time losses in the Enhanced COI estimate is appropriate only for marginal changes in time use; it is not appropriate for the types of lifetime changes considered in the comparison.

The Enhanced COI estimates are based on an approach developed in the EPA report, Valuing Time Losses Due to Illness under the 1996 Amendments to the Safe Drinking Water Act (USEPA 2005e). This report has been subject to two rounds of independent peer review. In conclusion, EPA believes that including the Enhanced COI in conjunction with the Traditional COI is justified theoretically and that including both measures increases EPA's ability to understand the impacts of the rule.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, [58 FR 51735, (October 4, 1993)] the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities:
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it may have an annual effect on the economy of \$100 million or more (estimated annual costs are \$93 to 133 million and \$107 to 150 million at 3 and 7 percent discount rates, respectively). As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the public record.

B. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information

collection requirements contained in this rule under the provisions of the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2040–0266.

The information collected as a result of this rule will allow the States and EPA to determine appropriate requirements for specific PWSs and to evaluate compliance with the rule. For the first 3 years after LT2ESWTR promulgation, the major information requirements concern monitoring activities and compliance tracking. The information collection requirements are mandatory (40 CFR part 141) and the information collected is not confidential.

The estimate of annual average burden hours for the LT2ESWTR during the first three years following promulgation is 141,295 hours. The annual average cost estimate is \$4.4 million for labor and \$7 million per year for operation and maintenance including lab costs (which is a purchase of service). The burden hours per response is 0.63 hours and the cost per response is \$50.35. The frequency of response (average responses per respondent) is 90.3, annually. The estimated number of likely respondents is 2,503 (the product of burden hours per response, frequency, and respondents does not total the annual average burden hours due to rounding). Note that the burden hour estimates for the first 3-year cycle include some large PWS but not small PWS monitoring. Conversely, burden estimate for the second 3-year cycle will include remaining monitoring for large systems (those serving between 10,000 and 49,999 people) and small PWS monitoring, but not for large PWS serving 50,000 or more, which will have been completed by then.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to

respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. In addition, EPA is amending the table in 40 CFR part 9 of currently approved OMB control numbers for various regulations to list the regulatory citations for the information requirements contained in this final rule.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. Small entities are defined as: (1) a small business as defined by the Small Business Administrations's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any "not-forprofit enterprise which is independently owned and operated and is not dominant in its field." However, the RFA also authorizes an agency to use alternative definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternative definition(s) in the **Federal Register** and taking comment. 5 U.S.C. 601(3)–(5). In addition, to establish an alternative small business definition, agencies must consult with SBA's Chief Counsel for Advocacy.

For purposes of assessing the impacts of today's rule on small entities, EPA considered small entities to be public water systems serving 10,000 or fewer persons. As required by the RFA, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7620, February 13, 1998), requested public comment, consulted with the Small Business Administration (SBA), and finalized the alternative definition in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that Final Rule, the alternative definition is applied to this regulation as well.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities directly regulated by

this final rule are PWSs serving fewer than 10,000 people. We have determined that 152 of the 6,574 small PWSs, or 2.3 percent, regulated by the LT2ESWTR will experience an impact of 1 percent or greater of average annual revenues; further, 18 PWSs, which are 0.3 percent of the small PWSs regulated by this rule, will experience an impact of 3 percent or greater of average annual revenues (see Table VII.C-1).

TABLE VII.C-1.—ANNUALIZED COMPLIANCE COST AS A PERCENTAGE OF REVENUES FOR SMALL ENTITIES (2003\$)

PWSs by ownership type and system	Number of small	Percent of small	small				costs of ≥	xperiencing 1% of their nues	Systems ex costs of ≥3 rever	% of their
size	systems	systems	revenues per sys- tem(\$)	Number of systems	Percent of systems	Number of systems	Percent of systems			
	Α	В	С	D=A*E	E	F=A*G	G			
Small Government PWSs	2,827 2,452 1,295	43 37 20	2,649,186 2,555,888 4,750,838	65 57 5	2.3 2.3 0.4	8 7 2	0.3 0.3 0.1			
All Small Entity PWSs	6,574	100	2,981,331	152	2.3	18	0.3			

Note: Detail may not add due to independent rounding. Data are based on the means of the highest modeled distributions using Information Collection Rule occurrence data set. Costs are discounted at 3 percent, summed to present value, and annualized over 25 years. Source: Chapter 7 and Appendix H of the LT2ESWTR EA (USEPA 2005a).

Although this final rule will not have a significant economic impact on a substantial number of small entities. EPA nonetheless has tried to reduce the impact of this rule on small entities. The LT2ESWTR contains a number of provisions to minimize the impact of the rule on PWSs generally, and on small PWSs in particular. The risktargeted approach of the LT2ESWTR will impose additional treatment requirements only on the subset of PWSs with the highest vulnerability to Cryptosporidium, as indicated by source water pathogen levels. This approach will spare the majority of PWSs from the cost of installing additional treatment. Also, development of the microbial toolbox under the LT2ESWTR will provide both large and small PWSs with broad flexibility in selecting costeffective compliance options to meet additional treatment requirements.

Small PWSs will monitor for E. coli as a screening analysis for source waters with low levels of fecal contamination. Cryptosporidium monitoring will only be required of small PWSs if they exceed the E. coli trigger value. Because E. coli analysis is much cheaper than Cryptosporidium analysis, the use of E. coli as a screen will significantly reduce monitoring costs for the majority of small PWSs. Further, small PWSs will not be required to initiate their monitoring until large PWS monitoring has been completed. This will provide small PWSs with additional time to become familiar with the rule and to prepare for monitoring and other compliance activities.

Funding may be available from programs administered by EPA and

other Federal agencies to assist small PWSs in complying with the LT2ESWTR. The Drinking Water State Revolving Fund (DWSRF) assists PWSs with financing the costs of infrastructure needed to achieve or maintain compliance with SDWA requirements. Through the DWSRF, EPA awards capitalization grants to States, which in turn can provide lowcost loans and other types of assistance to eligible PWSs. Loans made under the program can have interest rates between 0 percent and market rate and repayment terms of up to 20 years. States prioritize funding based on projects that address the most serious risks to human health and assist PWSs most in need. Congress provided \$1.275 billion for the DWSRF program in fiscal year 1997, and has provided an additional \$4.113 billion for the DWSRF program for fiscal years 1999 through 2003.

The DWSRF places an emphasis on small and disadvantaged communities. States must provide a minimum of 15% of the available funds for loans to small communities. A State has the option of providing up to 30% of the grant awarded to the State to furnish additional assistance to State-defined disadvantaged communities. This assistance can take the form of lower interest rates, principal forgiveness, or negative interest rate loans. The State may also extend repayment terms of loans for disadvantaged communities to up to 30 years. A State can set aside up to 2% of the grant to provide technical assistance to PWSs serving communities with populations fewer than 10,000.

In addition to the DWSRF, money is available from the Department of Agriculture's Rural Utility Service (RUS) and Housing and Urban Development's Community Development Block Grant (CDBG) program. RUS provides loans, guaranteed loans, and grants to improve, repair, or construct water supply and distribution systems in rural areas and towns of up to 10,000 people. In fiscal year 2003, RUS had over \$1.5 billion of available funds for water and environmental programs. The CDBG program includes direct grants to States, which in turn are awarded to smaller communities, rural areas, and coloñas in Arizona, California, New Mexico, and Texas and direct grants to U.S. territories and trusts. The CDBG budget for fiscal year 2003 totaled over \$4.4 billion.

Although not required by the RFA to convene a Small Business Advocacy Review (SBAR) Panel because EPA determined that the proposed rule would not have a significant economic impact on a substantial number of small entities, EPA did convene a panel to obtain advice and recommendations from representatives of the small entities potentially subject to this rule's requirements. For a description of the SBAR Panel and stakeholder recommendations, please see the proposed rule (USEPA 2003a).

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local and Tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most costeffective or least burdensome alternative that achieves the objectives of the rule.

The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and

timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule contains a Federal mandate that may result in expenditures of \$100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Accordingly, EPA has prepared under section 202 of the UMRA a written statement which is summarized below.

Table VII.D–1 illustrates the annualized public and private costs for the LT2ESWTR.

Table VII.D-1.- Public and Private Costs of the LT2ESWTR

	F	_	of Annua Million\$,	alized Costs 2003\$)			,		
	3% Disco	unt R	ate	7% Disco	unt Ra	ate	Percent of	f Tot	al Cost
Publicly Owned PWS									
Costs	\$57.4	-	\$82.7	\$65.9	-	\$88.6	61.8%	-	62.0%
State Costs	\$1.1	-	\$1.2	\$1.4	-	1.4	1.2%	-	0.9%
Tribal Costs	\$0.2	-	\$0.2	\$0.2	-	\$0.3	0.2%	-	0.2%
Total Public Costs	\$58.6	-	84.1	\$67.5	-	90.3	63.1%	-	63.0%
Total Private Costs	\$34.3	-	49.4	\$39.3	-	60.2	36.9%	-	37.0%
Total Costs	\$92.9	-	\$133.4	\$106.8	-	150.5	100.0%	-	100.0%

Note: The ranges represent the ICRSSL (lowest) and Information Collection Rule (highest) modeled *Cryptosporidium* occurrence distributions. Detail may not add due to independent rounding. Source: The LT2ESWTR Economic Analysis (USEPA 2005a).

A more detailed description of this analysis is presented in Economic Analysis for the LT2ESWTR (USEPA 2005a).

As noted in section III, today's final rule is promulgated pursuant to section 1412 (b)(1)(A) of the Safe Drinking Water Act (SDWA), as amended in 1996, which directs EPA to promulgate a national primary drinking water

regulation for a contaminant if EPA determines that the contaminant may have an adverse effect on the health of persons, occurs in PWSs with a frequency and at levels of public health concern, and regulation presents a meaningful opportunity for health risk reduction

Section VI of this preamble discusses the cost and benefits associated with the LT2ESWTR. Details are presented in the Economic Analysis for the LT2ESTWR (USEPA 2005a). EPA quantified costs and benefits for four regulatory alternatives. The four alternatives are described in section VI. Table VII.D–2 summarizes the range of annual costs and benefits for each alternative.

Regulatory Alternative	Enhanced COI Range of Annualized Benefits (3%)	Traditional COI Range of Annualized Benefits (3%)	Enhanced COI Range of Annualized Benefits (7%)	Traditional COI Range of Annualized Benefits (7%)	Range of Anualized Costs (3%)	Range of Anualized Costs (7%)
Alternative A1	221 - 2891	160 - 2093	221 - 2341	130 - 1700	403 - 403	437 - 436
Alternative A2	191 - 2851	139 - 2066	154 - 2309	113 - 1678	123 - 163	139 - 182
Alternative A3						
(Preferred Alternative)	177 - 2822	130 - 2047	144 - 2286	105 - 1662	93 - 133	107 - 150
Alternative A4	155 - 2661	115 - 1037	126 - 2156	93 - 1574	57 - 91	68 - 03

Table VII.D-2.— Annual Benefits and Costs of Rule Alternatives (\$million, 2003\$)

Source: The LT2ESWTR Economic Analysis (USEPA 2005a).

