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National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141, and 142

[EPA–HQ–OW–2002–0039; FRL–8013–1]

RIN 2040—AD37

National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating National Primary Drinking Water Regulations that require the use of treatment techniques, along with monitoring, reporting, and public notification requirements, for all public water systems that use surface water sources. The purposes of the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) are to protect public health from illness due to Cryptosporidium and other microbial pathogens in drinking water and to address risk-risk trade-offs with the control of disinfection byproducts.

Key provisions in the LT2ESWTR include the following: source water monitoring for Cryptosporidium, with a screening procedure to reduce monitoring costs for small systems; risk-targeted Cryptosporidium treatment by filtered systems with the highest source water Cryptosporidium levels; inactivation of Cryptosporidium by all unfiltered systems; criteria for the use of Cryptosporidium treatment and control processes; and covering or treating uncovered finished water storage facilities.

EPA believes that implementation of the LT2ESWTR will significantly reduce levels of infectious Cryptosporidium in finished drinking water. This will substantially lower rates of endemic cryptosporidiosis, the illness caused by Cryptosporidium, which can be severe and sometimes fatal in sensitive subpopulations (e.g., infants, people with weakened immune systems). In addition, the treatment technique requirements of this regulation will increase protection against other microbial pathogens like Giardia lamblia.

DATES: This final rule is effective on March 6, 2006. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of March 6, 2006. For judicial review purposes, this final rule is promulgated as of January 5, 2006.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OW–2002–0039. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Water Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: Daniel C. Schmelling, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MC 4607M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–5281; fax number: (202) 564–3767; e-mail address: *schmelling.dan@epa.gov.* For general information, contact the Safe Drinking Water Hotline, telephone number: (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 9 a.m. to 5 p.m., Eastern time.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Who Is Regulated by This Action?

Entities potentially regulated by the LT2ESWTR are public water systems (PWSs) that use surface water or ground water under the direct influence of surface water (GWUDI). Regulated categories and entities are identified in the following chart.

Category	Examples of regulated entities
Industry	Public Water Systems that use surface water or ground water under the direct influence of surface water.
State, Local, Tribal or Federal Governments	Public Water Systems that use surface water or ground water under the direct influence of surface water.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of public water system in § 141.3 of Title 40 of the Code of Federal Regulations and applicability criteria in § 141.700(b) of today's rule. If you have questions regarding the applicability of the LT2ESWTR to a particular entity, consult one of the persons listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT.**

Abbreviations Used in This Document

ASTM American Society for Testing and Materials
AWWA American Water Works Association
°C Degrees Centigrade
CDC Centers for Disease Control and Prevention
CFE Combined Filter Effluent
CFR Code of Federal Regulations
COI Cost-of-Illness
CT The Residual Concentration of Disinfectant (mg/L) Multiplied by the Contact Time (in minutes)
CWS Community Water Systems
DAPI 4′,6-Diamindino-2-phenylindole
DBPs Disinfection Byproducts
DBPR Disinfectants/Disinfection Byproducts Rule
DE Diatomaceous Earth
DIC Differential Interference Contrast (microscopy)
EA Economic Analysis
EPA United States Environmental Protection Agency
GAC Granular Activated Carbon
GWUDI Ground Water Under the Direct Influence of Surface Water
HAA5 Five Haloacetic Acids (Monochloroacetic, Dichloroacetic, Trichloroacetic, Monobromoacetic and Dibromoacetic Acids)
ICR Information Collection Rule (also Information Collection Request)
ICRSS Information Collection Rule Supplemental Surveys

ICRSSM Information Collection Rule Supplemental Survey of Medium Systems
ICRSSL Information Collection Rule Supplemental Survey of Large Systems
IESWTR Interim Enhanced Surface Water Treatment Rule
Log Logarithm (common, base 10)
LRAA Locational Running Annual Average
LRV Log Removal Value
LT1ESWTR Long Term 1 Enhanced Surface Water Treatment Rule
LT2ESWTR Long Term 2 Enhanced Surface Water Treatment Rule
MCL Maximum Contaminant Level
MCLG Maximum Contaminant Level Goal
MG Million Gallons
M–DBP Microbial and Disinfectants/Disinfection Byproducts
MF Microfiltration
NPDWR National Primary Drinking Water Regulation
NTTAA National Technology Transfer and Advancement Act
NTU Nephelometric Turbidity Unit
OMB Office of Management and Budget
PE Performance Evaluation
PWS Public Water System
QC Quality Control
QCRV Quality Control Release Value
RAA Running Annual Average
RFA Regulatory Flexibility Act
RO Reverse Osmosis
SAB Science Advisory Board
SBAR Small Business Advocacy Review
SDWA Safe Drinking Water Act
SWAP Source Water Assessment Program
SWTR Surface Water Treatment Rule
TCR Total Coliform Rule
TTHM Total Trihalomethanes
UF Ultrafiltration
UMRA Unfunded Mandates Reform Act

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II. Summary of the Final Rule

A. Why Is EPA Promulgating the LT2ESWTR?

EPA is promulgating the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) to further protect public health against Cryptosporidium and other microbial pathogens in drinking water. Cryptosporidium is a protozoan parasite that is common in surface water used as drinking water sources by public water systems (PWSs). In drinking water, Cryptosporidium is a particular concern because it is highly resistant to chemical disinfectants like chlorine. When ingested, Cryptosporidium can cause acute gastrointestinal illness, which may be severe and sometimes fatal for people with weakened immune systems. Cryptosporidium has been identified as the cause of a number of waterborne disease outbreaks in the United States (details in section III.C).

The LT2ESWTR supplements existing microbial treatment regulations and targets PWSs with higher potential risk from Cryptosporidium. Existing regulations require most PWSs using surface water sources to filter the water, and those PWSs that are required to filter must remove at least 99 percent (2-log) of the Cryptosporidium (details in section III.B). As explained in the proposal for today's rule (68 FR 47640, August 11, 2003) (USEPA 2003a), new data on the occurrence, infectivity, and treatment of Cryptosporidium in drinking water indicate that existing regulations are sufficient for most PWSs. A subset of PWSs with greater vulnerability to Cryptosporidium, however, requires additional treatment.

In particular, recent national survey data show that the level of Cryptosporidium in the sources of most filtered PWSs is lower than previously estimated, but also that Cryptosporidium levels vary widely from source to source. Accordingly, a subset of filtered PWSs has relatively high levels of source water Cryptosporidium contamination. In addition, data from human health studies indicate that the potential for Cryptosporidium to cause infection is likely greater than previously recognized (details in section III.E). These findings have led EPA to conclude that existing requirements do not provide adequate public health protection in filtered PWSs with the highest source water Cryptosporidium levels. Consequently, EPA is establishing risk-targeted additional treatment requirements for such filtered PWSs under the LT2ESWTR.

For PWSs that use surface water sources and are not required to filter (i.e., unfiltered PWSs), existing regulations do not require any treatment for Cryptosporidium. New survey data suggest that typical Cryptosporidium levels in the treated water of unfiltered PWSs are higher than in the treated water of filtered PWSs (USEPA 2003a). Thus, Cryptosporidium treatment by unfiltered PWSs is needed to achieve comparable public health protection (details in section III.E). Further, results from recent treatment studies have allowed EPA to develop standards for the inactivation of Cryptosporidium by ozone, ultraviolet (UV) light, and chlorine dioxide (details in section IV.D). Based on these developments, EPA is establishing requirements under the LT2ESWTR for all unfiltered PWSs to treat for Cryptosporidium, with the required degree of treatment depending on the source water contamination level.

Additionally, the LT2ESWTR addresses risks in uncovered finished water storage facilities, in which treated water can be subject to significant contamination as a result of runoff, bird and animal wastes, human activity, algal growth, insects, fish, and airborne deposition (details in section IV.F). Existing regulations prohibit the building of new uncovered finished water storage facilities but do not deal with existing ones. Under the LT2ESWTR, PWSs must limit potential risks by covering or treating the discharge of such storage facilities.

Most of the requirements in today's final LT2ESWTR reflect consensus recommendations from the Stage 2 Microbial and Disinfection Byproducts (M–DBP) Federal Advisory Committee. These recommendations are set forth in the Stage 2 M–DBP Agreement in Principle (65 FR 83015, December 29, 2000) (USEPA 2000a).

B. What Does the LT2ESWTR Require?

1. Source Water Monitoring

The LT2ESWTR requires PWSs using surface water or ground water under the direct influence (GWUDI) of surface water to monitor their source water (i.e., the influent water entering the treatment plant) to determine an average Cryptosporidium level. As described in the next section, monitoring results determine the extent of Cryptosporidium treatment requirements under the LT2ESWTR.

Large PWSs (serving at least 10,000 people) must monitor for Cryptosporidium (plus E. coli and turbidity in filtered PWSs) for a period of two years. To reduce monitoring costs, small filtered PWSs (serving fewer than 10,000 people) initially monitor just for E. coli for one year as a screening analysis and are required to monitor for Cryptosporidium only if their E. coli levels exceed specified "trigger" values. Small filtered PWSs that exceed the E. coli trigger, as well as all small unfiltered PWSs, must monitor for Cryptosporidium for one or two years, depending on the sampling frequency (details sections IV.A).

Under the LT2ESWTR, specific criteria are set for sampling frequency and schedule, sampling location, using previously collected data (i.e., grandfathering), providing treatment instead of monitoring, sampling by PWSs that use surface water for only part of the year, and monitoring of new plants and sources (details in section IV.A). The LT2ESWTR also establishes requirements for reporting of monitoring results (details in section IV.I), using analytical methods (details in section IV.J), and using approved laboratories (details in section IV.K).

The date for PWSs to begin monitoring is staggered by PWS size, with smaller PWSs starting at a later time than larger ones (details in section IV.G). Today's rule also requires a second round of monitoring to begin approximately 6.5 years after the first round concludes in order to determine if source water quality has changed to a degree that should affect treatment requirements (details in section IV.A).

2. Additional Treatment for Cryptosporidium

The LT2ESWTR establishes risk-targeted treatment technique requirements to control Cryptosporidium in PWSs using surface water or GWUDI. These treatment requirements supplement those established by existing regulations, all of which remain in effect under the LT2ESWTR.

Filtered PWSs will be classified in one of four treatment categories (or "bins") based on the results of the source water Cryptosporidium monitoring described in the previous section. This bin classification determines the degree of additional Cryptosporidium treatment, if any, the filtered PWS must provide. Occurrence data indicate that the majority of filtered PWSs will be classified in Bin 1, which carries no additional treatment requirements. PWSs classified in Bins 2, 3, or 4 must achieve 1.0- to 2.5-log of treatment (i.e., 90 to 99.7 percent reduction) for Cryptosporidium over and above that provided with conventional treatment. Different additional treatment requirements may apply to PWSs using other than conventional treatment, such as direct filtration, membranes, or cartridge filters (details in section. IV.B). Filtered PWSs must meet the additional Cryptosporidium treatment required in Bins 2, 3, or 4 by using one or more treatment or control processes from a "microbial toolbox" of options (details in section. IV.D).

The LT2ESWTR requires all unfiltered PWSs to provide at least 2-log (i.e., 99 percent) inactivation of Cryptosporidium. If the average source water Cryptosporidium level exceeds 0.01 oocysts/L based on the monitoring described in the previous section, the unfiltered PWS must provide at least 3-log (i.e., 99.9 percent) inactivation of Cryptosporidium. Further, under the LT2ESWTR, unfiltered PWSs must achieve their overall inactivation requirements (including Giardia lamblia and virus inactivation as established by earlier regulations) using a minimum of two disinfectants (details in section IV.C).

3. Uncovered Finished Water Storage Facilities

Under the LT2ESWTR, PWSs with uncovered finished water storage facilities must take steps to address contamination risks. Existing regulations require PWSs to cover all new storage facilities for finished water but do not address existing uncovered finished water storage facilities. Under the LT2ESWTR, PWSs using uncovered finished water storage facilities must either cover the storage facility or treat the storage facility discharge to achieve inactivation and/or removal of 4-log virus, 3-log Giardia lamblia, and 2-log Cryptosporidium on a State-approved schedule (details in section. IV.F).

C. Will This Regulation Apply to My Water System?

The LT2ESWTR applies to all PWSs using surface water or GWUDI, including both large and small PWSs, community and non-community PWSs, and non-transient and transient PWSs. Wholesale PWSs must comply with the requirements of today's rule based on the population of the largest PWS in the combined distribution system. Consecutive PWSs that purchase treated water from wholesale PWSs that fully comply with the monitoring and treatment requirements of the LT2ESWTR are not required to take additional steps for that water under today's rule.

III. Background Information

The sections in this part provide summary background information for today's final LT2ESWTR. Individual sections address the following topics: (A) Statutory requirements and legal authority for the LT2ESWTR; (B) existing regulations for microbial pathogens in drinking water; (C) the problem with Cryptosporidium in drinking water; (D) specific public health concerns addressed by the LT2ESWTR; (E) new information for Cryptosporidium risk management in PWSs; and (F) recommendations from the Stage 2 M-DBP Advisory Committee for the LT2ESWTR. For additional information on these topics, see the proposed LT2ESWTR (USEPA 2003a) and supporting technical material where cited.

A. Statutory Requirements and Legal Authority

The Safe Drinking Water Act (SDWA or the Act), as amended in 1996, requires EPA to publish a maximum contaminant level goal (MCLG) and promulgate a national primary drinking water regulation (NPDWR) with enforceable requirements for any contaminant that the Administrator determines may have an adverse effect on the health of persons, is known to occur or has a substantial likelihood of occurring in public water systems (PWSs) with a frequency and at levels of public health concern, and for which, in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs (section 1412 (b)(1)(A)).

MCLGs are non-enforceable health goals and are to be set at a level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety (sections 1412(b)(4) and 1412(a)(3)). EPA established an MCLG of zero for Cryptosporidium under the Interim Enhanced Surface Water Treatment Rule (IESWTR) (63 FR 69478, December 16, 1998) (USEPA 1998a). In today's rule, the Agency is not making any changes to the current MCLG for Cryptosporidium.

The Act also requires each NPDWR for which an MCLG is established to specify a maximum contaminant level (MCL) that is as close to the MCLG as is feasible (sections 1412(b)(4) and 1401(1)(C)). The Agency is authorized to promulgate an NPDWR that requires the use of a treatment technique in lieu of establishing an MCL if the Agency finds that it is not economically or technologically feasible to ascertain the level of the contaminant (sections 1412(b)(7)(A) and 1401(1)(C)). The Act specifies that in such cases, the Agency shall identify those treatment techniques that would prevent known or anticipated adverse effects on the health of persons to the extent feasible (section 1412(b)(7)(A)).

The Agency has concluded that it is not currently economically or technologically feasible for PWSs to determine the level of Cryptosporidium in finished drinking water for the purpose of compliance with a finished water standard. As described in section IV.C, the LT2ESWTR is designed to protect public health by lowering the level of infectious Cryptosporidium in finished drinking water to less than 1 oocyst/10,000 L. Approved Cryptosporidium analytical methods, which are described in section IV.K, are not sufficient to routinely determine the level of Cryptosporidium at this concentration. Consequently, the LT2ESWTR relies on treatment technique requirements to reduce health risks from Cryptosporidium in PWSs.

When proposing an NPDWR that includes an MCL or treatment technique, the Act requires EPA to publish and seek public comment on an analysis of health risk reduction and costs. This includes an analysis of quantifiable and nonquantifiable costs and health risk reduction benefits, incremental costs and benefits of each alternative considered, the effects of the contaminant upon sensitive subpopulations (e.g., infants, children, pregnant women, the elderly, and individuals with a history of serious illness), any increased risk that may occur as the result of compliance, and other relevant factors (section 1412(b)(3)(C)). EPA's analysis of health benefits and costs associated with the LT2ESWTR is presented in the Economic Analysis of the LT2ESWTR (USEPA 2005a) and is summarized in section VI of this preamble. The Act does not, however, authorize the Administrator to use a determination of whether benefits justify costs to establish an MCL or treatment technique requirement for the control of Cryptosporidium (section 1412(b)(6)(C)).

Finally, section 1412(b)(2)(C) of the Act requires EPA to promulgate a Stage 2 Disinfectants and Disinfection Byproducts Rule within 18 months after promulgation of the LT1ESWTR, which occurred on January 14, 2002. Consistent with statutory requirements for risk balancing (section 1412(b)(5)(B)), EPA is finalizing the LT2ESWTR in conjunction with the Stage 2 DBPR to ensure parallel protection from microbial and DBP risks.

B. Existing Regulations for Microbial Pathogens in Drinking Water

This section summarizes existing rules that regulate treatment for pathogenic microorganisms by PWSs using surface water sources. The LT2ESWTR supplements these rules with additional risk-targeted requirements, but does not withdraw any existing requirements.

1. Surface Water Treatment Rule

The Surface Water Treatment Rule (SWTR) (54 FR 27486, June 29, 1989) (USEPA 1989a) applies to all PWSs using surface water or ground water under the direct influence (GWUDI) of surface water as sources (i.e., Subpart H PWSs). It established MCLGs of zero for Giardia lamblia, viruses, and Legionella, and includes the following treatment technique requirements to reduce exposure to pathogenic microorganisms: (1) Filtration, unless specific avoidance criteria are met; (2) maintenance of a disinfectant residual in the distribution system; (3) removal and/or inactivation of 3-log (99.9%) of Giardia lamblia and 4-log (99.99%) of viruses; (4) maximum allowable turbidity in the combined filter effluent (CFE) of 5 nephelometric turbidity units (NTU) and 95th percentile CFE turbidity of 0.5 NTU or less for plants using conventional treatment or direct filtration (with different standards for other filtration technologies); and (5) watershed protection and source water quality requirements for unfiltered PWSs.

2. Total Coliform Rule

The Total Coliform Rule (TCR) (54 FR 27544, June 29, 1989) (USEPA 1989b) applies to all PWSs. It established an MCLG of zero for total and fecal coliform bacteria and an MCL based on the percentage of positive samples collected during a compliance period. Coliforms are used as an indicator of fecal contamination and to determine the integrity of the water treatment process and distribution system. Under the TCR, no more than 5 percent of distribution system samples collected in any month may contain coliform bacteria (no more than 1 sample per month may be coliform positive in those PWSs that collect fewer than 40 samples per month). The number of samples to be collected in a month is based on the number of people served by the PWS.

3. Interim Enhanced Surface Water Treatment Rule

The Interim Enhanced Surface Water Treatment Rule (IESWTR) (63 FR 69478, December 16, 1998) (USEPA 1998a) applies to PWSs serving at least 10,000 people and using surface water or

GWUDI sources. Key provisions established by the IESWTR include the following: (1) An MCLG of zero for Cryptosporidium; (2) Cryptosporidium removal requirements of 2-log (99 percent) for PWSs that filter; (3) more stringent CFE turbidity performance standards of 1.0 NTU as a maximum and 0.3 NTU or less at the 95th percentile monthly for treatment plants using conventional treatment or direct filtration; (4) requirements for individual filter turbidity monitoring; (5) disinfection benchmark provisions to assess the level of microbial protection that PWSs provide as they take steps to comply with new DBP standards; (6) inclusion of Cryptosporidium in the definition of GWUDI and in the watershed control requirements for unfiltered PWSs; (7) requirements for covers on new finished water storage facilities; and (8) sanitary surveys for all surface water systems regardless of size.

The IESWTR was developed in conjunction with the Stage 1 Disinfectants and Disinfection Byproducts Rule (Stage 1 DBPR) (63 FR 69389, December 16, 1998) (USEPA 1998b), which reduced allowable levels of certain DBPs, including trihalomethanes, haloacetic acids, chlorite, and bromate.

4. Long Term 1 Enhanced Surface Water Treatment Rule

The Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR) (67 FR 1812, January 14, 2002) (USEPA 2002a) builds upon the microbial control provisions established by the IESWTR for large PWSs through extending similar requirements to small PWSs. The LT1ESWTR applies to PWSs that use surface water or GWUDI as sources and that serve fewer than 10,000 people. Like the IESWTR, the LT1ESWTR established the following: 2-log (99 percent) Cryptosporidium removal requirements by PWSs that filter; individual filter turbidity monitoring and more stringent combined filter effluent turbidity standards for conventional and direct filtration plants; disinfection profiling and benchmarking; inclusion of Cryptosporidium in the definition of GWUDI and in the watershed control requirements for unfiltered PWSs; and the requirement that new finished water storage facilities be covered.

5. Filter Backwash Recycle Rule

The Filter Backwash Recycling Rule (FBRR) (66 FR 31085, June 8, 2001) (USEPA 2001a) requires PWSs to consider the potential risks associated with recycling contaminants removed during the filtration process. The provisions of the FBRR apply to all PWSs that recycle, regardless of population served. In general, the provisions include the following: (1) PWSs must return certain recycle streams to a point in the treatment process that is prior to primary coagulant addition unless the State specifies an alternative location; (2) direct filtration PWSs recycling to the treatment process must provide detailed recycle treatment information to the State; and (3) certain conventional PWSs that practice direct recycling must perform a one-month, one-time recycling self assessment.

C. Concern With Cryptosporidium in Drinking Water

1. Introduction

EPA is promulgating the LT2ESWTR to reduce the public health risk associated with Cryptosporidium in drinking water. This section describes the general basis for this public health concern through reviewing information in several areas: the nature of Cryptosporidium, health effects, efficacy of water treatment processes, and the incidence of epidemic and endemic disease. Further information about Cryptosporidium is available in the following documents: Cryptosporidium: Human Health Criteria Document (USEPA 2001b), Cryptosporidium: Drinking Water Advisory (USEPA 2001c), and Cryptosporidium: Risks for Infants and Children (USEPA 2001d).

2. What Is Cryptosporidium?

Cryptosporidium is a protozoan parasite that lives and reproduces entirely in one host. Ingestion of Cryptosporidium can cause cryptosporidiosis, a gastrointestinal (GI) illness. Cryptosporidium is excreted in feces. Transmission of cryptosporidiosis occurs through consumption of water or food contaminated with feces or by direct or indirect contact with infected persons or animals (Casemore 1990).

In the environment, Cryptosporidium is present as a thick-walled oocyst containing four organisms (sporozoites); the oocyst wall insulates the sporozoites from harsh environmental conditions. Oocysts are 4–5 microns in length and width. Upon a host's ingestion of oocysts, enzymes and chemicals produced by the host's digestive system cause the oocyst to excyst, or break open. The excysted sporozoites embed themselves in the surfaces of the epithelial cells of the lower small intestine. The organisms then begin absorbing nutrients from their host cells. When these organisms sexually reproduce, they produce thick- and thin-walled oocysts. The host excretes the thick-walled oocysts in its feces; thin-walled oocysts excyst within the host and contribute to further host infection.

The exact mechanism by which Cryptosporidium causes GI illness is not known. Factors may include damage to intestinal structure and cells, changes in the absorption/secretion processes of the intestine, toxins produced by Cryptosporidium or the host, and proteins that allow Cryptosporidium to adhere to host cell surfaces (Carey et al. 2004).

Upon excretion, Cryptosporidium oocysts may survive for months in various environmental media, including soil, river water, seawater, and human and cattle feces at ambient temperatures (Kato et al. 2001, Pokorny et al. 2002, Fayer et al. 1998a and 1998b, and Robertson et al. 1992). Cryptosporidium can also withstand temperatures as low as −20 °C for periods of a few hours (Fayer and Nerad 1996) but are susceptible to desiccation (Robertson et al. 1992).

Cryptosporidium is a widespread contaminant in surface water used as drinking water supplies. For example, among 67 drinking water sources surveyed by LeChevallier and Norton (1995), 87 percent had positive samples for Cryptosporidium. A more recent survey of 80 medium and large PWSs conducted by EPA detected Cryptosporidium in 85 percent of water sources (USEPA 2003a). Cryptosporidium contamination can come from animal agriculture, wastewater treatment plant discharges, slaughterhouses, birds, wild animals, and other sources of fecal matter.

Because different species of Cryptosporidium are very similar in morphology, researchers have focused on genetic differences in trying to classify them. However, discussion on Cryptosporidium taxonomy is complicated by the fact that even within species or strains, there may be differences in infectivity and virulence. Cryptosporidium parvum (C. parvum) has been the primary species of concern to humans. Until recently, some researchers divided C. parvum into two primary strains, genotype 1, which infects humans, and genotype 2, which infects both humans and cattle (Carey et al. 2004). In 2002, Morgan-Ryan et al. proposed that genotype 1 be designated a separate species, C. hominis. Additional Cryptosporidium species infecting other mammals, birds, and reptiles have been documented. In some cases, these species can infect both immunocompromised (having weakened immune systems) and otherwise healthy humans (Carey et al. 2004).

3. Cryptosporidium Health Effects

Cryptosporidium infection is characterized by mild to severe diarrhea, dehydration, stomach cramps, and/or a slight fever. Incubation is thought to range from 2 to 10 days (Arrowood 1997). Symptoms typically last from several days to 2 weeks, though in a small percentage of cases, the symptoms may persist for months or longer in otherwise healthy individuals.

Symptoms may be more severe in immunocompromised persons (Frisby et al. 1997, Carey et al. 2004). Such persons include those with AIDS, cancer patients undergoing chemotherapy, organ transplant recipients treated with drugs that suppress the immune system, and patients with autoimmune disorders (e.g., Lupus). In AIDS patients, Cryptosporidium has been found in the lungs, ear, stomach, bile duct, and pancreas in addition to the small intestine (Farthing 2000). Immunocompromised patients with severe persistent cryptosporidiosis may die (Carey et al. 2004). Besides the immunocompromised, children and the elderly may be at higher risk from Cryptosporidium than the general population (discussed in section VII.G).

Studies with human volunteers have demonstrated that a low dose of C. parvum (e.g., 10 oocysts) is sufficient to cause infection in healthy adults, although some strains are more infectious than others (DuPont et al. 1995, Chappell et al. 1999, Okhuysen et al. 2002). Studies of immunosuppressed adult mice have demonstrated that a single viable oocyst can induce C. parvum infections (Yang et al. 2000, Okhuysen et al. 2002). The lowest dose tested in any of the human challenge studies was 10 oocysts. Because drinking water exposures are generally projected to be at lower levels (e.g., 1 oocyst), statistical modeling is necessary to project the effects of such exposure. Following the advice of its Science Advisory Board (SAB), EPA has developed a range of models to predict effects of exposure to low doses of Cryptosporidium. These models are discussed in section VI and in the LT2ESWTR Economic Analysis (USEPA 2005a).

The degree and duration of the immune response to Cryptosporidium is not well characterized. In a study by Chappell et al. (1999), volunteers with IgG Cryptosporidium antibodies in their blood were immune to low doses of oocysts. The ID50 (the dose that infects 50 percent of the challenged population) was 1,880 oocysts for those individuals compared to 132 oocysts for individuals that tested negative for those antibodies. However, earlier studies did not observe a correlation between the development of antibodies after Cryptosporidium infection and subsequent protection from illness (Okhuysen et al. 1998).

No cure for cryptosporidiosis is known. Medical care usually involves treatment for dehydration and nutrient loss. Certain antimicrobial drugs like Azithromycin, Paromomycin, and nitazoxanide, the only drug approved for cryptosporidiosis in children, have been partially effective in treating immunocompromised patients (Rossignol et al. 1998). Therapies used to treat retroviruses can be helpful in fighting cryptosporidiosis in people with AIDS and are more effective when used in conjunction with antimicrobial therapy. The effectiveness of antiretroviral therapy is thought to be related to the associated increase in white blood cells rather than the decrease in the amount of virus present.

4. Efficacy of Water Treatment Processes on Cryptosporidium

EPA is particularly concerned about Cryptosporidium because, unlike pathogens such as bacteria and most viruses, Cryptosporidium oocysts are highly resistant to standard disinfectants like chlorine and chloramines (Korich et al. 1990, Ransome et al. 1993, Finch et al. 1997). Consequently, control of Cryptosporidium in most treatment plants is dependent on physical removal processes. However, due to their size (4–5 microns), oocysts can sometimes pass through filters.

Monitoring data on finished water show that Cryptosporidium is sometimes present in filtered, treated drinking water (LeChevallier et al. 1991, Aboytes et al. 2004). For example, Aboytes et al. (2004) analyzed 1,690 finished water samples from 82 plants. Of these, 22 plants had at least one positive sample for infectious Cryptosporidium (1.4 percent of all samples were positive). All positive samples occurred at plants that met existing regulatory standards and many had very low turbidity.

Waterborne outbreaks of cryptosporidiosis have occurred even in areas served by filtered surface water supplies (Solo-Gabriele and Neumeister, 1996). In some cases, outbreaks were attributed to treatment deficiencies, but in others, the treatment provided by the water system met the regulatory requirements in place at that time. These data indicate that even surface water systems that filter and disinfect can still be vulnerable to Cryptosporidium, depending on the source water quality and treatment effectiveness.

Certain alternative disinfectants can be more effective in treating for Cryptosporidium. Both ozone and chlorine dioxide have been shown to inactivate Cryptosporidium, albeit at doses much higher than those required to inactivate Giardia, which has typically been used to set disinfectant doses (summarized in USEPA 2003a). Studies have also demonstrated a synergistic effect of treatment using ozone followed by chlorine or monochloramine (Rennecker et al. 2000, Driedger et al. 2001). Significantly, UV light has recently been shown to achieve high levels of Cryptosporidium inactivation at feasible doses (summarized in USEPA 2003a).

Other processes that can help reduce Cryptosporidium levels in finished water include watershed management programs, pretreatment processes like bank filtration, and additional clarification and filtration processes during water treatment. Further, optimizing treatment performance and achieving very low levels of turbidity in the finished water has been shown to improve Cryptosporidium removal in treatment plants (summarized in USEPA 2003a).

5. Epidemic and Endemic Disease From Cryptosporidium

Cryptosporidium has caused a number of waterborne disease outbreaks since 1984 when the first was reported in the United States. Data from the Centers for Disease Control and Prevention (CDC) include ten outbreaks caused by Cryptosporidium in drinking water between 1984 and 2000, with approximately 421,000 cases of illness (CDC 1993, 1996, 1998, 2000, and 2002). The most serious outbreak occurred in 1993 in Milwaukee; an estimated 403,000 people became sick (MacKenzie et al. 1994), and at least 50 Cryptosporidium-associated deaths occurred among the severely immunocompromised (Hoxie et al. 1997). Further, a study by McDonald et al. (2001) using blood samples from Milwaukee children suggests that Cryptosporidium infection was more widespread than might be inferred from the illness estimates by MacKenzie et al. (1994).

The number of identified and reported outbreaks in the CDC database is believed to substantially understate the actual incidence of waterborne disease outbreaks and cases (Craun and Calderon 1996, National Research Council 1997). This under reporting is due to a number of factors. Many people experiencing gastrointestinal illness do not seek medical attention. Where medical attention is provided, the pathogenic agent may not be identified through routine testing. Physicians and patients often lack sufficient information to attribute gastrointestinal illness to any specific origin, such as drinking water, and few States have an active outbreak surveillance program. In addition, if drinking water is investigated as the source of an outbreak, oocysts may not be detected in water samples even if they are present, due to limitations in analytical methods. Consequently, outbreaks may not be recognized in a community or, if recognized, may not be traced to a drinking water source.

In addition, an unknown but probably significant portion of waterborne disease is endemic (i.e., isolated cases not associated with an outbreak) and, thus, is even more difficult to recognize. In an outbreak, if the pathogen has been identified, medical providers and public health investigators know what to look for. In endemic disease, there is no investigation, so the illness may never be identified, or if it is, it may not be linked to a source (e.g., drinking water, person-to-person transmission). In addition, where a pathogen is identified, lab results may not be reported to public health agencies.

Because of this under reporting, the actual incidence of cryptosporidiosis associated with drinking water is unknown. However, indications of this incidence rate can be roughly extrapolated from different sources. Mead et al. (1999) estimated approximately 300,000 total cases of cryptosporidiosis annually that result in a physician visit, with 90 percent of these attributed to waterborne (drinking water and recreational water) and secondary transmission. This estimate is based on the percentage of stools that test positive for Cryptosporidium and applying this percentage to the approximately 15 million physician visits for diarrhea each year. While the fraction of cryptosporidiosis cases that result in a physician visit is unknown, Corso et al. (2003) reported that during the 1993 outbreak in Milwaukee, medical care was sought in approximately 12 percent of all cryptosporidiosis cases.

