for initial bin classification range from $45 million to $59 million depending on the occurrence data set and discount rate. Appendix D of the LT2ESWTR EA provides a full explanation of how these costs were developed (USEPA 2005a).

b. *Filtered PWSs treatment costs.* The Agency calculated treatment costs by estimating the number of plants that will add treatment technologies and coupling these estimates with unit costs ($/plant) of the selected technologies. Table VI.D–5 shows the number of plants estimated to select different treatment technologies; Table VI.D–6 summarizes the present value treatment costs and annualized present value costs for both filtered and unfiltered PWSs.

Table VI.D-4.– Summary of Present Value Monitoring Costs for Initial Bin Classification ($millions, 2003$)

System Size	ICR			ICRSSL			ICRSSM		
	Mean	Confidence Bounds		Mean	Confidence Bounds		Mean	Confidence Bounds	
		5th %ile	95th %ile		5th %ile	95th %ile		5th %ile	95th %ile
3 Percent									
< 10,000	$ 33.79	$ 32.11	$. 36.63	$ 25.24	$ 22.02	$ 27.44	$ 28.57	$ 26.36	$ 30.43
≥ 10,000	$ 25.22	$ 25.22	$ 25.22	$ 25.22	$ 25.22	$ 25.22	$ 25.22	$ 25.22	$ 25.22
Total	$ 59.01	$ 57.33	$ 61.86	$ 50.46	$ 47.24	$ 52.66	$ 53.79	$ 51.58	$ 55.66
7 Percent									
< 10,000	$ 29.05	$ 27.64	$ 31.45	$ 21.85	$ 19.13	$ 23.70	$ 24.65	$ 22.79	$ 26.22
≥ 10,000	$ 23.38	$ 23.38	$ 23.38	$ 23.38	$ 23.38	$ 23.38	$ 23.38	$ 23.38	$ 23.38
Total	$ 52.42	$ 51.01	$ 54.82	$ 45.22	$ 42.50	$ 47.07	$ 48.02	$ 46.17	$ 49.60

Source: Chapter 6 of the LT2ESWTR Economic Analysis (USEPA 2005a)

To estimate the number of filtered plants that would select a particular treatment technology, EPA followed a two step process. First, the number of plants that will be assigned to treatment bins requiring additional treatment was estimated. Second, the treatment technologies that plants will choose to meet these requirements was estimated using a "least-cost decision tree." In this estimate, EPA assumed that PWSs will select the least expensive technology or combination of technologies to meet the log removal requirements of a given treatment bin. Technology selections were constrained by maximum use percentages, which recognize that some plants will not be able to implement certain technologies because of site-specific conditions. In addition, certain potentially lower cost components of the microbial toolbox, such as changes to the plant intake, were not included because EPA lacked data to estimate the number of plants that could select it. These limitations on technology use may result in an overestimate of costs. An in-depth discussion of the technology selection methodology and unit cost estimates can be found in Appendices E and F of the LT2ESWTR EA (USEPA 2005a).

Table VI.D-5.– Filtered Plant Technology Selection Forecasts

Technology Selections[1]	Data Set[2]			Technology Selections[1]	Data Set[2]		
	ICR	ICRSSL	ICRSSM		ICR	ICRSSL	ICRSSM
Bag Filter 1.0 Log	1,523	1,219	1,421	Ozone 0.5 Log	27	21	25
Cartridge Filter 2.0 Log	209	20	58	Ozone 1.0 Log	18	14	16
Combined Filter Performance 0.5 Log	16	12	14	Ozone 2.0 Log	10	3	4
In-bank Filtration 1.0 Log	6	5	6	Secondary Filter 1.0 Log	0	0	0
MF/UF 2.5 Log	37	13	18	UV 2.5 Log	979	503	641
				WS Control 0.5 Log	0	0	0

[1]Some plants are projected to select more than one technology to meet LT2ESWTR bin requirements.
[2]Forecasts represent the median occurrence distribution.
Source: Chapter 6 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

c. *Unfiltered PWSs treatment costs.* The LT2ESWTR requires all unfiltered PWSs to achieve 2-log of inactivation if their mean source water Cryptosporidium concentration is less than or equal to 0.01 oocysts/L and 3-log of inactivation if it is greater than 0.01 oocysts/L. For most PWSs, UV appears to be the least expensive technology that can achieve these levels of Cryptosporidium inactivation, and EPA expects UV to be widely used by unfiltered PWSs to meet today's rule requirements. However, as with filtered PWSs, EPA estimated that a small percentage of plants would elect to install a technology more expensive than UV due to the configuration of

existing equipment or other factors. Ozone is the next least expensive technology that will meet the inactivation requirements for some PWSs and EPA estimated that it will be used by plants that do not use UV.

All unfiltered PWSs must meet requirements of the LT2ESWTR; therefore, 100 percent of unfiltered PWSs are estimated to add technology. This assumes that no unfiltered PWSs currently use these additional treatment technologies. For this cost analysis, EPA assumed that all very small unfiltered PWSs will use UV; for all other unfiltered PWS sizes, EPA estimated that 90 percent will install UV and 10 percent will add ozone. Treatment costs for unfiltered PWSs are included in Table VI.D–6.

Table VI.D-6.–Total Present Value and Annualized Present Value Treatment Costs for Filtered and Unfiltered Plants

	Capital - Present Value			O & M - Annualized			Total - Annualized		
	Mean	5th %ile	95th %ile	Mean	5th %ile	95th %ile	Mean	5th %ile	95th %ile
Dataset	A	B	C	D	E	F	G	H	I
3 percent									
ICR	$1,426.5	$1,128.4	$1,780.9	$ 33.7	$ 28.7	$ 39.6	$ 115.6	$ 93.5	$ 141.9
ICRSSL	$ 998.5	$ 723.2	$1,263.1	$ 18.8	$ 14.2	$ 22.6	$ 76.1	$ 55.7	$ 95.2
ICRSSM	$1,141.0	$ 875.4	$1,413.9	$ 23.2	$ 19.1	$ 27.2	$ 88.8	$ 69.4	$ 108.4
7 percent									
ICR	$1,157.1	$ 915.3	$1,444.3	$ 29.4	$ 25.0	$ 34.6	$ 128.7	$ 103.6	$ 158.5
ICRSSL	$ 812.2	$ 588.7	$1,027.0	$ 16.4	$ 12.4	$ 19.7	$ 86.1	$ 62.9	$ 107.9
ICRSSM	$ 927.1	$ 711.5	$1,148.7	$ 20.3	$ 16.7	$ 23.7	$ 99.8	$ 77.7	$ 122.3

Source: Chapter 6 of the LT2ESWTR Economic Analysis (USEPA 2005a)

d. *Uncovered finished water storage facilities.* As part of the LT2ESWTR, PWSs with uncovered finished water storage facilities must either cover the storage facility or treat the discharge to achieve inactivation and/or removal of at least 2-log Cryptosporidium, 3-log Giardia lamblia, and 4-log viruses. To develop national cost estimates for PWSs to comply with these provisions, unit costs for each compliance alternative and the percentage of PWSs selecting each alternative were estimated for the inventory of uncovered finished water storage facilities. From a recent survey of EPA Regions, EPA estimates that there are currently 81 uncovered finished water storage facilities for which PWSs must take steps to comply with the LT2ESWTR. A full description of the unit costs and other assumptions used in this analysis is presented in Chapter 6 and Appendix I of the LT2ESWTR EA (USEPA 2005a).