To meet the UMRA requirement in section 202, EPA analyzed future compliance costs and possible disproportionate budgetary effects. The Agency believes that the cost estimates, indicated earlier and discussed in more detail in section VI of this preamble, accurately characterize future compliance costs of today's rule.

In analyzing disproportionate impacts, EPA considered the impact on (1) different regions of the United States, (2) State, local, and Tribal governments, (3) urban, rural and other types of communities, and (4) any segment of the private sector. This analysis is presented in Chapter 7 of Economic Analysis for the LT2ESWTR (USEPA 2005a).

EPA has concluded that the LT2ESWTR will not cause a disproportionate budgetary effect. This rule imposes the same requirements on PWSs nationally and does not disproportionately affect any segment. This rule will treat similarly situated PWSs (in terms of size, water quality, available data, installed technology, and presence of uncovered finished storage facilities) in similar (proportionate) ways, without regard to geographic location, type of community, or segment of industry. The LT2ESWTR is a rule where requirements are proportionate to risk. Although some groups may have differing budgetary effects as a result of the LT2ESWTR, those costs are proportional to the need for greater information (monitoring) and risk posed (degree of treatment required). The variation in cost between large and small PWSs is due to economies of scale (a larger PWS can distribute cost across more customers). Regions will have varying impacts due to the number of affected PWSs.

Under UMRA section 202, EPA is required to estimate the potential macro-economic effects of the regulation. These types of effects include those on productivity, economic growth, full employment, creation of productive jobs, and international

competitiveness. Macro-economic effects tend to be measurable in nationwide econometric models only if the economic impact of the regulation reaches 0.25 percent to 0.5 percent of Gross Domestic Product (GDP). In 2003, real GDP was \$10,398 billion, so a rule would have to cost at least \$26 billion to have a measurable effect. A regulation with a smaller aggregate effect is unlikely to have any measurable impact unless it is highly focused on a particular geographic region or economic sector.

The macro-economic effects on the national economy from the LT2ESWTR should not have a measurable effect because the total annual costs for today's rule range from \$93 million to \$133 million based on median Cryptosporidium occurrence distributions from the ICRSSL and Information Collection Rule data sets and a discount rate of 3 percent (\$107 to \$150 million at a 7 percent discount rate). These annualized figures will remain constant over the 25-year implementation period that was evaluated, while GDP will probably continue to rise. Thus, the LT2ESWTR costs as a percentage of the national GDP will only decline over time. Costs will not be highly focused on a particular geographic region or sector.

Consistent with the intergovernmental consultation provisions of section 204 of the UMRA, EPA initiated consultations with the governmental entities affected by this rule prior to the proposal. A description of the consultations is found in the proposed rule (USEPA 2003a).

As required under section 205 of UMRA, EPA considered several regulatory alternatives to address PWSs at risk for contamination by microbial pathogens, specifically including Cryptosporidium. A detailed discussion of these alternatives can be found in section VI of the preamble and also in the Economic Analysis for the LT2ESWTR (USEPA 2005a).

Among the regulatory alternatives considered for the LT2ESWTR, as described in section VI, EPA believes the alternative in today's rule is the most cost-effective that achieves the objectives of the rule. The objective of the LT2ESWTR is to achieve feasible risk reduction from Cryptosporidium and other pathogens in vulnerable PWSs where current regulations do not provide sufficient protection.

EPA evaluated a less costly and less burdensome alternative. However, that alternative would provide no benefit to several thousand consumers who, under the alternative in today's final rule, will receive benefits that most likely exceed their costs, based on EPA estimates. This is illustrated in the LT2ESWTR Economic Analysis (USEPA 2005a). By failing to reduce risk for consumers where additional treatment requirements would be cost-effective, the less costly alternative does not appear to achieve the objectives of the LT2ESWTR.

The other alternatives considered by the Agency achieve the objectives of the rule, but are more costly, more burdensome, and potentially less costeffective. The alternative in today's rule targets additional treatment requirements to PWSs with the highest vulnerability to Cryptosporidium and maximizes net benefits under a broad range of conditions (USEPA 2005a). Consequently, EPA has found the alternative in today's rule to be the most cost-effective among those that achieve the objectives of the rule.

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, today's rule is not subject to the requirements of section 203 of UMRA. As described in section VII.C, EPA has certified that today's rule will not have a significant economic impact on a substantial number of small entities. Average annual expenditures for small PWSs to comply with the LT2ESWTR range from

\$8.1 to \$13.4 million at a 3% discount rate and \$8.3 to \$13.5 million at a 7% discount rate. While the treatment requirements of the LT2ESWTR apply uniformly to both small and large PWSs, large PWSs bear a majority of the total costs of compliance with the rule. This is due to the fact that large PWSs treat a majority of the drinking water that originates from surface water sources.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'

Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the regulation.

EPA has concluded that this final rule may have federalism implications, because it may impose substantial direct compliance costs on State or local governments, and the Federal government will not provide the funds necessary to pay those costs. The final rule may result in expenditures by State, local, and Tribal governments, in the aggregate of \$100 million or more in any one year. Costs are estimated to range from \$93 to \$133 million at a 3 percent discount rate and \$107 to \$150 million using a 7 percent discount rate based on the median distribution modeled from ICRSSL and Information Collection Rule Cryptosporidium occurrence data sets. Accordingly, EPA provides the following federalism summary impact statement as required by section 6(b) of Executive Order 13132.

EPA consulted with representatives of State and local officials early in the process of developing today's rule to permit them to have meaningful and timely input into its development. As described in the proposed rule (USEPA 2003a), this consultation included State and local government representatives on the Stage 2 M–DBP Federal Advisory

Committee (whose recommendations were largely adopted in today's rule), the representatives from small local governments to the SBAR panel, a meeting with representatives from the Association of State Drinking Water Administrators, the National Governors' Association, the National Conference of State Legislatures, the International City/County Management Association, the National League of Cities, the County Executives of America, and health departments, consultation with Tribal governments at four meetings and through the Advisory Committee process, and comments from State and local governments on a pre-proposal draft of the LT2ESWTR.

Representatives of State and local officials were generally concerned with ensuring that drinking water regulations are adequately protective of public health and that any additional regulations achieve significant health benefits in return for required expenditures. They were specifically concerned with the burden of the rule, both in cost and technical complexity, giving flexibility to PWSs and States, balancing the control of microbial risks and DBP risks, funding for implementing new regulations, equal protection for small PWSs, and early implementation of monitoring by large PWSs.

EPA has concluded that the LT2ESWTR is needed to reduce the public health risk associated with Cryptosporidium in drinking water. As shown in section VI, estimated benefits for the rule are significantly higher than costs. Further, EPA believes that today's rule addresses many of the concerns expressed by representatives of government officials.

Under the LT2ESWTR, expenditures for additional treatment are targeted to the fraction of PWSs with the highest vulnerability to Cryptosporidium, thereby minimizing burden for the majority of PWSs, which will not be required to provide additional treatment. The microbial toolbox of compliance options will provide flexibility to PWSs in meeting additional treatment requirements, and States have the flexibility to award treatment credits based on site-specific demonstrations. Disinfection profiling provisions are intended to ensure that PWSs do not reduce microbial protection as they take steps to reduce exposures to DBPs.

The LT2ESWTR achieves equal public health protection for small PWSs. However, the use of E. coli monitoring by small PWSs as a screening analysis to determine the need for Cryptosporidium monitoring will

reduce monitoring costs for most small PWSs. Capital projects related to the rule will be eligible for funding from the Drinking Water State Revolving Fund, which includes specific funding for small communities. EPA is planning to support the initial monitoring by large PWSs that takes place within the first few years after rule promulgation. This will substantially reduce the burden on States associated with early implementation of monitoring requirements.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed rule from State and local officials.

As required by section 8(a) of Executive Order 13132, EPA included a certification from its Federalism Official stating that EPA had met the Executive Order's requirements in a meaningful and timely manner, when it sent the draft of this final rule to OMB for review pursuant to Executive Order 12866. A copy of this certification has been included in the public version of the official record for this final rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop "an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." Under Executive Order 13175, EPA may not issue a regulation that has Tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by Tribal governments, or EPA consults with Tribal officials early in the process of developing the proposed regulation and develops a Tribal summary impact statement.

EPA has concluded that this final rule may have Tribal implications, because it may impose substantial direct compliance costs on Tribal governments, and the Federal government will not provide the funds necessary to pay those costs. EPA has identified 93 Tribal water systems serving a total population of 82,216 that may be subject to the LT2ESWTR. They will bear an estimated total annualized cost of \$207,105 at a 3 percent discount rate (\$309,583 at 7 percent) to

implement this rule. Estimated mean annualized cost per system ranges from \$1,944 to \$7,068 at a 3 percent discount rate (\$2,905 to \$10,681 at 7 percent) depending on PWS size (see Chapter 7 of the LT2ESWTR Economic Analysis (USEPA 2005a) for details). Accordingly, EPA provides the following Tribal summary impact statement as required by section 5(b).

EPA consulted with Tribal officials early in the process of developing this regulation to permit them to have meaningful and timely input into its development. This consultation is described in the proposed rule (USEPA 2003a). Tribal officials were represented on the M–DBP Advisory Committee.

As required by section 7(a), EPA's Tribal Consultation Official has certified that the requirements of the Executive Order have been met in a meaningful and timely manner. A copy of this certification is included in the docket for this rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is subject to the Executive Order because it is an economically significant regulatory action as defined in Executive Order 12866, and we believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Accordingly, we have evaluated the environmental health or safety effects of Cryptosporidium on children. The results of this evaluation are contained in Cryptosporidium: Risk for Infants and Children (USEPA 2001d), which is available in the public docket for this action, and are summarized in this section of the preamble. Further, while available information is not adequate to conduct a quantitative risk assessment specifically for children, EPA has assessed the risk associated with Cryptosporidium in drinking water for

the general population, including children. This assessment is described in the Economic Analysis for the LT2ESWTR (USEPA 2005a) and is summarized in section VI of this preamble.

Children's Environmental Health

Cryptosporidiosis in children is similar to adult disease (USEPA 2001d). Diarrhea is the most common symptom. Other common symptoms in otherwise healthy (i.e., immunocompetent) children include anorexia, vomiting, abdominal pain, fever, dehydration and

weight loss.

The risk of illness and death due to cryptosporidiosis depends on several factors, including age, nutrition, exposure, genetic variability, disease and the immune status of the individual. Mortality resulting from diarrhea generally occurs at a greater rate among the very young and elderly (Gerba et al., 1996). During the 1993 Milwaukee drinking water outbreak, associated mortalities in children were reported. Also, children with laboratoryconfirmed cryptosporidiosis were more likely to have an underlying disease that altered their immune status (Cicirello et al., 1997). In that study, the observed association between increasing age of children and increased numbers of laboratory-confirmed cryptosporidiosis suggested to the authors that the data are consistent with increased tap water consumption of older children. Asymptomatic infection can have a substantial effect on childhood growth (Bern et al., 2002).

Cryptosporidiosis appears to be more prevalent in populations, such as children, that may not have established immunity against the disease and may be in greater contact with environmentally contaminated surfaces (DuPont et al., 1995). In the United States, children aged one to four years are more likely than adults to have the disease. The most recent reported data on cryptosporidiosis shows the occurrence rate (for the year 1999) is higher in children ages one to four (3.03 incidence rate per 100,000) than in any adult age group (CDC, 2001). Evidence from blood sera antibodies collected from children during the 1993 Milwaukee outbreak suggest that children had greater levels of Cryptosporidium infection than predicted for the general community (based on the random-digit dialing telephone survey method) (McDonald et al., 2001).