Surveillance data from the CDC for 2001 show an overall incidence of 1.5 laboratory diagnosed cases of cryptosporidiosis per 100,000 population (CDC, 2002). Although the fraction of all cryptosporidiosis cases that are laboratory confirmed is unknown, during the 1993 Milwaukee outbreak, 739 cases from an estimated 403,000 cases total were confirmed by a laboratory (MacKenzie et al., 1994). These data indicate a ratio of 1 laboratory confirmed case per 545 people estimated to be ill with cryptosporidiosis.

A few studies have attempted to determine exposure in certain areas by measuring seroprevalence of Cryptosporidium antibodies (the frequency at which antibodies are found in the blood). Detection of such antibodies (seropositivity), however, does not mean that the person actually experienced symptoms of cryptosporidiosis. An individual can be asymptomatically infected and still excrete oocysts. Seroprevalence, though, is still a method for estimating the exposure to Cryptosporidium that has occurred within a limited time period (the antibodies may last only a few months).

Frost et al. (2001) conducted a paired city study, in which the serological response of blood donors in a city using ground water as its water source was compared to that of donors in a city using surface water as its source. Rates of seropositivity were higher (49 vs. 36 percent) in the city with the surface water source. A similar study in two other cities (Frost et al. 2002) showed a seropositivity rate of 54 percent in the city served by surface water compared to 38 percent in the city served by ground water. These studies suggest that drinking water from surface sources may be a factor in the higher rates of seropositivity.

D. Specific Concerns Following the IESWTR and LT1ESWTR

In the LT2ESWTR, EPA is addressing a number of public health concerns that remain following implementation of the IESWTR and LT1ESWTR. These are as follows:

- The need for filtered PWSs with higher levels of source water Cryptosporidium contamination to provide additional risk-based treatment for Cryptosporidium beyond IESWTR or LT1ESWTR requirements;
- The need for unfiltered PWSs to provide risk-based treatment for Cryptosporidium to achieve equivalent public health protection with filtered PWSs; and
- The need for PWSs with uncovered finished water storage facilities to take steps to reduce the risk of contamination of treated water prior to distribution to consumers.

EPA and stakeholders identified each of these issues as public health concerns during development of the IESWTR (USEPA 1994, 1997). However, the Agency was unable to address these concerns in those regulations due to data gaps in the areas of health effects, occurrence, analytical methods, and treatment. Consequently, EPA followed a two-stage strategy for microbial and disinfection byproducts rules. Under this strategy, the IESWTR and LT1ESWTR were promulgated to provide an initial improvement in public health protection in large and small PWSs, respectively, while additional data to support a more comprehensive regulatory approach were collected.

Since promulgating the IESWTR and LT1ESWTR, EPA has worked with stakeholders to collect and analyze significant new information to fill data gaps related to Cryptosporidium risk management in PWSs. The next section presents EPA's evaluation of these data and their implications for both the risk of Cryptosporidium in filtered and unfiltered PWSs and the feasibility of steps to limit this risk. In addition, the Agency has evaluated additional data related to mitigating risks with uncovered finished water storage facilities, which are presented in section IV.F.

E. New Information on Cryptosporidium Risk Management

EPA and stakeholders determined during development of the IESWTR that in order to establish risk-based treatment requirements for Cryptosporidium, additional information was needed in the following areas: (1) The risk associated with a given level of Cryptosporidium (i.e., infectivity); (2) the occurrence of Cryptosporidium in PWS sources; (3) analytical methods that would suffice for making site-specific source water Cryptosporidium density estimates; and (4) the use of treatment technologies to achieve specific levels of Cryptosporidium disinfection (USEPA 1997).

In today's final LT2ESWTR, EPA is promulgating risk-based Cryptosporidium treatment requirements for filtered and unfiltered PWSs. The Agency believes that the critical data gaps in the areas of infectivity, occurrence, analytical methods, and treatment that prevented the adoption of such an approach under earlier regulations have been addressed. The new information that the Agency and stakeholders evaluated in each of these areas and its significance for today's LT2ESWTR are summarized as follows. See section VI.L for a summary of public comments on EPA's use of Cryptosporidium infectivity and occurrence data in assessing benefits of the LT2ESWTR.

1. Infectivity

Infectivity relates the probability of infection to the number of Cryptosporidium oocysts that a person ingests. It is used to predict the disease burden associated with a particular Cryptosporidium level in drinking water. Information on Cryptosporidium infectivity comes from dose-response studies where healthy human volunteers ingest different numbers of oocysts (i.e., the ''dose'') and are subsequently evaluated for signs of infection and illness (i.e., the ''response'').

Prior to the IESWTR, data from a human dose-response study of one Cryptosporidium isolate (IOWA) had been published (DuPont et al. 1995). Following IESWTR promulgation, a study of two additional isolates (TAMU and UCP) was completed and published (Okhuysen et al. 1999). This 1999 study also reanalyzed the IOWA study results. The measured infectivity of Cryptosporidium oocysts varied over a wide range in the Okhuysen et al. (1999) study. The UCP oocysts were much less infective than the IOWA oocysts, and the TAMU oocysts were much more infective.

EPA analyzed these new data for the proposed LT2ESWTR using two different dose-response models. This analysis suggested that the overall infectivity of Cryptosporidium is greater than was estimated for the IESWTR (USEPA 2003a). Specifically, EPA estimated the mean probability of infection from ingesting a single infectious oocyst ranges from 7 to 10 percent. This infection rate is approximately 20 times higher than the estimate of 0.4 percent used in the IESWTR.

Since the publication of the proposed LT2ESWTR, EPA has evaluated three additional studies of Cryptosporidium infectivity. EPA also received a recommendation from the SAB that it analyze Cryptosporidium infectivity data using a wider range of models. Accordingly, EPA re-estimated Cryptosporidium infectivity using the new data and six different dose-response models, including the two models used at proposal. Estimates from the new data and models for the probability of infection from ingesting a single infectious oocyst range from 4 to 16 percent. A detailed discussion of the models and their varying assumptions is provided in the LT2ESWTR Economic Analysis (USEPA 2005a).

As is apparent from these results, substantial uncertainty about the infectivity of Cryptosporidium remains in several areas. These include the variability in host susceptibility, response at very low oocyst doses typical of drinking water ingestion, and the relative infectivity and occurrence of different Cryptosporidium isolates in the environment. To address this uncertainty, EPA conducted its health risk reduction and benefits analyses using a representative range of model results. In the summary tables for these analyses, three sets of estimates are presented: A ''high'' estimate based on the model that showed the highest mean baseline risk; a ''medium'' estimate, based on the models and data used at proposal, which also happens to be in the middle of the range of estimates produced by the six models using the newly available data; and a ''low'' estimate, based on the model that showed the lowest mean baseline risk.

These estimates should not be construed as upper and lower bounds on illnesses avoided and benefits. 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. The detailed distribution of effects is presented for the proposal model in the Economic Analysis (USEPA 2005a). Further, the six dose-response models used in this analysis do not cover all possible variations of models that might have been used with the data, and it is possible that estimates with other models would fall outside the range presented. However, as discussed in the Economic Analysis, EPA believes that the models used in the analyses reflect a reasonable range of results based on important dimensions of model choice.

Regardless of which model is chosen, the available infectivity data suggest that the risk associated with a given concentration of Cryptosporidium is most likely higher than EPA had estimated for the IESWTR. This finding supports the need for increased treatment for Cryptosporidium as required under the LT2ESWTR.

2. Occurrence

Information on the occurrence of Cryptosporidium oocysts in drinking water sources is a critical parameter for assessing risk and the need for additional treatment for this pathogen. For the IESWTR, EPA had no national survey data on Cryptosporidium occurrence and relied instead on several studies that were local or regional. After promulgating the IESWTR, EPA obtained data from two national surveys, the Information Collection Rule (ICR) and the ICR Supplemental Surveys (ICRSS), which were designed to provide improved estimates of occurrence on a national basis.

The ICR included monthly sampling for Cryptosporidium and other water quality parameters from the sources of approximately 350 large PWSs over 18 months. The ICRSS involved twice-per-month Cryptosporidium sampling from the sources of a statistically random sample of 40 large and 40 medium PWSs over 12 months. In addition, the ICRSS required the use of an improved analytical method for Cryptosporidium analysis that had a higher method recovery (the likelihood that an oocyst present in the sample will be counted) and enhanced sample preparation procedures.

EPA analyzed ICR and ICRSS data using a statistical model to account for factors like method recovery and sample volume analyzed. As described in more detail in EPA's Occurrence and Exposure Assessment for the LT2ESWTR (USEPA 2005b), the ICR and ICRSS results demonstrate two main differences for filtered PWSs in comparison to Cryptosporidium occurrence data used for the IESWTR:

(1) The occurrence of Cryptosporidium in many drinking water sources is lower than was indicated by the data used in IESWTR. For example, median Cryptosporidium levels for the ICR and ICRSS data are approximately 0.05/L, which is nearly 50 times lower than the median IESWTR estimates of 2.3 oocysts/L (USEPA 1998a).

(2) Cryptosporidium occurrence is more variable from location to location than was shown by the data considered for the IESWTR. This finding demonstrates that, although median occurrence levels are below those estimated for the IESWTR, a subset of PWSs contains Cryptosporidium levels that are considerably greater than the median.

These results, therefore, indicate that Cryptosporidium levels are relatively low in most water sources, but a subset of sources with relatively higher concentrations may require additional treatment. These findings support a risk-targeted approach for the LT2ESWTR wherein additional Cryptosporidium treatment is required only for filtered PWSs with the highest source water pathogen levels.

Only the ICR provided data to evaluate Cryptosporidium occurrence in unfiltered PWS sources. The median Cryptosporidium level among unfiltered PWS sources was 0.0079 oocysts/L. This level is approximately 10 times lower than the median level for filtered PWS sources.

When the Cryptosporidium removal that filtered PWSs achieve is taken into account, these occurrence data suggest that unfiltered PWSs typically have higher concentrations of Cryptosporidium in their treated water than filtered PWSs. EPA has estimated that on average, conventional filtration plants remove around 99.9 percent (3-log) of the Cryptosporidium present in the source water. Most unfiltered PWSs, however, provide no treatment for Cryptosporidium. If an unfiltered PWS had a source water Cryptosporidium level 10 times lower than a filtered PWS and the filtered PWS achieved 3-log Cryptosporidium removal, then the Cryptosporidium level in the treated water of the unfiltered PWS would be 100 times higher than in the filtered PWS.

These results suggest that to achieve public health protection equivalent to that provided by filtered PWSs, unfiltered PWSs must take additional steps. Thus, this finding supports the need for Cryptosporidium treatment requirements for unfiltered PWSs under the LT2ESWTR.

3. Analytical Methods

To establish risk-targeted treatment requirements, analytical methods must be available to estimate the contaminant densities in PWS sources. These density estimates are used to determine the level of treatment that is needed at a particular site.

When EPA developed the IESWTR, the best available method for measuring Cryptosporidium was the Information Collection Rule Protozoan Method (ICR Method). The ICR Method provided a quantitative measurement of Cryptosporidium oocysts, but typically undercounted the actual occurrence due to low method recovery. For example, in a spiking study (studies in which known quantities of oocysts are added to water samples) conducted during the ICR survey, the mean recovery of spiked Cryptosporidium oocysts was only 12 percent (Scheller et al. 2002). EPA concluded that the ICR Method was adequate for making national occurrence estimates in the ICR survey but would not suffice for making estimates of Cryptosporidium levels at specific sites.

Subsequent to promulgating the IESWTR, EPA developed an improved Cryptosporidium method, EPA Method 1622 (and later, 1623), to achieve higher recovery rates and lower inter- and intra-laboratory variability than previous methods. Methods 1622 and 1623 incorporate improvements in the concentration, separation, staining, and microscope examination procedures. During the ICRSS, which required the use of Method 1622 or 1623, a spiking study demonstrated a mean Cryptosporidium recovery of 43 percent (Connell et al. 2000). Thus, mean Cryptosporidium recovery with Methods 1622 and 1623 was more than 3.5 times higher compared to the ICR Method performance in the earlier spiking study. In addition, the relative variation in recovery from sample to sample was lower with Methods 1622 and 1623.

As described in section IV of this preamble, EPA has concluded that a monitoring program using Methods 1622 or 1623 can be effective in characterizing PWSs source water Cryptosporidium levels for purposes of determining the need for additional treatment requirements. This finding supports the feasibility of risk-targeted treatment requirements under the LT2ESWTR.

4. Treatment

To establish risk-targeted Cryptosporidium treatment requirements, feasible treatment processes must be available that allow PWSs to inactivate or remove Cryptosporidium. PWSs may then implement these treatment processes to comply with additional treatment requirements.

During development of the IESWTR, EPA recognized that chlorine, the most commonly used disinfectant, is ineffective for inactivating Cryptosporidium. Studies suggested that other disinfectants like ozone and chlorine dioxide could be effective against Cryptosporidium. However, EPA concluded that data available at that time were not sufficient to define how any disinfectant could be applied to achieve a specific level of Cryptosporidium inactivation (USEPA 1997). This conclusion was due in part to methodological inconsistencies and shortcomings in the available studies.

With the completion of major studies since promulgation of the IESWTR, EPA has acquired the data necessary to establish standards for Cryptosporidium inactivation by several disinfectants. For ozone and chlorine dioxide, EPA reviewed new studies by Rennecker et al. (1999), Owens et al. (1999, 2000), Oppenheimer et al. (2000), Ruffell et al. (2000), and Li et al. (2001). Collectively, these studies cover a wide range of both natural and laboratory water conditions. Based on these studies, EPA has developed tables that specify the product of ozone or chlorine dioxide concentration and time of exposure (i.e., CT tables) needed to achieve up to 3-log Cryptosporidium inactivation. Section IV.D of this preamble shows these tables.

Most significantly, many recent studies have demonstrated that UV light is efficient for inactivating high levels of Cryptosporidium. These studies include 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). Using results from these studies, EPA has defined the UV light intensity and exposure time required for up to 4-log Cryptosporidium inactivation. Section IV.D presents these values. EPA has determined that UV light is a feasible technology for PWSs of all sizes to inactivate Cryptosporidium.

EPA has also developed standards for processes that physically remove Cryptosporidium contamination. These processes include river bank filtration, sedimentation basins, bag filters, cartridge filters, and membranes. Section IV.D presents design and operational standards for these processes, along with a summary of supporting studies.

The development of these standards for Cryptosporidium inactivation and removal processes overcomes a significant limitation that existed when EPA developed the IESWTR. These standards will allow PWSs to implement cost-effective strategies to comply with additional Cryptosporidium treatment requirements under the LT2ESWTR.

F. Federal Advisory Committee Recommendations

EPA convened the Stage 2 M–DBP Federal Advisory Committee in March 1999 to evaluate new information and develop recommendations for the LT2ESWTR and Stage 2 DBPR. The Committee was comprised of representatives from EPA, State and local public health and regulatory agencies, local elected officials, Indian Tribes, drinking water suppliers, chemical and equipment manufacturers, and public interest groups. A technical workgroup provided analytical support for the Committee's discussions.

Committee members signed an Agreement in Principle in September 2000 stating consensus recommendations of the group. The Agreement was published in a December 29, 2000 **Federal Register** notice (USEPA 2000a). For the LT2ESWTR, the consensus recommendations of the Committee are summarized as follows:

(1) Supplemental risk-targeted Cryptosporidium treatment by filtered PWSs with higher source water contaminant levels as shown by monitoring results;

(2) Cryptosporidium inactivation by all unfiltered PWSs, which must meet

overall treatment requirements using a minimum of 2 disinfectants;

(3) A ''toolbox'' of treatment and control processes for PWSs to comply with Cryptosporidium treatment requirements;

(4) Reduced monitoring burden for small filtered PWSs;

(5) Future monitoring to confirm or revise source water quality assessments;

(6) Development of guidance for UV disinfection and other toolbox components; and

(7) Cover or treat existing uncovered finished water reservoirs (i.e., storage facilities) or implement risk mitigation plans.

These recommendations reflect a Committee judgement that, based on available information, additional risk-based Cryptosporidium treatment requirements for filtered and unfiltered PWSs are appropriate and feasible under the LT2ESWTR. Much of today's final LT2ESWTR reflects the Committee's recommendations. The next part of this preamble describes specific requirements of the rule.

IV. Explanation of Today's Action

A. Source Water Monitoring Requirements

Today's rule requires PWSs using surface water or GWUDI sources to monitor their source water to assess the level of Cryptosporidium. Monitoring results assign a PWS to a Cryptosporidium treatment bin, which determines the extent of additional Cryptosporidium treatment requirements (sections IV.B and IV.C described treatment requirements for filtered and unfiltered PWSs, respectively).

Source water monitoring under the LT2ESWTR is designed to ascertain the mean level of Cryptosporidium in the influent to a surface water treatment plant. Requirements differ by PWS size (above or below 10,000 people served) and treatment plant type (filtered or unfiltered PWS). This section describes monitoring requirements for sampling parameters and frequency, sampling location, sampling schedule, monitoring plants that operate only part of the year, failing to monitor, providing treatment instead of monitoring, grandfathering previously collected data, ongoing watershed assessment, second round of monitoring, and new source monitoring.

Other sections of this preamble describe additional requirements related to monitoring, including compliance schedules (section IV.G), reporting of monitoring results (section IV.I), use of approved analytical methods, including minimum sample volume (section IV.J), and use of approved laboratories (section IV.K). As described in section IV.G, monitoring compliance dates under the LT2ESWTR are staggered: smaller PWSs begin monitoring after larger PWSs.

For additional information, see Source Water Monitoring Guidance Manual for Public Water Systems under the Long Term 2 Enhanced Surface Water Treatment Rule. This document provides guidance on sampling location, procedures for collecting and shipping samples, contracting with laboratories, and related topics to assist PWSs in complying with LT2ESWTR monitoring requirements. It may be acquired from EPA's Safe Drinking Water Hotline, which can be contacted as described under **FOR FURTHER INFORMATION CONTACT** at the beginning of this document.

1. Today's Rule

a. *Sampling parameters and frequency.* Requirements for the source water parameters that PWSs must measure under the LT2ESWTR, as well as the sampling frequency and duration, are stated as follows for large and small PWSs, including both filtered and unfiltered plants:

Large Filtered PWSs

Filtered PWSs serving at least 10,000 people must sample at least monthly for Cryptosporidium, E. coli, and turbidity for a period of two years. Sampling may be conducted at a higher frequency (e.g., twice-per-month, once-per-week) but the sampling must be evenly spaced throughout the monitoring period. As described in section IV.B, filtered PWSs that sample at least twice-per-month over two years use a different calculation, which is less conservative, to determine their treatment bin classification under the LT2ESWTR.

Large Unfiltered PWSs

Unfiltered PWSs serving at least 10,000 people must also sample for Cryptosporidium at least monthly for a period of 2 years. No E. coli or turbidity monitoring is required for unfiltered PWSs. Unfiltered PWSs may choose to sample more frequently; however, as described in section IV.C, a higher sampling frequency does not change the calculation used to determine unfiltered PWS Cryptosporidium treatment requirements.

Small Filtered PWSs

Filtered PWSs serving fewer than 10,000 people (i.e., small PWSs) monitor under the LT2ESWTR using a two-phase strategy that begins with an indicator screening analysis. Small filtered PWSs must initially sample for E. coli at least once every two weeks for a period of one year. Cryptosporidium monitoring is required of these PWSs only if the indicator monitoring results meet one of the following conditions:

(1) For PWSs using lake/reservoir sources, the annual mean E. coli concentration is greater than 10 E. coli/100 mL.

(2) For PWSs using flowing stream sources, the annual mean E. coli concentration is greater than 50 E. coli/100 mL.

PWSs using ground water under the direct influence of surface water must comply with the requirement to monitor for Cryptosporidium based on the E. coli level that applies to the nearest surface water body. If no surface water body is nearby, the PWS must comply based on the requirements that apply to PWSs using lake/reservoir sources.

The State may approve small filtered PWSs to monitor for an indicator other than E. coli. The State also may approve an alternative E. coli concentration to trigger Cryptosporidium monitoring. This approval must be in writing and must be based on a State determination that the alternative indicator and/or trigger level will more accurately identify whether a PWS will exceed the Bin 1 Cryptosporidium level of 0.075 oocysts/L, as stated in section IV.B.1 of this preamble. EPA will issue guidance to States on alternative indicators and trigger levels, if warranted, based on large PWS monitoring results.

Small filtered PWSs may elect to skip E. coli monitoring if they notify the State that they will monitor for Cryptosporidium. PWSs must notify the State no later than three months prior to the date the PWS is required to begin monitoring (see section IV.G for specific dates).

Small filtered PWSs that are required to monitor for Cryptosporidium must conduct this monitoring using either of two frequencies: (1) Sample at least twice-per-month for a period of one year or (2) sample at least once-per-month for a period of two years. Note that the same treatment compliance dates apply to the PWS regardless of which Cryptosporidium sampling frequency is used (i.e., selecting the two-year Cryptosporidium sampling frequency does not extend Cryptosporidium treatment compliance deadlines).

Small Unfiltered PWSs

All unfiltered PWSs serving fewer than 10,000 people must monitor for Cryptosporidium. The E. coli screening analysis used by small filtered PWSs is not applicable to small unfiltered PWSs. Small unfiltered PWSs must use either of the same two Cryptosporidium sampling frequencies available to small filtered PWSs: (1) Sample twice-per-month for one year or (2) sample once-per-month for two years. As with small filtered PWSs, the same treatment compliance dates apply to the PWS regardless of which Cryptosporidium sampling frequency is used.

b. *Sampling location.* PWSs must collect source water samples for each plant that treats a surface water or GWUDI source. However, where multiple plants receive all of their water from the same influent, such as plants that draw water from the same intake or pipe, the State may approve one set of monitoring results to be applied to all plants.

PWSs must collect source water samples prior to chemical treatment, such as coagulants, oxidants, and disinfectants, unless the following condition is met: The State may approve a system to collect a sample after chemical treatment if the State determines that collecting a sample prior to chemical treatment is not feasible and that the chemical treatment is unlikely to have a significant adverse effect on the analysis of the sample. PWSs that recycle filter backwash must collect samples prior to the point of filter backwash addition due to the likely presence of coagulant and other treatment chemicals in the backwash. See section IV.D.6 for directions on sampling location for PWSs using bank filtration.

For plants that use multiple water sources at the same time, PWSs must collect samples from a tap where the sources are combined prior to treatment, if available. If a blended source tap is not available, PWSs must collect samples from each source and either analyze a weighted composite (blended) sample or analyze samples from each source separately and determine a weighted average of the results. The weighting of sources must reflect the relative usage of the different sources by the treatment plant at the time the sample is collected.

PWSs must submit a description of their proposed sampling location(s) to the State no later than three months prior to the date the PWS must begin monitoring (see section IV.G for specific dates). This description must address the position of the sampling location in relation to the PWS's water source(s) and treatment processes, including points of chemical addition and filter backwash recycle. If the State does not respond to a PWS regarding sampling location(s), the PWS must begin sampling at the reported location. See Source Water Monitoring Guidance Manual for Public Water Systems under the Long Term 2 Enhanced Surface Water Treatment Rule, which can be acquired as stated previously, for guidance on sampling location descriptions.

c. *Sampling schedule.* PWSs must collect samples in accordance with a schedule that the PWS develops and reports prior to initiating monitoring. The sampling schedule must specify the calendar dates when the PWS will collect each required sample in a particular round of monitoring. Scheduled sampling dates must be evenly distributed throughout the monitoring period, but may be arranged to accommodate holidays, weekends, and other events when collecting or analyzing a sample would be problematic (e.g., a PWS is not required to schedule samples on the same calendar date each month).

PWSs must submit sampling schedules no later than three months prior to the date the PWS must begin a round of monitoring (see section IV.G for specific dates). Unless the State approves an alternative procedure, large PWSs (serving at least 10,000 people) must report their sampling schedule for initial source water monitoring to EPA using the LT2ESWTR electronic data reporting and review system described in section IV.I. Schedules for initial monitoring by small PWSs and for the second round of monitoring by all PWSs must be reported to the State. PWSs should verify that their laboratory can accommodate the scheduled sampling dates before submitting the schedule.

EPA will not formally approve sampling schedules but will notify a PWS if its sampling schedules does not meet the requirements of today's rule (e.g., does not include the required number of samples). If a PWS does not receive notification from the State or EPA regarding the sampling schedule, the PWS must begin monitoring according to the reported sampling schedule.

PWSs must collect samples within two days before or two days after the dates indicated in their sampling schedules (i.e., within a 5-day period around the schedule date) unless one of the following two conditions applies:

(1) If an extreme condition or situation exists that may pose danger to the sample collector, or that cannot be avoided and causes the PWS to be unable to sample in the scheduled 5-day period, the PWS must sample as close to the scheduled date as is feasible unless the State approves an alternative sampling date. The PWS must submit an explanation for the delayed sampling date to the State concurrent with the shipment of the samples to the laboratory.

(2) If a PWS is unable to report a valid analytical result for a scheduled sampling date due to equipment failure, loss of or damage to the sample, failure to comply with the analytical method requirements, or the failure of an approved laboratory to analyze the sample, then the PWS must collect a replacement sample. Collection of the replacement sample must occur within 21 days of the PWS receiving information that an analytical result cannot be reported for the scheduled date unless the PWS demonstrates that collecting a replacement sample within this time frame is not feasible or the State approves an alternative resampling date. The PWS must submit an explanation for the resampling date to the State concurrent with the shipment of the sample to the laboratory.

Failure to collect a required sample within the 5-day period around a scheduled date that does not meet one of these two conditions is a monitoring violation. PWSs must revise their sampling schedules to add dates for collecting all missed samples and must submit the revised schedule to the State for approval prior to when the PWS begins collecting the missed samples.

d. *Plants operating only part of the year.* Some PWSs operate surface water treatment plants for only part of the year. This includes PWSs that provide water for only a fraction of the year (e.g., resorts open only in the summer) and PWSs that use a surface water plant to supplement another source only during periods of high demand.

Most LT2ESWTR monitoring, treatment, and implementation schedule requirements apply to such plants. Monitoring requirements, however, differ in two respects:

(1) PWSs must conduct sampling only during months of the 2 year monitoring period when the plant operates unless the State specifies another monitoring period based on plant operating practices; and

(2) For plants that operate less than six months per year and where Cryptosporidium monitoring is required, PWSs must collect at least six Cryptosporidium samples per year during each of two years of monitoring.

e. *Failing to monitor.* Today's rule requires PWSs to provide a Tier 3 public notice for violation of monitoring and testing procedure requirements, including the failure to collect one or two source water Cryptosporidium samples. If a PWS fails to collect three or more Cryptosporidium samples, other than in specifically exempted situations (see section IV.A.1.c), the PWS must provide a Tier 2 special public notice. Violations for failing to monitor persist until the State determines that the PWS has begun sampling on a revised schedule that includes dates for the collection of missed samples. Section IV.H provides further details on public notice requirements of the LT2ESWTR.

PWSs must report their bin classification (or mean Cryptosporidium level for unfiltered PWSs) 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 or mean Cryptosporidium level by the compliance date is a treatment technique violation and the PWS must provide a Tier 2 special public notice (unless the PWS has already provided a Tier 2 public notice for missing three sampling dates and is successfully meeting a State-approved schedule for sampling). The treatment technique violation and public notice requirements persist 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, as described next.

f. *Providing treatment instead of monitoring.* PWSs are not required to conduct source water monitoring under the LT2ESWTR for plants that will provide the highest level of treatment required under the rule. This applies both to plants that provide this level of treatment at the time the plant would otherwise begin source water monitoring and to plants that commit to install technology to achieve this level of treatment by the applicable compliance date for meeting Cryptosporidium treatment requirements under the LT2ESWTR.

Filtered PWSs are not required to monitor at plants that will provide a total of at least 5.5-log of treatment for Cryptosporidium, equivalent to meeting the treatment requirements of Bin 4 as discussed in section IV.B. Unfiltered PWSs are not required to monitor for plants that will provide a total of at least 3-log of Cryptosporidium inactivation, equivalent to meeting the treatment requirements for unfiltered PWSs with source water Cryptosporidium levels above 0.01 oocysts/L as discussed in section IV.C.

PWSs that intend to provide this level of treatment rather than initiate monitoring must notify the State no later than three months prior to the month the PWS must otherwise begin monitoring. PWSs submit this notification in lieu of submitting a sampling schedule. In addition, a PWS may choose to stop sampling at any point after it has initiated monitoring if it notifies the State that it will provide the highest level of treatment. In both cases, the PWSs must install and operate technologies to achieve this level of treatment no later than the applicable Cryptosporidium treatment compliance date for the PWS as specified in section IV.G. Failure to provide this treatment by the compliance date is a treatment technique violation.

g. *Grandfathering previously collected data.* If the State approves, PWSs may comply with the initial source water monitoring requirements of today's rule by using (i.e., grandfathering) sample results collected before the PWS is required to begin monitoring. PWSs may grandfather monitoring results either in lieu of or in addition to conducting new monitoring under the rule. To be eligible for grandfathering, monitoring results must be equivalent in data quality to monitoring PWSs conduct under today's rule and the PWS must comply with reporting requirements. Details of these requirements follow.

Grandfathered Data Quality Requirements

- Analysis of E. coli samples must meet the analytical method and approved laboratory requirements for source water monitoring under today's rule. PWSs are not required to report E. coli and turbidity data in order to grandfather Cryptosporidium monitoring results, although EPA requests that PWSs report these data if they are available. PWSs that grandfather Cryptosporidium data without associated E. coli and turbidity data are not required to conduct separate monitoring for these parameters when they have satisfied Cryptosporidium monitoring requirements.
- Analysis of Cryptosporidium samples must meet the criteria of a validated version of EPA Method 1622 or 1623, which are described in USEPA 1999a, USEPA 1999b, USEPA 2001e, USEPA 2001f, USEPA 2005c, and USEPA 2005d. The volume analyzed for each sample must meet the criteria described in section IV.J, which are at least 10 L of sample or at least 2 mL of packet pellet volume or as much volume as two approved filters can accommodate before clogging.
- The sampling location must meet the criteria for LT2ESWTR monitoring, as described previously.
- For Cryptosporidium samples, the sampling frequency must be at least monthly and on a regular schedule. The collection of individual samples may deviate from a regular schedule under the same criteria that apply to deviation from LT2ESWTR sampling schedules, as described previously. Additionally, deviations in the sampling frequency of previously collected data are allowed under the following conditions: (1) PWSs may grandfather data where there are gaps in the sampling frequency if the State approves and if the PWS conducts additional monitoring when specified by the State to ensure the data used for bin classification are seasonally representative and unbiased; and (2) PWSs may grandfather data where the sampling frequency varies (e.g., one year of sampling monthly and one year of sampling twice-per-month); monthly average sample concentrations must be used to calculate the bin classification, as described in section IV.B.

Grandfathered Data Reporting Requirements

PWSs that request to grandfather previously collected monitoring results must report the following information by the applicable dates listed in this section. PWSs serving at least 10,000 people must report this information to EPA unless the State approves an alternate procedure for reporting. PWSs serving fewer than 10,000 people must report this information to the State.

PWSs must report that they intend to submit previously collected monitoring results for grandfathering. This report must specify the number of previously collected results the PWS will submit, the dates of the first and last sample, and whether a PWS will conduct additional source water monitoring for initial bin classification. PWSs must report this information no later than three months prior to the date the PWSs is required to start monitoring, as shown in section IV.G.

PWSs must report previously collected monitoring results for grandfathering, along with the required documentation listed in this section, no later than two months after the month the PWS is required to start monitoring, as shown in section IV.G.

- For each sample Cryptosporidium or E. coli result, PWSs must report the applicable data elements in section IV.I.1.
- PWSs must certify to EPA or the State that the reported monitoring results include all results the PWS generated during the time period beginning with the first reported result and ending with the final reported result. This applies to samples that were collected from the sampling location specified for source water monitoring

under this subpart, not spiked, and analyzed using the laboratory's routine process for the analytical methods listed in this section.