To comply with the treatment requirements, EPA determined that the least-cost treatment option is a combination of chlorine and UV. For PWSs with uncovered storage facility capacities of 5 million gallons (MG) or less, covering the storage facilities is the least expensive alternative. Although disinfection is the least expensive alternative for the remaining PWSs, the ability of a PWS to use booster chlorination depends on their current residual disinfectant type. Somewhat less than half of all surface water PWSs are predicted to use chloramination following implementation of the Stage 2 DBPR. Adding chlorine to water that has been treated with chloramines is not a feasible alternative; therefore, the fraction of PWSs projected to add UV and booster chlorination to the effluent from the uncovered storage facility was estimated at 50 percent, with the remaining 50 percent projected to add covers.

Table VI.D–7 summarizes total annualized present value costs for the uncovered finished water storage facility requirements using both 3 and 7 percent discount rates. EPA estimates the total annualized present value cost for covering or treating the water from uncovered finished water storage facilities to be approximately $10 million at a 3 percent discount rate and $13 million at a 7 percent discount rate.

Table VI.D-7.– Estimated Annualized Present Value Cost for Uncovered Finished Water Storage Facility Provision ($millions, 2003$)

System Size (Population Served)	Annualized Cost at 3%			Annualized Cost at 7%		
	Capital	O&M	Total	Capital	O&M	Total
<10,000	$ 0.01	$ 0.00	$ 0.01	$ 0.01	$ 0.00	$ 0.02
≥10,000	$ 6.52	$ 3.73	$ 10.24	$ 9.39	$ 3.68	$ 13.07
Total	$ 6.53	$ 3.73	$ 10.26	$ 9.40	$ 3.68	$ 13.08

Source: Appendix II of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

e. *Future monitoring costs.* Six years after initial bin classification, filtered and unfiltered PWSs must conduct a second round of monitoring to assess whether source water Cryptosporidium levels have changed significantly. EPA will evaluate new analytical methods and surrogate indicators of microbial water quality in the interim. While the costs of monitoring are likely to change in the 9 years following rule promulgation, it is difficult to predict how they will change. In the absence of any other information, EPA assumed that the laboratory costs will be the same as for the initial monitoring.

All PWSs that conducted initial monitoring were assumed to conduct the second round of monitoring, except for those PWSs that installed treatment that achieves a total of 5.5-log or greater treatment for Cryptosporidium as a result of the rule. These PWSs are exempt from monitoring under the LT2ESWTR. EPA estimates that the cost of the second round of source water monitoring will range from $21 million to $36 million, depending on the occurrence data set and discount rate used in the estimate. Appendix D of the EA provides further details (USEPA 2005a).

f. Sensitivity analysis-influent bromide levels on technology selection for filtered plants. One concern with the ICR data set is that it may not reflect influent bromide levels in some PWSs during droughts. High influent bromide levels (the precursor for bromate formation) limits ozone use because some PWSs would not be able to meet the MCL for bromate. EPA conducted a sensitivity analysis to estimate the impact that higher influent bromide levels would have on technology decisions. The sensitivity analysis assumed influent bromide concentrations of 50 parts per billion (ppb) above the ICR concentrations. Results of the analysis indicate that this higher bromide level has a minimal impact on costs.

3. State/Primacy Agency Costs

EPA estimates that States (including primacy agencies) will incur an annualized present value cost of $1.1 to 1.2 million using a 3 percent discount rate and $1.4 million at 7 percent. State implementation activities include regulation adoption, program implementation, training State staff, training PWS staff, providing technical assistance to PWSs, and updating management systems. To estimate implementation costs to States, the number of full-time employees (FTEs) per activity is multiplied by the number of labor hours per FTE, the cost per labor hour, and the number of States and Territories.

In addition to implementation costs, States will also incur costs associated with managing monitoring data. Because EPA will directly manage reporting, approval, and analysis of results from the initial round of monitoring by large PWSs (serving at least 10,000 people), States are not predicted to incur costs for these activities. States will, however, incur costs associated with small PWS monitoring. This is a result of the later start of small PWS monitoring, which will mean that some States will assume primacy for small PWS monitoring. In addition, States will review the second round of monitoring results. States will also incur costs for reviewing technology compliance data and consulting with PWSs regarding disinfection benchmarking (for PWSs that change their disinfection procedures to comply with today's rule). Appendix D of the LT2ESWTR EA provides more information about the State cost analysis (USEPA 2005a).

4. Non-Quantified Costs

EPA has quantified all the major costs for this rule and has provided uncertainty analyses to bound the over or underestimates in the costs. There are some costs that EPA has not quantified, however, because of lack of data. For example, some PWSs may merge with neighboring PWSs to comply with this rule. Such changes have both costs (legal fees and connecting infrastructure) and benefits (economies of scale). Likewise, PWSs would incur costs for procuring a new source of water that may result in lower overall treatment costs.

In addition, the Agency was unable to predict the usage or estimate the costs of several options in the microbial toolbox. These options include intake management and demonstrations of performance. They have not been included in the quantified analysis because data are not available to estimate the number of PWSs that may use these toolbox options to comply with the LT2ESWTR. Not including these generally lower-cost options may result in overestimation of costs.

E. What Are the Household Costs of the LT2ESWTR?

Another way to assess a rule's impact is to consider how it may impact residential water bills. This analysis considers the potential increase in a household's water bill if a CWS passed the entire cost increase resulting from this rule on to its customers. This serves as a tool to gauge potential impacts and should not be construed as precise estimates of potential changes to individual water bills.

Included in this analysis are all PWS costs, including rule implementation, initial and future monitoring for bin classification, additional Cryptosporidium treatment, and treating

or covering uncovered finished water storage facilities. Costs for Cryptosporidium monitoring by small PWSs, additional Cryptosporidium treatment, and uncovered finished water storage facilities are assigned only to the subset of PWSs expected to incur them. Although implementation and monitoring represent relatively small, one-time costs, they have been included in the analysis to provide a complete distribution of the potential household cost. A detailed description of the derivation of household costs is in Chapter 6 and Appendix J of the LT2ESTWR EA (USEPA 2005a).

For PWSs that purchase treated water (i.e., purchased PWSs) from larger nonpurchased PWSs, the households costs are calculated based on the unit treatment costs of the larger PWS but included in the distribution for the size category of the purchased PWS. Households costs for these purchased PWSs are based on the household usage rates appropriate for the retail PWS and not the PWS selling (wholesaling) the water. This approach for purchased PWSs reflects the fact that although they will not face increased costs from adding their own treatment, whatever costs the wholesale PWS incurs will likely be passed on as higher water costs.