Data indicate a lower incidence of cryptosporidiosis infection during the first year of life. This is attributed to breast-fed infants consuming less tap

water and, hence, having less exposure to Cryptosporidium, as well as the possibility that mothers confer short term immunity to their children. For example, in a survey of over 30,000 stool sample analyses from different patients in the United Kingdom, the one to five year age group suffered a much higher infection rate than individuals less than one year of age. For children under one year of age, those older than six months of age showed a higher rate of infection than individuals aged less than six months (Casemore, 1990). Similarly, in the U.S., of 2,566 reported Cryptosporidium illnesses in 1999, 525 occurred in ages one to four (incidence rate of 3.03 per 100,000) compared with 58 cases in infants under one year (incidence rate of 1.42 per 100,000) (CDC, 2001).

An infected child may spread the disease to other children or family members (Heijbel et al., 1987, Osewe et al., 1996). Millard et al. (1994) documented greater household secondary transmission of cryptosporidiosis from children than from adults to household and other close contacts. Children continued to shed oocysts for more than two weeks (mean 16.5 days) after diarrhea cessation (Tangerman et al., 1991).

While Cryptosporidium may have a disproportionate effect on children, available data are not adequate to distinctly assess the health risk for children resulting from Cryptosporidium-contaminated drinking water. In assessing risk to children when evaluating regulatory alternatives for the LT2ESWTR, EPA assumed the same risk for children as for the population as a whole.

Section VI of this preamble presents the regulatory alternatives that EPA evaluated for the proposed LT2ESWTR. Among the four alternatives the Agency considered, three involved a risktargeting approach in which additional Cryptosporidium treatment requirements are based on source water monitoring results. A fourth alternative involved additional treatment requirements for all PWSs. The alternative requiring additional treatment by all PWSs was not selected because of concerns about feasibility and because it imposed costs but provided few benefits to PWSs with high quality source water (i.e., relatively low Cryptosporidium risk). The three risk-targeting alternatives were evaluated based on several factors, including costs, benefits, net benefits, feasibility of implementation, and other specific impacts (e.g., impacts on small PWSs or sensitive subpopulations).

The alternative that today's final rule establishes was recommended by the M–DBP Federal Advisory Committee and selected by EPA as the Preferred Regulatory Alternative because it was deemed feasible and provides significant public health benefits in terms of avoided illnesses and deaths. EPA's analysis of benefits and costs indicates that this alternative ranks highly among those evaluated with respect to maximizing net benefits, as shown in the LT2ESWTR Economic Analysis (USEPA 2005a). This document is available in the docket for this action.

The result of the LT2ESWTR will be a reduction in the risk of illness for the entire population, including children. Because available evidence indicates that children may be more vulnerable to cryptosporidiosis than the rest of the population, the LT2ESWTR may, therefore, result in greater risk reduction for children than for the general population.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This determination is based on the following analysis.

The first consideration is whether the LT2ESWTR would adversely affect the supply of energy. The LT2ESWTR does not regulate power generation, either directly or indirectly. The public and private utilities that the LT2ESWTR regulates do not, as a rule, generate

power. Further, the cost increases borne by customers of water utilities as a result of the LT2ESWTR are a low percentage of the total cost of water, except for a very few small PWSs that might install advanced technologies and then need to spread that cost over a narrow customer base. Therefore, the customers that are power generation utilities are unlikely to face any significant effects as a result of the LT2ESWTR. In sum, the LT2ESWTR does not regulate the supply of energy, does not generally regulate the utilities that supply energy, and is unlikely to affect significantly the customer base of energy suppliers. Thus, the LT2ESWTR would not translate into adverse effects on the supply of energy.

The second consideration is whether the LT2ESWTR would adversely affect the distribution of energy. The LT2ESWTR does not regulate any aspect of energy distribution. The utilities that are regulated by the LT2ESWTR already have electrical service. As derived later in this section, the final rule is projected to increase peak electricity demand at water utilities by only 0.036 percent. Therefore, EPA estimates that the existing connections are adequate and that the LT2ESWTR has no discernable adverse effect on energy distribution.

The third consideration is whether the LT2ESWTR would adversely affect the use of energy. Because some drinking water utilities are expected to add treatment technologies that use electrical power, this potential impact is evaluated in more detail. The analyses that underlay the estimation of costs for the LT2ESWTR are national in scope and do not identify specific plants or utilities that may install treatment in response to the rule. As a result, no analysis of the effect on specific energy

suppliers is possible with the available data. The approach used to estimate the impact of energy use, therefore, focuses on national-level impacts. The analysis estimates the additional energy use due to the LT2ESWTR, and compares that to the national levels of power generation in terms of average and peak loads.

The first step in the analysis is to estimate the energy used by the technologies expected to be installed as a result of the LT2ESWTR. Energy use is not directly stated in Technologies and Costs for Control of Microbial Contaminants and Disinfection By-Products (USEPA 2003c), but the annual cost of energy for each technology addition or upgrade necessitated by the LT2ESWTR is provided. An estimate of plant-level energy use is derived by dividing the total energy cost per plant for a range of flows by an average national cost of electricity of \$0.070/ kWh (USDOE 2004a). These calculations are shown in detail in Chapter 7 of the Economic Analysis for the LT2ESWTR (USEPA 2005a). The energy use per plant for each flow range and technology is then multiplied by the number of plants predicted to install each technology in a given flow range. The energy requirements for each flow range are then added to produce a national total. No electricity use is subtracted to account for the technologies that may be replaced by new technologies, resulting in a conservative estimate of the increase in energy use. Results of the analysis are shown in Table VII.H-1 for each of the modeled Cryptosporidium occurrence distributions. The incremental national annual energy usage is estimated at 165 million megawatt-hours (mW) based on the modeled Information Collection Rule occurrence distribution.

Table VII.H-1.— Total Increased Annual National Energy Usage Attributable to the LT2ESWTR

	Plants Selecting Technology	Total Annual Energy Required (kWh/yr)
Technology	Α	В
UV	1,038	100,829,791
O ₃ (0.5 log)	27	20,617,993
O ₃ (1.0 log)	18	18,827,749
O ₃ (2.0 log)	14	16,245,643
ME/UF	37	7,343,320
Bag Filters	1,523	1,605,380
Cartridge Filters	209	82,022
Total	2,867	165,551,898

Source: The LT2ESWTR Economic Analysis (USEPA 2005a).

To determine if the additional energy required for PWSs to comply with the rule would have a significant adverse effect on the use of energy, the numbers in Table VII.H-1 are compared to the national production figures for electricity. According to the U.S. Department of Energy's Information Administration, electricity producers generated 3,848 million mW of electricity in 2003 (USDOE 2004b). Therefore, even using the highest assumed energy use for the LT2ESWTR, the rule when fully implemented would result in only a 0.004 percent increase in annual average energy use.

In addition to average energy use, the impact at times of peak power demand is important. To examine whether increased energy usage might significantly affect the capacity margins of energy suppliers, their peak season generating capacity reserve was compared to an estimate of peak incremental power demand by water utilities.

Both energy use and water use are highest in the summer months, so the most significant effects on supply would be seen then. In the year of 2003, U.S. generation capacity exceeded consumption by 15 percent, or approximately 160,00 mW (USDOE EIA 2004b). Assuming around-the-clock operation of water treatment plants, the total energy requirement can be divided by 8,760 hours per year to obtain an average power demand of 19 mW for the modeled Information Collection Rule occurrence distribution. A more

detailed derivation of this value is shown in Chapter 7 of the Economic Analysis for the LT2ESWTR (USEPA 2005a). Assuming that power demand is proportional to water flow through the plant, and that peak flow can be as high as twice the average daily flow during the summer months, about 38 mW could be needed for treatment technologies installed to comply with the LT2ESWTR. This is only 0.024 percent of the capacity margin available at peak use.

Although EPA recognizes that not all areas have a 15 percent capacity margin and that this margin varies across regions and through time, this analysis reflects the effect of the rule on national energy supply, distribution, or use. While certain areas, notably California, have experienced shortfalls in generating capacity in the recent past, a peak incremental power requirement of 38 mW nationwide is not likely to significantly change the energy supply, distribution, or use in any given area. Considering this analysis, EPA has concluded that LT2ESWTR is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act ("NTTAA") of 1995, Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking involves technical standards. EPA has decided to use methods previously approved in 40 CFR 136.3 for the analysis of E. coli in surface waters. These include several voluntary consensus methods that were developed or adopted by the following organizations: American Public Health Association in Standard Methods for the Examination of Water and Wastewater, 20th, 19th, and 18th Editions, the American Society of Testing Materials in Annual Book of ASTM Standards-Water and Environmental Technology, and the Association of Analytical Chemists in Official Methods of Analysis of AOAC International, 16th Edition. EPA has concluded that these methods have the necessary sensitivity and specificity to meet the data quality objectives of the LT2ESWTR.

The Agency conducted a search to identify potentially applicable voluntary consensus standards for analysis of Cryptosporidium. However, we identified no such standards. Therefore,

EPA approves the use of the following methods for Cryptosporidium analysis: Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA, 2004, United States Environmental Protection Agency, EPA-815-R-05-002 or Method 1622: Cryptosporidium in Water by Filtration/IMS/FA, 2004, United States Environmental Protection Agency, EPA-815-R-05-001.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations or Low-Income Populations

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agency missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. EPA has considered environmental justice related issues concerning the potential impacts of this action and consulted with minority and low-income stakeholders. A description of this consultation can be found in the proposed rule (USEPA 2003a).

K. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with Section 1412 (d) and (e) of the SDWA, the Agency did consult with the Science Advisory Board, the National Drinking Water Advisory Council (NDWAC), and the Secretary of Health and Human Services on today's rule.

EPA charged the SAB panel with reviewing the following aspects of the LT2ESWTR proposal:

- The analysis of Cryptosporidium occurrence:
- The pre- and post-LT2ESWTR Cryptosporidium risk assessment; and
- The treatment credits for the following four microbial toolbox components: raw water off-stream storage, pre-sedimentation, lime softening, and lower finished water turbidity.

EPA met with the SAB to discuss the LT2ESWTR on June 13, 2001 (Washington, DC), September 25–26, 2001 (teleconference), and December 10–12, 2001 (Los Angeles, CA). The SAB issued its final report for this

review, Disinfection Byproducts and Surface Water Treatment: A EPA Science Advisory Board Review of Certain Elements of the Stage 2 Regulatory Proposals, in May 2003.

Comments from the SAB were generally supportive of EPA's analysis of Cryptosporidium occurrence and the Cryptosporidium risk assessment for today's rule. The SAB recommended some additional quality assurance checks for statistical models, improved descriptions of underlying data sets, and better characterization of uncertainty for key parameters. USEPA 2005a and 2005b provide information on revisions EPA made in response to these comments.

SAB comments on microbial toolbox options and the Agency's responses to those comments are described in section IIII.D of this preamble. In general, the SAB supported treatment credit for two-stage softening, recommended additional performance criteria to award treatment credit to presedimentation basins, recommended modifications to the treatment credit for combined and individual filter performance, and opposed treatment credit for off-stream raw water storage.