- PWSs must certify to EPA or the State that the samples were representative of a plant's source water(s) and the source water(s) have not changed. PWSs must submit to EPA a description of the sampling location(s) for each water treatment plant, which must address the position of the sampling location in relation to the PWS's water source(s) and treatment processes, including points of chemical addition and filter backwash recycle.
- For Cryptosporidium samples, the laboratory or laboratories that analyzed the samples must provide a letter certifying that the quality control criteria specified in the methods listed in this section were met for each sample batch associated with the reported results. Alternatively, the laboratory may provide bench sheets and sample examination report forms for each field, matrix spike, initial precision and recovery (IPR), ongoing precision and recovery (OPR), and method blank sample associated with the reported results.
- If the State determines that a previously collected data set submitted for grandfathering was generated during source water conditions that were not normal for the PWS, such as a drought, the State may disapprove the data. Alternatively, the State may approve the previously collected data if the PWS reports additional source water monitoring data, as determined by the State, to ensure that the overall data set used for bin classification represents average source water conditions for the PWS.

If a PWS submits previously collected data that fully meet the number of samples required for initial source water monitoring and some of the data are rejected due to not meeting the requirements of this section, PWSs must conduct additional monitoring to replace rejected data on a schedule the State approves. PWSs are not required to begin this additional monitoring until at least two months after notification that data have been rejected and additional monitoring is necessary.

h. *Ongoing watershed assessment.* Today's rule includes provisions to assess changes in a PWS's source water quality following initial bin classification. As required by 40 CFR 142.16(b)(3)(i), source water is one of the components that States must address during the sanitary surveys that are required for surface water PWSs. These sanitary surveys must be conducted every 3 years for community PWSs and every 5 years for non-community PWSs. Under today's rule, if the State determines during the sanitary survey or an equivalent source water assessment that significant changes have occurred in the watershed that could lead to increased contamination of the source water by Cryptosporidium, the PWS must take actions specified by the State to address the contamination. These actions may include additional source water monitoring and/or implementing options from the microbial toolbox discussed in section IV.D.

i. *Second round of monitoring.* PWSs must begin a second round of source water monitoring beginning six years after initial bin classification (see compliance dates in section IV.G). If EPA does not modify LT2ESWTR requirements by issuing a new regulation prior to the second round of monitoring, PWSs must carry out this monitoring according to the requirements that apply to the initial round of source water monitoring. PWSs will then be reclassified in LT2ESWTR treatment bins based on the second-round monitoring result. However, if EPA changes the LT2ESWTR treatment bin structure to reflect a new analytical method or new risk information, PWSs will undergo a risk characterization in accordance with the revised rule.

j. *New source monitoring.* A PWS that begins using a new surface water source after the date the PWS is required to conduct source water monitoring under the LT2ESWTR must monitor the new source on a schedule approved by the State. This applies to both new plants that begin operation and previously operating plants that bring a new source on-line after the required monitoring date for the PWS. The State may determine that monitoring should be conducted before a new plant or source is brought on-line or initiated within some time period afterward. The new source monitoring must meet all LT2ESWTR requirements as specified previously in this section. The PWS must also determine its treatment bin classification and comply with any additional Cryptosporidium treatment requirements based on the monitoring results on a schedule approved by the State.

2. Background and Analysis

Monitoring requirements in today's rule are designed to ascertain Cryptosporidium levels with suitable accuracy for making treatment bin classifications and in a time frame that does not delay the installation of Cryptosporidium treatment where needed. The following discussion summarizes the basis for monitoring requirements with respect to sampling parameters and frequency, sampling location, sampling schedule, monitoring plants that operate for only part of the year, failing to monitor, grandfathering previously collected data, ongoing watershed assessment, and the second round of monitoring. Most of these requirements were part of the August 11, 2003, proposal for today's final rule, and supporting analyses are presented in greater detail in the proposal (USEPA 2003a). Differences from proposed requirements are noted in the following discussion where applicable.

a. *Sampling parameters and frequency.* The requirements in today's final rule for the parameters and frequency of source water monitoring are unchanged from those in the proposed rule (USEPA 2003a), with the exception of an additional option for lower frequency Cryptosporidium sampling by small PWSs. These requirements reflect recommendations by the Stage 2 M-DBP Advisory Committee. They are designed to ensure a low potential for misclassification in assigning PWSs to Cryptosporidium treatment bins. The supporting analyses are summarized as follows for Cryptosporidium and indicator (E. coli) monitoring:

Cryptosporidium Monitoring

EPA analyzed bin misclassification rates for different Cryptosporidium monitoring programs by evaluating the likelihood of two types of errors:

(1) A PWS with a true mean Cryptosporidium concentration of 0.5-log (i.e., factor of 3.2) above a bin boundary is incorrectly assigned to a lower bin (false negative) and

(2) A PWS with a true mean concentration of 0.5-log below a bin boundary is incorrectly assigned to a higher bin (false positive).

The first type of error, a false negative, could lead to PWSs not providing an adequate level of treatment while the second type of error, a false positive, could lead to PWSs incurring additional costs for unnecessary treatment.

EPA evaluated false positive and false negative rates for monitoring programs that differed based on the number of samples collected and the calculation used to determine the bin classification. The analysis accounted for the sample volume assayed, variation in source water Cryptosporidium occurrence, variation in analytical method recovery, and other factors.

Results of this analysis indicate that PWSs must collect at least 24 samples in order to keep the likelihood of both false positives and false negatives at five percent or less. Under a monitoring program involving fewer samples, such as eight or twelve, a very conservative calculation for bin classification would be required to achieve a low false negative rate (e.g., bin classification based on the maximum or second highest sample concentration). However, such an approach would result in false positive rates in the range of 50 to 70 percent. Conversely, collecting more than 24 samples can further reduce false positive and false negative rates, albeit to a small degree. See the proposed LT2ESWTR for additional details on this analysis (USEPA 2003a).

Based on the results of this analysis, EPA concluded that PWSs operating year-round should collect at least 24 samples when they monitor for Cryptosporidium. This number of samples ensures a high likelihood of appropriate bin classification. Today's rule does not allow bin classification based on fewer samples (except in the case of PWSs operating only part of the year) as this would involve unacceptably high false positive or false negative rates and would, therefore, be an inappropriate basis to determine Cryptosporidium treatment requirements. EPA believes, though, that PWSs should have the choice to collect more than 24 samples to further improve the accuracy of bin classification, and today's rule allows this.

In regard to the time frame for LT2ESWTR monitoring, the Agency considered the trade-off between monitoring over a long period to better capture temporal fluctuations and the desire to prescribe additional treatment quickly to PWSs with higher Cryptosporidium levels. Today's rule requires large PWSs to evaluate their source water Cryptosporidium levels using two years of monitoring. This will account for some degree of yearly variability, without significantly delaying additional public health protection where needed.

Because many small PWSs will monitor for E. coli for one year before monitoring for Cryptosporidium, today's rule allows two options. Small PWSs can collect 24 Cryptosporidium samples over just one year (resulting in a total of two years of source water monitoring when E. coli monitoring is considered) or they can spread their 24 Cryptosporidium samples over two years. Spreading the Cryptosporidium monitoring over two years will reduce the monitoring costs a PWS incurs in a single year but will not push back the treatment compliance deadline. This allowance for small PWSs to monitor for Cryptosporidium over two years is a change from the proposal (USEPA 2003a). It stems from recognition of the benefit this approach will provide to some small PWSs in budgeting for monitoring.

Indicator Monitoring

Due to the relatively high cost of analyzing samples for Cryptosporidium, the Advisory Committee and EPA investigated indicators that are less costly to analyze to determine if any could be used in place of Cryptosporidium monitoring. No indicators were identified that correlated strongly with Cryptosporidium and could fully substitute for Cryptosporidium monitoring for determining treatment bin classifications. However, this investigation did identify an indicator, E. coli, that can be used to identify some of the water sources that are unlikely to exceed a Cryptosporidium level of 0.075 oocysts/L—the level at which filtered PWSs must provide additional treatment under the LT2ESWTR.

Data from the ICR and ICRSS were used in the investigation of indicators. With these data, E. coli performed the best in identifying sources with low Cryptosporidium levels. In addition, analyzing plants separately based on source water type was necessary due to a different relationship between E. coli and Cryptosporidium in reservoir/lake sources compared to flowing stream sources.

The analysis of E. coli concentrations that could trigger Cryptosporidium monitoring was based on false negative and false positive rates. For this indicator, false negatives occur when sources do not exceed the E. coli trigger value but exceed a Cryptosporidium level of 0.075 oocysts/L. False positives occur when sources exceed the E. coli trigger value but do not exceed a Cryptosporidium level of 0.075 oocysts/L. The false negative rate is critical because it characterizes the ability of the indicator to identify those plants with higher Cryptosporidium levels that should conduct Cryptosporidium monitoring to determine if additional treatment is needed.

For plants with flowing stream sources, a mean E. coli trigger concentration of 50/100 mL produced zero false negatives for both ICR and ICRSS data sets. This means that in these data sets, all plants that exceeded mean Cryptosporidium concentrations of 0.075 oocysts/L also exceeded the E. coli trigger concentration. The false positive rate for this trigger concentration was near 50 percent, meaning it was not highly specific in targeting only those plants with high Cryptosporidium levels. However, at a higher E. coli trigger concentration, such as 100/100 mL, the false negative rate increased without a significant reduction in the false positive rate.

For plants with lake or reservoir sources, a mean E. coli trigger of 10/100 mL resulted in a false negative rate of 20 percent with ICR data and 67 percent with ICRSS data. While this false negative rate in the ICRSS data set appears high, it is based on just three plants in this survey that used a reservoir/lake source and had a mean Cryptosporidium level above 0.075 oocysts/L. With a lower E. coli trigger concentration, such as 5/100 mL, the number of false negatives in both data sets decreased by one plant, but the false positive rate increased from 20 to 40 percent.

After evaluating these results, the Advisory Committee recommended that all large PWSs monitor for Cryptosporidium, rather than using E. coli in a screening analysis. EPA concurred with this recommendation because it achieves the highest certainty that these PWSs will be classified in the correct Cryptosporidium treatment bin and provide the appropriate level of public health protection. In addition, the Advisory Committee recommended and today's rule requires that large filtered PWSs collect E. coli and turbidity samples along with Cryptosporidium. EPA will use these data to confirm or, if necessary, further refine the use of E. coli and possibly turbidity as indicators for monitoring by small filtered PWSs.

Cryptosporidium monitoring places a relatively greater economic burden on small PWSs, and EPA will have additional E. coli and Cryptosporidium data from large PWS monitoring prior to the initiation of small PWS monitoring. Based on these considerations and the available data on E. coli as an indicator of sources with lower Cryptosporidium levels, the Advisory Committee recommended that small filtered PWSs initially monitor for E. coli for one year as a screening analysis. Biweekly sampling (i.e., 1 sample every two weeks) for E. coli is required to achieve high confidence in the results, since no additional monitoring is required if the E. coli level is less than the trigger value. Mean E. coli concentrations above 10 and 50/100 mL trigger Cryptosporidium monitoring in PWSs using reservoir/lake and flowing stream sources, respectively.

EPA concurred with these recommendations by the Advisory Committee and believes they achieve an appropriate balance between enhancing public health protection and reducing the economic impact of today's rule on small PWSs. Survey data indicate that approximately 75 to 80 percent of small PWSs will not exceed the E. coli trigger values and, consequently, will not be required to monitor for Cryptosporidium. Because E. coli is far less costly to analyze than Cryptosporidium (costs listed in USEPA 2005a), this approach will significantly reduce the burden of today's rule for these PWSs. Further, EPA will review indicator data from large PWS monitoring and, if appropriate, issue guidance to States on alternative indicator triggers prior to when small PWSs begin monitoring. Today's rule allows States to approve alternative approaches to indicator monitoring for small PWSs.

EPA could not identify an indicator screening analysis for unfiltered PWSs. As described in section IV.C, a mean Cryptosporidium concentration of 0.01 oocysts/L determines whether unfiltered PWSs are required to provide 2- or 3-log Cryptosporidium inactivation. No E. coli concentration was effective in determining whether PWSs were likely to fall above or below this level. Consequently, today's rule requires all unfiltered PWSs to monitor for Cryptosporidium, unless they choose to provide 3-log Cryptosporidium inactivation.

b. Sampling location. The requirements in today's final rule for the source water sample collection location are similar to those in the proposed rule (USEPA 2003a). They are designed to achieve two objectives: (1) Characterize the influent water to the treatment plant at the time each sample is collected and (2) ensure that samples are not affected by treatment chemicals that could interfere with Cryptosporidium analysis.

The first objective is the basis for requiring PWSs that use multiple sources to either analyze a blended source sample or calculate a weighted average of sources that reflects the influent at the time of sample collection. It is also the reason that PWSs are required to sample after certain pretreatment processes like bank filtration (described in section IV.D) that do not involve chemical addition.

The second objective is why PWSs are generally required to sample upstream of chemical addition and prior to backwash addition (for PWSs that recycle filter backwash). However, EPA recognizes that in some situations, sampling prior to chemical addition will not be feasible and discontinuing chemical addition for a period of time prior to sampling will not be advisable. This situation could occur when a treatment chemical is added at an intake that is difficult to access. Further, some treatment chemicals may not interfere with Cryptosporidium analyses when present at very low levels. Consequently, today's rule allows States to approve PWSs sampling after chemical addition when the State determines that collection prior to chemical treatment is not feasible and the treatment chemical is not expected to interfere with the analysis of the sample.

EPA believes that States should review source water monitoring locations for their PWSs. State review of monitoring locations will ensure that PWSs collect source water samples at the correct location to determine the appropriate level of public health protection. Consequently, today's rule requires PWSs to report a description of their monitoring location to the State. This requirement is a change from the proposed rule, which did not require PWSs to report a description of their sampling location (USEPA 2003a). This change reflects public comment on the proposal, as described later, which strongly supported State review of monitoring locations. If a PWS does not hear back from the State by the time it is scheduled to begin sampling, it may assume that its monitoring location is acceptable.

c. *Sampling schedule.* The requirement in today's final rule that PWSs must develop a schedule for sample collection before the start of monitoring was part of the proposal (USEPA 2003a). This requirement will help to ensure that monitoring determines the mean concentration of Cryptosporidium in the treatment plant influent. To achieve this objective, the timing of sample collection must not be adjusted in response to fluctuations in water quality—for example, the avoidance of sampling when the influent water is expected to be of poor quality.

EPA believes that the 5-day window for sample collection and associated allowances for sampling outside this window provide sufficient flexibility. If circumstances arise that prevent the PWS from sampling within the scheduled 5-day window, such as a weather event or plant emergency, the PWS must collect a sample as soon as feasible. In this case, feasibility includes both the ability of the PWS to safely collect a sample and the availability of an approved laboratory to conduct the analysis within method specifications. In addition, today's rule allows States to authorize a different date for collecting the delayed sample. Such an authorization may be appropriate in cases where sampling is significantly delayed and collecting the delayed sample during the same time period in the following year of monitoring is preferable.

PWSs that collect a sample as scheduled but are unable to have the sample analyzed as required due to problems like shipping or laboratory analysis must collect a replacement sample within 21 days of receiving information that one is needed, unless the PWS demonstrates that collecting a replacement sample within this time frame is not feasible. This time frame is a minor change from the proposal, which allowed only 14 days for resampling (USEPA 2003a), and it provides greater flexibility for scheduling replacement samples. Information that resampling is needed includes information the PWS acquires directly, as well as notice from the shipping company, laboratory, State, or EPA. Today's rule allows States to authorize an alternative date for collection of the replacement sample. This may be needed for resampling to occur during the same conditions as the originally scheduled sample.

If collecting a sample was feasible but the PWS failed to do so, EPA believes that the PWSs must develop a revised sampling schedule and submit it to the State. This will allow for State consultation regarding the reason for the missed sample(s) and strategies for the PWS to complete the required monitoring.

d. *Plants operating only part of the year.* The proposed LT2ESWTR did not include distinct monitoring requirements for plants that operate only part-year. However, EPA requested comment in the proposal on an approach to plants that operate only part-year that is similar to the requirements in today's final rule (USEPA 2003a).

Monitoring requirements for plants that operate only part-year derive from three considerations: (1) A PWS should sample only during the months when a treatment plant operates; (2) the mean Cryptosporidium level used for bin classification can be determined with fewer samples in plants that operate only part-year because source water quality typically varies less during the shorter operating period; and (3) a minimum number of samples is necessary to classify any plant in an LT2ESWTR bin with high confidence.

The basis for the first consideration is straightforward. Source water monitoring under the LT2ESWTR is used to establish treatment requirements, and these should be based on the water quality when a plant is in operation. The rationale for the second and third considerations stems from analyses, similar to those described previously, of potential misclassification rates in assigning plants to LT2ESWTR treatment bins.

Source water variability is one factor that influences the number of samples needed to accurately classify plants in LT2ESWTR treatment bins. As variability increases, more samples are needed to determine the mean Cryptosporidium level with high confidence. EPA does not have data on source water variability specifically in plants that operate only part-year. However, survey data show that pathogen levels vary seasonally, and plants operating part-year will generally experience less variability during a given year than plants operating year-round. Consequently, fewer samples are typically needed to determine the mean Cryptosporidium level during the period of operation for a part-year plant.

Nevertheless, even when a plant operates for only a few months per year and source water exhibits little variability, a minimum number of samples is necessary for bin classification. This is due to the relatively low sample volume, variable method recovery, nonhomogeneous distribution of Cryptosporidium in water, and other factors that limit the accuracy of any individual sample for characterizing the source water. Data suggest that for plants operating for six months per year or less, collecting a minimum of six samples per year over two years may allow bin classification with comparable accuracy to that achieved by year-round plants sampling monthly (USEPA 2005a).

Based on these considerations, today's rule requires similar source water monitoring for plants that operate only part-year during their months of operation as is required for year-round plants. However, if the plant is required to monitor for Cryptosporidium and operates for six months or less, the PWS must collect at least six Cryptosporidium samples per year over two years.

e. *Failing to monitor.* Requirements for PWSs that fail to conduct source water monitoring are based on the need for PWSs to determine a Cryptosporidium bin classification and provide the appropriate level of public health protection within the compliance time frame. The LT2ESWTR proposal required PWSs that did not complete all source water monitoring requirements to meet the requirements of the highest treatment bin (USEPA 2003a). In today's final rule, EPA has significantly changed requirements from those in the proposal for PWSs that fail to monitor. These changes are intended to give States more flexibility in working with PWSs to fulfill monitoring requirements and ensure they achieve the appropriate Cryptosporidium treatment level.

For most monitoring and testing procedure violations under the LT2ESWTR, PWSs must provide a Tier 3 public notification, which is standard for this type of violation under an NPDWR. However, if a PWS fails to collect three or more Cryptosporidium samples, the violation is elevated to a Tier 2 special public notice. The reason for elevating the public notice at this point is the persistence of the violation and the difficulty the PWS will have in collecting the required number of samples for bin classification by the compliance date. Section IV.H provides further details on public notice requirements of the LT2ESWTR.

As described in section IV.G, today's rule requires bin classification within six months following the end of the monitoring period specified for the PWS. This six-month period provides some opportunity for collecting and analyzing missed samples. The number of samples that can be made up in this period is limited, though, due to the need for samples to be evenly distributed throughout the year, as well as for PWSs and States to spend time during this period evaluating monitoring results to determine bin classification. In consideration of these factors, EPA believes that elevating the public notice when a PWS has missed three or more Cryptosporidium samples is appropriate. This violation will end when the State determines that the PWS has begun sampling on a schedule to collect the required number of samples.

Failure by a PWS to collect the required number of Cryptosporidium samples for bin classification by the compliance date is a treatment technique violation with a required Tier 2 public notice. This violation reflects the inability of the PWS to determine and comply with its Cryptosporidium treatment requirements under the LT2ESWTR and provide the appropriate level of public health protection. The violation ends when the State determines that the PWS is carrying out a monitoring plan that will lead to bin classification. A PWS that has already provided a Tier 2 public notice for missing three sampling dates and is successfully meeting a State-approved sampling schedule is not required to issue another public notice for missing the bin classification date. Alternatively, the PWS can choose to provide the highest level of Cryptosporidium treatment required under the rule, which is 5.5-log for filtered PWSs and 3-log for unfiltered PWSs.

f. *Grandfathering previously collected data.* Requirements for grandfathering previously collected monitoring data in today's final rule are similar to those in the proposal (USEPA 2003a). These requirements are based on the principle that to be eligible for grandfathering, previously collected data must be equivalent in quality to data that will be collected under the rule.

The Stage 2 M–DBP Advisory Committee recommended that EPA accept previously collected Cryptosporidium data that are ''equivalent in sample number, frequency, and data quality (e.g. volume analyzed, percent recovery) to data that would be collected under the LT2ESWTR * * * to determine bin classification in lieu of further monitoring'' (USEPA 2000a). The Advisory Committee recognized that accepting previously collected data could have a number of benefits, including early determination of LT2ESWTR compliance needs, increasing laboratory capacity, and allowing PWSs to determine their bin classification using a larger, and potentially more representative, data set.

To ensure equivalent data quality, today's rule requires that grandfathered data meet the same requirements for analytical methods, sampling location, and sample volume as data collected under the rule. PWSs must not selectively report monitoring results for grandfathering. Further, grandfathered Cryptosporidium data must generally be collected at least monthly and on a regular schedule, with the same provisions for delayed or replacement samples as allowed for regular monitoring. Today's final rule differs from the proposal, however, in making allowances for use of previously collected data where irregularities or gaps in the sampling frequency occur.

EPA recognizes that when PWSs collected Cryptosporidium data prior to the proposed or final LT2ESWTR, there may have been months when a PWS either failed to collect or lost a sample due to problems with equipment, transportation, laboratory analysis, or other reasons. If the PWS did not collect a replacement sample, gaps in the previously collected data set occurred. EPA believes that grandfathering of such a data set may be appropriate despite these gaps if the PWS conducts additional monitoring, as necessary, to ''fill-in'' gaps and ensure that the data set is unbiased. Consequently, today's rule allows grandfathering of data with gaps in the sampling frequency if approved by the State.

In addition, if the frequency of sampling in a previously collected data set varies, EPA believes the data could still be appropriate for use in bin classification. For example, a PWS might have sampled for Cryptosporidium once per month for a number of months and then increased the sampling frequency to twice per month. Today's rule allows the use of such a data set. However, to avoid bias, the PWS must calculate a monthly average for each month of sampling and then determine the bin classification using these monthly averages, rather than the individual sample concentrations.

Today's rule requires PWSs that plan to grandfather monitoring data to notify EPA or the State regarding the number and time span of sample results no later than three months prior to when the PWS must begin monitoring. The timing for submission of this notice is concurrent with the submission of a sampling schedule. This notification is necessary for the State to determine that a PWS is not required to submit a sampling schedule (when a PWS will fully comply with initial monitoring through grandfathering) or that a sampling schedule may include less than the full number of required samples (when a PWS will conduct new monitoring in conjunction with grandfathering to complete a data set). Further, this notice will assist EPA and States in determining the resources necessary to ensure timely review of grandfathered data.

PWSs must submit all monitoring results for grandfathering to EPA or the State, along with required supporting documentation, no later than two months after the PWS is required to begin monitoring. This timing will allow a PWS to continue collecting data for grandfathering until the month the PWS is required to begin monitoring under today's rule, plus an additional two months for sample analysis and compilation of the data for submission.

This reporting deadline for grandfathering monitoring results is a change from the proposed rule. In the proposal, a PWS that intended to grandfather data in lieu of conducting new monitoring under the rule had to submit its grandfathered results no later than four months prior to when the PWS was otherwise required to begin monitoring under the rule. This proposed approach had the shortcoming that a PWS could not complete its monitoring for grandfathering within this four month period. In today's final rule, a PWS may continue monitoring for grandfathering all the way until the date when the PWS must begin monitoring under the rule, if necessary. PWSs that conclude their monitoring for grandfathering earlier may submit the data at an earlier date.

g. *Ongoing watershed assessment.* Treatment requirements under the LT2ESWTR are based on source water quality. Consequently, today's rule requires watershed assessment and, as described in the next section, a second round of monitoring following initial bin classification to determine if source water quality has changed to the degree that the treatment level should be modified. These requirements are unchanged from those in the proposed LT2ESWTR (USEPA 2003a), with the exception of an allowance for States to use programs other than the sanitary survey to assess changes in the watershed.

Today's rule leverages the existing requirement for States to perform sanitary surveys on surface water PWSs. During the source water review in the sanitary survey, today's rule requires States to determine if significant changes have occurred in the watershed that could lead to increased contamination by Cryptosporidium. The State can also choose to make this determination through an equivalent review of the source water under a program other than the sanitary survey, such as a Source Water Protection Assessment. If the State determines that significant changes have occurred, the State may specify that the PWS conduct additional source water monitoring or treat the potential contamination. This approach allows the PWS and State to respond to a significant change in source water quality prior to initiating a second round of monitoring or any time thereafter.

h. *Second round of monitoring.* A more rigorous reassessment of the source water occurs through a second round of monitoring that begins six years after initial bin classification. If EPA does not develop and finalize modifications to the LT2ESWTR prior to the date when PWSs must begin the second round of monitoring, then this second round must conform to the same requirements that applied to the initial round of monitoring. PWSs may be classified in a different treatment bin, depending on the results of the second round of monitoring.

The Stage 2 M–DBP Advisory Committee recommended that EPA initiate a stakeholder process several years prior to the second round of monitoring to review new information and determine if today's rule should be modified. If the Agency modifies the LT2ESWTR, the second round of monitoring would potentially involve a new analytical method and a different treatment bin structure.

3. Summary of Major Comments

Public comment on the August 11, 2003, LT2ESWTR proposal generally supported the use of source water monitoring to determine additional treatment requirements. The following discussion summarizes major comments and EPA's responses in regard to sampling parameters and frequency, sampling location, sampling schedule, monitoring plants that operate only part-year, failing to monitor, providing treatment instead of monitoring, grandfathering previously collected data, ongoing source water assessment, second round of monitoring, and new source monitoring.

a. *Sampling parameters and frequency.* Most commenters supported the proposed requirements for large PWSs to sample monthly for Cryptosporidium, as well as for E. coli and turbidity in filtered PWSs, for 24 months. Alternatives recommended by some commenters included ending monitoring after one year if no oocysts are detected, allowing large PWSs to use an E. coli screening analysis to determine if Cryptosporidium monitoring is necessary, and using watershed data to determine treatment needs instead of source water monitoring.

In response, EPA continues to believe that large PWSs should complete 24 months of Cryptosporidium monitoring, regardless of the first-year results, in order to capture a degree of annual variability in Cryptosporidium occurrence. Moreover, for the reasons discussed previously in this preamble, EPA continues to support the Advisory Committee recommendation that all large PWSs should monitor for Cryptosporidium, rather than use the E. coli screening analysis. EPA is not aware of studies that support the use of other watershed data in place of Cryptosporidium monitoring to determine treatment needs.

Regarding requirements for small PWSs, most commenters supported the E. coli screening analysis for small filtered PWSs. Several commenters recommended more options for Cryptosporidium monitoring by small PWSs, such as allowing monitoring to be spread over two years, instead of the one year required in the proposal, or allowing fewer samples. EPA agrees that budgeting for Cryptosporidium monitoring by some small PWSs will be easier if it is spread over two years, and today's rule allows this as an option.

However, based on the analysis of false negative and false positive rates described previously, EPA continues to believe that at least 24 Cryptosporidium samples are necessary to determine the appropriate bin classification for year-round plants.

b. *Sampling location.* With respect to sampling location requirements, several commenters recommended that PWSs be allowed to collect samples either before or after pretreatment processes. These commenters stated that the chemicals used in pretreatment processes are unlikely to affect the analysis of Cryptosporidium oocysts at typical concentrations. Further, where sampling is conducted prior to a pretreatment process like presedimentation, commenters supported allowing PWSs to receive additional treatment credit for the process.

In response, EPA continues to believe that common pretreatment chemicals like oxidants and coagulants have the potential to adversely affect the performance of Cryptosporidium analytical methods. Consequently, today's rule requires that in most cases, PWSs must sample upstream of chemical addition. Where PWSs sample prior to pretreatment processes like presedimentation with coagulation, they are eligible to receive additional treatment credit for the process. However, if sampling prior to chemical addition is not feasible for a particular plant and the treatment chemical is present at a very low level that is unlikely to interfere with sample analysis, the State may approve sampling after chemical addition.

Many commenters recommended that States approve sampling locations for their PWSs. Commenters indicated that State review and approval of monitoring plans will help to prevent confusion and PWSs potentially sampling at an incorrect location. EPA agrees with these commenters and has established a requirement in today's rule for PWSs to report a description of the sampling location to the State. If a PWS does not hear back from the State by the time it is scheduled to begin sampling, it may assume that its monitoring location is acceptable.

c. *Sampling schedule.* In regard to sampling schedule requirements, several commenters requested that PWSs be given a time window larger than 5 days around scheduled sampling dates to collect samples. Recommended alternatives included a 7 or 9-day window, or only requiring that PWSs collect a sample within a specified month. In addition, commenters identified situations that interfere with sample collection, such as plant interruptions and laboratory or transportation problems, and noted that some of these are outside the conditions under which the proposal allowed a PWS to collect a delayed or replacement sample without penalty.

In response, EPA continues to believe that for routine sample collection, a 5-day window provides sufficient flexibility, given that PWSs will pick the sampling days and can schedule around holidays, weekends, and other times when sampling would be problematic. However, today's rule allows PWSs to sample outside of this window without penalty if necessary due to unforeseen conditions. Further, if a PWS collects a sample but is unable to have it analyzed due to problems with equipment, transportation or the laboratory, today's rule allows the PWS to collect a replacement sample without penalty.

In regard to the time frame for collecting missed or replacement samples, commenters recommended a number of approaches. These include adding extra sampling days to the original sampling schedule, which a PWS could then use in the event of missed sampling dates, and allowing PWSs to collect make-up samples either immediately after the scheduled sampling date or at the end of the monitoring period.

In general, EPA considers it preferable for PWSs to collect missed or replacement samples as close as is feasible to scheduled sampling dates. However, if there is a significant delay with respect to the original sampling date, collecting make-up samples at an alternate time may be appropriate to ensure that sampling results are seasonally representative. Therefore, today's rule requires PWSs to collect a missed sample as close as is feasible to the scheduled sampling date, and to collect replacement samples within 21 days of receiving information that one is needed, unless doing so within this time frame is not feasible. However, the State can authorize alternative sampling dates so that monitoring is not seasonally biased. This could include sampling during the same time in the following year, if the missed sample occurred during the first year of monitoring, or sampling after the end of the scheduled monitoring period.

d. *Plants operating only part of the year.* Commenters on monitoring requirements for surface water plants that operate for only part of the year generally recommended that sampling occur only during the period of operation. However, several different options were put forward for how the sampling be conducted. Some commenters recommended a minimum of 12 samples per year for two years distributed evenly over the period that the plant operates. Others suggested allowing the PWS to collect the required number of samples over a longer time period in order to limit the frequency of required samples when the plant is operating. Several commenters said that State input is critical to determining the appropriate monitoring period since States may have historical knowledge of plant operating practices.

In response, EPA agrees that monitoring of plants that operate only part-year under today's rule should be conducted only during months when the plant is operating, unless the State determines that a longer monitoring period is appropriate due to historical operating practices. Further, plants that operate only part-year should maintain the same sampling frequency as plants operating year-round, with the exception that plants monitoring for Cryptosporidium must collect at least six samples per year to allow for appropriate bin classification. EPA does not believe extending monitoring over more years in plants that operate only part-year is appropriate, as this would delay the installation of additional treatment where needed.

e. *Failing to monitor.* Most commenters opposed automatically classifying PWSs in the highest treatment bin (Bin 4) if they fail to complete required monitoring, as the proposed rule stipulated. Commenters suggested alternative approaches, such as giving States the flexibility to address missed samples using current enforcement mechanisms, classifying a PWS only one level higher than the bin determined by the collected data, allowing an additional year of sampling, and allowing States to use other information (e.g., sanitary surveys, other monitoring data) to aid in the classification. A few commenters, however, supported Bin 4 classification for PWSs that fail to monitor, on the basis that any other approach would create an incentive for PWSs to stop testing if poor water quality is suspected.

EPA agrees that States should have flexibility in dealing with PWSs that fail to monitor. Further, providing the highest level of treatment may not be in the best interests of consumers where a PWS has minor problems in carrying out source water monitoring. However, EPA also believes that violations for monitoring failures must reasonably ensure that PWSs complete monitoring as required to determine a bin classification within the compliance date. Failure to do so would potentially compromise public health protection.