Table VI.E–1 shows the results of the household cost analysis. In addition to mean and median estimates, EPA calculated the 90th and the 95th percentiles. EPA estimates that all households served by surface and GWUDI sources will face some increase in household costs due to implementation of the LT2ESWTR. Of all the households subject to the rule, from 22 to 41 percent are projected to incur costs for adding treatment, depending on the Cryptosporidium occurrence data set used.

Approximately 92 percent of the households potentially subject to the rule are served by PWSs serving at least 10,000 people and 99.8 percent are served by PWSs serving at least 500 people; these PWSs experience the lowest increases in costs due to significant economies of scale. Over 95 percent of all households are estimated to face an annual cost increase of less than $12. Households served by small PWSs that install advanced technologies will face the greatest increases in annual costs. EPA expects that the model's projections for these PWSs are, in some cases, overstated. Some PWSs are likely to find alternative treatment techniques such as other toolbox options not included in this analysis, or sources of water (ground water, purchased water, or consolidating with another PWS) that would be less costly than installing more expensive treatment technologies.

Table VI.E-1.– Potential Annual Household Costs Impacts for the Preferred Regulatory Option (2003$)

System Type/Size	Households	Mean	Median	90th Percentile	95th Percentile	Percent of Systems with Household Cost Increase < $12	Percent of Systems with Household Cost Increase < $120
ICR							
All CWS	68,857,992	$2.59	$0.21	$6.43	$9.97	96.49%	99.99%
CWS ≤ 10,000	5,587,602	$4.14	$0.56	$9.97	$14.79	91.19%	99.88%
CWS < 500	158,900	$13.09	$3.86	$28.66	$53.60	63.20%	98.87%
ICRSSL							
All CWS	68,857,992	$1.67	$0.09	$6.37	$6.42	97.96%	100.00%
CWS ≤ 10,000	5,587,602	$2.49	$0.36	$6.60	$9.37	96.46%	99.94%
CWS < 500	158,900	$8.58	$2.91	$17.44	$29.01	72.61%	99.50%
ICRSSM							
All CWS	68,857,992	$1.97	$0.09	$6.37	$6.85	97.47%	99.99%
CWS ≤ 10,000	5,587,602	$3.00	$0.49	$7.02	$11.39	95.19%	99.93%
CWS < 500	158,900	$10.10	$2.90	$26.24	$35.97	68.73%	99.31%
ICR - High							
All CWS	68,857,992	$2.84	$0.21	$6.43	$9.97	96.09%	99.99%
CWS ≤ 10,000	5,587,602	$4.58	$0.61	$11.50	$15.30	90.22%	99.86%
CWS < 500	158,900	$7.21	$2.91	$16.81	$26.25	75.79%	99.80%
ICRSSL - Low							
All CWS	68,857,992	$1.42	$0.03	$5.65	$6.42	98.37%	100.00%
CWS ≤ 10,000	5,587,602	$2.06	$0.23	$6.58	$7.47	97.21%	99.96%
CWS < 500	158,900	$14.42	$4.79	$30.00	$54.42	62.07%	98.58%

Source: Chapter 6 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)

F. What Are the Incremental Costs and Benefits of the LT2ESWTR?

Incremental costs and benefits are those that are incurred or realized in reducing Cryptosporidium exposures from one regulatory alternative to the next. Estimates of incremental costs and benefits are useful in considering the economic efficiency of different regulatory alternatives evaluated by EPA. Generally, the goal of an incremental analysis is to identify the most efficient regulatory alternative. However, this analysis is incomplete because some benefits from this rule are unquantified and not monetized. Incremental analyses should consider both quantified and unquantified (where possible) benefits and costs.

Usually an incremental analysis implies increasing levels of stringency along a single parameter, with each alternative providing all the protection of the previous alternative, plus additional protection. However, the regulatory alternatives evaluated for the LT2ESWTR vary by multiple parameters (e.g., treatment bin boundaries, treatment requirements). The comparison between any two alternatives is, therefore, between two separate sets of benefits, in the sense that they may be distributed to somewhat different population groups.

The regulatory alternatives, however, do achieve increasing levels of benefits at increasing levels of costs. As a result, displaying incremental net benefits from the baseline and alternative to alternative is possible. Tables VI.F–1a and VI.F–1b show incremental costs, benefits, and net benefits for the four regulatory alternatives, A1–A4, shown in Table VI.A–1, using the enhanced and traditional COI, respectively. All values are annualized present values expressed in Year 2003 dollars. The displayed values are the mean estimates for each occurrence distribution and infectivity model.

With the enhanced COI, incremental costs are generally closest to incremental benefits for A2, a more stringent alternative than A3, which is today's final rule. For the traditional COI, incremental costs most closely equal incremental benefits for A3 under the majority of conditions evaluated.

G. Are There Benefits From the Reduction of Co-Occurring Contaminants?

While the quantified and monetized benefits for the LT2ESWTR includes only reductions in illness and mortality attributable to Cryptosporidium, today's rule will reduce exposure to and disease from other microbial pathogens and, in some cases, chemical contaminants.

Table VI.F-1a.– Incremental Net Benefits by Rule Alternative—Enhanced COI (Annualized Present Value, $millions, 2003$)*