EPA met with the NDWAC on November 8, 2001, in Washington, DC, to discuss the LT2ESWTR proposal. EPA specifically requested comments from the NDWAC on the regulatory approach taken in the proposed microbial toolbox (e.g., proposal of specific design and implementation criteria for treatment credits). The Council was generally supportive of EPA establishing criteria for awarding treatment credit to toolbox components, but recommended that EPA provide flexibility for States to address PWS specific situations. EPA believes that the demonstration of performance credit, described in section IV.D.9 provides this flexibility by allowing States to award higher or lower levels of treatment credit for microbial toolbox components based on site specific conditions.

EPA has consulted with the U.S. Department of Health and Human Services (HHS) regarding Cryptosporidium health effects and has provided HHS with today's rule.

L. Plain Language

Executive Order 12866 requires each agency to write its rules in plain language. Readable regulations help the

public find requirements quickly and understand them easily. They increase compliance, strengthen enforcement, and decrease mistakes, frustration, phone calls, appeals, and distrust of government. EPA made every effort to write this preamble to the final rule in as clear, concise, and unambiguous manner as possible.

M. Analysis of the Likely Effect of Compliance With the LT2ESWTR on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of SDWA, as amended, requires that in promulgating an NPDWR, the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, managerial, and financial capacity of public water systems. This analysis can be found in the LT2ESWTR Economic Analysis (USEPA 2005a). Analyses reflect only the impact of new or revised requirements, as established by the LT2ESWTR; the impacts of previously established requirements on system capacity are not considered.

EPA has defined overall water system capacity as the ability to plan for, achieve, and maintain compliance with applicable drinking water standards. Capacity encompasses three components: technical, managerial, and financial. Technical capacity is the physical and operational ability of a water system to meet SDWA requirements. This refers to the physical infrastructure of the water system, including the adequacy of source water and the adequacy of treatment, storage, and distribution infrastructure. It also refers to the ability of system personnel to adequately operate and maintain the system and to otherwise implement requisite technical knowledge. Managerial capacity is the ability of a water system to conduct its affairs to achieve and maintain compliance with SDWA requirements. Managerial capacity refers to the system's institutional and administrative capabilities. Financial capacity is a water system's ability to acquire and manage sufficient financial resources to allow the system to achieve and maintain compliance with SDWA requirements. Technical, managerial, and financial capacity can be assessed through key issues and questions, including the following:

Technical Capacity

Does the system have a reliable source of water with adequate quantity? Is the source generally of good quality and adequately protected?

Infrastructure adequacy	Can the system provide water that meets SDWA standards? What is the condition of its infrastructure, including wells or source water intakes, treatment and storage facilities, and distribution systems? What is
	the infrastructure's life expectancy? Does the system have a capital improvement plan?
Technical knowledge and implementation.	Are the system's operators certified? Do the operators have sufficient knowledge of applicable standards? Can the operators effectively implement this technical knowledge? Do the operators understand the system's technical and operational characteristics? Does the system have an effective O&M program?
	Managerial Capacity
Ownership accountability	Are the owners clearly identified? Can they be held accountable for the system?
Staffing and organization	Are the operators and managers clearly identified? Is the system properly organized and staffed? Do personnel understand the management aspects of regulatory requirements and system operations? Do they have adequate expertise to manage water system operations (i.e., to conduct implementation, monitor for E. coli and Cryptosporidium, install treatment, and cover or disinfect reservoir discharge to meet the LT2ESWTR requirements)? Do personnel have the necessary licenses and certifications?
Effective external linkages	Does the system interact well with customers, regulators, and other entities? Is the system aware of available external resources, such as technical and financial assistance?
	Financial Capacity
Revenue sufficiency	Do revenues cover costs? Is the system financially healthy? Does it have access to capital through public or private sources? Are adequate books and records maintained? Are appropriate budgeting, accounting, and financial planning methods used? Does the system manage its revenues effectively?

After determining the type and number of systems to which each requirement applies, EPA evaluated the capacity impact of each rule requirement on large and small systems affected by that particular requirement. EPA determined that the overall impacts on small systems' technical, managerial, and financial capacity will vary. Monitoring and familiarization with new rules will have no significant effects on small systems, with the exception of moderate revenue constraints on those systems that need to implement monitoring for Cryptosporidium. The largest impacts will occur as a result of attaining 2.5 log treatment levels, covering uncovered reservoirs, or disinfecting reservoir discharge. EPA assumed that large systems will have the technical, financial, and managerial capacity to implement LT2ESWTR requirements based on the scale and complexity of their operations. The nature of their operations generally assures that they have access to the technical and managerial expertise to carry out all activities required by the LT2ESWTR. It is also generally easier for large systems to fund capital improvements than small systems, since costs can be spread over a larger customer base, making them smaller on a per-household basis.

To meet challenges posed by rule requirements, it is likely that some small and medium systems will need to develop or enhance linkages with technical and financial assistance providers (including State extension agents). Technical and financial assistance providers can help systems analyze their needs as well as the tradeoffs between cost and health protection. In addition, they may be able to assist

systems in finding the funding necessary to install and operate new equipment. The Safe Drinking Water Act, as amended in 1996, established the Drinking Water State Revolving Fund to make funds available to drinking water systems to finance infrastructure improvements. EPA also works closely with organizations such as the National Rural Water Association and the American Water Works Association to develop technical and managerial tools, materials, and assistance to aid small systems.

N. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small **Business Regulatory Enforcement** Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States, EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the Federal Register. This action is a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective March 6, 2006.

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List of Subjects

40 CFR Part 9

Reporting and recordkeeping.

40 CFR Part 141

Environmental protection, Chemicals, Indians-lands, Incorporation by reference, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Environmental protection, Administrative practice and procedure, Chemicals, Indians-lands, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: December 15, 2005.

Stephen L. Johnson,

Administrator.

■ For the reasons set forth in the preamble, title 40 chapter I of the Code of Federal Regulations is amended as follows:

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; Executive Order 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 et seq., 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

- 2. In § 9.1 the table is amended as follows:
- a. Under the heading "National Primary Drinking Water Regulations Implementation" by adding entries in numerical order for "§ 141.706–141.710, 141.713–141.714, 141.716–141.723".
- b. Under the heading "National Primary Drinking Water Regulations Implementation" by removing entries § 142.15(c), 142.15(c)(6)–(7) and adding entries in numerical order for "142.14(a)(9), 142.15(c)(6), and 142.16(n)" as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

40 CFR citation OMB control No. **National Primary Drinking Water Regulations** 2040-0266 141.706–141.710 2040-0266 141.713–141.714 141.716–141.723 2040-0266 **National Primary Drinking Water Regulations Implementation** 142.14(a)(9) 2040-0266 142.15(c)(6) 2040-0266 142.16(n) 2040-0266

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

■ 3. The authority citation for Part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 4. Section 141.2 is amended by adding, in alphabetical order, definitions for "Bag filters", "Bank filtration", "Cartridge filters", "Flowing stream", "Lake/reservoir", "Membrane filtration", "Plant intake", "Presedimentation", and "Two-stage lime softening", and revising the definition for "Uncovered finished water storage facility" to read as follows:

§ 141.2 Definitions.

* * * * *

Bag filters are pressure-driven separation devices that remove particulate matter larger than 1 micrometer using an engineered porous filtration media. They are typically 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 outside.

Bank filtration is a water treatment process that uses a well to recover surface water that has naturally infiltrated into ground water through a river bed or bank(s). Infiltration is typically enhanced by the hydraulic gradient imposed by a nearby pumping water supply or other well(s).

Cartridge filters are pressure-driven separation devices that remove particulate matter larger than 1 micrometer using an engineered porous filtration media. They are typically constructed as rigid or semi-rigid, self-supporting filter elements housed in pressure vessels in which flow is from the outside of the cartridge to the inside.

Flowing stream is a course of running water flowing in a definite channel.

* * * * * * *

Lake/reservoir refers to a natural or man made basin or hollow on the Earth's surface in which water collects or is stored that may or may not have a current or single direction of flow.

Membrane filtration is 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. This definition includes the common membrane technologies of microfiltration, ultrafiltration, nanofiltration, and reverse osmosis.

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 the treatment plant.

* * * * *

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.

Two-stage lime softening is a process in which chemical addition and hardness precipitation occur in each of two distinct unit clarification processes in series prior to filtration.

Uncovered finished water storage facility is a tank, reservoir, or other facility used to store water that will undergo no further treatment to reduce microbial pathogens except residual disinfection and is directly open to the atmosphere.

■ 5. Subpart Q of part 141 is amended by adding § 141.211 to read as follows:

§ 141.211 Special notice for repeated failure to conduct monitoring of the source water for *Cryptosporidium* and for failure to determine bin classification or mean *Cryptosporidium* level.

(a) When is the special notice for repeated failure to monitor to be given? The owner or operator of a community or non-community water system that is required to monitor source water under § 141.701 must notify persons served by the water system that monitoring has not been completed as specified no later than 30 days after the system has failed to collect any 3 months of monitoring as specified in § 141.701(c). The notice must be repeated as specified in § 141.203(b).

(b) When is the special notice for failure to determine bin classification or mean Cryptosporidium level to be given? The owner or operator of a community or non-community water system that is required to determine a bin classification under § 141.710, or to determine mean Cryptosporidium level under § 141.712, must notify persons served by the water system that the determination has not been made as required no later than 30 days after the system has failed report the determination as specified in § 141.710(e) or § 141.712(a), respectively. The notice must be

- repeated as specified in § 141.203(b). The notice is not required if the system is complying with a State-approved schedule to address the violation.
- (c) What is the form and manner of the special notice? The form and manner of the public notice must follow the requirements for a Tier 2 public notice prescribed in § 141.203(c). The public notice must be presented as required in § 141.205(c).
- (d) What mandatory language must be contained in the special notice? The notice must contain the following language, including the language necessary to fill in the blanks.
- (1) The special notice for repeated failure to conduct monitoring must contain the following language:

We are required to monitor the source of your drinking water for Cryptosporidium. Results of the monitoring are to be used to determine whether water treatment at the (treatment plant name) is sufficient to adequately remove Cryptosporidium from your drinking water. We are required to complete this monitoring and make this determination by (required bin determination date). We "did not monitor or test" or "did not complete all monitoring or testing" on schedule and, therefore, we may not be able to determine by the required date what treatment modifications, if any, must be made to ensure adequate Cryptosporidium removal. Missing this deadline may, in turn, jeopardize our ability to have the required treatment modifications, if any, completed by the deadline required, (date).

For more information, please call (name of water system contact) of (name of water system) at (phone number).

(2) The special notice for failure to determine bin classification or mean Cryptosporidium level must contain the following language:

We are required to monitor the source of your drinking water for Cryptosporidium in order to determine by (date) whether water treatment at the (treatment plant name) is sufficient to adequately remove Cryptosporidium from your drinking water. We have not made this determination by the required date. Our failure to do this may jeopardize our ability to have the required treatment modifications, if any, completed by the required deadline of (date). For more information, please call (name of water system contact) of (name of water system) at (phone number).