Based on these considerations, EPA has not established an automatic Bin 4 classification for monitoring failures under today's rule. Rather, if a PWS misses three or more Cryptosporidium samples, this persistent violation requires a Tier 2 public notice (other violations require a Tier 3 notice). 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 with a required Tier 2 public notice (unless the PWS has already issued a Tier 2 notice for missing 3 Cryptosporidium samples and is monitoring on a State-approved schedule). These violations last until the State determines that a PWS has begun monitoring on a schedule that will lead to bin classification or the PWS agrees to install treatment instead of monitoring.

f. *Providing treatment instead of monitoring.* Commenters supported the option for a PWS to provide the highest level of Cryptosporidium treatment required under today's rule rather than conducting source water monitoring. Several commenters recommended that a PWS should be allowed to take this option after having initiated monitoring. EPA agrees, and today's rule allows a PWS to stop monitoring at any time by notifying the State that it will provide 5.5-log Cryptosporidium treatment for filtered PWSs or 3-log Cryptosporidium inactivation for unfiltered PWSs by the compliance deadline specified in section IV.G.

g. *Grandfathering previously collected data.* With respect to grandfathering previously collected data, many commenters expressed concern with a proposed requirement that samples must have been collected in equal time intervals. Commenters stated that although PWSs may have sampled on a regular schedule, previously collected data sets are likely to have gaps due to samples rejected for method QC violations or periods when the PWS was unable to collect a sample. In addition, there are instances where PWSs have changed the frequency of sampling, such as from monthly to twice per month.

EPA agrees that if a PWS has collected samples according to a regular schedule and met other data quality standards, then rejecting a large data set due to isolated gaps in the sampling frequency would be inappropriate. Consequently, today's rule allows States to approve grandfathering of previously collected data with omissions in the sampling interval, provided the PWS conducts additional monitoring if required by the State to ensure the data set is seasonally representative. Further, PWSs may grandfather previously collected data sets in which the sampling frequency varies, as long as samples were collected at least monthly. In this situation, PWSs must use monthly average concentrations, rather than individual sample concentrations, for bin classification.

With respect to data quality standards, such as meeting analytical method QC criteria, sampling at the correct location, and analyzing the minimum sample volume, several commenters stated that EPA should apply the same acceptance standards to previously collected data as are applied to data collected under today's rule. Other commenters, though, suggested that States should have the flexibility to accept previously collected data that deviate from the data quality standards for monitoring under the rule. These commenters stated that such data sets might include samples collected over a longer period of time and may reflect more worst-case weather events.

In response, EPA believes that data quality standards should be uniformly applied under today's rule, so that previously collected data should not be held to a lower standard than new data or evaluated differently from State to State. The requirements in today's rule with respect to Cryptosporidium analytical methods and minimum sample volume reflect recommendations of the Advisory Committee, which also recommended that the same data quality standards be applied for grandfathering. Further, because today's rule allows PWSs to collect make-up samples to address gaps in previously collected data sets, PWSs will have the opportunity to collect make-up samples for results that are rejected due to data quality standards without losing an entire data set.

In regard to notification of the acceptability of data for grandfathering, commenters recommended that if previously collected data submitted by a PWS are rejected, the PWS should have at least two months between notification and the date new monitoring must be initiated. These two months will give the PWS time to address rejection of the data and prepare for sampling. EPA agrees with this recommendation. Under today's rule, if a PWS properly submits a complete data set for grandfathering and the PWS must conduct new monitoring due to rejection of the data, the PWS has at least two months following notification by the State to initiate sampling.

h. *Ongoing watershed assessment.* Commenters asked for greater flexibility in the requirement for States to determine whether there have been significant changes in the watersheds of their PWSs that could lead to increased contamination. The proposed rule specified that States must make this determination during sanitary surveys. However, several commenters noted that some States perform source water protection assessments on the same frequency as sanitary surveys, and these detailed assessments might be a better mechanism to monitor changes in the watershed. EPA agrees and today's rule allows States to determine whether significant changes have occurred in the watershed through either a sanitary survey or an equivalent review of the source water under another program.

i. *Second round of monitoring.* Some commenters supported the proposed requirement for a second round of source water monitoring, but most opposed requiring it for all PWSs. These commenters recommended that States should be authorized to use sanitary surveys, source water assessments, ambient water quality data, treatment plant data, and other information to determine if a second round of monitoring is necessary for a PWS. Some commenters suggested that EPA fund research to allow the use of finished water monitoring as the determinant for treatment requirements in a second round of monitoring.

In response, EPA continues to believe that PWSs should conduct a second round of monitoring to determine if the level of treatment required as a result of the first round of monitoring is still appropriate. Consequently, today's rule requires this. However, EPA agrees that prior to a second round of monitoring, the Agency should evaluate the results of the first round of monitoring, along with whatever new information is available on Cryptosporidium analytical methods, risk, and other relevant issues. If EPA determines that there should be changes to the requirements for a second round of monitoring in today's rule, the Agency will issue a new rule establishing those changes.

j. *New source monitoring.* EPA requested comment in the proposal on monitoring requirements for new plants and sources (USEPA 2003a). Most commenters recommended that new plants and sources undergo monitoring equivalent to that required for existing plants and sources, and suggested that States should have discretion to determine when monitoring should take place. EPA agrees with these recommendations and today's rule requires PWS to conduct source water monitoring for new plants and sources on a schedule approved by the State. This schedule must include dates for the PWS to determine its treatment bin classification and, if necessary, comply with additional Cryptosporidium treatment requirements.

B. Filtered System Cryptosporidium Treatment Requirements

1. Today's Rule

Today's rule requires filtered PWSs using surface water or GWUDI sources to provide greater levels of treatment if their source waters have higher concentrations of Cryptosporidium. Specifically, filtered PWSs are classified in one of four treatment bins based on results from the source water monitoring described in the previous section. PWSs classified in the lowest concentration bin are subject to no additional treatment requirements, while PWSs assigned to higher concentration bins must reduce Cryptosporidium levels beyond IESWTR and LT1ESWTR requirements. All PWSs must continue to comply with the requirements of the SWTR, IESWTR, and LT1ESWTR, as applicable.

This section addresses procedures for classifying filtered PWSs in Cryptosporidium treatment bins and the treatment requirements associated with each bin. Section IV.D presents the treatment and control options, collectively termed the ''microbial toolbox,'' that PWSs must use to meet additional Cryptosporidium treatment requirements under today's rule.

a. *Bin classification.* After completing initial source water monitoring, filtered PWSs must calculate a Cryptosporidium bin concentration for each treatment plant where Cryptosporidium monitoring is required. This Cryptosporidium bin concentration is used to classify filtration plants in one of the four treatment bins shown in Table IV.B–1.

TABLE IV.B–1.—BIN CLASSIFICATION TABLE FOR FILTERED PWSS

For PWSs that are:	with a Cryptosporidium bin concentration of . . .	The bin classification is . . .
* * * required to monitor for Cryptosporidium	less than 0.075 oocysts/L	Bin 1.
	0.075 oocysts/L or higher, but less than 1.0 oocysts/L	Bin 2.
	1.0 oocysts/L or higher, but less than 3.0 oocysts/L	Bin 3.
	3.0 oocysts/L or higher	Bin 4.
* * * serving fewer than 10,000 people and NOT required to monitor for Cryptosporidium [1].	NA	Bin 1.

[1] Filtered PWSs serving fewer than 10,000 people are not required to monitor for Cryptosporidium if they monitor for E. coli and demonstrate a mean concentration of E. coli less than or equal to 10/100 mL for lake/reservoir sources or 50/100 mL for flowing stream sources or do not exceed an alternative State-approved indicator trigger (see section IV.A.1).

In general, the Cryptosporidium bin concentration is calculated by averaging individual sample results from one or more years of monitoring. Specific procedures vary, however, depending on the frequency and duration of monitoring. These procedures are as follows:

(1) For PWSs that collect a total of at least 24 but not more than 47 Cryptosporidium samples over two or more years, the Cryptosporidium bin concentration is equal to the highest arithmetic mean of all sample concentrations in any 12 consecutive months of Cryptosporidium monitoring.

(2) For PWSs that collect a total of at least 48 samples, the Cryptosporidium bin concentration is equal to the arithmetic mean of all sample concentrations.

(3) For PWSs that serve fewer than 10,000 people and monitor for Cryptosporidium for only one year (i.e., collect 24 samples in 12 months), the Cryptosporidium bin concentration is equal to the arithmetic mean of all sample concentrations.

(4) For PWSs with plants that operate only part-year that monitor for less than 12 months per year, the Cryptosporidium bin concentration is equal to the highest arithmetic mean of all sample concentrations during any year of Cryptosporidium monitoring.

In data sets with variable sampling frequency, PWSs must first calculate an arithmetic mean for each month of sampling and then apply one of these four procedures using the monthly mean concentrations. As described in section IV.A, PWSs may grandfather previously collected Cryptosporidium data where the sampling frequency varies (e.g., one year of monthly sampling and one year of twice-per-month sampling).

Filtered PWSs serving fewer than 10,000 people are not required to monitor for Cryptosporidium if they demonstrate a mean E. coli concentration less than or equal to 10/100 mL for lake/reservoir sources or 50/100 mL for flowing stream sources or do not exceed an alternative State-approved indicator trigger. PWSs that meet this criterion are classified in Bin 1 as shown in Table IV.B–1.

When determining the Cryptosporidium bin concentration, PWSs must calculate individual sample concentrations as the total number of oocysts counted, divided by the volume assayed (see section V.K for details). In samples where no oocysts are detected, the result is assigned a value of zero for the purpose of calculating the bin concentration. Sample analysis results are not adjusted for analytical method recovery or the percent of Cryptosporidium oocysts that are infectious.

PWSs must report their treatment bin classification to the State for approval following initial source water monitoring (see section IV.G for specific compliance dates). The report must include a summary of the data and calculation procedure used to determine the bin concentration. If EPA does not amend today's rule before the second round of monitoring described in section IV.A, PWSs must recalculate their bin classification after completing the second round of monitoring and report the results to the State for approval. If the State does not respond to a PWS regarding its bin classification after either report, the PWS must comply with the Cryptosporidium treatment requirements of today's rule based on the reported bin classification.

b. Bin treatment requirements. Table IV.B–2 shows the additional Cryptosporidium treatment requirements associated with the four treatment bins for filtered PWSs under today's rule. All filtered PWSs must comply with these treatment requirements based on their bin classification, which must be determined using the procedures just described.

TABLE IV.B–2.—TREATMENT REQUIREMENTS FOR LT2ESWTR BIN CLASSIFICATIONS

If your bin classification is . . .	And you use the following filtration treatment in full compliance with the SWTR, IESWTR, and LT1ESWTR (as applicable), then your additional treatment requirements are . . .		
	Conventional filtration treatment [1], diatomaceous earth filtration, or slow sand filtration	Direct filtration	Alternative filtration technologies
Bin 1	No additional treatment	No additional treatment	No additional treatment.
Bin 2	1-log treatment [2]	1.5-log treatment [2]	As determined by the State [2 4]
Bin 3	2-log treatment [3]	2.5-log treatment [3]	As determined by the State [3 5]
Bin 4	2.5-log treatment [3]	3-log treatment [3]	As determined by the State [3 6]

[1] Applies to a treatment train using separate, sequential, unit processes for coagulation/flocculation, clarification, and granular media filtration. Clarification includes any solid/liquid separation process following coagulation where accumulated solids are removed during this separate component of the treatment system.
[2] PWSs may use any technology or combination of technologies from the microbial toolbox in section IV.D.
[3] PWSs must achieve at least 1-log of the required treatment using ozone, chlorine dioxide, UV, membranes, bag filtration, cartridge filtration, or bank filtration.
[4] Total Cryptosporidium removal and inactivation must be at least 4.0 log.
[5] Total Cryptosporidium removal and inactivation must be at least 5.0 log.
[6] Total Cryptosporidium removal and inactivation must be at least 5.5 log.

The total Cryptosporidium treatment required for plants in Bins 2, 3, and 4 is 4.0-log, 5.0-log, and 5.5-log, respectively. Conventional treatment (including softening), slow sand, and diatomaceous earth filtration plants in compliance with the IESWTR or LT1ESWTR, as applicable, receive a prescribed 3.0-log Cryptosporidium treatment credit toward these total bin treatment requirements. Accordingly, these plant types must provide 1.0- to 2.5-log of additional treatment when classified in Bins 2–4, respectively. Direct filtration plants in compliance with existing regulations receive a prescribed 2.5-log treatment credit and, consequently, must achieve 0.5-log greater treatment to comply with Bins 2–4. Section IV.D describes how States may award a level of treatment credit that differs from the prescribed credit based on a demonstration of performance by the PWS.

For PWSs using alternative filtration technologies, such as membranes, bag filters, or cartridge filters, no prescribed treatment credit is available because the performance of these processes is specific to individual products. Consequently, when PWSs using these processes are classified in Bins 2–4, the State must determine additional treatment requirements based on the credit the State awards to a particular technology. The additional treatment requirements must ensure that plants classified in Bins 2–4 achieve total Cryptosporidium reductions of 4.0- to 5.5-log, respectively. Section IV.D describes challenge testing procedures to determine treatment credit for membranes, bag filters, and cartridge filters.

PWSs can achieve additional Cryptosporidium treatment credit through implementing pretreatment processes like presedimentation or bank filtration, by developing a watershed control program, and by applying additional treatment steps like ozone, chlorine dioxide, UV, and membranes. In addition, PWSs can receive a higher level of credit for existing treatment processes through achieving very low filter effluent turbidity or through a demonstration of performance. Section IV.D presents criteria for awarding Cryptosporidium treatment credit to these and other treatment and control options, which collectively comprise the microbial toolbox.

PWSs in Bin 2 can meet additional Cryptosporidium treatment requirements by using any option or combination of options from the microbial toolbox. For Bins 3 and 4, PWSs must achieve at least 1-log of the additional treatment requirement by using ozone, chlorine dioxide, UV, membranes, bag filtration, cartridge filtration, or bank filtration.

2. Background and Analysis

Today's rule will increase protection against Cryptosporidium and other pathogens in PWSs with the highest source water contamination levels. This targeted approach builds upon existing regulations under which all filtered PWSs must provide the same level of treatment regardless of source water quality. EPA's intent with today's rule is to ensure that PWSs with higher risk source waters achieve public health protection commensurate with PWSs with less contaminated sources.

The Cryptosporidium treatment requirements for filtered PWSs in today's rule are unchanged from the August 11, 2003 proposal (USEPA 2003a) and reflect consensus recommendations by the Stage 2 M–DBP Advisory Committee (USEPA 2000a). The following discussion summarizes the Agency's basis for establishing risk-targeted Cryptosporidium treatment requirements and for setting the specific bin concentration ranges and treatment requirements that apply to filtered PWSs in today's rule.

a. *Basis for targeted treatment requirements.* In developing today's rule, EPA evaluated the degree to which new information on Cryptosporidium warranted moving beyond existing regulations. As discussed in section III, the IESWTR established a Cryptosporidium MCLG of zero and requires large filtered PWSs to achieve 2-log Cryptosporidium removal. The LT1ESWTR extended this requirement to small PWSs. After these rules were promulgated, advances were made in analytical methods and treatment for Cryptosporidium, and EPA collected new information on Cryptosporidium occurrence and infectivity. Consequently, EPA assessed the implications of these developments for further controlling Cryptosporidium to approach the zero MCLG.

The risk-targeted approach for filtered PWSs in today's final rule stems from four general findings based on new information on Cryptosporidium:

(1) New data on Cryptosporidium infectivity suggest that the risk associated with a particular level of Cryptosporidium is most likely higher than EPA estimated at the time of earlier rules;

(2) New data on Cryptosporidium occurrence indicate that levels are relatively low in most water sources, but a subset of sources has substantially higher concentrations;

(3) The finding that UV light can readily inactivate Cryptosporidium, as well as other technology developments, makes achieving high levels of

treatment for Cryptosporidium feasible for PWSs of all sizes; and

(4) EPA Methods 1622 and 1623 are capable of assessing annual mean levels of Cryptosporidium in drinking water sources.

These findings led EPA to conclude that most filtered PWSs currently provide sufficient treatment for Cryptosporidium, but additional treatment is needed in those PWSs with the highest source water Cryptosporidium levels to protect public health. Further, PWSs can characterize Cryptosporidium levels in their source waters with available analytical methods and can provide higher levels of treatment with available technologies. Consequently, risk-targeted treatment requirements for Cryptosporidium based on source water contamination levels are appropriate and feasible to implement.

b. *Basis for bin concentration ranges and treatment requirements.* To establish the risk-targeted treatment requirements in today's rule, EPA had to determine the degree of treatment that should be required for different source water Cryptosporidium levels to protect public health. This determination involved addressing several questions:

- What is the risk associated with Cryptosporidium in a drinking water source?
- How much Cryptosporidium removal do filtration plants achieve?
- What is the appropriate statistical measure for classifying PWSs into treatment bins?
- What degree of additional treatment is needed for higher source water Cryptosporidium levels?
- How should PWSs calculate their treatment bin classification?

This section summarizes how EPA evaluated these questions in developing today's rule. See the proposed LT2ESWTR for further details (USEPA 2003a).

What is the Risk Associated With Cryptosporidium in a Drinking Water Source?

The risk of infection from Cryptosporidium in drinking water is a function of exposure (i.e., the dose of oocysts ingested) and infectivity (i.e., likelihood of infection as a function of ingested dose). Primary (i.e., direct) exposure to Cryptosporidium depends on the concentration of oocysts in the source water, the fraction removed by the treatment plant, and the volume of water consumed (secondary exposure occurs through interactions with infected individuals). Thus, the daily risk of infection (DR) is as follows:

DR = (oocysts/L in source water) × (fraction remaining after treatment) × (liters consumed per day) × (likelihood of infection per oocyst dose).

Assuming 350 days of consumption per year for people served by community water systems (CWSs), the annual risk (AR) of infection is as follows:

$AR = 1 - (1 - DR)^{350}$.

As discussed in section III.E, EPA has estimated the mean likelihood of infection from ingesting one Cryptosporidium oocyst to range from 4 to 16 percent. Median individual daily water consumption is estimated as 1.07 L/day. Figure IV.B–1 illustrates ranges for the annual risk of infection by Cryptosporidium in CWSs based on these values for different source water infectious oocyst concentrations and treatment plant removal efficiencies. The dashed lines represent the uncertainty associated with Cryptosporidium infectivity for each log-removal curve. See Chapter 5 of the LT2ESWTR Economic Analysis for details (USEPA 2005a).

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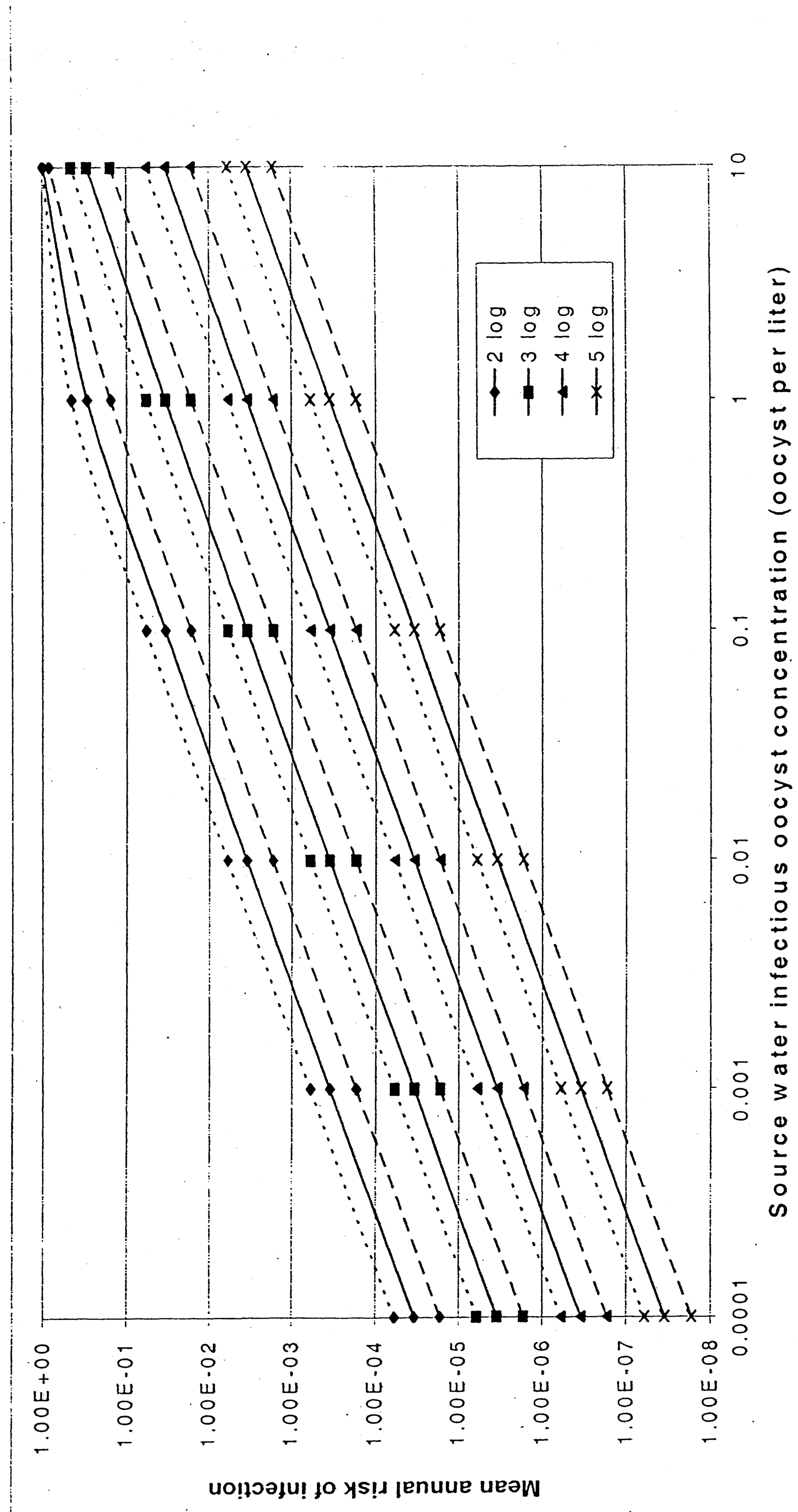

Figure IV.B-1.– Annual risk of *Cryptosporidium* infection as a function of source water infectious oocyst concentration for treatment plants achieving 2-log, 3-log, 4-log, or 5-log removal of oocysts.

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The results in Figure IV.B–1 show, for example, that if a treatment plant had a concentration of infectious Cryptosporidium in the source water of 0.1 oocysts/L and the plant achieved 3-log removal, the mean annual risk of

Cryptosporidium infection would range from 0.0017 to 0.0060 (17 to 60 infections per 10,000 consumers). In comparison, if the same plant had a source water infectious Cryptosporidium level of 0.01 oocysts/L, the annual infection risk would range from 1.7 to 6 per 10,000 consumers.

How much Cryptosporidium removal do filtration plants achieve?

The amount of Cryptosporidium removal that filtration plants achieve was a key factor in assessing the additional treatment that plants with higher source water Cryptosporidium levels should provide. To evaluate this factor, EPA reviewed studies of Cryptosporidium removal by common treatment processes. As described in the proposal for today's rule, these processes were conventional treatment, direct, slow sand, and diatomaceous earth filtration, as well as membrane, bag, and cartridge filtration (USEPA 2003a).

The majority of plants treating surface water use conventional treatment, which is defined in 40 CFR 141.2 as coagulation, flocculation, sedimentation, and filtration. In the proposal, EPA reviewed studies of conventional treatment by Dugan et al. (2001), Nieminski and Bellamy (2000), McTigue et al. (1998), Patania et al. (1999), Huck et al. (2000), Emelko et al. (2000), and Harrington et al. (2001). Based on these studies, EPA estimated that conventional treatment plants in compliance with the IESWTR or LT1ESWTR typically achieve a Cryptosporidium removal efficiency of approximately 3-log. Consequently, conventional treatment plants receive 3-log credit toward Cryptosporidium treatment requirements under today's rule.

This 3-log credit for conventional treatment is consistent with the Stage 2 M–DBP Agreement in Principle (USEPA 2000a), which states as follows:

> "The additional treatment requirements in the bin requirement table are based, in part, on the assumption that conventional treatment plants in compliance with the IESWTR achieve an average of 3 logs removal of Cryptosporidium."

The M–DBP Advisory Committee did not recommend a level of Cryptosporidium treatment credit for other types of filtration plants.

EPA also reviewed studies of the performance of clarification processes like dissolved air flotation, which can be used in place of sedimentation in a conventional treatment train (Gregory and Zabel 1990, Plummer et al. 1995, Edzwald and Kelley 1998). These studies indicate that plants using clarification processes other than sedimentation that are located after coagulation and prior to filtration can achieve performance equivalent to conventional treatment plants. As a result, any treatment train that includes coagulation/flocculation, clarification, and granular media filtration is regarded as conventional treatment for purposes of awarding treatment credit under today's rule. The clarification step must be a solid/liquid separation process where accumulated solids are removed during this separate component of the treatment system.

Direct filtration plants use coagulation, flocculation, and filtration processes just as conventional treatment plants do, but they lack a sedimentation basin or equivalent clarification process. In the proposal, EPA reviewed studies of sedimentation by Dugan et al. (2001), States et al. (1997), Edzwald and Kelly (1998), Payment and Franco (1993), Kelly et al. (1995), and Patania et al. (1995). Results from these studies demonstrate that sedimentation basins can achieve 0.5-log or greater Cryptosporidium removal. In addition, some studies have observed that direct filtration achieves less Cryptosporidium removal than conventional treatment (Patania et al. 1995) and the incidence of Cryptosporidium in the treated water is higher (McTigue et al. 1998). Given these findings, EPA has awarded direct filtration plants a 2.5-log credit towards Cryptosporidium treatment requirements under today's rule (i.e., 0.5-log less credit than for conventional treatment).

Slow sand filtration involves passing raw water through a bed of sand at low velocity and without prior coagulation. Diatomaceous earth filtration is a process by which a filtration medium is initially deposited onto a support membrane and medium is added throughout the operation to keep the filter from clogging. In the proposal, EPA reviewed slow sand filtration studies by Fogel et al. (1993), Hall et al. (1994), Schuler and Ghosh (1991), and Timms et al. (1995) and diatomaceous earth filtration studies by Schuler and Gosh (1990) and Ongerth and Hutton (1997, 2001). For both processes, these studies indicate that a well-designed and properly operated filter can achieve Cryptosporidium removal efficiencies similar to those observed for conventional treatment plants. Slow sand and diatomaceous earth filtration plants, therefore, receive a 3-log credit towards Cryptosporidium treatment requirements under today's rule.

Estimating a typical Cryptosporidium removal efficiency for filtration technologies like membranes, bag filters, and cartridge filters is not possible because the performance of such filters is specific to a particular product. As a result, credit for these devices must be determined by the State based on product-specific testing using the procedures described in section IV.D or other criteria approved by the State.

Table IV.B–3 summarizes the credits various types of filtration plants receive toward Cryptosporidium treatment requirements under today's rule. This credit determines the degree of additional treatment that plants classified in Bins 2–4 must apply, as shown in Table IV.B–2.

TABLE IV.B–3.—CRYPTOSPORIDIUM TREATMENT CREDIT TOWARDS LT2ESWTR REQUIREMENTS [1]

Plant type	Conventional treatment (includes softening)	Direct filtration	Slow sand or diatomaceous earth filtration	Alternative filtration technologies
Treatment credit	3.0-log	2.5-log	3.0-log	Determined by State. [2]

[1] Applies to plants in full compliance with the IESWTR or LT1ESWTR as applicable.
[2] Credit must be determined through product or site-specific assessment.

As discussed previously, studies indicate that conventional treatment plants producing very low filtered water turbidity can achieve a higher level of Cryptosporidium removal than 3-log, and today's rule allows such plants to receive additional treatment credit. Further, States can award a higher or lower level of credit to an individual plant based on a site-specific demonstration of performance. Section IV.D provides details on both of these topics.

The Cryptosporidium removal credits for filtration plants in today's rule differ from the amount of credit awarded under the IESWTR and LT1ESWTR. As discussed in section III, those rules require all filtered PWSs to achieve 2-log removal of Cryptosporidium. PWSs using conventional treatment, or direct, slow sand, or diatomaceous earth filtration are in compliance with this requirement if they meet specified filtered water turbidity standards. These regulatory criteria were based on consideration of the minimum level of removal that all these filtration processes will achieve (USEPA 1998a). However, in the risk assessments that supported these regulations, EPA estimated that most filtration plants will achieve significantly more removal, with median Cryptosporidium reductions near 3-log.

Today's rule will supplement IESWTR and LT1ESWTR requirements by mandating additional treatment at certain PWSs based on source-water Cryptosporidium levels. When assessing the need for additional treatment at potentially higher risk PWSs, EPA believes that considering the full removal efficiency achieved by different types of treatment plants is appropriate. Because making a site-specific assessment of removal efficiency at all treatment plants individually is not feasible, establishing prescribed treatment credits based on available data is necessary. Accordingly, EPA has concluded that available data support the higher levels of prescribed credit towards Cryptosporidium treatment requirements for filtration plants established by today's rule.

What is the appropriate statistical measure for classifying PWSs into treatment bins?

EPA and the Advisory Committee evaluated different statistical measures for characterizing Cryptosporidium monitoring results to determine if additional treatment should be required. These measures included the arithmetic mean, median, 90th percentile, and maximum.

EPA concluded, consistent with Advisory Committee recommendations, that Cryptosporidium levels should be characterized by an arithmetic mean. This conclusion is based on two factors: (1) Available data suggest that the mean concentration directly relates to the average risk of the exposed population (i.e., drinking water consumers); and (2) with a limited number of samples, the mean can be estimated more accurately than other statistical measures, such as a 90th percentile estimate.

What degree of additional treatment is needed for higher source water Cryptosporidium levels?

Development of the risk-based treatment requirements in today's rule involved first determining the threshold source-water Cryptosporidium level at which filtered PWSs should provide additional treatment to protect public health. The key factors in making this determination were the estimations of Cryptosporidium risk and treatment plant removal efficiency discussed previously, along with the performance of analytical methods for classifying PWSs in different treatment bins.

EPA and Advisory Committee deliberations focused on mean source-water Cryptosporidium concentrations in the range of 0.01 to 0.1 oocysts/L as threshold levels for requiring additional treatment. Based on the type of risk information shown in Figure IV.B–1, these levels are estimated to result in an annual infection risk in the range of 1.7 $\times 10^{-4}$ to 6.0×10^{-3} (or 1.7 to 60 infections per 10,000 consumers) for a treatment plant achieving 3-log Cryptosporidium removal (the treatment efficiency estimated for conventional plants under existing regulations).

A shortcoming with establishing the threshold for additional treatment at 0.01 oocysts/L, however, is that a PWS would exceed this concentration with only a very few oocysts being detected. For a PWS collecting monthly 10-L samples and bin classification based on the maximum running annual average, as required under today's rule, detecting two oocysts during one year of monitoring would exceed a mean of 0.01 oocysts/L. Given the uncertainty associated with Cryptosporidium monitoring, EPA and the Advisory Committee did not support requiring additional treatment for filtered PWSs based on so few counts. Although this shortcoming could theoretically be addressed by a higher sampling frequency, the feasibility of increased sampling is limited by the capacity of laboratories and the cost of sample analysis.

A related concern in establishing the threshold concentration for requiring additional treatment was bin misclassification. If the threshold concentration was set at 0.1 oocysts/L, for example, some PWSs with actual mean source-water concentrations greater than this level would measure a concentration less than this level and would be misclassified in the bin that requires no additional treatment. Consequently, they would not provide sufficient public health protection. As discussed previously, this type of error is due to the limited number and volume of samples that can be analyzed, imperfect method recovery, and variability in Cryptosporidium occurrence.