Data Set	Rule Alternative	Annual Costs	Annual Benefits			Incremental Costs	Incremental Benefits			Incremental Net Benefits		
			Low	Medium	High		Low	Medium	High	Low	Medium	High
		A	B			C	D			E=D-C		
3 Percent Discount Rate												
ICR	A4	$ 81	$ 645	$ 1,753	$ 2,661	$ 81	$ 645	$ 1,753	$ 2,661	$ 565	$ 1,673	$ 2,580
	A3 - Preferred	$ 133	$ 687	$ 1,853	$ 2,822	$ 53	$ 42	$ 100	$ 161	$ (11)	$ 47	$ 108
	A2	$ 163	$ 695	$ 1,871	$ 2,851	$ 30	$ 7	$ 18	$ 29	$ (23)	$ (12)	$ (1)
	A1	$ 403	$ 705	$ 1,895	$ 2,891	$ 239	$ 10	$ 24	$ 40	$ (229)	$ (216)	$ (200)
ICRSSL	A4	$ 57	$ 155	$ 405	$ 657	$ 57	$ 155	$ 405	$ 657	$ 98	$ 347	$ 600
	A3 - Preferred	$ 93	$ 177	$ 458	$ 744	$ 35	$ 22	$ 53	$ 87	$ (13)	$ 18	$ 52
	A2	$ 123	$ 191	$ 489	$ 795	$ 30	$ 13	$ 31	$ 51	$ (17)	$ 1	$ 21
	A1	$ 403	$ 221	$ 558	$ 910	$ 280	$ 31	$ 69	$ 115	$ (249)	$ (210)	$ (165)
ICRSSM	A4	$ 65	$ 306	$ 796	$ 1,247	$ 65	$ 306	$ 796	$ 1,247	$ 241	$ 731	$ 1,182
	A3 - Preferred	$ 106	$ 344	$ 886	$ 1,393	$ 41	$ 38	$ 90	$ 146	$ (3)	$ 49	$ 105
	A2	$ 137	$ 359	$ 919	$ 1,447	$ 31	$ 15	$ 33	$ 54	$ (16)	$ 2	$ 23
	A1	$ 403	$ 386	$ 981	$ 1,548	$ 266	$ 27	$ 62	$ 102	$ (239)	$ (204)	$ (164)
7 Percent Discount Rate												
ICR	A4	$ 93	$ 523	$ 1,421	$ 2,156	$ 93	$ 523	$ 1,421	$ 2,156	$ 430	$ 1,328	$ 2,063
	A3 - Preferred	$ 150	$ 556	$ 1,501	$ 2,286	$ 57	$ 34	$ 80	$ 130	$ (24)	$ 23	$ 72
	A2	$ 182	$ 562	$ 1,515	$ 2,309	$ 31	$ 6	$ 14	$ 23	$ (26)	$ (17)	$ (8)
	A1	$ 436	$ 570	$ 1,534	$ 2,341	$ 255	$ 8	$ 19	$ 32	$ (246)	$ (236)	$ (223)
ICRSSL	A4	$ 68	$ 126	$ 328	$ 533	$ 68	$ 126	$ 328	$ 533	$ 58	$ 261	$ 465
	A3 - Preferred	$ 107	$ 144	$ 371	$ 603	$ 39	$ 18	$ 43	$ 70	$ (21)	$ 4	$ 31
	A2	$ 139	$ 154	$ 396	$ 644	$ 32	$ 11	$ 25	$ 41	$ (21)	$ (7)	$ 9
	A1	$ 437	$ 221	$ 452	$ 737	$ 298	$ 67	$ 56	$ 92	$ (231)	$ (242)	$ (205)
ICRSSM	A4	$ 76	$ 248	$ 645	$ 1,011	$ 76	$ 248	$ 645	$ 1,011	$ 172	$ 569	$ 935
	A3 - Preferred	$ 121	$ 279	$ 718	$ 1,128	$ 45	$ 31	$ 73	$ 118	$ (14)	$ 27	$ 72
	A2	$ 154	$ 291	$ 744	$ 1,171	$ 33	$ 12	$ 27	$ 43	$ (21)	$ (6)	$ 10
	A1	$ 437	$ 313	$ 794	$ 1,253	$ 283	$ 22	$ 50	$ 82	$ (261)	$ (233)	$ (201)

Table VI.F-1b.– Incremental Net Benefits by Rule Alternative—Traditional COI (Annualized Present Value, $millions, 2003$)*

Data Set	Rule Alternative	Annual Costs	Annual Benefits			Incremental Costs	Incremental Benefits			Incremental Net Benefits		
			Low	Medium	High		Low	Medium	High	Low	Medium	High
		A	B			C	D			E=D-C		
3 Percent Discount Rate												
ICR	A4	$ 81	$ 468	$ 1,273	$ 1,937	$ 81	$ 468	$ 1,273	$ 1,937	$ 388	$ 1,193	$ 1,856
	A3 - Preferred	$ 133	$ 497	$ 1,341	$ 2,047	$ 53	$ 29	$ 68	$ 110	$ (24)	$ 15	$ 57
	A2	$ 163	$ 502	$ 1,353	$ 2,066	$ 30	$ 5	$ 12	$ 20	$ (25)	$ (18)	$ (10)
	A1	$ 403	$ 509	$ 1,369	$ 2,093	$ 239	$ 7	$ 16	$ 27	$ (232)	$ (223)	$ (212)
ICRSSL	A4	$ 57	$ 115	$ 299	$ 486	$ 57	$ 115	$ 299	$ 486	$ 57	$ 242	$ 429
	A3 - Preferred	$ 93	$ 130	$ 335	$ 546	$ 35	$ 15	$ 36	$ 59	$ (20)	$ 1	$ 24
	A2	$ 123	$ 139	$ 356	$ 580	$ 30	$ 9	$ 21	$ 35	$ (21)	$ (9)	$ 4
	A1	$ 403	$ 160	$ 403	$ 658	$ 280	$ 21	$ 47	$ 78	$ (259)	$ (233)	$ (201)
ICRSSM	A4	$ 65	$ 224	$ 583	$ 915	$ 65	$ 224	$ 583	$ 915	$ 159	$ 518	$ 851
	A3 - Preferred	$ 106	$ 250	$ 644	$ 1,014	$ 41	$ 26	$ 61	$ 99	$ (15)	$ 20	$ 58
	A2	$ 137	$ 260	$ 666	$ 1,051	$ 31	$ 10	$ 23	$ 37	$ (21)	$ (9)	$ 6
	A1	$ 403	$ 279	$ 708	$ 1,120	$ 266	$ 18	$ 42	$ 69	$ (247)	$ (224)	$ (197)
7 Percent Discount Rate												
ICR	A4	$ 93	$ 380	$ 1,034	$ 1,574	$ 93	$ 380	$ 1,034	$ 1,574	$ 287	$ 941	$ 1,481
	A3 - Preferred	$ 150	$ 403	$ 1,089	$ 1,662	$ 57	$ 23	$ 55	$ 88	$ (34)	$ (3)	$ 31
	A2	$ 182	$ 407	$ 1,099	$ 1,678	$ 31	$ 4	$ 10	$ 16	$ (28)	$ (22)	$ (15)
	A1	$ 436	$ 413	$ 1,112	$ 1,700	$ 255	$ 6	$ 13	$ 22	$ (249)	$ (242)	$ (233)
ICRSSL	A4	$ 68	$ 93	$ 243	$ 396	$ 68	$ 93	$ 243	$ 396	$ 26	$ 175	$ 328
	A3 - Preferred	$ 107	$ 105	$ 272	$ 443	$ 39	$ 12	$ 29	$ 48	$ (27)	$ (10)	$ 9
	A2	$ 139	$ 113	$ 289	$ 471	$ 32	$ 7	$ 17	$ 28	$ (25)	$ (15)	$ (4)
	A1	$ 437	$ 130	$ 327	$ 534	$ 298	$ 17	$ 38	$ 63	$ (281)	$ (260)	$ (235)
ICRSSM	A4	$ 76	$ 182	$ 474	$ 744	$ 76	$ 182	$ 474	$ 744	$ 106	$ 398	$ 668
	A3 - Preferred	$ 121	$ 203	$ 523	$ 824	$ 45	$ 21	$ 49	$ 80	$ (24)	$ 4	$ 35
	A2	$ 154	$ 211	$ 541	$ 853	$ 33	$ 8	$ 18	$ 29	$ (25)	$ (15)	$ (3)
	A1	$ 437	$ 226	$ 575	$ 909	$ 283	$ 15	$ 34	$ 56	$ (268)	$ (249)	$ (227)

*Notes: The traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The enhanced COI also factors in valuations for lost personal time (non-worktime) such as child care and homemaking (to the extent not covered by the traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway. Source: Chapter 8 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)
High, medium, and low estimates reflect the mean estimates for a range of dose-response modeling assumptions. See Appendix N of the LT2ESWTR Economic Analysis.