- (3) Each special notice must also include a description of what the system is doing to correct the violation and when the system expects to return to compliance or resolve the situation.
- 6. Appendix A to Subpart Q of part 141 is amended by adding entry number 10 under I.A. to read as follows:

Subpart Q—Public Notification of Drinking Water Violations

APPENDIX A TO SUBPART Q OF PART 141-NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE 1

	MCL/MRDI	_/TT violations ²	Monitoring & testing procedure violations			
Contaminant	Tier of public notice required	Citation	Tier of public notice required	Citation		
Violations of National Primary Drinking Water Regulations (NPDWR): ³ A. Microbiological Contaminants						
* *	*	*	*	* *		
10. LT2ESWTR violations	2	141.710–141.720	²² 2, 3	141.701-141.705 and 141.708-141.70		
* *	*	*	*	* *		

¹ Violations and other situations not listed in this table (e.g., failure to prepare Consumer Confidence Reports) do not require notice, unless otherwise determined by the primary agency. Primacy agencies may, at their option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under § 141.202(a) and § 141.203(a)

■ 7. Part 141 is amended by adding a new subpart W to read as follows:

Subpart W-Enhanced Treatment for Cryptosporidium

General Requirements

141.700 General requirements.

Source Water Monitoring Requirements

- 141.701 Source water monitoring.
- Sampling schedules. 141.702
- 141.703 Sampling locations.
- 141.704 Analytical methods.
- 141.705 Approved laboratories.
- 141.706 Reporting source water monitoring results.
- 141.707 Grandfathering previously collected data.

Disinfection Profiling and Benchmarking Requirements

- 141.708 Requirements when making a significant change in disinfection practice.
- 141.709 Developing the disinfection profile and benchmark.

Treatment Technique Requirements

- 141.710 Bin classification for filtered systems.
- 141.711 Filtered system additional Cryptosporidium treatment requirements.
- 141.712 Unfiltered system Cryptosporidium treatment requirements.
- 141.713 Schedule for compliance with Cryptosporidium treatment requirements.
- 141.714 Requirements for uncovered finished water storage facilities.

Requirements for Microbial Toolbox Components

- 141.715 Microbial toolbox options for meeting Cryptosporidium treatment requirements.
- 141.716 Source toolbox components.

- 141.717 Pre-filtration treatment toolbox components.
- 141.718 Treatment performance toolbox components.
- 141.719 Additional filtration toolbox components.
- 141.720 Inactivation toolbox components.

Reporting and Recordkeeping Requirements

141.721 Reporting requirements.

141.722 Recordkeeping requirements.

Requirements for Sanitary Surveys Performed by EPA

141.723 Requirements to respond to significant deficiencies identified in sanitary surveys performed by EPA.

Subpart W—Enhanced Treatment for Cryptosporidium

General Requirements

§141.700 General requirements.

- (a) The requirements of this subpart W are national primary drinking water regulations. The regulations in this subpart establish or extend treatment technique requirements in lieu of maximum contaminant levels for Cryptosporidium. These requirements are in addition to requirements for filtration and disinfection in subparts H, P, and T of this part.
- (b) Applicability. The requirements of this subpart apply to all subpart H systems, which are public water systems supplied by a surface water source and public water systems supplied by a ground water source under the direct influence of surface water.
- (1) Wholesale systems, as defined in § 141.2, must comply with the requirements of this subpart based on the population of the largest system in the combined distribution system.

- (2) The requirements of this subpart for filtered systems apply to systems required by National Primary Drinking Water Regulations to provide filtration treatment, whether or not the system is currently operating a filtration system.
- (3) The requirements of this subpart for unfiltered systems apply only to unfiltered systems that timely met and continue to meet the filtration avoidance criteria in subparts H, P, and T of this part, as applicable.
- (c) Requirements. Systems subject to this subpart must comply with the following requirements:
- (1) Systems must conduct an initial and a second round of source water monitoring for each plant that treats a surface water or GWUDI source. This monitoring may include sampling for Cryptosporidium, E. coli, and turbidity as described in §§ 141.701 through 141.706, to determine what level, if any, of additional Cryptosporidium treatment they must provide.
- (2) Systems that plan to make a significant change to their disinfection practice must develop disinfection profiles and calculate disinfection benchmarks, as described in §§ 141.708 through 141.709.
- (3) Filtered systems must determine their Cryptosporidium treatment bin classification as described in § 141.710 and provide additional treatment for Cryptosporidium, if required, as described in § 141.711. All unfiltered systems must provide treatment for Cryptosporidium as described in § 141.712. Filtered and unfiltered systems must implement Cryptosporidium treatment according to the schedule in § 141.713.

³ The term Violations of National Primary Drinking Water Regulations (NPDWR) is used here to include violations of MCL, MRDL, treatment ³ The term Violations of National Primary Drinking Water Regulations (NPDWR) is used here to include violations of MCL, MRDL, treatment technique, monitoring, and testing procedure requirements.

²² Failure to collect three or more samples for Cryptosporidium analysis is a Tier 2 violation requiring special notice as specified in § 141.211. All other monitoring and testing procedure violations are Tier 3.

- (4) Systems with uncovered finished water storage facilities must comply with the requirements to cover the facility or treat the discharge from the facility as described in § 141.714.
- (5) Systems required to provide additional treatment for *Cryptosporidium* must implement microbial toolbox options that are designed and operated as described in §§ 141.715 through 141.720.
- (6) Systems must comply with the applicable recordkeeping and reporting requirements described in §§ 141.721 through 141.722.
- (7) Systems must address significant deficiencies identified in sanitary surveys performed by EPA as described in § 141.723.

Source Water Monitoring Requirements

§ 141.701 Source water monitoring.

- (a) Initial round of source water monitoring. Systems must conduct the following monitoring on the schedule in paragraph (c) of this section unless they meet the monitoring exemption criteria in paragraph (d) of this section.
- (1) Filtered systems serving at least 10,000 people must sample their source water for *Cryptosporidium*, *E. coli*, and turbidity at least monthly for 24 months.
- (2) Unfiltered systems serving at least 10,000 people must sample their source water for *Cryptosporidium* at least monthly for 24 months.
- (3)(i) Filtered systems serving fewer than 10,000 people must sample their source water for *E. coli* at least once every two weeks for 12 months.

- (ii) A filtered system serving fewer than 10,000 people may avoid *E. coli* monitoring if the system notifies the State that it will monitor for *Cryptosporidium* as described in paragraph (a)(4) of this section. The system must notify the State no later than 3 months prior to the date the system is otherwise required to start *E. coli* monitoring under § 141.701(c).
- (4) Filtered systems serving fewer than 10,000 people must sample their source water for *Cryptosporidium* at least twice per month for 12 months or at least monthly for 24 months if they meet one of the following, based on monitoring conducted under paragraph (a)(3) of this section:
- (i) For systems using lake/reservoir sources, the annual mean *E. coli* concentration is greater than 10 *E. coli*/100 mL.
- (ii) For systems using flowing stream sources, the annual mean *E. coli* concentration is greater than 50 *E. coli*/100 mL.
- (iii) The system does not conduct *E. coli* monitoring as described in paragraph (a)(3) of this section.
- (iv) Systems using ground water under the direct influence of surface water (GWUDI) must comply with the requirements of paragraph (a)(4) of this section based on the *E. coli* level that applies to the nearest surface water body. If no surface water body is nearby, the system must comply based on the requirements that apply to systems using lake/reservoir sources.
- (5) For filtered systems serving fewer than 10,000 people, the State may

- approve monitoring for an indicator other than *E. coli* under paragraph (a)(3) of this section. The State also may approve an alternative to the *E. coli* concentration in paragraph (a)(4)(i), (ii) or (iv) of this section to trigger *Cryptosporidium* monitoring. This approval by the State must be provided to the system in writing and must include the basis for the State's determination that the alternative indicator and/or trigger level will provide a more accurate identification of whether a system will exceed the Bin 1 *Cryptosporidium* level in § 141.710.
- (6) Unfiltered systems serving fewer than 10,000 people must sample their source water for *Cryptosporidium* at least twice per month for 12 months or at least monthly for 24 months.
- (7) Systems may sample more frequently than required under this section if the sampling frequency is evenly spaced throughout the monitoring period.
- (b) Second round of source water monitoring. Systems must conduct a second round of source water monitoring that meets the requirements for monitoring parameters, frequency, and duration described in paragraph (a) of this section, unless they meet the monitoring exemption criteria in paragraph (d) of this section. Systems must conduct this monitoring on the schedule in paragraph (c) of this section.
- (c) Monitoring schedule. Systems must begin the monitoring required in paragraphs (a) and (b) of this section no later than the month beginning with the date listed in this table:

Source Water Monitoring Starting Dates Table

Systems that serve	Must begin the first round of source water monitoring no later than the month beginning	And must begin the second round of source water monitoring no later than the month beginning
(1) At least 100,000 people	(i) April 1, 2008(i) October 1, 2008	(ii) October 1, 2016. (ii) October 1, 2017.

^a Applies only to filtered systems.

- b Applies to filtered systems that meet the conditions of paragraph (a)(4) of this section and unfiltered systems.
- (d) Monitoring avoidance. (1) Filtered systems are not required to conduct source water monitoring under this subpart if the system will provide a total of at least 5.5-log of treatment for Cryptosporidium, equivalent to meeting the treatment requirements of Bin 4 in § 141.711.
- (2) Unfiltered systems are not required to conduct source water monitoring under this subpart if the
- system will provide a total of at least 3-log *Cryptosporidium* inactivation, equivalent to meeting the treatment requirements for unfiltered systems with a mean *Cryptosporidium* concentration of greater than 0.01 oocysts/L in § 141.712.
- (3) If a system chooses to provide the level of treatment in paragraph (d)(1) or (2) of this section, as applicable, rather than start source water monitoring, the
- system must notify the State in writing no later than the date the system is otherwise required to submit a sampling schedule for monitoring under § 141.702. Alternatively, a system may choose to stop sampling at any point after it has initiated monitoring if it notifies the State in writing that it will provide this level of treatment. Systems must install and operate technologies to provide this level of treatment by the

applicable treatment compliance date in § 141.713.

- (e) Plants operating only part of the year. Systems with subpart H plants that operate for only part of the year must conduct source water monitoring in accordance with this subpart, but with the following modifications:
- (1) Systems must sample their source water only during the months that the plant operates unless the State specifies another monitoring period based on plant operating practices.
- (2) Systems with plants that operate less than six months per year and that monitor for *Cryptosporidium* must collect at least six *Cryptosporidium* samples per year during each of two years of monitoring. Samples must be evenly spaced throughout the period the plant operates.
- (f)(1) New sources. A system that begins using a new source of surface water or GWUDI after the system is required to begin monitoring under paragraph (c) of this section must monitor the new source on a schedule the State approves. Source water monitoring must meet the requirements of this subpart. The system must also meet the bin classification and Cryptosporidium treatment requirements of §§ 141.710 and 141.711 or § 141.712, as applicable, for the new source on a schedule the State approves.
- (2) The requirements of § 141.701(f) apply to subpart H systems that begin operation after the monitoring start date applicable to the system's size under paragraph (c) of this section.
- (3) The system must begin a second round of source water monitoring no later than 6 years following initial bin classification under § 141.710 or determination of the mean *Cryptosporidium* level under § 141.712, as applicable.
- (g) Failure to collect any source water sample required under this section in accordance with the sampling schedule, sampling location, analytical method, approved laboratory, and reporting requirements of §§ 141.702 through 141.706 is a monitoring violation.
- (h) Grandfathering monitoring data. Systems may use (grandfather) monitoring data collected prior to the applicable monitoring start date in paragraph (c) of this section to meet the initial source water monitoring requirements in paragraph (a) of this section. Grandfathered data may substitute for an equivalent number of months at the end of the monitoring period. All data submitted under this paragraph must meet the requirements in § 141.707.