Based on these considerations, the Advisory Committee recommended and today's rule establishes that filtered PWSs must provide additional treatment for Cryptosporidium when their mean source-water concentration exceeds 0.075 oocysts/L. At this concentration, PWSs collecting monthly 10-L samples must count at least nine oocysts in one year (9 oocysts per 120 L total sample volume) before additional treatment is required. Further, any PWS with a mean source-water infectious Cryptosporidium level above 0.1 oocysts/L, which corresponds to an estimated infection risk range of 1.7 to 6.0×10^{-3}, is highly likely to be appropriately classified in a bin requiring additional treatment.

After identifying this first threshold for requiring additional treatment, determining the Cryptosporidium concentrations that should bound higher treatment bins was necessary. In making these determinations, EPA concurred with Advisory Committee recommendations that sought to balance the possibility of bin misclassification against equitable risk reduction and public health protection.

Treatment bins that span a wider concentration range result in lower bin misclassification rates. The analysis summarized in section IV.A shows that the monitoring required under today's rule can accurately characterize a PWS's mean Cryptosporidium level within a 0.5-log margin, but error rates increase for smaller margins (USEPA 2005a). Conversely, treatment bins that span a narrower concentration range provide more equitable protection from risk among different PWSs. This is due to identical treatment requirements applying to all PWSs in the same bin. In consideration of these issues, today's rule establishes two higher treatment bins at Cryptosporidium concentrations of 1.0 oocysts/L and 3.0 oocysts/L. These values result in the four bins shown in Table IV.B–1. Available occurrence data indicate that few PWSs will measure mean Cryptosporidium concentrations greater than 3.0 oocysts/L, so there is no need to establish a treatment bin above this level.

With respect to the degree of additional Cryptosporidium treatment that PWSs in Bins 2–4 must provide, EPA and the Advisory Committee considered values of 0.5-log and greater. Today's rule establishes a 1-log additional treatment requirement for conventional plants in Bin 2. Because the concentration range of Bin 2 spans approximately one order of magnitude, this degree of treatment ensures that plants classified in Bin 2 will achieve treated water Cryptosporidium levels comparable to plants in Bin 1. Conventional plants in Bins 3 and 4 must provide 2.0- and 2.5-log of additional treatment, respectively. As recommended by the Advisory Committee, these higher additional treatment levels are required based on the recognition that plants in Bins 3 and 4 have a much greater potential vulnerability to Cryptosporidium. Consequently, significantly higher treatment is appropriate to protect public health.

These additional treatment requirements for conventional treatment plants in Bins 2–4 are based on a prescribed 3-log Cryptosporidium treatment credit for compliance with the IESWTR or LT1ESWTR, as discussed previously. They translate to total Cryptosporidium treatment requirements of 4.0-, 5.0-, and 5.5-log for Bins 2, 3, and 4, respectively. Plants receiving higher or lower levels of prescribed treatment credit are required to provide less or more additional treatment if classified in Bins 2–4.

Plants using slow sand or diatomaceous earth filtration, which also receive a 3-log treatment credit, incur the same additional treatment requirements as conventional plants if classified in Bins 2–4. Direct filtration plants, however, must provide 0.5-log greater additional treatment if classified in Bins 2–4 because they receive a 2.5-log prescribed credit. EPA expects, though, that most direct filtration plants will be classified in Bin 1 because direct filtration is typically applied only to higher quality source waters.

Because EPA is unable to establish a prescribed treatment credit for other types of filtration technologies like membranes, bag filters, and cartridge filters, today's rule requires that States assign a treatment credit to a particular filtration product. This credit then determines the amount of additional treatment that a plant using this product must provide if classified in Bins 2–4 in order to achieve the required total treatment level. Section IV.D provides criteria for assigning Cryptosporidium treatment credit to membranes, bag filters, and cartridge filters.

As described in Section IV.D, today's rule establishes a wide range of treatment and control options through the microbial toolbox for PWSs to meet additional Cryptosporidium treatment requirements. PWSs may choose any option or combination of options from the microbial toolbox to meet the treatment requirements of plants in Bin 2. For plants in Bins 3 or 4, though, PWSs must achieve at least 1-log of the additional treatment requirement using UV, ozone, chlorine dioxide, membranes, bag filters, cartridge filters, or bank filtration. EPA is establishing this provision in today's rule as recommended by the Advisory Committee because these processes will serve as significant additional treatment barriers for PWSs with the highest levels of pathogens in their sources.

How should PWSs calculate their treatment bin classification?

The specific calculations that PWSs use to determine their bin classification are based on analyses of misclassification rates and bias. As described in section IV.A, today's rule requires PWSs to collect at least 24 samples (except for plants that operate only part-year) when they monitor for Cryptosporidium. Most PWSs will collect these 24 samples over two years, but PWSs may sample at a higher frequency and small PWSs may complete this monitoring in one year. These differences affect the bin classification calculation.

PWSs that sample monthly over two years (24 samples total) must use the maximum running annual average (Max-RAA) for bin classification because this achieves a low false negative rate (the likelihood a PWS will be incorrectly classified in a lower bin). In comparison, if such PWSs used the mean of all samples over two years for bin classification, the false negative rate would be almost four times higher (see Table IV.B.4).

PWSs that choose to sample at least twice per month over two years (48 samples total) must use the mean of all 48 samples for their bin classification. This approach achieves a low false negative rate similar to the Max-RAA for 24 samples and, in addition, reduces the false positive rate (the likelihood a PWS will be incorrectly classified in higher bin—see Table IV.B.4). Due to the lower false positive rate associated with 48 samples, EPA expects that some PWSs will choose to sample for Cryptosporidium twice per month.

Small PWSs (serving fewer than 10,000 people) that complete their Cryptosporidium monitoring over one year must use the mean of all 24 samples for bin classification. This approach has a higher false negative rate than the approaches allowed for PWSs that monitor over two years. However, it is the only feasible option for PWSs that conduct just one year of Cryptosporidium sampling. Averaging sample concentrations over less than one year is not appropriate (except in the case of plants that operate only part-year that monitor for less than one year) as this would bias the bin classification due to seasonal variation in water quality.

TABLE IV.B–4.—FALSE POSITIVE AND FALSE NEGATIVE RATES FOR MONITORING AND BINNING STRATEGIES CONSIDERED FOR THE LT2ESWTR

Strategy	False positive [1]	False negative [2]
48 sample arithmetic mean ...	1.7%	1.4%
24 sample Max-RAA	5.3%	1.7%
24 sample arithmetic mean ...	2.8%	6.2%

[1] False positive rates calculated for systems with Cryptosporidium concentrations 0.5 log below the Bin 1 boundary of 0.075 oocysts/L.

[2] False negative rates calculated for systems with Cryptosporidium concentrations 0.5 log above the Bin 1 boundary of 0.075 oocysts/L.

Two additional considerations that relate to characterizing Cryptosporidium monitoring results to determine treatment requirements are (1) fewer than 100 percent of oocysts in a sample are recovered and counted by the analyst and (2) not all the oocysts measured with Methods 1622 or 1623 are capable of causing infection. These two factors are offsetting, in that oocyst counts not adjusted for recovery tend to underestimate the true concentration, while the total oocyst count typically overestimates the infectious concentration that presents a health risk.

As described in section III, matrix spike data indicate that average recovery of Cryptosporidium oocysts with Methods 1622 or 1623 in a national monitoring program will be approximately 40 percent. Regarding the fraction of oocysts that are infectious, LeChevallier et al. (2003) tested natural waters for Cryptosporidium using both Method 1623 and a method (cell culture-PCR) to test for infectivity. Results suggested that 37 percent of the Cryptosporidium oocysts detected by Method 1623 were infectious. This finding is consistent with the observation that 37 percent of the oocysts counted during the ICRSS using Methods 1622 or 1623 had internal structures, which indicate a higher likelihood of infectivity (among the remaining oocysts, 47 percent had amorphous structures and 16 percent were empty).

While it is not possible to establish a precise value for method recovery or the fraction of oocysts that are infectious, available data suggest that these parameters may be of similar magnitude. Consequently, the Advisory Committee recommended that monitoring results should not be adjusted to account for either recovery or the fraction infectious. EPA concurs with this recommendation and today's rule requires that PWSs be classified in treatment bins using the total number of Cryptosporidium oocysts counted, without further adjustment. The LT2ESWTR treatment bins in today's rule are constructed to reflect this approach.

3. Summary of Major Comments

For filtered PWS treatment requirements in the LT2ESWTR proposal, EPA received significant public comment on the risk-based approach to requiring additional treatment, the role of States in determining bin classification, and the treatment credit for filtration plants. The following discussion summarizes comments in these areas and EPA's responses.

Most commenters supported the risk-based approach of the LT2ESWTR in which filtered PWSs monitor for microbial contaminants and only those PWSs finding higher levels of contamination are required to provide additional treatment for Cryptosporidium. Among these comments, many stated support for the four treatment bins for filtered PWSs, with some noting that future research will indicate whether the bins should be restructured in a later rulemaking. Several commenters expressed support for EPA's combination of the Stage 2 DBPR and LT2ESWTR as essential to creating a balanced approach between DBP control and microbial risk.

A few commenters opposed the expenditure of funds to reduce risk from Cryptosporidium on the basis that epidemiological evidence suggests this risk is low and most communities have not experienced cryptosporidiosis outbreaks. EPA agrees that additional treatment for Cryptosporidium in drinking water is not warranted in all communities. Under today's rule, most PWSs are expected to be classified in the lowest bin, which requires no additional treatment. However, based on risk information presented in USEPA (2005a) and summarized in this preamble, EPA believes that additional treatment is necessary to protect public health in PWSs with the highest Cryptosporidium levels. Further, as described in USEPA (2005a), EPA's assessment of Cryptosporidium risk in drinking water is consistent with the limited available epidemiological data on disease incidence.

With respect to the role of States in bin classification, most commenters recommended that States assign or approve the bin classification for their PWSs. Commenters maintained that State approval of bin classification is an inherent governmental function and will avoid confusion as to the level of treatment each PWS must provide. Further, the approval process will provide an opportunity for dialog between States and PWSs. EPA agrees with these comments and today's rule requires PWSs to submit their calculation of bin classification to the State for review. If the PWS does not hear back from the State, it must proceed to apply the level of treatment appropriate for its calculated bin classification in accordance with its applicable compliance schedule.

In regard to the Cryptosporidium treatment credit that should be awarded to filtration plants, many commenters supported the 3-log Cryptosporidium removal credit for conventional treatment and slow sand filtration. Some comments included data showing that conventional treatment can achieve greater than 4-log removal of Cryptosporidium, and several commenters stated concerns that EPA has underestimated the level of treatment achievable through conventional treatment. Commenters supported the inclusion of plants using softening and dissolved air flotation for conventional treatment credit and requested that EPA extend this credit to similar treatment trains using other types of clarification processes.

EPA recognizes that studies show conventional treatment can achieve more than 3-log Cryptosporidium removal under optimal conditions. However, studies also demonstrate that removal efficiencies can be significantly less for suboptimal plant set-up and operation. EPA does not expect that all plants will operate under optimal conditions at all times. Consequently, today's rule awards a prescribed 3-log credit to conventional plants complying with the IESWTR or LT1ESWTR and allows plants to receive higher credit through demonstrating low finished water turbidity or through an alternative demonstration of performance, as describe in section IV.D. EPA agrees that plants using alternative clarification process that involves solids removal between coagulation and filtration should qualify for 3-log credit and today's rule provides for this.

C. Unfiltered System Cryptosporidium Treatment Requirements

1. Today's Rule

Today's rule requires all PWSs that use a surface water or GWUDI source and are unfiltered to provide treatment for Cryptosporidium. The degree of required treatment depends on the level of Cryptosporidium in the source water, as determined through required monitoring. Further, unfiltered PWSs must meet overall treatment requirements using at least two disinfectants and must continue to meet all applicable filtration avoidance criteria. Details of these requirements follow.

a. *Determination of mean Cryptosporidium level.* Following completion of the required initial source water monitoring described in section IV.A, each unfiltered PWS must determine the arithmetic mean of all its Cryptosporidium sample results generated during the monitoring period. As required for filtered PWSs, individual sample results must be calculated as the total number of oocysts counted, divided by the volume assayed (see section V.K for details). Samples are not adjusted for method recovery and, in samples where no oocysts are detected, the result is treated as zero.

Unfiltered PWSs must report their mean Cryptosporidium level to the State for approval (see section IV.G for specific reporting dates). The report must include a summary of the data used to determine the mean concentration. If the State does not respond to a PWS regarding its mean Cryptosporidium level, the PWS must comply with the Cryptosporidium treatment requirements of today's rule, as described next, based on the reported level.

If EPA does not amend today's rule before the second round of monitoring described in section IV.A, unfiltered PWSs must recalculate their mean Cryptosporidium level using results from the second round of monitoring. Unfiltered PWSs must report this level to the State as described for the initial round of monitoring.

b. *Cryptosporidium treatment requirements.* Unfiltered PWSs must comply with the following treatment requirements based on their mean source-water Cryptosporidium level: if the level is less than or equal to 0.01 oocysts/L then at least 2-log Cryptosporidium inactivation is required; if the level is greater than 0.01 oocysts/L, or if the unfiltered PWS chooses not to monitor for Cryptosporidium, then at least 3-log Cryptosporidium inactivation is required. See section IV.G for treatment compliance dates.

EPA has developed criteria, described in section IV.D, to award Cryptosporidium inactivation credit for treatment with chlorine dioxide, ozone, or UV light. Unfiltered PWSs may use any of these disinfectants to meet their Cryptosporidium inactivation requirements under today's rule. Further, unfiltered PWSs must achieve the following with respect to disinfection treatment:

(1) A PWS that uses chlorine dioxide or ozone and fails to achieve the required level of Cryptosporidium inactivation on more than one day in the calendar month is in violation of the treatment technique requirement.

(2) A PWS that uses UV light and fails to achieve the required level of Cryptosporidium inactivation in at least 95 percent of the water delivered to the public every month is in violation of the treatment technique requirement.

c. *Use of two disinfectants.* Unfiltered PWSs must use at least two different disinfectants to provide 4-log virus, 3-log Giardia lamblia, and 2- or 3-log Cryptosporidium inactivation as required under 40 CFR 141.72(a) and today's rule. Further, each of two disinfectants must achieve by itself the total inactivation required for one of these target pathogens. This requirement does not modify the existing requirement under 40 CFR 141.72(a) for PWSs to provide a disinfectant residual in the distribution system.

2. Background and Analysis

The intent of the Cryptosporidium treatment requirements for unfiltered PWSs in today's final rule is to ensure that they achieve public health protection equivalent to that achieved by filtered PWSs. These requirements are unchanged from the August 11, 2003 proposal (USEPA 2003a), and they reflect consensus recommendations by the Stage 2 M–DBP Advisory Committee (USEPA 2000a). The following discussion summarizes the Agency's basis for establishing risk-targeted Cryptosporidium treatment requirements for unfiltered PWSs in today's rule and for requiring the use of two disinfectants.

a. *Basis for Cryptosporidium treatment requirements.* As described in section III, available data suggest that unfiltered PWSs must take additional steps to achieve public health protection against Cryptosporidium equivalent to that provided by filtered PWSs.

In occurrence data from the ICR, the median Cryptosporidium level in unfiltered PWS sources was 0.0079 oocysts/L, which is approximately 10 times less than the median level of 0.052 oocysts/L in filtered PWS sources. In translating these source water levels to finished water concentrations, EPA and the Advisory Committee assumed that conventional filtration treatment plants in compliance with the IESWTR or LT1ESWTR achieve an average of 3-log (99.9 percent) removal of Cryptosporidium. Existing regulations do not require unfiltered PWSs to provide any treatment for Cryptosporidium.

If the median source water Cryptosporidium level in filtered PWSs is approximately 10 times higher than in unfiltered PWSs, and filtered PWSs achieve 3-log Cryptosporidium removal, then the median finished water Cryptosporidium level in filtered PWSs is approximately 100 times lower than in unfiltered PWSs. Thus, these data suggest that most unfiltered PWSs must provide 2-log Cryptosporidium treatment to ensure equivalent public health protection.

Some unfiltered PWSs must provide greater than 2-log Cryptosporidium treatment to ensure equitable protection, depending on their source water level. Under today's rule, the Cryptosporidium treatment requirements for filtered PWSs, as described in section IV.B.1, will achieve mean finished water Cryptosporidium levels of less than 1 oocyst/10,000 L. An unfiltered PWS with a mean source water Cryptosporidium concentration above 0.01 oocysts/L would have to provide at least 3-log inactivation to achieve an equivalent finished water Cryptosporidium level.

As stated earlier, EPA has determined that UV light is a feasible technology for PWSs of all sizes, including unfiltered PWSs, to inactivate Cryptosporidium. In addition, treating for Cryptosporidium using ozone is feasible for some unfiltered PWSs. Inactivating Cryptosporidium with chlorine dioxide, while allowed under today's rule, does not appear to be feasible for most unfiltered PWSs due to regulatory limits on chlorite—a chlorine dioxide byproduct.

Based on these findings, today's rule requires all unfiltered PWSs to provide at least 2-log Cryptosporidium inactivation, and to provide at least 3-log inactivation if the mean source water level exceeds 0.01 oocysts/L. These treatment requirements will ensure that unfiltered PWSs achieve public health protection against Cryptosporidium that is comparable to filtered PWSs in the finished water that is distributed to consumers.

Available data indicate that no unfiltered PWSs will show measured mean source water Cryptosporidium levels of 0.075 oocysts/L or higher—the level at which a filtered PWS must provide at least 4-log Cryptosporidium under today's rule. Consequently, EPA is not establishing treatment requirements in today's rule to address Cryptosporidium at this higher level. Under existing regulations (40 CFR 141.171 and 141.521), unfiltered PWSs must maintain a watershed control program that minimizes the potential for contamination by Cryptosporidium oocysts in the source water. If the measured mean Cryptosporidium level in an unfiltered PWS is 0.075 oocysts/L or higher, EPA believes the State should critically evaluate the adequacy of the watershed control program.

Under today's rule, unfiltered PWSs using ozone or chlorine dioxide to treat for Cryptosporidium must demonstrate the required 2- or 3-log inactivation every day the PWS serves water to the public, except any one day each month. Existing regulations (40 CFR 141.72(a)(1)) require unfiltered PWSs to ensure inactivation of 3-log Giardia lamblia and 4-log viruses every day except any one day per month. Consequently, today's rule extends this compliance standard to Cryptosporidium inactivation.

For unfiltered PWSs that use UV to treat for Cryptosporidium, today's rule requires demonstration of the required 2- or 3-log inactivation in at least 95 percent of the water delivered to the public every month. EPA intends this standard to be comparable to the "every day except any one day per month" standard established for ozone and chlorine dioxide. Because UV disinfection systems will typically consist of multiple reactors that will be monitored continuously, EPA believes that a compliance standard based on the percentage of water disinfected to the required level is more appropriate than a single daily measurement. Section IV.D describes an equivalent standard for filtered PWSs.

b. *Basis for requiring the use of two disinfectants.* Unfiltered PWSs must use at least two different disinfectants to meet the inactivation requirements for Cryptosporidium (2- or 3-log), Giardia lamblia (3-log) and viruses (4-log), and each of two disinfectants must achieve by itself the total inactivation required for one of these target pathogens. For example, a PWS could use UV light to achieve 3-log inactivation of Giardia lamblia and Cryptosporidium and use chlorine to provide 4-log virus inactivation. The use of two disinfectants protects public health by creating multiple barriers against microbial pathogens. This has two general advantages over a single barrier: improved reliability and a broader spectrum of efficacy.

Because unfiltered PWSs rely solely on inactivation for microbial treatment, an unfiltered PWS using only one disinfectant would provide no primary microbial treatment if that disinfection process were to fail. While disinfection processes should be designed for a high level of reliability, they are not generally 100 percent reliable. Existing regulations and today's rule recognize this limitation by allowing unfiltered PWSs to fail to achieve required disinfection levels one day per month. Consequently, EPA believes that for effective public health protection, unfiltered PWSs should use at least two primary disinfection processes. If one process fails, a second process will provide some degree of protection against pathogens.

A second advantage of a PWS using multiple disinfectants is that this approach will typically be more effective against a broad spectrum of pathogens. The efficacy of different disinfectants against different types of pathogens varies widely. For example, UV light appears to be very effective for inactivating protozoa like Cryptosporidium and Giardia lamblia, but is less effective against certain enteric viruses like adenovirus. Chlorine, however, is highly effective against enteric viruses but less effective against protozoa. As a result, multiple disinfectants will generally provide more effective inactivation of a wide range of pathogens than a single disinfectant.

c. *Filtration avoidance.* Today's rule does not withdraw or modify any existing criteria for avoiding filtration under 40 CFR 141.71. Accordingly, unfiltered PWSs must continue to comply with all existing filtration avoidance criteria. EPA believes these criteria help to ensure that watershed protection provides a microbial barrier in those PWSs that do not filter.

Further, today's rule does not establish any new criteria for filtration avoidance. In the proposed LT2ESWTR, EPA indicated that compliance with DBP standards under the Stage 2 DBPR would be incorporated into the criteria for filtration avoidance. However, EPA has not done this in today's final rule in order to give States more flexibility in working with unfiltered PWSs to comply with the Stage 2 DBPR.

3. Summary of Major Comments

EPA received significant public comment on the following treatment requirements for unfiltered PWSs in the LT2ESWTR proposal: the requirement for all unfiltered PWSs to provide at least 2-log Cryptosporidium inactivation, treatment requirements for unfiltered PWSs with high Cryptosporidium levels, and the requirement for unfiltered PWSs to use at least two disinfectants. A summary of these comments and EPA's responses follows.

Several commenters supported the requirement that all unfiltered PWSs achieve at least 2-log inactivation of Cryptosporidium, noting that this was part of the Agreement in Principle (USEPA 2000a). Some commenters, however, requested that EPA not establish a minimum Cryptosporidium treatment level due to the following factors: monitoring of unfiltered PWS sources has shown very low levels of Cryptosporidium, and some sources may have no Cryptosporidium; the Cryptosporidium in an unfiltered PWS source are likely to be of non-human origin and are less likely to infect humans; and disease incidence data have not established a link between unfiltered PWSs and cryptosporidiosis in consumers.

In response, EPA continues to believe that all unfiltered PWSs should provide treatment for Cryptosporidium to protect public health. Monitoring has shown that unfiltered PWS sources are contaminated with Cryptosporidium, and no source is likely to be entirely free of Cryptosporidium due to the ubiquity of Cryptosporidium in both human and many animal populations. Studies, such as those cited in section III, have established that Cryptosporidium from animals can infect humans. EPA does not regard the absence of cryptosporidiosis cases attributed to drinking water in a particular community as evidence that no treatment for Cryptosporidium is needed. As described in section III, cryptosporidiosis incidence data generally do not indicate overall disease burden because most cases are undetected, unreported, and not traced to a particular source.

Some commenters recommended that EPA require only 1-log Cryptosporidium inactivation for unfiltered PWSs that demonstrate source water levels below 0.001 oocysts/L. EPA does not support this approach, though, due to concerns with the reliability of monitoring to establish such an extremely low level of Cryptosporidium. In addition, UV light is a feasible technology for unfiltered PWSs of all sizes to achieve at least 2-log Cryptosporidium inactivation. For these reasons, EPA has concluded that the minimum Cryptosporidium treatment level should be 2-log, as recommended by the Advisory Committee.

In the proposed LT2ESWTR, EPA requested comment on the treatment that should be required if an unfiltered PWS measured a Cryptosporidium level of 0.075 oocysts/L or higher—the concentration at which a filtered PWS must provide at least 4-log treatment. Several commenters supported equivalent treatment requirements (i.e., at least 4-log reduction) for unfiltered and filtered PWSs with Cryptosporidium at this level. Other commenters stated that available data indicate no unfiltered PWSs are likely to measure Cryptosporidium at such a high level.

EPA agrees that available data on Cryptosporidium occurrence suggest that no unfiltered PWSs will measure a mean level of 0.075 oocysts/L or higher. Moreover, establishing a 4-log treatment requirement on the precautionary basis that an unfiltered PWS might measure a high level of Cryptosporidium has a significant cost—it would require any unfiltered PWS to provide 4-log, rather than 3-log, inactivation to avoid Cryptosporidium monitoring. EPA expects that many small unfiltered PWSs will choose to provide 3-log Cryptosporidium inactivation rather than monitor for Cryptosporidium. Accordingly, EPA has concluded that establishing a 4-log Cryptosporidium treatment requirement for unfiltered PWSs that measure a Cryptosporidium level of 0.075 oocysts/L or higher is unnecessary and inappropriate at this time. In the event that an unfiltered PWS does measure Cryptosporidium at this level, the State can require the PWS to take steps to reduce the contamination under existing watershed control program requirements for unfiltered PWSs.

Some commenters supported the requirement for unfiltered PWSs to use at least two disinfectants to meet overall inactivation requirements for Cryptosporidium, Giardia lamblia, and viruses and for each disinfectant to achieve the total inactivation required for one target pathogen. These commenters stated that this requirement will improve inactivation against a wide variety of pathogens and increase treatment reliability. Other commenters, though, opposed this requirement for a number of reasons: it will unnecessarily limit the ability of PWSs to minimize DBPs, there is no similar requirement for filtered PWSs, the requirement for each disinfectant to achieve the total inactivation for one pathogen goes beyond the Agreement in Principle, and EPA has not provided a risk analysis to justify the requirement.

In response, EPA believes that the benefits of both redundancy and a broad spectrum of microbial protection justify requiring the use of two disinfectants. Further, requiring each disinfectant to achieve the full inactivation of one target pathogen establishes a minimal performance level so that each disinfectant will serve as a substantive barrier. In most cases, PWSs will comply with this requirement by using UV or ozone to inactivate Giardia lamblia and Cryptosporidium and using chlorine to inactivate viruses.

D. Options for Systems To Meet Cryptosporidium Treatment Requirements

1. Microbial Toolbox Overview

Today's rule includes a variety of treatment and control options, collectively termed the ''microbial toolbox,'' that PWSs can implement to comply with additional Cryptosporidium treatment requirements. Options in the microbial toolbox include source protection and management programs, prefiltration processes, treatment performance programs, additional filtration components, and inactivation technologies. The Stage 2 M–DBP Advisory Committee recommended the microbial toolbox to provide PWSs with broad flexibility in selecting cost-effective LT2ESWTR compliance strategies.

Most options in the microbial toolbox carry prescribed credits toward Cryptosporidium treatment requirements. PWSs receive these credits by demonstrating compliance with required design and operational criteria, which are described in the sections that follow. In addition, States may award treatment credits other than the prescribed credit through a ''demonstration of performance,'' which involves site-specific testing by a PWS with a State-approved protocol. Under a demonstration of performance, a State may award credit to a treatment plant or to a unit process of a treatment plant that is higher or lower than the prescribed credit. This option also allows States to award credit to a unit process that does not meet the design and operational criteria in the microbial toolbox for prescribed credit.

To be eligible for treatment credit for a microbial toolbox option, PWSs must initially report compliance with design criteria, where required, to the State (some options do not require design criteria). Thereafter, for most options, PWSs must report compliance with required operational criteria to the State each month (the watershed control program option requires yearly reporting). Failure by a PWS in any month to demonstrate treatment credit equal to or greater than its Cryptosporidium treatment requirements under today's rule 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.

As described in section IV.B, filtered PWSs may use any option or combination of options from the microbial toolbox to comply with the additional Cryptosporidium treatment requirements of Bin 2. PWSs in Bins 3 or 4 must achieve at least 1-log of the additional Cryptosporidium treatment requirement by using ozone, chlorine dioxide, UV, membranes, bag filtration, cartridge filtration, or bank filtration.

If allowed by the State, PWSs may use different microbial toolbox options in different months to comply with Cryptosporidium treatment requirements under today's rule. For example, a PWS in Bin 2, which requires 1-log additional Cryptosporidium treatment, could comply with this requirement in one month using ''individual filter performance,'' which carries a 1-log credit; in a subsequent month, this PWS could use ''combined filter performance'' and ''presedimentation basin with coagulation,'' which each carry 0.5-log credit. This approach is intended to provide greater operational flexibility to PWSs. It allows a PWS to receive treatment credit for a microbial toolbox option in any month the PWS is able to meet required operational criteria, even if the PWS does not meet these criteria during all months of the year.

Table IV.D–1 summarizes prescribed treatment credits and associated design and operational criteria for microbial toolbox options. The sections that follow describe each toolbox option in detail. In addition, EPA has developed three guidance documents to assist PWSs with selecting and implementing microbial toolbox options: Toolbox Guidance Manual, UV Disinfection Guidance Manual, and Membrane Filtration Guidance Manual. Each may be acquired from EPA's Safe Drinking Water Hotline, which can be contacted as described under **FOR FURTHER INFORMATION CONTACT** at the beginning of this notice.

TABLE IV.D–1.—MICROBIAL TOOLBOX: OPTIONS, CREDITS AND CRITERIA

Toolbox option	Cryptosporidium treatment credit with design and operational criteria [1]
Source Protection and Management Toolbox Options	
Watershed control program	0.5-log credit for State-approved program comprising required elements, annual program status report to State, and regular watershed survey. Unfiltered PWSs are not eligible for credit.
Alternative source/intake management.	No prescribed credit. PWSs may conduct simultaneous monitoring for treatment bin classification at alternative intake locations or under alternative intake management strategies.
Prefiltration Toolbox Options	
Presedimentation basin with coagulation.	0.5-log credit during any month that presedimentation basins achieve a monthly mean reduction of 0.5-log or greater in turbidity or alternative State-approved performance criteria. To be eligible, basins must be operated continuously with coagulant addition and all plant flow must pass through basins.
Two-stage lime softening	0.5-log credit for two-stage softening where chemical addition and hardness precipitation occur in both stages. All plant flow must pass through both stages. Single-stage softening is credited as equivalent to conventional treatment.
Bank filtration	0.5-log credit for 25-foot setback; 1.0-log credit for 50-foot setback; horizontal and vertical wells only; aquifer must be unconsolidated sand containing at least 10 percent fines (as defined in rule); average turbidity in wells must be less than 1 NTU. PWSs using existing wells followed by filtration must monitor the well effluent to determine bin classification and are not eligible for additional credit.

TABLE IV.D–1.—MICROBIAL TOOLBOX: OPTIONS, CREDITS AND CRITERIA—Continued

Toolbox option	Cryptosporidium treatment credit with design and operational criteria [1]
Treatment Performance Toolbox Options	
Combined filter performance	0.5-log credit for combined filter effluent turbidity less than or equal to 0.15 NTU in at least 95 percent of measurements each month.
Individual filter performance	0.5-log credit (in addition to 0.5-log combined filter performance credit) if individual filter effluent turbidity is less than or equal to 0.15 NTU in at least 95 percent of samples each month in each filter and is never greater than 0.3 NTU in two consecutive measurements in any filter.
Demonstration of performance	Credit awarded to unit process or treatment train based on a demonstration to the State with a State-approved protocol.
Additional Filtration Toolbox Options	
Bag and cartridge filters	Up to 2-log credit with demonstration of at least 1-log greater removal in a challenge test when used singly. Up to 2.5-log credit with demonstration of at least 0.5-log greater removal in a challenge test when used in series.
Membrane filtration	Log credit equivalent to removal efficiency demonstrated in challenge test for device if supported by direct integrity testing.
Second stage filtration	0.5-log credit for second separate granular media filtration stage if treatment train includes coagulation prior to first filter.
Slow sand filters	2.5-log credit as a secondary filtration step; 3.0-log credit as a primary filtration process. No prior chlorination.
Inactivation Toolbox Options	
Chlorine dioxide	Log credit based on measured CT in relation to CT table.
Ozone	Log credit based on measured CT in relation to CT table.
UV	Log credit based on validated UV dose in relation to UV dose table; reactor validation testing required to establish UV dose and associated operating conditions.

[1] Table provides summary information only; refer to following preamble and regulatory language for detailed requirements.

2. Watershed Control Program

a. Today's Rule

Filtered PWSs can receive 0.5-log credit toward Cryptosporidium treatment requirements under today's rule for implementing a State-approved watershed control program designed to reduce the level of Cryptosporidium. To be eligible to receive this credit initially, PWSs must perform the following steps:

• Notify the State of the intent to develop a new or continue an existing watershed control program for Cryptosporidium treatment credit no later than two years prior to the date the PWS must comply with additional Cryptosporidium treatment requirements under today's rule.