All of the options in the microbial toolbox that PWSs will implement to comply with today's rule will also reduce levels of other microbial pathogens. For example, watershed control programs and intake relocation

will cut overall pathogen levels by reducing fecal contamination in the source water. Membrane, bag, and cartridge filters will remove pathogenic protozoa like Giardia lamblia that are similar in size to or larger than Cryptosporidium. Lowering finished water turbidity from conventional and direct filtration will improve removal of pathogens across a broad size range, including viruses, bacteria, and protozoa. Inactivation technologies like ozone and UV are highly effective against a large number of different pathogen types.

Some membrane technologies that PWSs may install to comply with the LT2ESWTR can also reduce or eliminate chemical contaminants including arsenic, DBPs, and atrazine. The use of UV for inactivation of Cryptosporidium may reduce the chlorine dosage that some PWSs must apply, which can reduce levels of DBPs. EPA has recently finalized a rule to further control arsenic levels in drinking water and is concurrently establishing the Stage 2 DBPR to address DBP control.

The extent to which the LT2ESWTR can reduce the overall risk from other contaminants has not been quantitatively evaluated because EPA lacks sufficient data on the co-occurrence among Cryptosporidium and other microbial pathogens and contaminants. Further, due to the difficulties in establishing which PWSs would have multiple problems, such as microbial contamination, arsenic, and DBPs or any combination of the three, no estimate was made of the potential cost savings from addressing more than one contaminant simultaneously.

H. Are There Increased Risks From Other Contaminants?

It is unlikely that the LT2ESWTR will result in a significant increase in risk from other contaminants for most PWSs. Many of the options that PWSs will select to comply with the LT2ESWTR, such as UV, additional or improved filtration, and watershed control, do not form DBPs. Ozone, another technology that is effective against Cryptosporidium, does form DBPs (e.g., bromate). However, bromate is currently regulated under the Stage 1 DBPR, and PWSs will have to comply with this regulation if they implement ozone to meet the LT2ESWTR.

I. What Are the Effects of the Contaminant on the General Population and Groups Within the General Populations That Are Identified as Likely To be at Greater Risk of Adverse Health Effects?

Section III of this preamble discusses the health effects associated with Cryptosporidium on the general population as well as the effects on other sensitive sub-populations. In addition, health effects associated with children and pregnant women are discussed in greater detail in section VII.G of this preamble.

J. What Are the Uncertainties in the Risk, Benefit, and Cost Estimates for the LT2ESWTR?

For today's final rule, EPA has modeled the current baseline risk from Cryptosporidium exposure through drinking water, along with the reduction in risk and the cost for various rule alternatives. There is uncertainty in the risk calculation, the benefit estimates, the cost estimates, and the interaction with other regulations. The LT2ESWTR EA has an extensive discussion of relevant uncertainties (USEPA 2005a), and a brief summary of the major uncertainties follows.

In regard to the risk estimates, the most significant areas of uncertainty are Cryptosporidium occurrence, treatment, and infectivity. Among the three available occurrence data sets, the ICR plant-mean data were higher than the ICRSSM or ICRSSL plant-mean data at the 90th percentile. The reasons for these differing results are not well understood but may stem from year-to-year variation in occurrence and differences in the sampling and measurement methods employed. The ICRSSM and ICRSSL data sets use a newer, more reliable sampling method but include fewer plants and a shorter time frame. Additional uncertainty is associated with estimating finished water occurrence because the analysis is based on estimates of treatment plant performance in removing Cryptosporidium.

EPA has addressed some of the uncertainty in occurrence by evaluating benefits and costs for regulatory alternatives with each Cryptosporidium data set. Further, in the 2-dimensional Monte Carlo simulation models used to estimate risk, key parameters like occurrence and treatment efficiency are treated as both variable and uncertain. This approach is intended to account for the limitations in available data and the recognized variability in these parameters among PWSs.

EPA has also considered occurrence data from additional sources. For example, the LT2ESWTR EA discusses a study of infectious Cryptosporidium in the finished water of 82 filtration plants by Aboytes et.al, 2004. The mean level of infectious Cryptosporidium measured in this study is higher than EPA has estimated using the ICR, ICRSSM, or ICRSSL data sets. This result suggests that Cryptosporidium occurrence at these plants may have exceeded levels during the ICR and ICRSS surveys or that EPA may have overestimated the efficiency of treatment plants in removing Cryptosporidium.

In regard to Cryptosporidium infectivity, EPA evaluated data from human feeding studies conducted with different Cryptosporidium isolates. The measured infectivity of these isolates varied widely, however, and how well these isolates represent Cryptosporidium that causes disease in PWSs is uncertain. In addition, extrapolating from the higher Cryptosporidium dosing levels used in the human feeding studies to the exposure levels typical for drinking water (e.g., one oocyst) is uncertain. Another source of uncertainty is differences that exist among populations groups, such as individuals that are more sensitive (e.g., children, immunocompromised) or less sensitive (previously infected adults).

EPA accounted for some of this uncertainty in infectivity by treating the human feeding study results for different Cryptosporidium isolates as random samples from a larger and unknown environmental distribution of Cryptosporidium infectivity. EPA used a variety of models for this analysis, as recommended by the SAB, and presents results for a range of models to account for uncertainty in model selection. In addition, limited data on levels of Cryptosporidium in the 1993 Milwaukee outbreak and associated disease incidence suggest that the infectivity of the Cryptosporidium responsible for that outbreak is within the range EPA has estimated for the risk assessment in today's rule.

Unquantified benefits from the reduction of co-occurring microbial pathogens, as described earlier, are a significant source of uncertainty in the estimate of benefits for the LT2ESWTR. EPA is also uncertain about the monetization of avoided disease from Cryptosporidium and has addressed this uncertainty through the use of both traditional and enhanced COI values for benefits estimates.

While all of the significant costs of today's rule have been identified by

EPA, there are uncertainties in the estimates. Occurrence is the most significant source of uncertainty in costs, and EPA has attempted to account for this uncertainty through the use of different occurrence data sets and Monte Carlo modeling as described previously. EPA has also estimated uncertainty in unit process costs for treatment technologies. In addition, the cost assessment for today's rule includes sensitivity analyses, such an assessment of the impact of influent bromide levels on technology selection. Chapter 6 of the LT2ESWTR EA provides a fuller description of uncertainties in the cost estimates (USEPA 2005a).

Last, EPA has recently finalized or is currently finalizing new regulations for arsenic, radon, Cryptosporidium in small surface water PWSs, filter backwash recycling, microbial pathogens in PWSs using ground water, and DBPs. These rules may have overlapping impacts on some PWSs, but the extent is not possible to estimate due to lack of information on co-occurrence. However, PWSs may choose treatment technologies that will address multiple contaminants. Therefore, while the total cost impact of these drinking water rules is uncertain, it is most likely less than the estimated total cost of all individual rules combined.