§141.702 Sampling schedules.

(a) Systems required to conduct source water monitoring under § 141.701 must submit a sampling schedule that specifies the calendar dates when the system will collect each required sample.

(1) Systems must submit sampling schedules no later than 3 months prior to the applicable date listed in § 141.701(c) for each round of required

monitoring.

(2)(i) Systems serving at least 10,000 people must submit their sampling schedule for the initial round of source water monitoring under § 141.701(a) to EPA electronically at https://intranet.epa.gov/lt2/.

(ii) If a system is unable to submit the sampling schedule electronically, the system may use an alternative approach for submitting the sampling schedule

that EPA approves.

- (3) Systems serving fewer than 10,000 people must submit their sampling schedules for the initial round of source water monitoring § 141.701(a) to the State
- (4) Systems must submit sampling schedules for the second round of source water monitoring § 141.701(b) to the State.
- (5) If EPA or the State does not respond to a system regarding its sampling schedule, the system must sample at the reported schedule.
- (b) Systems must collect samples within two days before or two days after the dates indicated in their sampling schedule (i.e., within a five-day period around the schedule date) unless one of the conditions of paragraph (b)(1) or (2) of this section 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 system to be unable to sample in the scheduled fiveday period, the system must sample as close to the scheduled date as is feasible unless the State approves an alternative sampling date. The system must submit an explanation for the delayed sampling date to the State concurrent with the shipment of the sample to the laboratory.
- (2)(i) If a system 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, including the quality control requirements in § 141.704, or the failure of an approved laboratory to analyze the sample, then the system must collect a replacement sample.
- (ii) The system must collect the replacement sample not later than 21 days after receiving information that an

- analytical result cannot be reported for the scheduled date unless the system demonstrates that collecting a replacement sample within this time frame is not feasible or the State approves an alternative resampling date. The system must submit an explanation for the delayed sampling date to the State concurrent with the shipment of the sample to the laboratory.
- (c) Systems that fail to meet the criteria of paragraph (b) of this section for any source water sample required under § 141.701 must revise their sampling schedules to add dates for collecting all missed samples. Systems must submit the revised schedule to the State for approval prior to when the system begins collecting the missed samples.

§141.703 Sampling locations.

- (a) Systems required to conduct source water monitoring under § 141.701 must collect samples for each plant that treats a surface water or GWUDI source. Where multiple plants draw water from the same influent, such as the same pipe or intake, the State may approve one set of monitoring results to be used to satisfy the requirements of § 141.701 for all plants.
- (b)(1) Systems must collect source water samples prior to chemical treatment, such as coagulants, oxidants and disinfectants, unless the system meets the condition of paragraph (b)(2) of this section.
- (2) The State may approve a system to collect a source water sample after chemical treatment. To grant this approval, the State must determine that collecting a sample prior to chemical treatment is not feasible for the system and that the chemical treatment is unlikely to have a significant adverse effect on the analysis of the sample.
- (c) Systems that recycle filter backwash water must collect source water samples prior to the point of filter backwash water addition.
- (d) Bank filtration. (1) Systems that receive Cryptosporidium treatment credit for bank filtration under § 141.173(b) or § 141.552(a), as applicable, must collect source water samples in the surface water prior to bank filtration.
- (2) Systems that use bank filtration as pretreatment to a filtration plant must collect source water samples from the well (i.e., after bank filtration). Use of bank filtration during monitoring must be consistent with routine operational practice. Systems collecting samples after a bank filtration process may not receive treatment credit for the bank filtration under § 141.717(c).

(e) Multiple sources. Systems with plants that use multiple water sources, including multiple surface water sources and blended surface water and ground water sources, must collect samples as specified in paragraph (e)(1) or (2) of this section. The use of multiple sources during monitoring must be consistent with routine operational practice.

(1) If a sampling tap is available where the sources are combined prior to treatment, systems must collect samples

from the tap.

(2) If a sampling tap where the sources are combined prior to treatment is not available, systems must collect samples at each source near the intake on the same day and must follow either paragraph (e)(2)(i) or (ii) of this section for sample analysis.

(i) Systems may composite samples from each source into one sample prior to analysis. The volume of sample from each source must be weighted according to the proportion of the source in the total plant flow at the time the sample

is collected.

(ii) Systems may analyze samples from each source separately and calculate a weighted average of the analysis results for each sampling date. The weighted average must be calculated by multiplying the analysis result for each source by the fraction the source contributed to total plant flow at the time the sample was collected and

then summing these values.

(f) Additional Requirements. Systems must submit a description of their sampling location(s) to the State at the same time as the sampling schedule required under § 141.702. This description must address the position of the sampling location in relation to the system's water source(s) and treatment processes, including pretreatment, points of chemical treatment, and filter backwash recycle. If the State does not respond to a system regarding sampling location(s), the system must sample at the reported location(s).

§ 141.704 Analytical methods.

(a) Cryptosporidium. Systems must analyze for Cryptosporidium using Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/FA, 2005, United States Environmental Protection Agency, EPA-815-R-05-002 or Method 1622: Cryptosporidium in Water by Filtration/IMS/FA, 2005, United States Environmental Protection Agency, EPA-815-R-05-001, which are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of

these methods online from http:// www.epa.gov/safewater/disinfection/lt2 or from the United States Environmental Protection Agency, Office of Ground Water and Drinking Water, 1201 Constitution Ave., NW, Washington, DC 20460 (Telephone: 800-426-4791). You may inspect a copy at the Water Docket in the EPA Docket Center, 1301 Constitution Ave., NW, Washington, DC, (Telephone: 202-566-2426) or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/ federal_register/ code_of_federal_regulations/

ibr_locations.html.

- (1) Systems must analyze at least a 10 L sample or a packed pellet volume of at least 2 mL as generated by the methods listed in paragraph (a) of this section. Systems unable to process a 10 L sample must analyze as much sample volume as can be filtered by two filters approved by EPA for the methods listed in paragraph (a) of this section, up to a packed pellet volume of at least 2 mL.
- (2)(i) Matrix spike (MS) samples, as required by the methods in paragraph (a) of this section, must be spiked and filtered by a laboratory approved for Cryptosporidium analysis under § 141.705.
- (ii) If the volume of the MS sample is greater than 10 L, the system may filter all but 10 L of the MS sample in the field, and ship the filtered sample and the remaining 10 L of source water to the laboratory. In this case, the laboratory must spike the remaining 10 L of water and filter it through the filter used to collect the balance of the sample in the field.
- (3) Flow cytometer-counted spiking suspensions must be used for MS samples and ongoing precision and recovery (OPR) samples.
- (b) E. coli. Systems must use methods for enumeration of E. coli in source water approved in § 136.3(a) of this title.
- (1) The time from sample collection to initiation of analysis may not exceed 30 hours unless the system meets the condition of paragraph (b)(2) of this
- (2) The State may approve on a caseby-case basis the holding of an *E. coli* sample for up to 48 hours between sample collection and initiation of analysis if the State determines that analyzing an E. coli sample within 30 hours is not feasible. *E. coli* samples held between 30 to 48 hours must be analyzed by the Colilert reagent version of Standard Method 9223B as listed in § 136.3(a) of this title.

- (3) Systems must maintain samples between 0°C and 10°C during storage and transit to the laboratory.
- (c) Turbidity. Systems must use methods for turbidity measurement approved in § 141.74(a)(1).

§ 141.705 Approved laboratories.

(a) Cryptosporidium. Systems must have Cryptosporidium samples analyzed by a laboratory that is approved under EPA's Laboratory Quality Assurance Evaluation Program for Analysis of Cryptosporidium in Water or a laboratory that has been certified for Cryptosporidium analysis by an equivalent State laboratory certification program.

(b) E. coli. Any laboratory certified by the EPA, the National Environmental Laboratory Accreditation Conference or the State for total coliform or fecal coliform analysis under § 141.74 is approved for *E. coli* analysis under this subpart when the laboratory uses the same technique for *E. coli* that the laboratory uses for § 141.74.

(c) Turbidity. Measurements of turbidity must be made by a party

approved by the State.

§141.706 Reporting source water monitoring results.

- (a) Systems must report results from the source water monitoring required under § 141.701 no later than 10 days after the end of the first month following the month when the sample is collected
- (b)(1) All systems serving at least 10,000 people must report the results from the initial source water monitoring required under § 141.701(a) to EPA electronically at https:// intranet.epa.gov/lt2/.
- (2) If a system is unable to report monitoring results electronically, the system may use an alternative approach for reporting monitoring results that EPA approves.
- (c) Systems serving fewer than 10,000 people must report results from the initial source water monitoring required under § 141.701(a) to the State.
- (d) All systems must report results from the second round of source water monitoring required under § 141.701(b) to the State.
- (e) Systems must report the applicable information in paragraphs (e)(1) and (2) of this section for the source water monitoring required under § 141.701.
- (1) Systems must report the following data elements for each Cryptosporidium analysis:

Data element.

1. PWS ID. 2. Facility ID.

Data element.

- 3. Sample collection date.
- 4. Sample type (field or matrix spike).
- 5. Sample volume filtered (L), to nearest 1/4 L.
- $6.\ Was\ 100\%$ of filtered volume examined.
- 7. Number of oocysts counted.
- (i) For matrix spike samples, systems must also report the sample volume spiked and estimated number of oocysts spiked. These data are not required for field samples.
- (ii) For samples in which less than 10 L is filtered or less than 100% of the sample volume is examined, systems must also report the number of filters used and the packed pellet volume.
- (iii) For samples in which less than 100% of sample volume is examined, systems must also report the volume of resuspended concentrate and volume of this resuspension processed through immunomagnetic separation.
- (2) Systems must report the following data elements for each *E. coli* analysis:

Data element.

- 1. PWS ID.
- 2. Facility ID.
- 3. Sample collection date.
- 4. Analytical method number.
- 5. Method type.
- 6. Source type (flowing stream, lake/reservoir, GWUDI).
- 7. E. coli/100 mL.
- 8. Turbidity.¹
- 1 Systems serving fewer than 10,000 people that are not required to monitor for turbidity under $\S 141.701$ are not required to report turbidity with their *E. coli* results.

§ 141.707 Grandfathering previously collected data.

- (a)(1) Systems may comply with the initial source water monitoring requirements of § 141.701(a) by grandfathering sample results collected before the system is required to begin monitoring (i.e., previously collected data). To be grandfathered, the sample results and analysis must meet the criteria in this section and the State must approve.
- (2) A filtered system may grandfather Cryptosporidium samples to meet the requirements of § 141.701(a) when the system does not have corresponding E. coli and turbidity samples. A system that grandfathers Cryptosporidium samples without E. coli and turbidity samples is not required to collect E. coli and turbidity samples when the system completes the requirements for Cryptosporidium monitoring under § 141.701(a).
- (b) *E. coli sample analysis*. The analysis of *E. coli* samples must meet the analytical method and approved laboratory requirements of §§ 141.704 through 141.705.