• Submit a proposed watershed control plan to the State for approval no later than one year prior to the date the PWS must comply with additional Cryptosporidium treatment requirements under today's rule. The watershed control plan must contain these elements:

(1) The designation of an ''area of influence'' in the watershed, which is defined as the area outside of which the likelihood of Cryptosporidium contamination affecting the treatment plant intake is not significant;

(2) The identification of both potential and actual sources of Cryptosporidium contamination, including a qualitative assessment of the relative impact of these contamination sources on water quality at the treatment plant intake;

(3) An analysis of control measures that could mitigate the sources of Cryptosporidium contamination, including the relative effectiveness of control measures in reducing Cryptosporidium loading to the source water and their feasibility; and

(4) A statement of goals and specific actions the PWS will undertake to reduce source water Cryptosporidium levels, including a description of how the actions will contribute to specific goals, watershed partners and their roles, resource requirements and commitments, and a schedule for plan implementation.

If the State approves the watershed control plan for Cryptosporidium treatment credit, PWSs must perform the following steps to be eligible to maintain the credit:

• Submit an annual watershed control program status report to the State no later than a date specified by the State. The status report must describe the following: (1) how the PWS is implementing the approved watershed control plan; (2) the adequacy of the plan to meet its goals; (3) how the PWS is addressing any shortcomings in plan implementation; and (4) any significant changes that have occurred in the watershed since the last watershed sanitary survey.

• Notify the State prior to making any significant changes to the approved watershed control plan. If any change is likely to reduce the planned level of source water protection, the PWS must include in this notification a statement of actions that will be taken to mitigate this effect.

• Perform a watershed sanitary survey no less frequently than the PWS must undergo a sanitary survey under 40 CFR 142.16(b)(3)(i), which is every three to five years, and submit the survey report to the State for approval. The State may require a PWS to perform a watershed sanitary survey at an earlier date if the State determines that significant changes may have occurred in the watershed since the previous sanitary survey. A person approved by the State must conduct the watershed sanitary survey and the survey must meet applicable State guidelines. The watershed sanitary survey must encompass the area of influence as identified in the State-approved watershed control plan, assess the implementation of actions to reduce source water Cryptosporidium levels, and identify any significant new sources of Cryptosporidium.

PWSs are eligible to receive Cryptosporidium treatment credit under today's rule for preexisting watershed control programs (e.g., programs in place at the time of rule promulgation).

To be eligible for credit, such programs must meet the requirements stated in this section and the watershed control plan must address future actions that will further reduce source water Cryptosporidium levels.

If the State determines that a PWS is not implementing the approved watershed control plan (i.e., the PWS is not carrying out the actions on the schedule in the approved plan), the State may revoke the Cryptosporidium treatment credit for the watershed control program. Failure by a PWS to demonstrate treatment credit at least equal to its Cryptosporidium treatment requirement under today's rule due to such a revocation of credit is a treatment technique violation. The violation lasts until the State determines that the PWS is implementing an approved watershed control plan or is otherwise achieving the required level of Cryptosporidium treatment credit.

PWSs must make the approved watershed control plan, annual status reports, and watershed sanitary surveys available to the public upon request. These documents must be in a plain language style and include criteria by which to evaluate the success of the program in achieving plan goals. If approved by the State, the PWS may withhold portions of these documents based on security considerations.

Unfiltered PWSs are not eligible to receive Cryptosporidium treatment credit for a watershed control program under today's rule. Under existing regulations (40 CFR 141.71), unfiltered PWSs must maintain a watershed control program that minimizes the potential for contamination by Cryptosporidium as a condition for avoiding filtration.

b. Background and Analysis

Cryptosporidium enters drinking water through fecal contamination of PWS source waters. Implementing a watershed control program that reduces or treats sources of fecal contamination in PWS sources will benefit public health by lowering the exposure of drinking water consumers to Cryptosporidium and other pathogenic microorganisms. In addition, a watershed control program may enhance treatment plant management practices through generating knowledge of the sources, fate, and transport of pathogens.

The Stage 2 M–DBP Advisory Committee recommended 0.5-log Cryptosporidium treatment credit for a watershed control program (USEPA 2000a), and the August 11, 2003 proposal included criteria for PWSs to receive this credit (USEPA 2003a). The following discussion summarizes the basis for this credit and for differences in associated requirements between the proposal and today's final rule.

The efficacy of a watershed control program in reducing levels of Cryptosporidium and other microbial pathogens depends on the ability of a PWS to identify and control sources of fecal contamination. The fecal sources that are significant in a particular watershed and the control measures that will be effective in mitigating these sources are site specific. Consequently, EPA believes that States should determine whether a watershed control program developed by a PWS to reduce Cryptosporidium contamination warrants 0.5-log treatment credit. Accordingly, today's rule requires State approval of watershed control programs for PWSs to receive credit.

If a PWS intends to implement a watershed control program to comply with Cryptosporidium treatment requirements under today's rule, EPA believes the PWS should notify the State at least two years prior to the required treatment compliance date. This notification will give the State an opportunity to communicate with the PWS regarding site-specific considerations for a watershed control program. Further, the PWS should submit the proposed watershed control plan to the State for approval at least one year prior to the treatment compliance date. This schedule will give the State time to evaluate the program for approval and, if necessary, allow the PWS to make modifications necessary for approval. Thus, today's rule establishes these reporting deadlines.

The required elements for a watershed control plan in today's rule are the minimum necessary for a program that will be effective in reducing levels of Cryptosporidium and other pathogens in a treatment plant intake. These elements include defining the area of the watershed where contamination can affect the intake water quality, identifying sources of contamination within this area, evaluating control measures to reduce contamination, and developing an action plan to implement specific control measures.

EPA encourages PWSs to leverage other Federal, State, and local programs in developing the elements of their watershed control plans. For example, SDWA section 1453 requires States to carry out a source water assessment program (SWAP) for PWSs. Depending on how a State implements this program, the SWAP may be used to define the area of influence in the watershed and identify actual and potential contamination sources. In 2002, EPA launched the Watershed Initiative (67 FR 36172, May 23, 2002) (USEPA 2002b), which will provide grants to support watershed-based approaches to preventing, reducing, and eliminating water pollution. In addition, EPA recently promulgated regulations for Concentrated Animal Feeding Operations that will limit discharges that contribute microbial pathogens to watersheds.

Many PWSs do not control the watersheds of their sources of supply. Their watershed control plans should involve partnerships with watershed landowners and government agencies that have authority over activities in the watershed that may contribute Cryptosporidium to the water supply. Stakeholders that control activities that could contribute to Cryptosporidium contamination include municipal government and private operators of wastewater treatment plants, livestock farmers and persons who spread manure, individuals with failing septic systems, logging operations, and other government and commercial organizations.

After a State approves a watershed control plan for a PWS and initially awards 0.5-log Cryptosporidium treatment credit, the PWS must submit a watershed control program status report to the State each year. These reports are required for States to exercise oversight and ensure that PWSs implement the approved watershed control plan. They also provide a mechanism for PWSs to work with the States to address any shortcomings or necessary modifications in watershed control plans that are identified after plan approval.

In addition, PWSs must undergo watershed sanitary surveys every three to five years by a State-approved party. These surveys will provide information to PWSs and States regarding significant changes in the watershed that may warrant modification of the approved watershed control plan. Also, they allow for an assessment of watershed control plan implementation.

The proposed rule required watershed sanitary surveys annually, but EPA has reduced the frequency to every three to five years in today's final rule. This frequency is consistent with existing requirements for PWS sanitary surveys. EPA is establishing this longer frequency on the basis that most watersheds will not undergo significant changes over the course of a single year. If significant changes in the watershed do occur, however, PWSs must identify these changes in their annual program status reports. In addition, States have the authority to require that a watershed sanitary survey be conducted at an earlier date if the State determines that significant changes may have occurred in the watershed since the previous survey.

In the proposed rule, approval of a watershed control program expired after a PWS completed the second round of source water monitoring, and the PWS had to reapply for program approval. Today's final rule, however, does not include this requirement. Instead, today's rule gives States authority to revoke Cryptosporidium treatment credit for a watershed control program at any point if a State determines that a PWS is not implementing the approved watershed control plan. EPA believes this approach is preferable to the automatic expiration of credit in the proposed rule for two reasons: (1) It assures PWSs that if they implement the approved watershed control plan, they will maintain the treatment credit; and (2) it gives States the authority to ensure PWSs implement watershed control programs for which they receive treatment credit and to take action at any time if a PWS does not.

EPA believes that PWSs should be eligible to receive Cryptosporidium treatment credit for watershed control programs that are in place prior to the treatment compliance date. The same requirements for watershed control program treatment credit apply regardless of whether the program is new or existing at the time the PWS submits the watershed control plan for approval. In the case of existing programs, the watershed control plan must list future activities the PWS will undertake that will reduce source water contamination.

The Toolbox Guidance Manual lists programmatic resources and guidance available to assist PWSs in building partnerships and implementing watershed protection activities. It also incorporates information on the effectiveness of different control measures to reduce Cryptosporidium levels and provides case studies of watershed control programs. This guidance is intended to assist both PWSs in developing watershed control programs and States in assessing and approving these programs.

In addition to this guidance and other technical resources, EPA provides funding for watershed and source water protection through the Drinking Water State Revolving Fund (DWSRF) and Clean Water State Revolving Fund (DWSRF). Under the DWSRF program, States may fund source water protection activities by PWSs, including watershed management and pathogen source reduction plans. CWSRF funds can be used for agricultural best management practices to reduce pathogen loading in receiving waters and for the replacement of failing septic systems.

c. Summary of Major Comments

Public comments on the August 11, 2003, LT2ESWTR proposal supported the concept of awarding credit towards Cryptosporidium treatment requirements for an effective watershed control program. Commenters expressed concerns, however, with specific criteria for awarding this credit, including annual watershed sanitary surveys, re-approval of watershed control programs, standards for existing watershed control programs, and public availability of documents related to the watershed control program. A summary of these comments and EPA's responses follows.

Regarding the proposed requirement for annual watershed sanitary surveys, commenters stated that this frequency is too high because activities to reduce Cryptosporidium contamination in the watershed will often take many years to implement. These commenters recommended that watershed sanitary surveys be performed every three to five years in conjunction with PWSs sanitary surveys or longer. In contrast, other commenters supported annual watershed sanitary surveys as being necessary to allow proper responses to new sources of contamination that can occur quickly in watersheds. Such sources can occur through development, new recreation programs, fires, unauthorized activities, and other factors.

While EPA believes that regular watershed sanitary surveys are necessary to identify new sources of contamination and allow States to properly oversee watershed control programs, EPA agrees that significant changes typically will not occur over one year. Therefore, today's final rule requires PWSs that receive Cryptosporidium treatment credit for a watershed control program to undergo watershed sanitary surveys every three to five years, rather than every year. To address the concern that new sources of watershed contamination can arise quickly, today's rule requires PWSs to identify any significant changes that have occurred in their watersheds in their annual program status reports. States can then require a watershed sanitary survey at an earlier date if significant changes have occurred since the previous survey.

Many commenters opposed the proposed requirement for PWSs to reapply for approval of their watershed control programs after completing the second round of source water monitoring. The concern was that this requirement would discourage PWSs from pursuing watershed control programs because they would be uncertain about whether they would continue to receive treatment credit for their programs in the future. As an alternative, commenters recommended that States monitor the progress of PWSs in implementing watershed control programs through the watershed sanitary surveys and annual status reports. A State could then deny treatment credit to a PWS if it failed to demonstrate adequate commitment to its approved watershed control plan.

EPA agrees with these comments and today's final rule does not include a requirement for re-approval of the watershed control program after the second round of monitoring. Instead, PWSs must submit annual program status reports to the State and undergo regular watershed sanitary surveys. If the State determines that a PWS is not implementing its approved watershed control plan on the basis of these measures, it can withdraw the treatment credit associated with the program. PWSs that implement their approved watershed control plans, however, can maintain the associated treatment credit indefinitely under today's rule.

Several commenters stated that PWSs with existing watershed control programs should be eligible for Cryptosporidium treatment credit under the same standards that apply to new programs. EPA agrees that both existing and new watershed control programs should be eligible for Cryptosporidium treatment credit under the same standards, and today's rule allows this. As is required for new programs, PWSs with existing watershed control programs must submit a watershed control plan that details future activities the PWS will implement to reduce source water contamination. As with new programs, States will have the discretion to approve the proposed watershed control plan for 0.5-log Cryptosporidium treatment credit.

With respect to a proposed requirement that the watershed control plan, annual status reports, and watershed sanitary surveys be made available to the public, commenters stated that homeland security concerns are associated with these documents. Homeland security concerns apply to information on the location of treatment plant intakes and other structures. EPA agrees that there are security concerns associated with watershed control program documents. EPA also believes, though, that the public should be allowed to learn about the actions PWSs plan to take to address Cryptosporidium contamination and the progress of PWSs in implementing these actions. Consequently, today's rule requires PWSs to make the approved watershed control plan, annual status reports, and watershed sanitary surveys available to the public. However, PWSs may withhold portions of these documents that raise security concerns with State approval.

3. Alternative Source

a. Today's Rule

If approved by the State, a PWS may determine its Cryptosporidium treatment requirements under today's rule using additional source water monitoring results for an alternative treatment plant intake location or an alternative intake operational strategy. By meeting the requirements of this option, which are described as follows, a PWS may reduce its Cryptosporidium treatment requirements under today's rule.

- Monitoring for an alternative intake location or operational strategy, termed ''alternative source monitoring,'' may only be performed in addition to monitoring the existing plant intake(s) (i.e., the intake(s) the PWS uses when it must begin monitoring under today's rule).
- Alternative source monitoring must meet the sample number, sample frequency, and data quality requirements that apply to source water monitoring for bin classification, as described in section IV.A.
- PWSs that perform alternative source monitoring must complete this monitoring by the applicable deadline for treatment bin classification under today's rule, as described in section IV.G. Unless a PWS grandfathers monitoring data for the existing plant intake, alternative source monitoring must be performed concurrently with monitoring the existing intake.
- PWSs must submit the results of alternative source monitoring to the State, along with supporting information documenting the location and/or operating conditions under which the alternative source monitoring was conducted. If a PWS fulfills these requirements, the PWS may request that the State classify the PWS in a treatment bin under today's rule using the alternative source monitoring results.
- If the State approves bin classification for a PWS using alternative source monitoring results, the PWS must relocate the plant intake or implement the intake operational strategy to reflect the alternative source monitoring. The PWS must complete these actions no later than the applicable date for the PWS to comply with Cryptosporidium treatment requirements under today's rule. The State may specify reporting requirements to verify operational practices.

Failure by a PWS that is classified in a treatment bin using alternative source monitoring to relocate the intake or implement the new intake operational strategy, as required, by the applicable treatment compliance deadline is a treatment technique violation. This violation lasts until the State determines that the PWS has carried out required changes to the intake location or operation or is providing the level of Cryptosporidium treatment required for the existing intake location and operation.

b. Background and Analysis

Plant intake refers to the works or structures at the head of a conduit through which water is diverted from a source (e.g., river or lake) into a treatment plant. Plants may be able to reduce influent Cryptosporidium levels by changing the intake placement (either within the same source or to an alternate source) or managing the timing or level of withdrawal.

The Stage 2 M–DBP Advisory Committee recommended that PWSs be allowed to modify their plant intakes to comply with today's rule, and the August 11, 2003 proposal included this option (USEPA 2000a). The requirements for this option in today's final rule are unchanged from the proposal. The following discussion summarizes the basis for these requirements.

The effect of changing the location or operation of a plant intake on influent Cryptosporidium levels can only be ascertained through monitoring. Consequently, EPA is not establishing a prescriptive credit for this option. Rather, if a PWS expects that Cryptosporidium levels from a current plant intake will result in a bin classification requiring additional treatment under today's rule, the PWS may conduct additional Cryptosporidium monitoring reflecting a different intake location or operational strategy (alternative source monitoring). The PWS may then request that the State approve bin classification for the plant based on alternative source monitoring results, provided the PWS will implement the corresponding changes to the intake location or operation.

PWSs that conduct alternative source monitoring must also monitor their existing plant intakes. Monitoring the existing intake is required for the State to determine a treatment bin classification for a plant in the event the PWS does not modify the intake (to reflect alternative source monitoring) prior to the treatment compliance deadline under today's rule.

Further, PWSs must conduct alternative source monitoring within the applicable time frame for source water monitoring under today's rule. This approach is required for the State to determine a bin classification for the plant based on alternative source monitoring by the bin classification deadline. In addition, this timing will allow the PWS to modify the intake or implement additional treatment, if necessary, by the treatment compliance deadline. This requirement means, however, that unless a PWS meets the requirement for monitoring its existing intake through grandfathering, the PWS must perform alternative source monitoring concurrently with existing intake monitoring, although it does not have to be on exactly the same schedule.

Because alternative source monitoring will be used for bin classification, this monitoring must comply with all applicable requirements for source water monitoring that are described in section IV.A. Further, the PWS must provide the State with supporting information documenting the conditions, such as the source location, under which the alternative source monitoring was conducted. This documentation is required so that if bin classification is based on alternative source monitoring results, the State can ensure the PWS implements the corresponding modifications to the intake.

c. Summary of Major Comments

Public comments on the August 11, 2003, LT2ESWTR proposal supported allowing PWSs to determine treatment bin classification by monitoring for an alternative intake location or operational strategy. Several commenters stated they were unsure if this option would be widely used due to the burden of performing Cryptosporidium monitoring at both the current intake and the alternative source. Commenters also recommended that PWSs first conduct source water assessments or watershed sanitary surveys to evaluate intake management strategies to reduce Cryptosporidium levels in the plant influent.

In response, EPA believes that PWSs who choose alternative source monitoring must also monitor their current intake so that the State can determine the appropriate bin classification if the PWS does not subsequently modify its intake. While few PWSs may choose to pursue alternative source monitoring, EPA believes this option should be available for PWSs that elect to do so. EPA agrees that it is appropriate for PWSs to assess contamination sources in the watershed when considering whether to relocate or change the operation of their intakes. The Toolbox Guidance Manual provides direction to PWSs on conducting these assessments.

EPA requested comment on whether representative Cryptosporidium monitoring can be performed prior to implementation of a new intake strategy (e.g., monitoring a new source prior to constructing a new intake structure). Commenters stated that there may be situations where allowing Cryptosporidium monitoring to demonstrate a reduction in oocyst levels prior to implementation of a new intake strategy is appropriate. Incurring costs for constructing a new intake before determining whether the strategy will reduce oocyst levels is not cost effective. EPA agrees with this comment and today's rule allows PWSs to conduct alternative source monitoring prior to constructing a new intake and to base their bin classification on these monitoring results with State approval.

4. Pre-Sedimentation With Coagulant

a. Today's Rule

Presedimentation is a preliminary treatment process used to remove gravel, sand and other particulate material from the source water through settling before the water enters the primary clarification and filtration processes in a treatment plant. PWSs receive 0.5-log credit towards Cryptosporidium treatment requirements under today's rule for a presedimentation process that meets the following conditions:

• Treats all flow reaching the treatment plant;
• Continuously adds a coagulant to the presedimentation basin;
• Achieves one of the following two performance criteria:

(1) Demonstrates at least 0.5-log mean reduction of influent turbidity. This reduction must be determined using daily turbidity measurements in the presedimentation process influent and effluent and must be calculated as follows: $\log_{10}$ (monthly mean of daily influent turbidity)—$\log_{10}$ (monthly mean of daily effluent turbidity).

(2) Complies with State-approved performance criteria that demonstrate at least 0.5-log mean removal of micron-sized particulate material, such as aerobic spores, through the presedimentation process.

PWSs may receive treatment credit for a presedimentation process during any month the process meets these conditions. To be eligible for credit, PWSs must report compliance with these conditions to the State each month. PWSs may earn presedimentation treatment credit for only part of the year if the process does not meet these conditions year-round. In this situation, PWSs must fully meet their Cryptosporidium treatment requirements under today's rule using other microbial toolbox options during those months when the PWS does not receive treatment credit for presedimentation.

Alternatively, PWSs may apply to the State for Cryptosporidium treatment credit for presedimentation processes using a demonstration of performance, as described in section IV.D.9. Demonstration of performance provides an option for PWSs with presedimentation processes that do not meet these prescribed conditions for treatment credit and for PWSs who seek greater than 0.5-log Cryptosporidium treatment credit for their presedimentation processes.

PWSs are not eligible for Cryptosporidium treatment credit for a presedimentation process if their sampling point for the source water Cryptosporidium monitoring used for bin classification was after (*i.e.*, downstream of) the presedimentation process. In this case, the removal achieved by the presedimentation process will be reflected in the monitoring results and bin classification.

b. Background and Analysis

Presedimentation involves passing raw water through retention basins in which particulate material is removed through settling. PWSs use presedimentation to reduce and stabilize particle concentrations prior to the primary clarification and filtration processes in a treatment plant. Presedimentation is often operated at higher hydraulic overflow rates than conventional sedimentation (the sedimentation process that directly precedes filtration in a conventional treatment plant) and may not involve coagulant addition. PWSs may operate a presedimentation process only during periods of high raw water turbidity.

As a process for removing particles, presedimentation can reduce Cryptosporidium levels to some degree. In addition, presedimentation can improve the performance of subsequent treatment processes by dampening variability in raw water quality. The efficacy of presedimentation in removing particles, including Cryptosporidium, is influenced by the use of coagulant, the hydraulic loading rate, water quality parameters like temperature and turbidity, and physical characteristics of the sedimentation basin.

The Stage 2 M–DBP Advisory Committee recommended 0.5-log Cryptosporidium treatment credit for presedimentation with coagulation (USEPA 2000a). The August 11, 2003 proposal included criteria, which were similar to those in today's final rule, for PWSs to receive this credit (USEPA 2003a). The following discussion summarizes the basis for this credit and for differences in associated requirements between the proposal and today's final rule.

In the proposal, EPA reviewed published studies of Cryptosporidium removal through conventional sedimentation processes by Payment and Franco (1993), Kelly et al. (1995), Patania et al. (1995), States et al. (1997), Edzwald and Kelly (1998), and Dugan et al. (2001). These studies included bench-, pilot-, and full-scale processes, and the reported levels of Cryptosporidium removal varied widely, ranging from 0.4- to 3.8-log. In addition, these studies also supported two other significant findings:

(1) Proper coagulation significantly improves Cryptosporidium removal through sedimentation. In Dugan et al. (2001), for example, average Cryptosporidium removal across a sedimentation basin was 1.3-log with optimal coagulation and decreased to 0.2-log when the coagulant dose was insufficient.

(2) The removal of aerobic spores correlates well with the removal of Cryptosporidium when a coagulant is present. This indicates that aerobic spores, which are naturally present in surface waters, may be used as an indicator of Cryptosporidium removal in coagulated full-scale sedimentation processes.

Cryptosporidium removal efficiencies in conventional sedimentation may be higher than in presedimentation due to differences in hydraulic loading rates, coagulant doses, and other factors. EPA identified no published studies of Cryptosporidium removal through presedimentation processes. In the proposal, however, EPA evaluated data on the removal of aerobic spores in the presedimentation processes of three PWSs as an indicator of Cryptosporidium removal (USEPA 2003a). All three PWSs added a coagulant (polymer, metal salts, or recycled sludge) to the presedimentation process. The mean removal of aerobic spores through presedimentation in the three PWSs ranged from 0.5- to 1.1-log over time spans ranging from several months to several years.

These data support the finding that full-scale presedimentation processes can achieve Cryptosporidium removals of 0.5-log and greater under routine operating conditions and over an extended time period. Accordingly, EPA concluded that 0.5-log Cryptosporidium treatment credit for presedimentation processes is appropriate under certain conditions. Today's rule establishes three conditions for PWSs to receive this credit.

The first condition for presedimentation to receive 0.5-log Cryptosporidium treatment credit is that the process must treat all flow reaching the treatment plant. Presedimentation cannot reduce the Cryptosporidium level entering a treatment plant by 0.5-log or greater on a continuous basis if the process is operated intermittently or treats only a fraction of the plant flow. EPA recognizes that for some PWSs, operating a presedimentation process intermittently in response to high turbidity levels is preferable to continuous operation. By establishing a requirement for continuous operation as a condition for treatment credit, EPA is not recommending against intermittent operation of presedimentation processes. Rather, EPA is only identifying one of the conditions under which a 0.5-log Cryptosporidium treatment credit for presedimentation appears to be justified.

A second condition for presedimentation treatment credit is that the process must operate with coagulant addition. Available data support awarding 0.5-log Cryptosporidium treatment credit to a presedimentation process only when a coagulant is present. The full-scale presedimentation data reviewed in the proposal involved coagulant addition, and literature studies indicate that Cryptosporidium removal through sedimentation can be substantially lower in the absence of sufficient coagulant. Further, the Stage 2 M–DBP Advisory Committee specifically recommended 0.5-log Cryptosporidium treatment credit for presedimentation with coagulation (USEPA 2000a). Based on these factors, EPA concluded that coagulation is a necessary condition for PWSs to receive treatment credit for presedimentation.

The third condition for awarding treatment credit to presedimentation is that the process must achieve a monthly mean turbidity reduction of at least 0.5-log or meet alternative State-approved performance criteria. This requirement stems from a recommendation by the SAB, which reviewed data for awarding treatment credit to presedimentation under the LT2ESWTR. In their report, the SAB concluded that available data were minimal to support 0.5-log prescribed credit for presedimentation and recommended that performance criteria other than overflow rate be included if credit is given for presedimentation (SAB 2003).

In response to this recommendation by the SAB, EPA analyzed the relationship between removal of aerobic spores (as an indicator of Cryptosporidium removal) and reduction in turbidity in the full-scale presedimentation processes of three PWSs. The results of this analysis, which are shown in Table IV.D–2, suggest that presedimentation processes achieving a monthly mean reduction in turbidity of at least 0.5-log have a high likelihood of reducing mean Cryptosporidium levels by 0.5-log or more. Consequently, EPA concluded that turbidity reduction is an appropriate performance criterion for awarding Cryptosporidium treatment credit to presedimentation basins. The Agency believes this performance criterion addresses the concern raised by the SAB.

TABLE IV.D–2.—RELATIONSHIP BETWEEN MEAN TURBIDITY REDUCTION AND THE PERCENT OF MONTHS WHEN MEAN SPORE REMOVAL WAS AT LEAST 0.5 LOG

Log reduction in turbidity (monthly mean)	Percent of months with at least 0.5 Log Mean Reduction in spores (percent)
at least 0.1-log	64
at least 0.2-log	68
at least 0.3-log	73
at least 0.4-log	78
at least 0.5-log	89
at least 0.6-log	91
at least 0.7-log	90
at least 0.8-log	89
at least 0.9-log	95
at least 1.0-log	96

Source: Data from Cincinnati Water Works, Kansas City Water Services Department, and St. Louis Water Division.

The proposed rule required PWSs to achieve at least 0.5-log turbidity reduction through presedimentation in at least 11 of the 12 previous consecutive months to be eligible for presedimentation treatment credit. EPA recognizes, however, that some PWSs will not be able to demonstrate at least 0.5-log turbidity reduction through presedimentation during months when raw water turbidity is lower. As a result, these PWSs would not be able to achieve treatment credit for their presedimentation basins. To provide more options for these PWSs, EPA has modified this requirement in today's final rule in two respects.

The first modification is that in today's final rule, PWSs must demonstrate compliance with the conditions for presedimentation treatment credit on a monthly, rather that a yearly basis. This requirement allows treatment credit for presedimentation in any month a PWS can demonstrate at least 0.5-log turbidity reduction, even if the PWS cannot achieve this level of turbidity reduction in all months of the year.

A PWS that meets the conditions for presedimentation treatment credit for only part of the year must implement other microbial toolbox options to comply with Cryptosporidium treatment requirements in the remainder of the year. Nevertheless, achieving presedimentation treatment credit for even part of the year may benefit certain PWSs. For example, a PWS may be able to reduce the level of disinfection it provides during the months it receives presedimentation treatment credit, or this treatment credit may provide a margin of safety to ensure compliance with Cryptosporidium treatment requirements.

The second modification is the allowance for States to approve alternative performance criteria to turbidity reduction that demonstrate at least 0.5-log mean removal of micron-sized particulate material through the presedimentation process. EPA believes that aerobic spores are an appropriate alternative criterion. As described earlier, studies support the use of aerobic spores as an indicator of Cryptosporidium removal in coagulated sedimentation processes. If approved by the State, a PWS could receive 0.5-log treatment credit for presedimentation by demonstrating at least 0.5-log reduction in aerobic spores. The Toolbox Guidance Manual provides information on analytical methods for measuring aerobic spores. This may provide an option for PWSs that are not able to demonstrate 0.5-log turbidity reduction but have a sufficient concentration of aerobic spores in their raw water. PWSs may work with States to identify other alternative criteria, as well as appropriate monitoring to support use of the criteria.

c. Summary of Major Comments

Public comments on the August 11, 2003, LT2ESWTR proposal supported allowing PWSs to achieve 0.5-log credit towards Cryptosporidium treatment requirements for presedimentation with coagulation. Some commenters also supported the proposed operational, monitoring, and performance conditions required for PWSs to receive this credit. Other commenters, however, opposed the proposed requirement for turbidity reduction as a condition for receiving presedimentation treatment credit. A summary of these commenters' concerns and EPA's responses follows.

Commenters who opposed requiring turbidity reduction for presedimentation treatment credit were concerned that PWSs cannot achieve this criterion during periods when raw water turbidity is low. Further, these commenters stated that turbidity removal does not reflect the overall benefits of presedimentation, which improves the performance of the primary treatment train by equalizing water quality. Some commenters also provided data showing the reduction in turbidity and aerobic spore levels in the presedimentation processes of several PWSs and stated that turbidity removal may not be an appropriate indicator of acceptable performance for presedimentation basins. Several commenters suggested that EPA establish a limit on hydraulic overflow rate in place of a turbidity removal requirement.

In response, EPA continues to believes that 0.5-log turbidity reduction is an appropriate performance indicator for 0.5-log Cryptosporidium reduction in presedimentation processes. EPA has reviewed the additional data submitted by commenters on the removal of turbidity and aerobic spores (as an indicator of Cryptosporidium removal) in full-scale presedimentation basins. These data are consistent with data reviewed for the proposal in showing that when turbidity removal was below 0.5-log, removal of aerobic spores was also usually below 0.5-log. Conversely, when turbidity reduction exceeded 0.5-log, aerobic spore removal was typically higher than 0.5-log. Consequently, while there is not a one-to-one relationship between reduction in turbidity and reduction in aerobic spores, 0.5-log turbidity reduction is a reasonable indicator of when Cryptosporidium removal is likely to be at least 0.5-log.

EPA recognizes, though, that 0.5-log turbidity reduction through presedimentation will not be feasible for some PWSs when raw water turbidity is low. Today's final rule contains several provisions to address this concern. First, PWSs can receive credit for presedimentation during any month the process achieves 0.5-log turbidity removal. Thus, PWSs that cannot achieve 0.5-log turbidity reduction year-round may receive credit for presedimentation in those months when they can meet this condition. Today's rule also allows PWSs to receive presedimentation credit using State-approved performance criteria other than turbidity reduction. If approved by the State, a PWS may receive credit for presedimentation by demonstrating, for example, 0.5-log reduction in aerobic spores. Finally, if presedimentation improves treatment plant performance by reducing and equalizing particle loading, a PWS can receive additional treatment credit under today's rule for achieving lower filtered water turbidity (see section IV.D.7).

5. Two-Stage Lime Softening

a. Today's Rule

Lime softening in drinking water treatment involves the addition of lime and other chemicals to remove hardness (calcium and magnesium) through precipitation. In single-stage softening, chemical addition and hardness precipitation occur in a single clarification process prior to filtration. In two-stage softening, chemical addition and hardness precipitation occur in each of two sequential clarification processes prior to filtration. In some water treatment plants, a portion of the raw water bypasses a softening process (i.e., split softening) in order to achieve a desired pH and alkalinity level in the treated water.

Under today's rule, single-stage softening with filtration receives a prescribed 3.0-log credit towards Cryptosporidium treatment requirements, which is equivalent to conventional treatment (see section IV.B). Two-stage softening receives an additional 0.5-log Cryptosporidium treatment credit during any month a PWS meets the following conditions:

(1) Chemical addition and hardness precipitation occur in two separate and sequential softening stages prior to filtration; and

(2) Both softening stages treat the entire plant flow taken from surface water sources or GWUDI (i.e., no portion of the plant flow from a surface water source may bypass either softening stage).