K. What Is the Benefit/Cost Determination for the LT2ESWTR?

The Agency has determined that the benefits of the LT2ESWTR justify the costs. As discussed in section VII.C, the rule provides a large reduction in endemic cryptosporidiosis illness and mortalities. More stringent alternatives provide greater reductions but at higher costs. Alternative A1 provides the greatest overall reduction in illnesses and mortalities but the incremental benefits between this option and alternative A3 (today's final rule) are relatively small while the incremental costs are significant. In addition, today's rule, unlike alternative A1, specifically targets those PWSs whose source water requires higher levels of treatment.

Tables VI.K–1a and VI.K–1b present net benefits for the four regulatory alternatives that were evaluated. Generally, analysis of net benefits is used to identify alternatives where benefits exceed costs, as well as the alternative that maximizes net benefits. However, as with the analysis of incremental net benefits discussed previously, the usefulness of this analysis in evaluating regulatory alternatives for the LT2ESWTR is somewhat limited because many benefits from this rule are unquantified and nonmonetized. Analyses of net benefits should consider both quantified and unquantified (where possible) benefits and costs.

Also, as noted earlier, the regulatory alternatives considered for the LT2ESWTR vary both in the population that experiences benefits and costs (i.e., treatment bin boundaries) and the magnitude of the benefits and costs (i.e., treatment requirements). Consequently, the more stringent regulatory alternatives provide benefits to population groups that do not experience any benefit under less stringent alternatives.

As shown by Tables VI.K–1a and VI.K–1b, net benefits are positive for all four regulatory alternatives evaluated under most occurrence and discount rate scenarios. With both the enhanced COI and traditional COI, net benefits are highest for the alternative A3, which is today's final rule, under the majority of occurrence distributions and discount rates evaluated.

Table VI.K-1a.–Mean Net Benefits by Rule Option—Enhanced COI[1] ($millions, 2003$)

Data Set	Rule Alternative	Annualized Value					
		3%, 25 Years			7%, 25 Years		
		Low	Medium	High	Low	Medium	High
ICR	A1	$ 260	$ 1,492	$ 2,447	$ 126	$ 1,098	$ 1,897
	A2	$ 498	$ 1,708	$ 2,655	$ 366	$ 1,333	$ 2,112
	A3 - Preferred	$ 527	$ 1,720	$ 2,662	$ 396	$ 1,351	$ 2,126
	A4	$ 550	$ 1,673	$ 2,566	$ 427	$ 1,328	$ 2,061
ICRSSL	A1	$ (223)	$ 156	$ 466	$ (265)	$ 15	$ 292
	A2	$ 43	$ 366	$ 647	$ 6	$ 257	$ 496
	A3 - Preferred	$ 65	$ 365	$ 632	$ 32	$ 264	$ 491
	A4	$ 87	$ 347	$ 589	$ 58	$ 261	$ 465
ICRSSM	A1	$ (58)	$ 578	$ 1,104	$ (132)	$ 358	$ 809
	A2	$ 198	$ 782	$ 1,285	$ 130	$ 591	$ 1,010
	A3 - Preferred	$ 218	$ 780	$ 1,267	$ 153	$ 597	$ 1,002
	A4	$ 230	$ 731	$ 1,171	$ 172	$ 569	$ 935

Table VI.K-1b.–Mean Net Benefits by Rule Option—Traditional COI[1] ($millions, 2003$)

Data Set	Rule Alternative	Annualized Value					
		3%, 25 Years			7%, 25 Years		
		Low	Medium	High	Low	Medium	High
ICR	A1	$ 64	$ 967	$ 1,649	$ (31)	$ 675	$ 1,256
	A2	$ 305	$ 1,190	$ 1,870	$ 211	$ 917	$ 1,481
	A3 - Preferred	$ 337	$ 1,208	$ 1,887	$ 243	$ 939	$ 1,502
	A4	$ 373	$ 1,193	$ 1,842	$ 285	$ 941	$ 1,478
ICRSSL	A1	$ (284)	$ 0	$ 214	$ (315)	$ (109)	$ 90
	A2	$ (9)	$ 233	$ 432	$ (35)	$ 150	$ 324
	A3 - Preferred	$ 18	$ 242	$ 433	$ (7)	$ 166	$ 331
	A4	$ 46	$ 242	$ 418	$ 25	$ 175	$ 327
ICRSSM	A1	$ (165)	$ 306	$ 676	$ (218)	$ 138	$ 465
	A2	$ 99	$ 529	$ 890	$ 50	$ 387	$ 692
	A3 - Preferred	$ 124	$ 538	$ 889	$ 77	$ 402	$ 698
	A4	$ 148	$ 518	$ 840	$ 106	$ 398	$ 668

[1]The traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The enhanced COI also factors in valuations for lost personal time (non-worktime) such as child care and homemaking (to the extent not covered by the traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway. Source: Chapter 8 of the *LT2ESWTR Economic Analysis* (USEPA 2005a) High, medium, and low estimates reflect the mean estimates for a range of dose-response modeling assumptions. See Appendix N of the LT2ESWTR Economic Analysis.

In addition to the net benefits of the LT2ESWTR, the Agency used several other techniques to compare costs and benefits. For example, EPA calculated the cost of the rule per case avoided. Tables VI.K–2a, b and c show both the cost of the rule per illness avoided and cost of the rule per death avoided. This cost effectiveness measure is another way of examining the benefits and costs of the rule but should not be used to compare alternatives because an alternative with the lowest cost per illness/death avoided may not result in the highest net benefits. With the exception of alternative A1, the rule options look favorable when the cost per case avoided is compared to both the weighted cost of cryptosporidiosis illness ($844 and $274 for the two COI approaches) and the mean value of a statistical death avoided—approximately $7 million dollars. Additional information about this analysis and other methods of comparing benefits and costs can be found in chapter 8 of the LT2ESWTR EA (USEPA 2005a).