(c) Cryptosporidium sample analysis. The analysis of Cryptosporidium samples must meet the criteria in this paragraph.

(1) Laboratories analyzed Cryptosporidium samples using one of the analytical methods in paragraphs (c)(1)(i) through (vi) of this section, which are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of these methods on-line from the United States Environmental Protection Agency, Office of Ground Water and Drinking Water, 1201 Constitution Ave, NW, Washington, DC 20460 (Telephone: 800-426-4791). You may inspect a copy at the Water Docket in the EPA Docket Center, 1301 Constitution Ave., NW, Washington, DC, (Telephone: 202-566-2426) or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/ federal_register/code_of_federal_ regulations/ibr locations.html.

(i) Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/ FA, 2005, United States Environmental Protection Agency, EPA–815–R–05–002.

(ii) Method 1622: Cryptosporidium in Water by Filtration/IMS/FA, 2005, United States Environmental Protection Agency, EPA-815-R-05-001.

(iii) Method 1623: Cryptosporidium and Giardia in Water by Filtration/IMS/ FA, 2001, United States Environmental Protection Agency, EPA–821–R–01–025.

(iv) Method 1622: Cryptosporidium in Water by Filtration/IMS/FA, 2001, United States Environmental Protection Agency, EPA–821–-R–01–026.

(v) *Method 1623: Cryptosporidium* and Giardia in Water by Filtration/IMS/FA, 1999, United States Environmental Protection Agency, EPA–821–R–99–006.

(vi) Method 1622: Cryptosporidium in Water by Filtration/IMS/FA, 1999, United States Environmental Protection Agency, EPA-821-R-99-001.

(2) For each Cryptosporidium sample, the laboratory analyzed at least 10 L of sample or at least 2 mL of packed pellet or as much volume as could be filtered by 2 filters that EPA approved for the methods listed in paragraph (c)(1) of this section

(d) Sampling location. The sampling location must meet the conditions in § 141.703.

(e) Sampling frequency.
Cryptosporidium samples were
collected no less frequently than each
calendar month on a regular schedule,
beginning no earlier than January 1999.
Sample collection intervals may vary for

the conditions specified in § 141.702(b)(1) and (2) if the system provides documentation of the condition when reporting monitoring results.

(1) The State may approve grandfathering of previously collected data where there are time gaps in the sampling frequency if the system conducts additional monitoring the State specifies to ensure that the data used to comply with the initial source water monitoring requirements of § 141.701(a) are seasonally representative and unbiased.

(2) Systems may grandfather previously collected data where the sampling frequency within each month varied. If the *Cryptosporidium* sampling frequency varied, systems must follow the monthly averaging procedure in § 141.710(b)(5) or § 141.712(a)(3), as applicable, when calculating the bin classification for filtered systems or the mean *Cryptosporidium* concentration for unfiltered systems.

(f) Reporting monitoring results for grandfathering. Systems that request to grandfather previously collected monitoring results must report the following information by the applicable dates listed in this paragraph. Systems serving at least 10,000 people must report this information to EPA unless the State approves reporting to the State rather than EPA. Systems serving fewer than 10,000 people must report this information to the State.

(1) Systems must report that they intend to submit previously collected monitoring results for grandfathering. This report must specify the number of previously collected results the system will submit, the dates of the first and last sample, and whether a system will conduct additional source water monitoring to meet the requirements of § 141.701(a). Systems must report this information no later than the date the sampling schedule under § 141.702 is required.

(2) Systems must report previously collected monitoring results for grandfathering, along with the associated documentation listed in paragraphs (f)(2)(i) through (iv) of this section, no later than two months after the applicable date listed in § 141.701(c).

(i) For each sample result, systems must report the applicable data elements in § 141.706.

(ii) Systems must certify that the reported monitoring results include all results the system 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.

(iii) Systems must certify that the samples were representative of a plant's source water(s) and the source water(s) have not changed. Systems must report a description of the sampling location(s), which must address the position of the sampling location in relation to the system's water source(s) and treatment processes, including points of chemical addition and filter backwash recycle.

(iv) 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 paragraph (c)(1) of 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, IPR, OPR, and method blank sample associated with the reported results.

(g) 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 system, such as a drought, the State may disapprove the data. Alternatively, the State may approve the previously collected data if the system reports additional source water monitoring data, as determined by the State, to ensure that the data set used under § 141.710 or § 141.712 represents average source water conditions for the system.

(h) If a system submits previously collected data that fully meet the number of samples required for initial source water monitoring under § 141.701(a) and some of the data are rejected due to not meeting the requirements of this section, systems must conduct additional monitoring to replace rejected data on a schedule the State approves. Systems are not required to begin this additional monitoring until two months after notification that data have been rejected and additional monitoring is necessary.

Disinfection Profiling and Benchmarking Requirements

§ 141.708 Requirements when making a significant change in disinfection practice.

(a) Following the completion of initial source water monitoring under § 141.701(a), a system that plans to make a significant change to its disinfection practice, as defined in paragraph (b) of this section, must

- develop disinfection profiles and calculate disinfection benchmarks for *Giardia lamblia* and viruses as described in § 141.709. Prior to changing the disinfection practice, the system must notify the State and must include in this notice the information in paragraphs (a)(1) through (3) of this section.
- (1) A completed disinfection profile and disinfection benchmark for *Giardia lamblia* and viruses as described in § 141.709.
- (2) A description of the proposed change in disinfection practice.
- (3) An analysis of how the proposed change will affect the current level of disinfection.
- (b) Significant changes to disinfection practice are defined as follows:
- (1) Changes to the point of disinfection;
- (2) Changes to the disinfectant(s) used in the treatment plant;
- (3) Changes to the disinfection process; or
- (4) Any other modification identified by the State as a significant change to disinfection practice.

§ 141.709 Developing the disinfection profile and benchmark.

(a) Systems required to develop disinfection profiles under § 141.708 must follow the requirements of this section. Systems must monitor at least weekly for a period of 12 consecutive months to determine the total log inactivation for Giardia lamblia and viruses. If systems monitor more frequently, the monitoring frequency must be evenly spaced. Systems that operate for fewer than 12 months per year must monitor weekly during the period of operation. Systems must determine log inactivation for Giardia lamblia through the entire plant, based on CT99.9 values in Tables 1.1 through 1.6, 2.1 and 3.1 of § 141.74(b) as applicable. Systems must determine log inactivation for viruses through the entire treatment plant based on a protocol approved by the State.

(b) Systems with a single point of disinfectant application prior to the entrance to the distribution system must conduct the monitoring in paragraphs (b)(1) through (4) of this section.

Systems with more than one point of disinfectant application must conduct the monitoring in paragraphs (b)(1) through (4) of this section for each disinfection segment. Systems must monitor the parameters necessary to determine the total inactivation ratio, using analytical methods in § 141.74(a).

(1) For systems using a disinfectant other than UV, the temperature of the disinfected water must be measured at

- each residual disinfectant concentration sampling point during peak hourly flow or at an alternative location approved by the State.
- (2) For systems using chlorine, the pH of the disinfected water must be measured at each chlorine residual disinfectant concentration sampling point during peak hourly flow or at an alternative location approved by the State.
- (3) The disinfectant contact time(s) (t) must be determined during peak hourly flow.
- (4) The residual disinfectant concentration(s) (C) of the water before or at the first customer and prior to each additional point of disinfectant application must be measured during peak hourly flow.

(c) In lieu of conducting new monitoring under paragraph (b) of this section, systems may elect to meet the requirements of paragraphs (c)(1) or (2) of this section.

(1) Systems that have at least one year of existing data that are substantially equivalent to data collected under the provisions of paragraph (b) of this section may use these data to develop disinfection profiles as specified in this section if the system has neither made a significant change to its treatment practice nor changed sources since the data were collected. Systems may develop disinfection profiles using up to three years of existing data.

(2) Systems may use disinfection profile(s) developed under § 141.172 or §§ 141.530 through 141.536 in lieu of developing a new profile if the system has neither made a significant change to its treatment practice nor changed sources since the profile was developed. Systems that have not developed a virus profile under § 141.172 or §§ 141.530 through 141.536 must develop a virus profile using the same monitoring data on which the *Giardia lamblia* profile is based.

(d) Systems must calculate the total inactivation ratio for *Giardia lamblia* as specified in paragraphs (d)(1) through (3) of this section.

(1) Systems using only one point of disinfectant application may determine the total inactivation ratio for the disinfection segment based on either of the methods in paragraph (d)(1)(i) or (ii) of this section.

(i) Determine one inactivation ratio (CTcalc/CT_{99.9}) before or at the first customer during peak hourly flow.

(ii) Determine successive CTcalc/ CT_{99.9} values, representing sequential inactivation ratios, between the point of disinfectant application and a point before or at the first customer during peak hourly flow. The system must

- calculate the total inactivation ratio by determining (CTcalc/CT_{99.9}) for each sequence and then adding the (CTcalc/CT_{99.9}) values together to determine (Σ (CTcalc/CT_{99.9})).
- (2) Systems using more than one point of disinfectant application before the first customer must determine the CT value of each disinfection segment immediately prior to the next point of disinfectant application, or for the final segment, before or at the first customer, during peak hourly flow. The (CTcalc/CT_{99.9}) value of each segment and (Σ (CTcalc/CT_{99.9})) must be calculated using the method in paragraph (d)(1)(ii) of this section.
- (3) The system must determine the total logs of inactivation by multiplying the value calculated in paragraph (d)(1) or (d)(2) of this section by 3.0.
- (4) Systems must calculate the log of inactivation for viruses using a protocol approved by the State.
- (e) Systems must use the procedures specified in paragraphs (e)(1) and (2) of this section to calculate a disinfection benchmark.
- (1) For each year of profiling data collected and calculated under paragraphs (a) through (d) of this section, systems must determine the lowest mean monthly level of both *Giardia lamblia* and virus inactivation. Systems must determine the mean *Giardia lamblia* and virus inactivation

- for each calendar month for each year of profiling data by dividing the sum of daily or weekly *Giardia lamblia* and virus log inactivation by the number of values calculated for that month.
- (2) The disinfection benchmark is the lowest monthly mean value (for systems with one year of profiling data) or the mean of the lowest monthly mean values (for systems with more than one year of profiling data) of *Giardia lamblia* and virus log inactivation in each year of profiling data.

Treatment Technique Requirements

§ 141.710 Bin classification for filtered systems.