Alternatively, PWSs may apply to the State for Cryptosporidium treatment credit for softening processes using a demonstration of performance, as described in section IV.D.9. Demonstration of performance provides an option for PWSs with softening processes that do not meet these conditions for prescribed treatment credit and for PWSs who seek greater than the prescribed Cryptosporidium treatment credit for their softening processes.

b. Background and Analysis

Lime softening is a common practice that PWSs use to reduce water hardness, which is primarily calcium and magnesium. The addition of lime elevates the pH of the raw water. Elevation to pH 9.4 or higher causes precipitation of calcium carbonate and further elevation to pH 10.6 or higher causes precipitation of magnesium hydroxide. Soda ash may be added with lime to precipitate non-carbonate hardness. Removal of the precipitate occurs through clarification (e.g., sedimentation basin) and filtration processes. Coagulants and recycled softening sludge are often used to enhance removal. In two-stage softening, the second stage is commonly used to precipitate magnesium, along with increased levels of calcium.

In addition to reducing hardness, softening processes remove particulate material present in the raw water, including microbial pathogens like Cryptosporidium. Particulate material flocculates with the softening precipitate and is removed through the clarification and filtration processes, similar to a conventional treatment plant. The degree of Cryptosporidium removal will depend on the amount of precipitate formation, the use of coagulants, the raw water quality, and other factors. Available data indicate that the elevated pH used in softening does not inactivate Cryptosporidium or Giardia (Logsdon et al. 1994, Li et al. 2001), though it does inactivate some microorganisms like viruses (Battigelli and Sobsey, 1993, Logsdon et al. 1994).

The Stage 2 M–DBP Advisory Committee recommended that lime softening be eligible for up to 1.0-log additional Cryptosporidium treatment credit based on a site-specific demonstration of performance, but did not recommend any prescribed credit for this process (USEPA 2000a). After reviewing available data, however, EPA included a prescribed 0.5-log Cryptosporidium treatment credit for two-stage lime softening in the August 11, 2003 proposal (USEPA 2003a). This approach reflected a recommendation by the SAB, which supported an additional 0.5-log treatment credit for two-stage lime softening if all the water passes through both stages (SAB 2003). The proposal also allowed for greater treatment credit through a demonstration of performance. The following discussion summarizes the basis for the lime softening treatment credit in today's final rule and differences with the proposal.

In the proposal, EPA reviewed a study by Logsdon et al. (1994) that evaluated

Cryptosporidium removal in full-scale lime softening plants. Cryptosporidium was detected in the raw water at 5 plants: one single-stage plant and four two-stage plants. Based on measured levels, the removal of Cryptosporidium across the softening clarification (sedimentation) stages was 1.0-log in the single stage plant and ranged from 1.1- to 2.3-log in the two-stage plants. Cryptosporidium reductions from raw to filtered water were 0.6- and 2.2-log in the single stage plant and ranged from greater than 2.67- to greater than 3.85-log in the two-stage plants.

EPA also evaluated data collected by PWSs on the removal of aerobic spores in full-scale lime softening plants. As discussed earlier, studies have shown the removal of aerobic spores to be an indicator for Cryptosporidium removal, and one pilot-scale study of a softening plant found significantly greater removal of Cryptosporidium than aerobic spores under similar treatment conditions (Clark et al., 2001). For the full-scale plants, average reductions in aerobic spores across the softening clarification stages were 2.4- and 2.8-log for two plants that practice two-stage softening and were 1.6- and 2.4-log for two plants that practice single-stage softening (USEPA 2003a).

The Cryptosporidium removal data from Logsdon et al. (1994) and the aerobic spore removal data provided by PWSs indicate that a lime softening clarification stage can achieve greater than 0.5-log Cryptosporidium removal during routine operation. Consequently, EPA agrees with the SAB recommendation to award an additional 0.5-log Cryptosporidium treatment credit for two-stage softening. Today's rule establishes two-conditions for PWSs to receive this credit.

The first condition for 0.5-log treatment credit for two-stage softening is that chemical addition and hardness precipitation must occur in two separate and sequential softening stages prior to filtration. The purpose of this condition is to ensure that plants receiving additional credit for two-stage softening actually have softening and associated particle removal occurring in each of two sequential clarification stages. Plants with other types of clarification processes in series with a softening stage are not eligible for two-stage softening credit. Such plants may, however, be eligible for additional treatment credit for other microbial toolbox options, such as presedimentation, or may achieve additional credit through a demonstration of performance.

The second condition for two-stage softening treatment credit is that both softening stages must treat the entire plant flow taken from a surface water source or GWUDI. The SAB recommended this condition, which reflects the understanding that a softening stage is unlikely to reduce overall Cryptosporidium levels by 0.5-log or more if it treats only a fraction of the plant flow.

EPA recognizes that some PWSs using softening will bypass a softening stage in order to maintain a desired pH and alkalinity level in the treated water, and EPA is not recommending against this practice generally. Rather, the restriction on bypassing a softening stage in today's rule applies only to PWSs that seek additional treatment credit for softening. Additionally, plants that soften both surface water and ground water are eligible for softening treatment credit if they bypass a softening stage only with ground water that is not under the direct influence of surface water.

The proposal also required that a coagulant be present in both clarifiers for a PWS to be eligible for additional treatment credit for two-stage softening. EPA is not establishing this requirement in today's final rule. While many PWSs that practice softening add coagulants to improve the removal of precipitates and other particles, the SAB did not recommend coagulant addition as a condition for receiving treatment credit. Further, available data do not indicate that additional coagulant is necessary to achieve at least 0.5-log Cryptosporidium removal across a softening clarification stage if hardness precipitation is occurring.

c. Summary of Major Comments

Public comments on the August 11, 2003, LT2ESWTR proposal supported awarding additional Cryptosporidium treatment credit for lime softening processes. EPA received specific comments on the types of lime softening processes eligible for additional treatment credit, the amount of additional treatment credit awarded, and the need for a coagulant. A summary of these commenters' concerns and EPA's responses follows.

In regard to the types of lime softening processes eligible for treatment credit, commenters recommended that EPA better define two-stage softening. Commenters stated that two-stage softening involves two separate reaction chambers with the addition of the softening chemical at the beginning of each chamber. Some commenters recommended that eligibility for additional treatment credit should be based on the level of softening precipitate formed or the settled water turbidity and not on whether a plant practices single- or two-stage softening. Another commenter recommended that any plant designs with multiple, continuously operated clarification processes in series should be eligible for additional treatment credit.

In response, EPA has refined the definition of two-stage softening in today's final rule, which requires that softening processes employ chemical addition and hardness precipitation in two sequential stages to be eligible for the prescribed additional treatment credit. EPA agrees with commenters that the level of precipitate formation will influence the degree of Cryptosporidium removal. Available data, however, indicate that two-stage softening will generally achieve more Cryptosporidium removal than single-stage softening. Consequently, EPA believes that two-stage softening should be eligible for the additional prescribed 0.5-log treatment credit. Plants with single-stage softening may receive additional treatment credit under today's rule through a demonstration of performance. Similarly, plants that employ multiple clarification process other than softening in series may receive additional treatment credit either as presedimentation or through a demonstration of performance.

With respect to the amount of additional Cryptosporidium treatment credit for two-stage softening, most commenters supported awarding 3.0-log treatment credit to single-stage lime softening, equivalent to a conventional treatment plant, and an additional prescribed 0.5-log treatment credit for two-stage lime softening. A few commenters requested that two-stage lime be granted an additional Cryptosporidium treatment credit of 1.0-log, based on the level of aerobic spore removal measured across softening clarifiers.

EPA agrees with most commenters and the SAB that 0.5-log is an appropriate level of additional prescribed Cryptosporidium treatment credit for two-stage softening. Where plants are able to demonstrate a significantly higher level of removal of Cryptosporidium or an indicator like aerobic spores, they may apply for additional treatment credit through a demonstration of performance.

Commenters stated that achieving particle removal in lime softening is not dependent on a coagulant like a metal salt or organic polymer. Some commenters recommended that coagulant be defined to include softening chemicals like lime and magnesium hydroxide (a softening precipitate). EPA agrees that available data do not demonstrate the need for a traditional metal salt or organic coagulant for effective particle removal in softening. Accordingly, today's final rule does not require the use of a coagulant as a condition for additional treatment credit in two-stage softening. Instead, each stage must involve chemical addition and hardness precipitation. EPA intends this requirement to ensure that softening and associated particle removal occur in each stage if a plant is to receive additional treatment credit for two-stage softening.

6. Bank Filtration

a. Today's Rule

Bank filtration is a water treatment process that uses one or more pumping wells to induce or enhance natural surface water infiltration and to recover that surface water from the subsurface after passage through a river bed or bank(s). Under today's rule, bank filtration that serves as pretreatment to a filtration plant is eligible for Cryptosporidium treatment credit if it meets the following criteria:

• Wells with a ground water flow path of at least 25 feet receive 0.5-log treatment credit; wells with a ground water flow path of at least 50 feet receive 1.0-log treatment credit. The ground water flow path must be determined as specified in this section.

• Only wells in granular aquifers are eligible for treatment credit. Granular aquifers are those comprised of sand, clay, silt, rock fragments, pebbles or larger particles, and minor cement. A system must characterize the aquifer at the well site to determine aquifer properties. Systems must extract a core from the aquifer and demonstrate that in at least 90 percent of the core length, grains less than 1.0 mm in diameter constitute at least 10 percent of the core material.

• Only horizontal and vertical wells are eligible for treatment credit.

• For vertical wells, the ground water flow path is the measured distance from the edge of the surface water body under high flow conditions (determined by the 100 year floodplain elevation boundary or by the floodway, as defined in Federal Emergency Management Agency flood hazard maps) to the well screen. For horizontal wells, the ground water flow path is the measured distance from the bed of the river under normal flow conditions to the closest horizontal well lateral screen.

• Systems must monitor each wellhead for turbidity at least once every four hours while the bank filtration process is in operation. If monthly average turbidity levels, based on daily maximum values in the well, exceed 1 NTU, the system must report this result to the State and conduct an assessment within 30 days to determine the cause of the high turbidity levels in the well. If the State determines that microbial removal has been compromised, the State may revoke treatment credit until the system implements corrective actions approved by the State to remediate the problem.

• Springs and infiltration galleries are not eligible for treatment credit under this section, but are eligible for credit under the demonstration of performance provisions described in section IV.D.9.

Alternatively, PWSs may apply to the State for Cryptosporidium treatment credit for bank filtration using a demonstration of performance. States may award greater than 1.0-log Cryptosporidium treatment credit for bank filtration based on a site-specific demonstration. For a bank filtration demonstration of performance study, today's rule establishes the following criteria:

• The study must follow a State-approved protocol and must involve the collection of data on the removal of Cryptosporidium or a surrogate for Cryptosporidium and related hydrogeologic and water quality parameters during the full range of operating conditions.

• The study must include sampling both from the production well(s) and from monitoring wells that are screened and located along the shortest flow path between the surface water source and the production well(s).

The Toolbox Guidance Manual provides guidance on conducting site-specific bank filtration studies, including analytical methods for measuring aerobic and anaerobic spores, which may serve as surrogates for Cryptosporidium removal.

PWSs using existing bank filtration as pretreatment to a filtration plant at the time the PWS must begin source water Cryptosporidium monitoring under today's rule must sample the well for the purpose of determining bin classification. These PWSs are not eligible to receive additional treatment credit for bank filtration. In these cases, the performance of the bank filtration process in reducing Cryptosporidium levels will be reflected in the monitoring results and bin classification.

PWSs using bank filtration without additional filtration must collect source water samples in the surface water (i.e., prior to bank filtration) to determine bin classification unless the State approves an alternative monitoring location. This applies to systems using bank filtration to meet the Cryptosporidium removal requirements of the IESWTR or LT1ESWTR under the provisions for alternative filtration demonstration in 40 CFR 141.173(b) or 141.552(a). Bank filtration criteria for Cryptosporidium removal credit under today's rule do not apply to existing State actions regarding alternative filtration Cryptosporidium removal credit for IESWTR or LT1ESWTR compliance. PWSs using GWUDI sources must collect samples from the well (i.e., the ground water).

b. Background and Analysis

Bank filtration is a water treatment process that makes use of surface water that has naturally infiltrated into ground water through a river bed or bank and is recovered via a pumping well. River bed infiltration is typically enhanced by the pumping action of nearby wells. Bank filtrate is water that is drawn into a pumping well from a nearby surface water source after having traveled through the subsurface (i.e., aquifer) and mixing with other ground water. In bank filtration, microorganisms and other particles are removed by contact with the aquifer materials.

The Stage 2 M–DBP Advisory Committee recommended a prescribed Cryptosporidium treatment credit of 1.0-log for bank filtration with the option for PWSs to receive greater treatment credit through a site-specific demonstration of performance (USEPA 2000a). The August 11, 2003 proposal included criteria, similar to those in today's final rule, for PWSs to receive prescribed treatment credits of 0.5- and 1.0-log (USEPA 2000a). The following discussion summarizes the basis for these credits and for differences in associated requirements between the proposal and today's final rule.

Directly measuring the removal of Cryptosporidium through bank filtration is difficult due to the relatively low oocyst concentrations typically present in surface and ground water. In the proposal, EPA reviewed bank filtration field studies that measured the removal of Cryptosporidium surrogates, specifically aerobic and anaerobic bacterial endospores (Havelaar et al. 1995, Rice et al. 1996, Pang et al. 1998, Arora et al. 2000, Medema et al. 2000, and Wang et al. 2001). These microorganisms are suitable surrogates because they are resistant to inactivation in the subsurface, similar in size and shape to Cryptosporidium, and present in both surface and ground water at concentrations that allow calculation of log removal across the surface water-ground water interface and within the aquifer. In addition, EPA reviewed studies of the transport of Cryptosporidium through soil materials in laboratory column studies (Harter et al. 2000).

Based on these studies, EPA concluded that bank filtration processes can achieve significant Cryptosporidium removal and that prescribed Cryptosporidium treatment credits of 0.5-log and 1.0-log are appropriate under certain conditions. These conditions are as follows: Only wells located in unconsolidated, predominantly sandy aquifers are eligible

The bank filtration removal process performs most efficiently when the aquifer is comprised of granular materials with open pore-space for water flow around the grains. In these granular porous aquifers, the flow path is meandering, thereby providing ample opportunity for microorganisms to come into contact with and attach to a grain surface. Accordingly, only wells located in unconsolidated, granular aquifers are eligible for bank filtration treatment credit.

Granular aquifers are those comprised of sand, clay, silt, rock fragments, pebbles or larger particles and minor cement. Specifically, a PWS must extract a core from the aquifer and demonstrate that in at least 90 percent of the core length, grains less than 1.0 mm in diameter constitute at least 10 percent of the core material. Laboratory column studies of Cryptosporidium transport (Harter et al., 2000) and field studies of aerobic bacterial endospore passage in the subsurface (Pang et al., 1998) support these criteria.

Only Horizontal and Vertical Wells Are Eligible

A number of devices are used for the collection of ground water including horizontal and vertical wells, spring boxes, and infiltration galleries. Among these, only horizontal and vertical wells are eligible for log removal credit because spring boxes and infiltration galleries are components of engineered systems designed to speed transport through or by-pass the naturally protective riverbed or bank.

Wells Must be Located 25 Feet From the Surface Water Source To Be Eligible for 0.5-Log Credit and Located at Least 50 Feet From the Surface Water Source To Be Eligible for 1.0-Log Credit

A vertical or horizontal well located adjacent to a surface water body is eligible for bank filtration credit if there is sufficient ground water flow path length to effectively remove oocysts. Specifically, the ground water flow path must be at least 25 feet and 50 feet for 0.5-log and 1.0-log Cryptosporidium treatment credit, respectively. The ground water flow path to a vertical well is the measured distance from the edge of the surface water body under high flow conditions (determined by the 100 year floodplain elevation boundary or floodway, as defined in Federal Emergency Management Agency flood hazard maps) to the wellhead. The ground water flow path to a horizontal well is the measured distance from the bed of the river under normal flow conditions to the closest horizontal well lateral.

These required flow path distances for Cryptosporidium treatment credit are based on pathogen and surrogate monitoring data from bank filtration field studies (Wang et al. 2001, Havelaar et al. 1995, Medema et al. 2000). Results from these studies show that significant removal of anaerobic and aerobic spores can occur during passage across the surface water—ground water interface, with lesser removal occurring during ground water transport within the aquifer away from that interface. The ground water—surface water interface is usually comprised of finer grained material that lines the bottom of the riverbed. Typically, the thickness of the interface is small, ranging from a few inches to a foot.

These results suggest that during normal and low surface water elevations, the surface water-ground water interface will perform effectively to remove microbial contamination like Cryptosporidium. During short periods of flooding, substantially lower removal rates may occur due to scouring of the riverbed and removal of the protective, fine-grained material. Assessing the mean Cryptosporidium removal that a bank filtration process will achieve over the period of a year requires consideration of both high and low removal periods. By considering all time intervals with differing removal rates over the period of a year, EPA concluded that 0.5-log removal over 25 feet and 1.0-log removal over 50 feet are appropriate estimates of the mean performance of a bank filtration process (USEPA 2003a).

Wells Must Be Continuously Monitored for Turbidity

Similar pathogen removal mechanisms are expected to occur in slow sand filtration and bank filtration. Under the 40 CFR 141.73(b)(1), the turbidity level of slow sand filtered water must be 1 NTU or less in 95 percent of the measurements taken each month. Turbidity sampling is required once every four hours, but may be reduced to once per day under certain conditions. Just as turbidity monitoring is used to provide assurance that the removal credit assigned to a slow sand filter is being realized, today's rule requires turbidity monitoring at least once every 4 hours for all bank filtration wells that receive treatment credit.

If monthly average turbidity levels (based on daily maximum values in the well) exceed 1 NTU, the PWS must report this result to the State and conduct an assessment to determine the cause of the high turbidity levels in the well. If the State determines that microbial removal has been compromised, the State may revoke treatment credit until the PWS implements corrective actions to remediate the problem.

Demonstration of Performance

EPA recognizes that some bank filtration processes may achieve mean Cryptosporidium removal greater than 1-log. Consequently, today's rule allows PWSs to receive greater than 1.0-log Cryptosporidium treatment credit for bank filtration through a State-approved demonstration of performance study. This allowance is a change from the proposed rule, which did not explicitly recognize demonstration of performance for bank filtration (USEPA 2003a). This change reflects EPA's agreement with public comment, described next, which recommended that EPA explicitly recognize the option to conduct a bank filtration performance study for greater than 1.0-log treatment credit.

A demonstration of performance study must involve the collection of data on the removal of Cryptosporidium or surrogates and related hydrogeologic and water quality parameters during the full range of operating conditions. PWSs must sample from both the production well(s) and one or more monitoring wells that are screened and located along the shortest flow path between the surface water and the production well(s). This will allow determination of the removal efficiency of the aquifer.

Because directly measuring Cryptosporidium removal will not be feasible for most PWSs, today's rule allows PWSs to sample for a State-approved indicator, such as aerobic bacterial endospores. Research has shown that aerobic spores can be very mobile in the subsurface environment (Pang et al. 1998), and data collected by Wang et al. (2001) indicate that aerobic spores are present in some surface waters in sufficient quantity to allow measurement of log removal values.

EPA has provided guidance on conducting site-specific bank filtration studies in the Toolbox Guidance Manual. This guidance discusses data needs and analysis for a performance demonstration so that the State may tailor the study plan to meet site-specific hydrogeological and operational conditions.

In summary, EPA believes that full-scale field data support prescribed Cryptosporidium treatment credit up to 1.0-log for bank filtration under the required conditions for set-back distance, aquifer material, collection device type, and turbidity monitoring. Demonstration of performance provides an appropriate opportunity for States to award higher Cryptosporidium treatment credit for bank filtration on a site-specific basis.

For PWSs using bank filtration when they must conduct source water monitoring for bin classification, the required sampling locations reflect the intent for this monitoring to capture the level of Cryptosporidium entering a PWS's primary filtration treatment process. Where bank filtration serves as pretreatment to a filtration plant, PWSs must collect source water samples after bank filtration but prior to the filtration plant. In this case, the Cryptosporidium removal that bank filtration achieves will be reflected in the monitoring results and bin classification for the filtration plant. In contrast, where bank filtration is the primary filtration process, meaning that a PWS uses bank filtration to comply with the Cryptosporidium treatment requirements of the IESWTR or LT1ESWTR, PWSs must collect samples in the surface water source (e.g, the river).

c. Summary of Major Comments

Public comments on the August 11, 2003, LT2ESWTR proposal supported awarding Cryptosporidium treatment credit for bank filtration. Many commenters, however, stated that the proposed levels of credit (0.5- and 1.0-log) were insufficient. To address this issue, commenters supported allowing PWSs to obtain greater treatment credit by performing a site-specific study of bank filtration removal efficiency. Commenters recommended that site-specific bank filtration studies involve the measurement of surrogates for Cryptosporidium removal using monitoring wells located along the shortest flow path between the surface water and the production well.

EPA agrees that some bank filtration sites may achieve greater than 1.0-log Cryptosporidium removal. Today's rule establishes the proposed bank filtration Cryptosporidium treatment credits of 0.5- and 1.0-log and allows PWSs to apply to the State for higher levels of credit through a site-specific demonstration of performance. In such a study, PWSs must measure the removal of Cryptosporidium or a State-approved surrogate using monitoring wells located along the flow path, as recommended by commenters.

Some commenters cited research addressing appropriate surrogate organisms for estimating Cryptosporidium removal in surface water treatment plants and bank filtration sites. Commenters recommended that EPA recognize aerobic endospores as a surrogate measure in Cryptosporidium removal studies, including those for bank filtration.

EPA agrees that based on available information, aerobic spores are suitable Cryptosporidium removal surrogates for bank filtration processes due to their size, resistance to inactivation, and concentration in surface and ground waters. Data from several bank filtration sites on the use of aerobic spores as a Cryptosporidium removal surrogate are available. The Toolbox Guidance Manual identifies aerobic spores as suitable in conjunction with other hydrogeologic data for making site-specific determinations for additional Cryptosporidium removal credit.

In guidance, EPA suggests that where feasible, PWSs measure diatom species in conjunction with aerobic spores in bank filtration studies because Cryptosporidium oocysts are intermediate in size between the two surrogate groups. Further, EPA recognizes the current uncertainties and limitations in available information on surrogates for bank filtration and will update guidance as warranted by new information.

7. Combined Filter Performance

a. Today's Rule

For water treatment plants that use filtration, the turbidity of the filtered water is an indicator of how effectively the plant is removing particulate matter, including microbial pathogens, from the raw water. PWSs using conventional filtration treatment or direct filtration receive an additional 0.5-log Cryptosporidium treatment credit during any month the PWS meets the following standard:

- The turbidity level of representative samples of a PWS's filtered water (i.e., the combined filter effluent) is less than or equal to 0.15 NTU in at least 95 percent of the measurements taken each month. PWSs must continue to measure turbidity as specified in 40 CFR 141.74(a) and (c), which generally require sampling at least every four hours using approved methods.

PWSs using other types of filtration processes, including slow sand, diatomaceous earth, membranes, bag, or cartridge filtration, are not eligible for this treatment credit.

b. Background and Analysis

Turbidity is a method defined parameter that is based on measuring the amount of light scattered by suspended particles in a solution. This measure can detect the presence of a wide variety of particles in water, including microorganisms, but cannot provide specific information on particle type, number, or size. In filtered water, the turbidity level indicates how well the filtration and other upstream clarification processes have performed in removing particles from the raw water, with lower turbidity indicating better particle removal. Thus, lower filtered water turbidity is associated with a decreased likelihood that microbial pathogens like Cryptosporidium have passed through the filtration plant and into the water distributed to consumers.

Under existing regulations, PWSs that filter must monitor turbidity in the combined filter effluent (CFE) at least every four hours using approved methods, although States may reduce this frequency to once per day for PWSs serving 500 people or fewer (40 CFR 141.74(a) and (c)). For PWSs using conventional or direct filtration, at least 95 percent of the CFE turbidity measurements must be less than or equal to 0.3 NTU, and the turbidity must never exceed 1 NTU (40 CFR 141.173(a) and 141.551(a)–(b)).

The Stage 2 M–DBP Advisory Committee recommended an additional 0.5-log Cryptosporidium treatment credit for PWSs that achieve a CFE turbidity less than or equal to 0.15 NTU in at least 95 percent of measurements per month (USEPA 2000a). This 95th percentile turbidity standard is one half the level required under existing regulations for PWSs using conventional or direct filtration, as stated earlier. The August 11, 2003 proposal included this treatment credit for PWSs using conventional or direct filtration (USEPA 2003a), and EPA is establishing it in today's final rule with no changes from the proposal. The following discussion summarizes the basis for this treatment credit.

In the proposal, EPA analyzed the improvement in Cryptosporidium removal that conventional and direct filtration plants realize when operating at lower effluent turbidity levels. For this analysis, EPA estimated that PWSs complying with the existing 95th percentile CFE turbidity standard of 0.3 NTU will typically operate with filter effluent turbidity between 0.1–0.2 NTU; PWSs complying with a CFE standard of 0.15 NTU were estimated to operate with filter effluent turbidity less than 0.1 NTU. Accordingly, EPA compared Cryptosporidium removal efficiencies when effluent turbidity was below 0.1 NTU with those when effluent turbidity was in the range of 0.1–0.2 NTU.

Studies by Patania et al. (1995), Emelko et al. (1999), and Dugan et al. (2001) observed the average removal of Cryptosporidium to be 0.5-to 1.2-log greater when filter effluent turbidity was less than 0.1 NTU in comparison to removal with effluent turbidity between 0.1–0.2 NTU. These studies, therefore, indicate that PWSs complying with a filter effluent turbidity standard of 0.15 NTU will achieve at least 0.5-log greater Cryptosporidium removal than PWSs complying with the existing 0.3 NTU standard. Based on this finding, EPA concluded that an additional 0.5-log Cryptosporidium treatment credit is appropriate for PWSs using conventional or direct filtration that meet a 95th percentile CFE turbidity standard of 0.15 NTU.

Other types of filtration processes, such as slow sand, diatomaceous earth, membranes, bag, or cartridge filtration, are not eligible for this treatment credit. These filtration processes remove Cryptosporidium through different mechanisms than those operative in rapid granular media filtration, which is used in conventional and direct filtration. Available data do not establish a similar relationship between lower filter effluent turbidity and improved Cryptosporidium removal efficiency for these other filtration processes.

The SAB reviewed the proposed additional Cryptosporidium treatment credit for PWSs that operate with very low filtered water turbidity. In their report, the SAB stated that further lowering of turbidity would result in further reductions in Cryptosporidium in the effluent from filtration processes, but available data were limited in showing the exact removal that can be achieved. Based on the data provided, the SAB recommended that no additional treatment credit be given to plants that demonstrate a CFE turbidity of 0.15 NTU or less (SAB 2003).

In addressing this SAB recommendation, EPA recognizes that precisely quantifying the increase in Cryptosporidium removal that a particular filtration plant will realize when operating at lower filter effluent turbidity is not generally feasible. Available data, though, consistently show that removal of Cryptosporidium is at least 0.5-log greater when filter effluent turbidity reflects compliance with a 0.15 NTU standard in comparison to a 0.3 NTU standard. Further, treatment plants operating at lower filter effluent turbidity will achieve increased removal of other microbial pathogens present in the raw water. In consideration of these factors, EPA believes that PWSs should receive an additional 0.5-log Cryptosporidium treatment credit when at least 95 percent of CFE turbidity measurements are less than or equal to 0.15 NTU.

Another key issue in establishing additional treatment credit based on low filtered water turbidity is the performance of analytical instruments (turbidimeters) to accurately measure turbidity at low levels. In the proposal, EPA reviewed studies of low level turbidity measurements by EPA (1998c), Sadar (1999), and Letterman et al. (2001). Among the significant findings of these studies are the following:

(1) On-line turbidimeters typically had a positive bias (i.e., a higher turbidity reading) in comparison to bench-top turbidimeters. EPA expects that most PWSs that receive additional treatment credit for low filter effluent turbidity will use on-line turbidimeters. This finding suggests that the error in turbidimeter readings may be generally conservative, so that PWSs will operate at lower than required turbidity levels.

(2) Different turbidimeters did not agree well when used to measure low level turbidity, which may be due to differences in instrument design. This finding suggests that low level turbidity measurements may be viewed as a relative indicator of water quality improvement at a particular PWS but may be less applicable for making comparisons among different PWSs.

In addition, the American Society for Testing and Materials (ASTM) has issued standard test methods for measurement of turbidity below 5 NTU by on-line (ASTM 2001) and static (ASTM 2003) instruments. These methods specify that the instrument should permit detection of turbidity differences of 0.01 NTU or less in waters having turbidities of less than 1.00 NTU (ASTM 2001) and 5.0 NTU (ASTM 2003), respectively.

After reviewing these studies and the ASTM methods, EPA concluded that currently available monitoring equipment can reliably measure turbidity at levels of 0.15 NTU and lower. Rigorous calibration and maintenance of turbidity monitoring equipment is necessary, however. EPA has developed guidance on proper calibration, operation, and maintenance of turbidimeters (USEPA 1999c).

c. Summary of Major Comments

Public comment on the August 11, 2003, LT2ESWTR proposal supported awarding additional Cryptosporidium treatment credit for PWSs that achieve lower filtered water turbidity. Commenters raised specific concerns with the criteria for PWSs to receive this credit, the available data that support this credit, and the performance of turbidimeters for measuring turbidity at very low levels. A summary of these comments and EPA's responses follows.

Most commenters supported awarding 0.5-log additional Cryptosporidium treatment credit for PWSs that achieve at least 95 percent of CFE turbidity measurements less than or equal to 0.15 NTU. A few commenters, however, recommended that PWSs only receive additional treatment credit for demonstrating this level of turbidity performance in each individual filter effluent (IFE), rather than the CFE. In addition, one commenter stated that PWSs should be required to monitor CFE turbidity every 15 minutes, rather than every four hours as required under current regulations.

In response, EPA agrees with the recommendation of most commenters and has established additional Cryptosporidium treatment credit based on meeting a 95th percentile turbidity level of 0.15 NTU in the CFE. EPA recognizes, however, that achieving low turbidity in each IFE may represent a higher level of performance than achieving low turbidity in the CFE. As described in the next section, EPA has also established standards for additional Cryptosporidium treatment credit based on low IFE turbidity in today's rule. EPA does not have data indicating that PWSs should monitor the CFE turbidity at a higher frequency than every four hours, as required under existing regulations. Consequently, EPA is not changing the frequency of required CFE turbidity monitoring as a condition for PWSs to receive additional treatment credit under today's rule.

One commenter summarized additional studies that provide data on the improvement in Cryptosporidium removal efficiency at lower filter effluent turbidity levels. According to this commenter, these studies demonstrate that lowering filter effluent turbidity from 0.3 to 0.15 NTU translates to an improvement in Cryptosporidium removal of more than 1.5-log, with individual studies showing a range of >0.7-log to >3-log based on median removal. EPA finds that these studies bolster the conclusion that PWSs operating to meet 0.15 NTU in the filter effluent will achieve at least 0.5-

log greater Cryptosporidium removal than PWSs operating to meet 0.3 NTU. Thus, they support the additional 0.5-log Cryptosporidium treatment credit under today's rule for PWSs meeting 0.15 NTU at the 95th percentile in the CFE.

In regard to the measurement of low level turbidity, some commenters raised concerns that turbidimeters used by the U.S. water supply industry do not agree when used to measure turbidity in the 0.01 to 0.5 NTU range. Further, these differences are independent of the calibration method used and can be significant when comparing instruments by different manufacturers. Other commenters stated that turbidimeters can accurately reflect turbidity values less than 0.15 NTU if properly calibrated, and some commenters cited the ASTM method development process to support this assessment. In addition, commenters suggested that available guidance on turbidity measurement provides quality assurance measure that can reduce analytical uncertainty.

EPA agrees with commenters that available methods and instruments are adequate to demonstrate compliance with a 0.15 NTU turbidity level. In particular, EPA believes that monitoring low level turbidity can be effective for demonstrating water quality improvements at individual plants, but also recognizes that the performance of turbidimeters used at different plants may vary. Further, calibration and maintenance of turbidity monitoring equipment is critical, and EPA has developed guidance on these procedures (USEPA 1999c).