Table VI.K-2a.–Cost per Illness or Death Avoided[1], Low Estimate

Data Set	Rule Alternative	Cost Per Illness Avoided ($)		Cost Per Death Avoided ($Millions, 2000$)		Benefit/Cost Ratio (Enhanced COI)		Benefit/Cost Ratio (Traditional COI)	
		3%	7%	3%	7%	3%	7%	3%	7%
ICR	A4	$ 398	$ 837	$ 1.8	$ 3.9	8.0	5.6	5.8	4.1
	A3 - Preferred	$ 566	$ 1,172	$ 2.7	$ 5.6	5.2	3.7	3.7	2.7
	A2	$ 739	$ 1,503	$ 3.5	$ 7.1	4.3	3.1	3.1	2.2
	A1	$ 1,791	$ 3,546	$ 8.5	$ 16.7	1.8	1.3	1.3	0.9
ICRSSL	A4	$ 1,241	$ 2,666	$ 5.3	$ 11.3	2.7	1.9	2.0	1.4
	A3 - Preferred	$ 1,598	$ 3,366	$ 7.2	$ 15.1	1.9	1.3	1.4	1.0
	A2	$ 2,073	$ 4,265	$ 9.4	$ 19.4	1.5	1.1	1.1	0.8
	A1	$ 5,683	$ 11,259	$ 27.0	$ 53.3	0.6	0.5	0.4	0.3
ICRSSM	A4	$ 690	$ 1,470	$ 3.1	$ 6.5	4.7	3.3	3.5	2.4
	A3 - Preferred	$ 913	$ 1,913	$ 4.2	$ 8.9	3.2	2.3	2.4	1.7
	A2	$ 1,207	$ 2,474	$ 5.6	$ 11.5	2.6	1.9	1.9	1.4
	A1	$ 3,259	$ 6,456	$ 15.4	$ 30.6	1.0	0.7	0.7	0.5

Table VI.K-2b.–Cost per Illness or Death Avoided[1], Medium Estimate

Data Set	Rule Alternative	Cost Per Illness Avoided ($)		Cost Per Death Avoided ($Millions, 2000$)		Benefit/Cost Ratio (Enhanced COI)		Benefit/Cost Ratio (Traditional COI)	
		3%	7%	3%	7%	3%	7%	3%	7%
ICR	A4	$ 147	$ 309	$ 0.7	$ 1.4	21.7	15.3	15.8	11.1
	A3 - Preferred	$ 227	$ 468	$ 1.1	$ 2.2	13.9	10.0	10.1	7.2
	A2	$ 275	$ 559	$ 1.3	$ 2.6	11.5	8.3	8.3	6.0
	A1	$ 668	$ 1,322	$ 3.1	$ 6.2	4.7	3.5	3.4	2.5
ICRSSL	A4	$ 476	$ 1,022	$ 2.0	$ 4.3	7.1	4.9	5.2	3.6
	A3 - Preferred	$ 661	$ 1,385	$ 2.9	$ 6.1	4.9	3.5	3.6	2.6
	A2	$ 808	$ 1,663	$ 3.7	$ 7.5	4.0	2.9	2.9	2.1
	A1	$ 2,258	$ 4,472	$ 10.6	$ 21.0	1.4	1.0	1.0	0.7
ICRSSM	A4	$ 265	$ 565	$ 1.2	$ 2.5	12.3	8.5	9.0	6.3
	A3 - Preferred	$ 382	$ 796	$ 1.7	$ 3.6	8.4	5.9	6.1	4.3
	A2	$ 473	$ 969	$ 2.2	$ 4.5	6.7	4.8	4.9	3.5
	A1	$ 1,287	$ 2,548	$ 6.0	$ 11.9	2.4	1.8	1.8	1.3

Table VI.K-2c.–Cost per Illness or Death Avoided[1], High Estimate

Data Set	Rule Alternative	Cost Per Illness Avoided ($)		Cost Per Death Avoided ($Millions, 2000$)		Benefit/Cost Ratio (Enhanced COI)		Benefit/Cost Ratio (Traditional COI)	
		3%	7%	3%	7%	3%	7%	3%	7%
ICR	A4	$ 97	$ 205	$ 0.4	$ 0.9	33.0	23.2	24.0	16.9
	A3 - Preferred	$ 140	$ 289	$ 0.7	$ 1.4	21.2	15.2	15.3	11.0
	A2	$ 182	$ 369	$ 0.8	$ 1.7	17.5	12.7	12.7	9.2
	A1	$ 440	$ 872	$ 2.1	$ 4.1	7.2	5.4	5.2	3.9
ICRSSL	A4	$ 295	$ 633	$ 1.3	$ 2.7	11.4	7.9	8.5	5.8
	A3 - Preferred	$ 385	$ 810	$ 1.7	$ 3.6	8.0	5.6	5.9	4.2
	A2	$ 500	$ 1,029	$ 2.3	$ 4.6	6.5	4.6	4.7	3.4
	A1	$ 1,394	$ 2,762	$ 6.6	$ 13.0	2.3	1.7	1.6	1.2
ICRSSM	A4	$ 170	$ 363	$ 0.8	$ 1.6	19.3	13.4	14.2	9.9
	A3 - Preferred	$ 228	$ 478	$ 1.1	$ 2.2	13.1	9.3	9.6	6.8
	A2	$ 302	$ 619	$ 1.4	$ 2.9	10.6	7.6	7.7	5.5
	A1	$ 820	$ 1,624	$ 3.9	$ 7.6	3.8	2.9	2.8	2.1

[1]The calculations presented here do not reflect discounting of the physical incidence of morbidity or mortality.
Source: Chapter 8 of the *LT2ESWTR Economic Analysis* (USEPA 2005a)
Note: High, medium, and low estimates reflect the mean estimates for a range of dose-response modeling assumptions. See Appendix N of the LT2ESWTR Economic Analysis (USEPA, 2005a).

L. Summary of Major Comments

EPA received significant public comment on the analysis of benefits and costs of the August 11, 2003 proposed LT2ESWTR in the following areas: Cryptosporidium occurrence, drinking water consumption, Cryptosporidium infectivity (i.e., dose-response), and valuation of benefits. The following discussion summarizes public comment in these areas and EPA's responses.

1. Cryptosporidium Occurrence

With respect to the analysis of Cryptosporidium occurrence, two areas that received significant public comment are the quality of the ICR and ICRSS data sets (i.e., whether the estimates derived from them should be regarded as equally plausible) and the treatment of samples in which no Cryptosporidium is detected (i.e., observed zeros).

a. *Quality of the ICR and ICRSS data sets.* As noted earlier, the ICR, ICRSSM, and ICRSSL data sets differ significantly in the high concentration portion of the occurrence distribution (e.g., 90th percentile). While the measurement method employed in the ICRSS had higher recovery and less variable volumes assayed, the ICR produced a much greater number of assays and source waters sampled. Lacking a technical basis to conclude that one data set provides a better estimate, EPA conducted separate analyses of costs and benefits for all three data sets. EPA requested comment on this approach.

The majority of commenters on this issue supported EPA's approach of analyzing the three data sets separately to represent uncertainty about occurrence. Two commenters suggested that the ICR data would be more reliable for estimating national occurrence due to the larger number of samples, while two others viewed the ICRSS data as more reliable due to the improved analytical method. No commenters provided a technical analysis indicating that one data set is more accurate. Given these comments, EPA has retained the approach of analyzing costs and benefits separately for each occurrence data set in today's final rule.

b. *Treatment of observed zeros.* One commenter remarked that the majority of samples in which no oocysts were detected (i.e., observed zeros) likely contained no oocysts in the volume assayed. This commenter was concerned with a parameter in EPA's occurrence analysis model for ''true zero,'' which characterizes the likelihood that a source water is entirely free of Cryptosporidium at all times. In EPA's model, the true zero parameter was assigned a value of 0.1 percent. As described in USEPA (2005b), EPA based this assumption on the finding that intensive sampling of surface waters usually detects Cryptosporidium, even in protected watersheds. The commenter concluded, however, that the true zero parameter resulted in the model assigning a value of at least 1 oocyst to 99.9 percent of samples.