8. Individual Filter Performance

a. Today's Rule

PWSs using conventional filtration treatment or direct filtration receive an additional 0.5-log Cryptosporidium treatment credit during any month the PWS meets the following criteria:

• The filtered water turbidity for each individual filter is less than or equal to 0.15 NTU in at least 95 percent of the measurements recorded each month; and

• No individual filter has a measured turbidity level greater than 0.3 NTU in two consecutive measurements taken 15 minutes apart.

PWSs must continue to monitor turbidity for each individual filter continuously and record the results every 15 minutes, as required under 40 CFR 141.174 and 141.560.

PWSs that receive this 0.5-log Cryptosporidium treatment credit for individual filter performance also receive 0.5-log treatment credit for combined filter performance, as described in section IV.D.7, for a total additional treatment credit of 1.0-log. Conversely, PWSs are not required to pursue individual filter performance credit to remain eligible for combined filter performance credit.

If a PWS has received credit for individual filter performance to comply with its Cryptosporidium treatment requirements and fails to meet the required criteria for this credit during any month, the PWS will not incur a treatment technique violation if the State determines the following:

• The failure to meet the required criteria for individual filter performance treatment credit was due to unusual and short-term circumstances that could not reasonably be prevented through optimizing treatment plant design, operation, and maintenance; and

• The PWS has experienced no more than two such failures in any calendar year.

This treatment credit is not applicable to other types of filtration processes, including slow sand, diatomaceous earth, membranes, bag, or cartridge filtration.

b. Background and Analysis

Awarding additional treatment credit for individual filter performance is based on the expectation that achieving low filtered water turbidity in each individual filter will provide increased protection against microbial pathogens. Most treatment plants have multiple filters. Moderately elevated turbidity in the effluent from a single filter may not significantly affect the turbidity of the combined filter effluent, but may indicate a reduction in the overall pathogen removal efficiency of the filtration process. Consequently, a primary goal in optimizing water treatment plant performance is ensuring that each filter always produces very low turbidity water.

The criteria for PWSs to achieve the additional 1.0-log Cryptosporidium treatment credit for individual filter performance reflect goals of Phase IV of the Partnership for Safe Water (Partnership). The Partnership is a voluntary cooperative program involving PWSs, professional associations, and Federal and State regulatory agencies that seeks to increase protection against microbial contaminants by optimizing water treatment plant performance. The Stage 2 M–DBP Advisory Committee recommended 1.0-log treatment credit for PWSs that successfully participate in a peer review program and identified Phase IV of the Partnership as a program where such credit would be appropriate (USEPA 2000a).

At the time of the Advisory Committee recommendation, the performance goals for Phase IV of the Partnership reflected those of the EPA Composite Correction Program (USEPA 1991a) and involved an on-site evaluation by a third-party team. Phase IV performance goals for individual filters included filtered water turbidity less than 0.1 NTU at least 95 percent of the time based on daily maximum values and a maximum measurement of 0.3 NTU. The purpose of the on-site evaluation was to confirm that a PWS had met Phase IV performance goals or had achieved the highest level of performance given its unique raw water quality.

After the Stage 2 M–DBP Agreement in Principle was signed in September 2000, the Partnership eliminated on-site third-party evaluation as a component of Phase IV. Instead, Phase IV required completion of an Optimization Assessment Spreadsheet in which the PWS entered water treatment data to demonstrate that it had achieved Phase IV performance levels. The application also required narratives related to the administrative support and operational capabilities necessary to sustain performance long-term.

The August 11, 2003 LT2ESWTR proposal included a 1.0-log Cryptosporidium treatment credit for PWSs that met the individual filter performance goals of Phase IV of the Partnership (i.e., 95 percent of daily maximum values below 0.1 and no values above 0.3 NTU) (USEPA 2003a). Rather than requiring an application package with historical data and narratives, however, the proposed rule required PWSs to report filter effluent turbidity data to the State each month to demonstrate compliance with these filter performance goals.

The Partnership modified the Phase IV goals for individual filter performance in 2003. A revised goal is filtered water turbidity less than 0.10 NTU at least 95 percent of the time based on values recorded at 15 minute time intervals. Thus, where the earlier goal was based on daily maximum values for each filter, the revised goal is based on all values for each filter—a less stringent approach. The Partnership made this modification after finding that none of the water treatment plants that had been evaluated could consistently meet the 0.1 NTU goal using daily maximum values and, further, that this goal was biased against plants with more filters.

In today's final rule, EPA has adjusted the criteria from the proposal for PWSs to receive additional treatment credit based on individual filter effluent turbidity. These adjustments are in response to the changes the Partnership made to Phase IV individual filter performance goals. Under today's rule, PWSs receive 1.0-log additional Cryptosporidium treatment credit if effluent turbidity from each filter is less than or equal to 0.15 NTU at least 95 percent of the time and never exceeds 0.3 NTU in two consecutive measurements taken 15 minutes apart.

EPA expects that PWSs will operate at less than 0.1 NTU in order to comply with a regulatory limit of 0.15 NTU. Further, EPA believes that assessing individual filter compliance with a maximum turbidity level of 0.3 NTU based on two consecutive measurements taken 15 minutes apart is appropriate. This approach allows for brief fluctuations in turbidimeter readings that may not indicate a degradation in filtered water quality to occur without penalizing a PWS, but it should catch filters that significantly exceed 0.3 NTU over the course of a month. EPA applied this approach to individual filter monitoring under the IESWTR and LT1ESWTR. Consequently, EPA regards these criteria as comparable to the revised Partnership Phase IV standards for individual filter performance.

In addition, today's rule gives States authority to determine whether to issue a treatment technique violation for PWSs that exceed individual filter performance limits. This authority applies in the case where a PWS receives credit for individual filter performance to meet the treatment requirements of today's rule and fails to achieve the criteria to receive this credit during a month. If the State determines that this failure was due to unusual and short-term circumstances that could not reasonably be prevented through treatment optimization, the State may choose not to issue a treatment technique violation, which the PWS otherwise will incur. Because this authority should be applied only to unusual plant circumstances, a State cannot make this determination if a PWS has experienced more than two such failures in any calendar year.

EPA is granting States this authority because PWSs that consistently meet the criteria for individual filter performance treatment credit may occasionally experience short-term deviations from these criteria due to circumstances largely beyond the PWS's control. An example of such a circumstance may be malfunctioning equipment that a PWS quickly removes from service, but that nevertheless prevents the PWS from fully meeting individual filter performance criteria in a particular month. EPA believes that States should only apply this authority in cases where PWSs have consistently achieved the criteria for individual filter performance treatment credit in previous months.

The approach in today's final rule for valuing individual filter performance treatment credit differs from the approach in the proposal. EPA's intent in both the proposal and today's rule is to award an additional 1.0-log Cryptosporidium treatment credit to PWSs that meet the criteria for individual filter performance. In the proposal, however, PWSs could receive 1.0-log additional treatment credit specifically for meeting the individual filter performance criteria, but were then not eligible to receive any treatment credit under the combined filter performance option. In today's rule, PWSs receive 0.5-log credit for the individual filter performance option and also receive an additional 0.5-log treatment credit for the combined filter performance option (discussed in section IV.D.7), resulting in 1.0-log total additional credit. EPA has made this modification so that if a PWS fails in an attempt to achieve individual filter performance credit, the PWS is clearly still eligible to received combined filter performance credit.

In a review of a draft LT2ESWTR proposal, the SAB recommended that PWSs receive 0.5-log, rather than 1.0-log, additional Cryptosporidium treatment credit for achieving individual filter effluent turbidity below 0.15 NTU at the 95th percentile (SAB 2003). In response to this SAB recommendation, today's rule requires additional individual filter performance criteria to support 1.0-log total additional treatment credit. Specifically, today's rule incorporates the Partnership Phase IV performance goal that individual filter effluent turbidity never exceed 0.3 NTU (as described earlier, EPA concluded that determining compliance with this standard based on two consecutive measurements taken 15 minutes is appropriate and consistent with existing regulations). Thus, EPA believes that these criteria, in conjunction with the expectation that controlling effluent turbidity at all filters individually rather than just the combined filter effluent will generally result in lower microbial risk, justify 1.0-log additional treatment credit.

c. Summary of Major Comments

Public comment on additional treatment credit for individual filter performance in the August 11, 2003 proposal raised a number of issues: changes in the Partnership Phase IV criteria and achievability of the proposed criteria for this credit, credit for participating in peer review programs, and a review process for data that exceed regulatory limit. A summary of these comments and EPA's responses follows.

Several commenters stated that PWSs could not consistently achieve the proposed individual filter effluent turbidity criterion of 95 percent of daily maximum measurements less than or equal to 0.1 NTU. Commenters provided data on turbidity levels in PWSs to support this assertion and indicated that the Partnership modified this criterion in the Phase IV individual filter performance goals because PWSs could not meet it. Alternatives recommended by commenters for the final rule included the use of the revised Partnership Phase IV goals for individual filter effluent turbidity or a more stringent criterion for combined filter effluent turbidity.

In response, EPA agrees that current Partnership Phase IV goals provide appropriate criteria for awarding 1.0-log total additional Cryptosporidium treatment credit. Today's rule grants this total credit to PWSs that meet a 95th percentile individual filter effluent turbidity limit of 0.15 NTU, and EPA expects that PWSs complying with this limit will operate under the Partnership goal of 0.10 NTU. EPA does not support awarding a higher level of additional treatment credit for a more stringent combined filter effluent turbidity criterion, beyond the 0.5-log credit available under combined filter performance (see section IV.D.7). The purpose of the individual filter performance toolbox option is to recognize the higher pathogen removal PWSs will likely achieve by maintaining very low effluent turbidity for each individual filter.

A few commenters suggested that as an alternative to establishing numerical criteria for individual filter performance, today's rule should award additional treatment credit for PWSs that successfully participate in a peer review program. In addition to the Partnership, commenters listed the Area Wide Optimization Program and the Texas Optimization Program as examples of programs that will provide for comprehensive improvements in treatment performance.

EPA agrees that participation in peer review programs is beneficial for PWSs. Further, such programs may assist PWSs in meeting the filtration performance criteria in today's rule for additional Cryptosporidium treatment credit. EPA does not believe, however, that mere participation in a peer review program is an appropriate basis for awarding additional treatment credit. Rather, to ensure national consistency in standards for compliance with treatment requirements, EPA has concluded that additional treatment credit should be based on PWSs meeting specified criteria for enhanced treatment performance.

Another significant issue raised by commenters is the need for a review process for deviations from the criteria for individual filter performance due to circumstances that cannot be prevented through plant optimization. An example given by several commenters is a filter that malfunctions and is taken out of service, but that may have exceeded the individual filter performance turbidity criteria for a short period when the filter was operating.

EPA agrees that circumstances may occur that are beyond the PWS's control and that prevent the PWS from fully meeting the criteria for individual filter performance in a particular month. If a PWS relies on individual filter performance treatment credit to meet the treatment requirements of today's rule and the PWS fails to meet all criteria for this credit in a given month, the State may review the reasons for this failure. If the State finds that the failure was due to circumstances that could not be prevented through plant optimization, the State may choose not to issue a treatment technique violation on up to two such occasions in a calendar year.

9. Demonstration of Performance

a. Today's Rule

A demonstration of performance is a site-specific test that assesses the Cryptosporidium removal efficiency of a water treatment plant or a treatment process within a plant. Under today's rule, PWSs may undertake demonstration of performance testing for the following purposes:

(1) To establish a Cryptosporidium treatment credit that is higher than the prescribed treatment credit in today's rule for a water treatment plant or a treatment process in the microbial toolbox; or

(2) To establish a Cryptosporidium treatment credit for a treatment process that is not included in the microbial toolbox or that does not meet the design or operational criteria for prescribed treatment credit in the microbial toolbox.

The specific requirements that apply to demonstration of performance testing are as follows:

- PWSs may receive Cryptosporidium treatment credit for a water treatment plant or a treatment process within a plant that is based on a site-specific demonstration of Cryptosporidium removal efficiency. This demonstration of performance treatment credit may be greater than or less than any prescribed treatment credit in today's rule.
- The site-specific demonstration of Cryptosporidium removal efficiency must follow a State-approved protocol and may involve the use of surrogates rather than Cryptosporidium.
- The State must approve through written notification any treatment credit based on a demonstration of performance. As a condition of approval, the State may designate monitoring and treatment performance criteria the PWS must meet and report on an ongoing basis to remain eligible for the credit. The State may designate such criteria to verify that the PWS maintains the operating conditions under which the State approved the demonstration of performance treatment credit.
- PWSs are not eligible for prescribed treatment credit for any treatment process that is included in a demonstration of performance credit.

b. Background and Analysis

The prescribed Cryptosporidium treatment credits in today's rule for water treatment plants and for treatment processes in the microbial toolbox are based on conservative estimates of mean Cryptosporidium removal efficiencies. Due to site-specific conditions, however, some PWSs will achieve greater Cryptosporidium removal than reflected in the prescribed treatment credits. In addition, some PWSs will have treatment processes that are not included in the microbial toolbox or that do not meet microbial toolbox criteria for prescribed treatment credit. In all these cases, PWSs have the option to undertake demonstration of performance testing to establish an appropriate level of Cryptosporidium treatment credit for the treatment plant or treatment process.

The option for demonstration of performance testing in today's rule reflects a recommendation by the Stage 2 M–DBP Advisory Committee. Specifically, the Committee stated that the LT2ESWTR should allow site-specific testing both to establish Cryptosporidium treatment credit above the prescribed credit for microbial toolbox processes and to demonstrate Cryptosporidium removal for technologies not listed in the microbial toolbox. The August 11, 2003 LT2ESWTR proposal included the demonstration of performance option (USEPA 2003a), and EPA is establishing it in today's final rule.

Demonstration of performance testing will be specific to a particular site and will depend on the treatment processes being tested, water quality, plant infrastructure, PWS resources, and other factors. Consequently, today's rule does not establish specific protocols for demonstration of performance testing. Rather, today's rule gives States the authority to approve testing protocols developed by PWSs and to determine what level of Cryptosporidium treatment credit is appropriate. The Toolbox Guidance Manual provides recommendations to PWSs and States on conducting demonstration of performance testing, including analytical methods for measuring aerobic and anaerobic spores.

In general, demonstration of performance testing should encompass the full range of expected operating conditions and should conservatively assess the degree of Cryptosporidium removal that a treatment process can reliably achieve. Directly quantifying the removal of Cryptosporidium typically is not feasible in full-scale testing due to limitations in source water concentrations and analytical method performance. Consequently, demonstration of performance testing that is conducted at full-scale may involve the use of surrogates, such as aerobic spores, that have been shown to correlate with the removal of Cryptosporidium. PWSs and States may also consider the use of pilot-scale studies in conjunction with full-scale studies for demonstration of performance testing.

As a condition of approving a demonstration of performance credit, the State may designate treatment performance criteria the PWS must meet on an ongoing basis to remain eligible for the credit. For example, if a PWS conducts a demonstration of performance study while operating with very low filtered water turbidity, the State may establish as a condition of approving treatment credit based on the study that the PWS must continue operating at the low filtered water turbidity. EPA believes this condition is necessary because, in this example, if the PWS were to begin operating at a higher filtered water turbidity level, the demonstration of performance study results might no longer represent the PWSs actual performance.

PWSs are not eligible for prescribed treatment credit for any treatment process that is included in a demonstration of performance credit. For example, if a PWS receives a demonstration of performance treatment credit of 4-log for Cryptosporidium removal through a conventional treatment plant (i.e., coagulation/sedimentation/filtration), the PWS is not also eligible for additional treatment credit for combined filter performance. In this case, the demonstration of performance testing accounts for the removal achieved by filtration.

c. Summary of Major Comments

Public comment on the August 11, 2003 LT2ESWTR proposed supported inclusion of the demonstration of performance option to award site-specific treatment credit to PWSs. Commenters stated that many well-run surface water treatment plants achieve significantly greater Cryptosporidium removal than the prescribed treatment credit, and demonstration of performance testing is needed to award an appropriate level of credit in such cases. Two aspects of this option that received significant public comment are the provision for States to award less than the prescribed treatment credit if indicated by testing results and the need for guidance on demonstration of performance testing. These comments and EPA's responses are summarized as follows.

Several commenters recommended that EPA eliminate the provision that allows States to award less than the prescribed treatment credit based on demonstration of performance testing. These commenters stated that pilot- and full-scale testing is conservative and challenging to implement and that for past regulations, States generally have not awarded lower treatment credit based on a site-specific study. If this provision remains in the regulation, commenters suggested that EPA provide criteria addressing how it should be applied. Such criteria should recognize the conservative nature of testing with surrogates for Cryptosporidium removal and the potential for misleading or flawed testing results.

In response, EPA believes that States should have the discretion to award either more or less treatment credit than the prescribed credit on a case-by-case basis where a State has site-specific information that an alternative credit is appropriate. Today's rule allows this. EPA recognizes, however, that demonstration of performance testing should be designed to provide a conservative estimate of treatment efficiency and, as such, is not generally intended to reduce the level of treatment credit a PWS receives. Further, results from demonstration of performance testing should be rigorously evaluated for flaws and bias prior to being used to support either a higher or lower treatment credit. The Toolbox Guidance Manual identifies approaches States may wish to consider in awarding higher or lower treatment credit.

Many commenters stated that EPA should provide thorough guidance on demonstration of performance testing. Topics for this guidance suggested by commenters include approaches to demonstrating treatment credit, minimum duration of testing, the use of safety factors, and periodic reconfirmation of testing results. Some commenters recommended that guidance address both full-scale testing with surrogates like aerobic spores and pilot-scale testing with Cryptosporidium or surrogates. Other commenters recommended that testing should be limited to full-scale processes and that testing with pilot-scale representations of full-scale equipment should be discouraged.

In the Toolbox Guidance Manual, EPA provides direction on procedures for demonstration of performance testing that addresses issues raised by commenters. These issues include surrogates for full-scale testing, potential roles for pilot-scale testing in conjunction with full-scale testing, minimum duration of testing to capture the full range of operating conditions, the analysis of data from testing to establish treatment credit, and routine monitoring to verify that the conditions under which demonstration of performance credit is awarded are maintained during routine operation. EPA believes that this guidance will assist PWSs and States with implementing demonstration of performance testing appropriately.

10. Bag and Cartridge Filtration

a. Today's Rule

Under today's rule, PWSs may receive Cryptosporidium treatment credit of up to 2.0-log for an individual bag or cartridge filter and up to 2.5-log for two or more bag or cartridge filters operated in series. To be eligible for this treatment credit, filters must meet the definition of a bag or cartridge filter and must undergo challenge testing to demonstrate removal efficiency with an applied safety factor, as described in this section.

Today's rule defines bag and cartridge filters as pressure driven separation processes that remove particulate matter larger than 1 micrometer using an engineered porous filtration media through either surface or depth filtration. Bag filters are constructed of a non-rigid, fabric filtration media housed in a pressure vessel in which the direction of flow is from the inside of the bag to the outside. Cartridge filters are typically constructed as rigid or semi-rigid, self-supporting filter elements housed in a pressure vessel in which flow is from the outside of the cartridge to the inside.

Today's rule treats bag and cartridge filters equivalently, with the following exception: If a cartridge filter meets the definition of a membrane filtration process and can be direct integrity tested according to the criteria specified in section IV.D.11, a PWS has the option to seek greater treatment credit for the filter as a membrane. Section IV.D.11 describes criteria for awarding treatment credit to membranes.

Today's rule requires challenge testing to establish Cryptosporidium treatment credit for bag and cartridge filters. This challenge testing is product-specific and not site-specific. Once challenge testing is performed on a specific bag or cartridge filtration product, PWSs that install the specific filtration product are not required to repeat challenge testing at individual sites. For a PWS to receive Cryptosporidium treatment credit for a bag or cartridge filter, challenge testing must meet the following criteria:

- Challenge testing must be conducted on full-scale filters that match the filters the PWS will use in materials, construction, and associated housing or pressure vessel. If treatment credit will be based on filters operated in series then challenge testing must be performed on the filters in series.
- Challenge testing must involve measuring the removal by the filter of either Cryptosporidium or a surrogate that is removed no more efficiently than Cryptosporidium (i.e., ''challenge particulate'').
- The analytical method used to measure removal in the challenge test must discretely quantify the specific challenge particulate. The maximum allowable feed water concentration of the challenge particulate used during a challenge test is 10,000 times the analytical method detection limit of the challenge particulate in the filtrate.
- During challenge testing, filters must be operated at the maximum design flow rate and for a duration sufficient to reach the maximum design pressure drop (i.e., ''terminal pressure drop''). PWSs may not operate bag or cartridge filters outside of these design parameters during routine use. In order to achieve terminal pressure drop during challenge testing, adding particulate matter, such as fine carbon test dust or bentonite clay particles, to the test water is allowed and may be necessary.
- In each challenge test, the removal of the challenge particulate must be measured during three periods over the

filtration cycle: (1) Within two hours of start-up of a new filter, (2) when the pressure drop is between 45 and 55 percent of the terminal pressure drop, and (3) when the pressure drop has reached 100 percent of the terminal pressure drop. A log removal value (LRV) must be calculated for each of these periods as follows: LOG_{10} (filter influent challenge particulate level) − LOG_{10} (filter effluent challenge particulate level). For each filter tested, the LRV for the filter (LRV_{filter}) is equal to the minimum of these three LRVs.

• The LRV_{filter} values for each filter that is tested are used to determine the removal efficiency that is assigned to the specific bag or cartridge filter product (*i.e.*, a filter product line) or combination of filters in series. If fewer than twenty filters are tested, the removal efficiency of the filter product line is equal to the lowest LRV_{filter} among the filters tested (today's rule does not specify a minimum number of filters to test). If twenty or more filters are tested, the removal efficiency of the filter product line is equal to the 10th percentile of the LRV_{filter} values among the filters tested.

• The Cryptosporidium treatment credit assigned to an individual bag or cartridge filter is equal to the removal efficiency established during challenge testing minus a 1.0-log factor of safety, up to a maximum treatment credit of 2.0-log (*e.g.*, if challenge testing demonstrates a removal efficiency of 3.0-log or greater, the filter is eligible to receive 2.0-log Cryptosporidium treatment credit).

• The Cryptosporidium treatment credit assigned to configurations of two or more bag or cartridge filters operated in series is equal to the removal efficiency established during challenge testing minus a 0.5-log factor of safety, up to a maximum treatment credit of 2.5-log (*e.g.*, if challenge testing demonstrates a removal efficiency of 3-log or greater, the filter receives 2.5-log Cryptosporidium treatment credit).

If a previously tested bag or cartridge filter is modified in a manner that could change the removal efficiency of the filter product line, a new removal efficiency must be established for the modified filter through challenge testing. 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.

b. Background and Analysis

Bag and cartridge filters are widely used by very small PWSs and in point-of-entry applications to remove particulate material from raw water, including microbial pathogens like Cryptosporidium. Depending on water quality and treatment plant infrastructure, these filters may be used as the sole filtration step or as a polishing filter that follows primary filtration processes. A critical aspect of bag and cartridge filters as defined in today's rule is that they cannot undergo direct integrity testing, which is used to detect leaks that could result in contamination of the treated water. Cartridge filters that meet the definition of a membrane process and can be direct integrity tested are considered membranes under today's rule, and these are described in section IV.D.11.

The Stage 2 M–DBP Advisory Committee recommended Cryptosporidium treatment credits of 1.0- and 2.0-log for bag and cartridge filters, respectively (USEPA 2000a), and the August 11, 2003 LT2ESWTR proposal included criteria for PWSs to receive these treatment credits. The proposed criteria required challenge testing and the application of a 1.0-log factor of safety to establish treatment credit. In today's final rule, EPA has modified these criteria to allow both bag and cartridge filters to be eligible for 2.0-log credit and to allow 2.5-log credit with a 0.5-log factor of safety for bag or cartridge filters operated in series. The following discussion summarizes the basis for these criteria and for differences between the proposal and today's final rule.

In the proposal, EPA reviewed bag and cartridge filtration studies by Long (1983), Schaub *et al.* (1993), Goodrich *et al.* (1995), Ciardelli (1996a and 1996b), Li *et al.* (1997), Roessler (1998), Enriquez *et al.* (1999), NSF (2001a and 2001b), and Cornwell and LeChevallier (2002). Results from these studies indicated that both bag and cartridge filters exhibit variable removal efficiency, ranging from 0.5- to 3.6-log. No correlation between the pore size rating established by the manufacturer and the removal efficiency of the filter was apparent. Additionally, available data did not indicate a strong relationship between commonly used process monitoring parameters, such as turbidity and pressure drop, and Cryptosporidium removal efficiency.

Due to this lack of correlation between either design criteria or process monitoring and removal efficiency, today's rule requires challenge testing of filters to establish Cryptosporidium treatment credit. Challenge testing must measure the removal across the filter of Cryptosporidium or a surrogate, like polystyrene microspheres, that is removed no more efficiently than Cryptosporidium (Long 1983, Li *et al.* 1997, NSF 2002b). Further, because studies have shown the removal efficiency of some bag and cartridge filters to decrease over the course of a filtration cycle (Li *et al.* 1997, NSF 2001a,b), challenge testing must assess removal efficiency during three periods: within two hours of startup of a new filter, between 45–55 percent of terminal pressure drop, and at the end of the run after terminal pressure drop is realized.

Bag and cartridge filter challenge testing is product-specific and not site-specific since the intent of this testing is to demonstrate the removal capabilities of the filtration device rather than evaluate the feasibility of implementing the technology at a specific plant. Challenge testing must be conducted using full-scale filter elements to assess the performance of the entire unit, including the filtration media, seals, filter housing and other components integral to the filtration system. To be eligible for treatment credit when operated in series, filters must be tested in series. Multiple filters of the same type can be tested to provide a better statistical basis for estimating removal efficiency. The Toolbox Guidance Manual provides information on bag and cartridge filter challenge testing.

Today's rule establishes the proposed requirement that a 1.0-log factor of safety be applied to the removal efficiency established during challenge testing for individual bag or cartridge filters when determining treatment credit. Thus, to receive a 2.0-log treatment credit, a removal efficiency of at least 3.0-log must be demonstrated during challenge testing. EPA believes that this factor of safety is necessary because integrity testing with bag and cartridge filters is not possible (note: under today's rule, cartridge filters that can be integrity tested are classified as membranes and no safety factor is required; see section IV.D.11).

Challenge testing provides an estimate of the removal efficiency of a bag or cartridge filter product line but does not involve testing every filter. Further, it does not fully capture the variation in filter performance that will occur over time during routine use. For membranes, the use of direct integrity tests, such as a pressure hold test, that is correlated to removal efficiency addresses this problem. With bag and cartridge filters, however, EPA is aware of no equivalent test, and parameters like turbidity and pressure differential that may be monitored with these filters have not been shown to correlate with Cryptosporidium removal efficiency. Consequently, a safety factor is necessary to account for variation in individual filter performance relative to challenge test results.

Individual bag and cartridge filters are eligible for a maximum Cryptosporidium treatment credit of 2.0-log. EPA proposed this level of credit for cartridge filters but proposed a 1.0-log maximum credit for bag filters, as recommended by the Advisory Committee. However, after further reviewing available data, EPA has concluded that treatment studies do not support establishing different limits on treatment credit for bag and cartridge filters. Accordingly, today's rule treats bag and cartridge filters equivalently. EPA continues to believe that 2.0-log is an appropriate maximum treatment credit for a single bag or cartridge filter, based on available data on the removal of Cryptosporidium and surrogates by these processes and the absence of a direct integrity test.

Today's rule also establishes criteria for awarding treatment credit to bag or cartridge filters operated in series. EPA believes that the use of these filters in series provides clear advantages in comparison to operation of a single filter. Series operation will achieve both greater removal efficiency and improved reliability by lessening the impact of variation in the performance of a single filter. In consideration of these factors, bag or cartridge filters operated in series are eligible for a higher Cryptosporidium treatment credit of 2.5-log and require a lower safety factor of 0.5-log applied to challenge test results when determining treatment credit.

c. Summary of Major Comments

In response to the August 11, 2003 proposal, EPA received significant public comment on the following issues related to bag and cartridge filtration: the allowable treatment credit, the factor of safety applied to challenge testing results to determine treatment credit, and the procedure for determining the removal efficiency. A summary of these comments and EPA's responses follows.

In regard to the proposed treatment credits, several commenters recommended that bag and cartridge filters should be eligible for up to 2.0- and 2.5-log credit, respectively, if supported by the challenge test results. Others commented that filters should be allowed to qualify for removal credits at or below the 1.0- and 2.0-log credits in the proposal. EPA agrees that additional flexibility should be provided with respect to the removal credit awarded to bag and cartridge filters. After reviewing these comments and reassessing data presented in the proposal on the removal efficiencies of bag and cartridge filters, EPA revised the proposal to allow up to 2.0-log treatment credit for either a single bag or cartridge filter. In addition, today's rule allows up to 2.5-log credit for bag or cartridge filters operated in series.

With respect to the 1.0-log safety factor applied to challenge test results to determine treatment credit, some commenters supported this approach, while others recommended a reduced safety factor. In response, EPA continues to believe that a 1.0-log safety factor is appropriate to address variability in individual filter performance and in the absence of a direct integrity test for bag and cartridge filters. Where filters are operated in series, however, EPA agrees that the safety factor should be reduced. Series operation provides an intrinsic process safety and will dampen some of the variability in removal efficiency observed for individual filters. Thus, EPA is reducing the factor of safety to 0.5-log for configurations consisting of two or more filters in series.

Commenters requested that EPA clarify the procedure used to determine the removal efficiency of bag and cartridge filters. In response, expanded and clarified guidance on conducting challenge tests to determine removal efficiency for bag and cartridge filters has been included in the Toolbox Guidance Manual.

11. Membrane Filtration

a. Today's Rule

Today's final rule establishes criteria for awarding Cryptosporidium treatment credit to membrane filtration processes. To receive removal credit, filters must meet the definition of a membrane filtration process and undergo challenge testing to establish removal efficiency; PWSs must periodically verify system integrity through direct integrity testing and perform continuous indirect integrity monitoring during use. The removal credit awarded to a membrane process is based on the removal efficiency demonstrated during challenge testing and the sensitivity of the direct integrity test.

For the purpose of today's rule, membrane filtration is defined as a pressure or vacuum driven separation process in which particulate matter larger than 1 micrometer is rejected by an engineered barrier, primarily through a size-exclusion mechanism, and which has a measurable removal efficiency of a target organism that can be verified through the application of a direct integrity test.

Membrane Challenge Testing

Any membrane filter used to meet the treatment requirements of today's rule must undergo challenge testing to determine its Cryptosporidium removal efficiency. Challenge testing establishes the maximum Cryptosporidium treatment credit a membrane filtration process is eligible to receive, provided this value is less than or equal to the sensitivity of the direct integrity test, as described later in this section. Challenge testing for membranes is product-specific, and PWSs that install membranes that have successfully undergone challenge testing are not required to repeat testing at their sites. Membrane challenge testing must meet the following criteria:

- Challenge testing must be conducted on either an identical full-scale module or a smaller-scale module identical in material and similar in construction to the membrane modules the PWS will use. A module is the smallest component of a membrane unit in which a specific membrane surface area is housed in a device with a filtrate outlet structure.
- Either Cryptosporidium or a surrogate that is removed no more efficiently than Cryptosporidium must be used as the challenge particulate during challenge testing.
- The analytical method used to measure removal in the challenge test must discretely quantify the specific challenge particulate. The maximum allowable feed water concentration used during a challenge test is 6.5-log (3.16×10^6) times the detection limit of the challenge particulate in the filtrate.
- Challenge testing must be conducted under representative hydraulic conditions at the maximum design flux and maximum design process recovery as specified by the manufacturer for the membrane filtration process. Flux is defined as the throughput of a pressure driven membrane process expressed as flow per unit of membrane area. Recovery is defined as the volumetric percent of feed water that is converted to filtrate over the course of an operating cycle uninterrupted by events such as chemical cleaning or a solids removal process (*i.e.*, backwashing).
- The removal efficiency for the membrane is determined from the results of the challenge test, expressed as a log removal value (LRV). A LRV must be calculated for each membrane module evaluated during the challenge