EPA responds that the true zero parameter in the occurrence analysis model does not operate in this way. While the model is set-up to estimate mean source water concentrations and not the concentrations in individual volumes assayed, the model recognizes that the majority of samples in the ICR and ICRSS contained no oocysts. The model does assume that few, if any, of the source waters sampled in these surveys never contained a single oocyst (the meaning of the true zero parameter). EPA has clarified the definition of the true zero parameter in USEPA (2005b). EPA has also conducted a sensitivity analysis in which the true zero parameter was varied from values of 0 to 50 percent, with little effect on estimates of risk, benefit, and cost for today's rule.

2. Drinking Water Consumption

Two commenters were concerned with the distribution for drinking water consumption that EPA used in the proposed LT2ESWTR. This distribution, which was based on a 1994–1996 survey by the United States Department of Agriculture (USDA), reflects water consumption from all sources. Commenters recommended two modifications to this approach: (1) Adjust the distribution to account for factors like bottled water and boiled water use; and (2) use an alternative distribution from the USDA survey that reflects consumption of community water system (CWS) water only.

In response, EPA agrees that the distribution should be adjusted to remove consumption attributable to bottled water. For the consumption distribution in today's final rule, EPA subtracted bottled water usage, based on information in the USDA survey, which had the effect of reducing consumption by approximately 14 percent in comparison to the proposal. EPA does not have information on the effectiveness of heating water to make coffee or tea for inactivating Cryptosporidium and has not modified the consumption distribution on this basis.

EPA continues to believe that the USDA distribution for consumption of water from all sources, minus bottled water consumption, provides the best available estimate for consumption of water from CWSs for people served by CWSs. The USDA distribution for consumption of CWS water only, which a commenter recommended, includes people not served by CWSs (e.g., people with private wells). Inclusion these individuals has the effect of underestimating the consumption of CWS water for people served by CWSs in this distribution. In contrast, the distribution for consumption of water from all sources includes people not served by CWSs and the sources those people use (e.g., private wells). This avoids the problem of underestimating consumption for individuals served by CWS. Accordingly, EPA has retained the use of this distribution in today's final rule, with the adjustment stated previously for bottled water consumption.

3. Cryptosporidium Infectivity

In regard to Cryptosporidium infectivity (i.e., dose-response assessment), EPA received significant comment on limitations in the human feeding studies (e.g. representativeness of Cryptosporidium isolates used in the studies, numbers of subjects) and uncertainty in extrapolating from high study doses to low drinking water doses. EPA believes that the statistical analysis of dose-response data, as described in USEPA (2005a), properly accounted for these limitations and uncertainties.

The statistical models used by EPA treated the isolates studied as a random sample from a larger population of environmental isolates, treated the subjects studied as a random sample from the larger population of healthy individuals, and treated each individual's outcome as a chance event, where the infection probability is a function of the challenge dose. Collectively, these uncertainties contributed to the significant uncertainty in EPA's estimate of the likelihood of infection given one oocyst ingested.

Since the LT2ESWTR proposal, EPA has reviewed results from additional human feeding studies with Cryptosporidium isolates and analyzed data from these and the feeding studies considered for the proposal with additional dose-response models (USEPA 2005a). As described in Chapter 5 and Appendix N of the LT2ESWTR EA, the infectivity estimates from the proposal are near the middle of the range of estimates derived with the additional feeding study data and dose-response models. Further, the mean estimates from these new analyses fall within the 90th percentile uncertainty bounds for infectivity estimates from the proposal (USEPA 2005a). Consequently, EPA believes that the infectivity estimates from the additional feeding study data and dose-response models are consistent with and supportive of the estimates of infectivity from the proposal. Further, EPA's estimates of infectivity are consistent with data on the infectivity of Cryptosporidium in the 1993 Milwaukee outbreak (USEPA 2005a).

4. Valuation of Benefits

In the area of benefits valuation, EPA received significant public comment on the valuation of morbidity, valuation of lost time under the Enhanced COI approach, and unquantified benefits.

a. *Valuation of morbidity.* EPA received a comment that endemic cases that do not show up in public health surveillance data may be too mild (and perhaps even asymptomatic) to be economically significant. EPA believes endemic cases are significant in terms of public health risk and economic impacts. As discussed earlier, only a small fraction of the millions of cases of gastrointestinal illnesses are traced to a specific illness (such as cryptosporidiosis); yet endemic disease clearly exists and those illnesses, even if mild, have public health consequences and economic impacts (e.g., missed work). For example, the benefits model in the EA assumes that 88 percent of all cases are mild, and yet those illnesses represent significant impacts nationally. Further, the risk assessment model separately computes infections and illnesses. Thus, asymptomatic infections are excluded; only avoided illnesses are assigned monetary benefits.

b. *Valuation of lost time under the enhanced cost of illness (COI) approach.* One commenter extensively questioned the approach used to value lost leisure and nonwork time under the Enhanced COI approach, noting concerns about the relationship of the approach to standard economics practices, the plausibility of the resulting values, and the extent of peer review. The following discussion summarizes EPA's responses on these issues.

As discussed in detail in the EA (USEPA 2005a), EPA recognizes that the preferred approach for valuing health risk reductions is to rely on estimates of individual willingness to pay (WTP). In the absence of suitable WTP estimates, analysts often rely on approaches similar to the Traditional COI approach used for this rule, as noted by the commenter. However, empirical research as well as theoretic concerns suggest that these types of COI approaches will generally understate true WTP.

EPA designed the Enhanced COI approach to correct for one potential source of understatement—the impact of illness on unpaid work and leisure time. While the Enhanced COI approach is innovative, it is rooted in standard welfare economic theory and builds on approaches used to value time in numerous studies in the labor, transportation, recreation, and health economics literature. The commenter is concerned, however, that the Enhanced COI approach values nonwork time at a higher rate than many recreational studies, several of which value travel time at one-third of the wage rate. EPA's extensive review of the recreational literature suggests, however, that there is no consensus regarding the value of travel time, as discussed in the Appendix P of the EA (USEPA 2005a). In addition, travel has both pleasant and unpleasant aspects and hence may be valued less than other leisure activities, many of which may be valued at a rate higher than foregone wages.

To test the plausibility of the results, the commenter compares the value of a ''lifetime case'' of cryptosporidiosis to the value of statistical life (VSL) and suggests that the results (which show that such a case would be roughly 70 percent of VSL) are improbably high. However, EPA believes that this comparison is seriously flawed. There is no generally accepted standard for determining whether values for nonfatal risk reductions are ''reasonable'' compared to values for fatal risk reductions. In addition, the calculation of the value of a lifetime case of cryptosporidiosis contains several computational errors, and represents the loss of all waking time (not just losses attributable to cryptosporidiosis) and so is seriously overstated. Perhaps most important, the approach used to value