- (a) Following completion of the initial round of source water monitoring required under § 141.701(a), filtered systems must calculate an initial *Cryptosporidium* bin concentration for each plant for which monitoring was required. Calculation of the bin concentration must use the *Cryptosporidium* results reported under § 141.701(a) and must follow the procedures in paragraphs (b)(1) through (5) of this section.
- (b)(1) For systems that collect a total of at least 48 samples, the bin concentration is equal to the arithmetic mean of all sample concentrations.
- (2) For systems that collect a total of at least 24 samples, but not more than 47 samples, the bin concentration is

- equal to the highest arithmetic mean of all sample concentrations in any 12 consecutive months during which *Cryptosporidium* samples were collected.
- (3) For systems that serve fewer than 10,000 people and monitor for *Cryptosporidium* for only one year (i.e., collect 24 samples in 12 months), the bin concentration is equal to the arithmetic mean of all sample concentrations.
- (4) For systems with plants operating only part of the year that monitor fewer than 12 months per year under § 141.701(e), the bin concentration is equal to the highest arithmetic mean of all sample concentrations during any year of *Cryptosporidium* monitoring.
- (5) If the monthly *Cryptosporidium* sampling frequency varies, systems must first calculate a monthly average for each month of monitoring. Systems must then use these monthly average concentrations, rather than individual sample concentrations, in the applicable calculation for bin classification in paragraphs (b)(1) through (4) of this section.
- (c) Filtered systems must determine their initial bin classification from the following table and using the *Cryptosporidium* bin concentration calculated under paragraphs (a)–(b) of this section:

BIN CLASSIFICATION TABLE FOR FILTERED SYSTEMS

For systems that are:	With a Cryptosporidium bin concentration of1	The bin classification is
required to monitor for <i>Cryptosporidium</i> under § 141.701.	Cryptosporidium <0.075 oocyst/L	Bin 1.
	0.075 oocysts/L ≤ <i>Cryptosporidium</i> <1.0 oocysts/L 1.0 oocysts/L ≤ <i>Cryptosporidium</i> <3.0 oocysts/L <i>Cryptosporidium</i> ≥3.0 oocysts/L	Bin 2. Bin 3. Bin 4.
serving fewer than 10,000 people and NOT required to monitor for <i>Cryptosporidium</i> under § 141.701(a)(4).	NA	Bin 1.

¹ Based on calculations in paragraph (a) or (d) of this section, as applicable.

- (d) Following completion of the second round of source water monitoring required under § 141.701(b), filtered systems must recalculate their *Cryptosporidium* bin concentration using the *Cryptosporidium* results reported under § 141.701(b) and following the procedures in paragraphs (b)(1) through (4) of this section. Systems must then redetermine their bin classification using this bin concentration and the table in paragraph (c) of this section.
- (e)(1) Filtered systems must report their initial bin classification under paragraph (c) of this section to the State

- for approval no later than 6 months after the system is required to complete initial source water monitoring based on the schedule in § 141.701(c).
- (2) Systems must report their bin classification under paragraph (d) of this section to the State for approval no later than 6 months after the system is required to complete the second round of source water monitoring based on the schedule in § 141.701(c).
- (3) The bin classification report to the State must include a summary of source water monitoring data and the calculation procedure used to determine bin classification.
- (f) Failure to comply with the conditions of paragraph (e) of this section is a violation of the treatment technique requirement.

§ 141.711 Filtered system additional Cryptosporidium treatment requirements.

(a) Filtered systems must provide the level of additional treatment for *Cryptosporidium* specified in this paragraph based on their bin classification as determined under § 141.710 and according to the schedule in § 141.713.

If the system	And the system uses the following filtration treatment in full compliance with subparts H, P, and T of this part (as applicable), then the additional <i>Cryptosporidium</i> treatment requirements are					
bin classifica- tion is	Conventional filtration treat- ment (including softening)	Direct filtration	Slow sand or diatomaceous earth filtration	Alternative filtration tech- nologies		
Bin 2 Bin 3	No additional treatment	2.5-log treatment	No additional treatment	No additional treatment. (1) (2) (3)		

- ¹ As determined by the State such that the total *Cryptosporidium* removal and inactivation is at least 4.0-log.
- ² As determined by the State such that the total *Cryptosporidium* removal and inactivation is at least 5.0-log.
- ³ As determined by the State such that the total *Cryptosporidium* removal and inactivation is at least 5.5-log.
- (b)(1) Filtered systems must use one or more of the treatment and management options listed in § 141.715, termed the microbial toolbox, to comply with the additional *Cryptosporidium* treatment required in paragraph (a) of this section.
- (2) Systems classified in Bin 3 and Bin 4 must achieve at least 1-log of the additional *Cryptosporidium* treatment required under paragraph (a) of this section using either one or a combination of the following: bag filters, bank filtration, cartridge filters, chlorine dioxide, membranes, ozone, or UV, as described in §§ 141.716 through 141.720.
- (c) Failure by a system in any month to achieve treatment credit by meeting criteria in §§ 141.716 through 141.720 for microbial toolbox options that is at least equal to the level of treatment required in paragraph (a) of this section is a violation of the treatment technique requirement.
- (d) If the State determines during a sanitary survey or an equivalent source water assessment that after a system completed the monitoring conducted under § 141.701(a) or § 141.701(b), significant changes occurred in the system's watershed that could lead to increased contamination of the source water by *Cryptosporidium*, the system must take actions specified by the State to address the contamination. These actions may include additional source water monitoring and/or implementing microbial toolbox options listed in § 141.715.

§ 141.712 Unfiltered system Cryptosporidium treatment requirements.

(a) Determination of mean Cryptosporidium level. (1) Following completion of the initial source water monitoring required under § 141.701(a), unfiltered systems must calculate the arithmetic mean of all Cryptosporidium sample concentrations reported under § 141.701(a). Systems must report this value to the State for approval no later than 6 months after the month the system is required to complete initial

source water monitoring based on the schedule in § 141.701(c).

- (2) Following completion of the second round of source water monitoring required under § 141.701(b), unfiltered systems must calculate the arithmetic mean of all *Cryptosporidium* sample concentrations reported under § 141.701(b). Systems must report this value to the State for approval no later than 6 months after the month the system is required to complete the second round of source water monitoring based on the schedule in § 141.701(c).
- (3) If the monthly *Cryptosporidium* sampling frequency varies, systems must first calculate a monthly average for each month of monitoring. Systems must then use these monthly average concentrations, rather than individual sample concentrations, in the calculation of the mean *Cryptosporidium* level in paragraphs (a)(1) or (2) of this section.
- (4) The report to the State of the mean *Cryptosporidium* levels calculated under paragraphs (a)(1) and (2) of this section must include a summary of the source water monitoring data used for the calculation.
- (5) Failure to comply with the conditions of paragraph (a) of this section is a violation of the treatment technique requirement.
- (b) Cryptosporidium inactivation requirements. Unfiltered systems must provide the level of inactivation for Cryptosporidium specified in this paragraph, based on their mean Cryptosporidium levels as determined under paragraph (a) of this section and according to the schedule in § 141.713.
- (1) Unfiltered systems with a mean *Cryptosporidium* level of 0.01 oocysts/L or less must provide at least 2-log *Cryptosporidium* inactivation.
- (2) Unfiltered systems with a mean *Cryptosporidium* level of greater than 0.01 oocysts/L must provide at least 3-log *Cryptosporidium* inactivation.

(c) Inactivation treatment technology requirements. Unfiltered systems must use chlorine dioxide, ozone, or UV as

- described in § 141.720 to meet the *Cryptosporidium* inactivation requirements of this section.
- (1) Systems that use chlorine dioxide or ozone and fail to achieve the *Cryptosporidium* inactivation required in paragraph (b) of this section on more than one day in the calendar month are in violation of the treatment technique requirement.
- (2) Systems that use UV light and fail to achieve the *Cryptosporidium* inactivation required in paragraph (b) of this section by meeting the criteria in § 141.720(d)(3)(ii) are in violation of the treatment technique requirement.
- (d) Use of two disinfectants. Unfiltered systems must meet the combined Cryptosporidium inactivation requirements of this section and Giardia lamblia and virus inactivation requirements of § 141.72(a) using a minimum of two disinfectants, and each of two disinfectants must separately achieve the total inactivation required for either Cryptosporidium, Giardia lamblia, or viruses.

§ 141.713 Schedule for compliance with Cryptosporidium treatment requirements.

- (a) Following initial bin classification under § 141.710(c), filtered systems must provide the level of treatment for *Cryptosporidium* required under § 141.711 according to the schedule in paragraph (c) of this section.
- (b) Following initial determination of the mean *Cryptosporidium* level under § 141.712(a)(1), unfiltered systems must provide the level of treatment for *Cryptosporidium* required under § 141.712 according to the schedule in paragraph (c) of this section.
- (c) Cryptosporidium treatment compliance dates.

CRYPTOSPORIDIUM TREATMENT COMPLIANCE DATES TABLE

Systems that serve	Must comply with Cryptosporidium treat- ment requirements no later than a
(1) At least 100,000 people.	(i) April 1, 2012.
(2) From 50,000 to 99,999 people.	(i) October 1, 2012.
(3) From 10,000 to 49,999 people.	(i) October 1, 2013.
(4) Fewer than 10,000 people.	(i) October 1, 2014.

- ^a States may allow up to an additional two years for complying with the treatment requirement for systems making capital improvements.
- (d) If the bin classification for a filtered system changes following the second round of source water monitoring, as determined under § 141.710(d), the system must provide the level of treatment for *Cryptosporidium* required under § 141.711 on a schedule the State approves.
- (e) If the mean *Cryptosporidium* level for an unfiltered system changes

following the second round of monitoring, as determined under § 141.712(a)(2), and if the system must provide a different level of *Cryptosporidium* treatment under § 141.712 due to this change, the system must meet this treatment requirement on a schedule the State approves.

§ 141.714 Requirements for uncovered finished water storage facilities.

- (a) Systems using uncovered finished water storage facilities must comply with the conditions of this section.
- (b) Systems must notify the State of the use of each uncovered finished water storage facility no later than April 1, 2008.
- (c) Systems must meet the conditions of paragraph (c)(1) or (2) of this section for each uncovered finished water storage facility or be in compliance with a State-approved schedule to meet these conditions no later than April 1, 2009.
- (1) Systems must cover any uncovered finished water storage facility.
- (2) Systems must treat the discharge from the uncovered finished water storage facility to the distribution system to achieve inactivation and/or

- removal of at least 4-log virus, 3-log *Giardia lamblia*, and 2-log *Cryptosporidium* using a protocol approved by the State.
- (d) Failure to comply with the requirements of this section is a violation of the treatment technique requirement.

Requirements for Microbial Toolbox Components

\S 141.715 Microbial toolbox options for meeting Cryptosporidium treatment requirements.

- (a)(1) Systems receive the treatment credits listed in the table in paragraph (b) of this section by meeting the conditions for microbial toolbox options described in §§ 141.716 through 141.720. Systems apply these treatment credits to meet the treatment requirements in § 141.711 or § 141.712, as applicable.
- (2) Unfiltered systems are eligible for treatment credits for the microbial toolbox options described in § 141.720 only.
- (b) The following table summarizes options in the microbial toolbox:

MICROBIAL TOOLBOX SUMMARY TABLE: OPTIONS, TREATMENT CREDITS AND CRITERIA

Toolbox Option	Cryptosporidium treatment credit with design and implementation criteria		
Sour	rce Protection and Management Toolbox Options		
(1) 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 systems are not eligible for credit. Specific criteria are in § 141.716(a).		
(2) Alternative source/intake management	No prescribed credit. Systems may conduct simultaneous monitoring for treatment bin classification at alternative intake locations or under alternative intake management strategies. Specific criteria are in § 141.716(b).		
	Pre Filtration Toolbox Options		
(3) 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. Specific criteria are in § 141.717(a).		
(4) 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. Specific criteria are in §141.717(b).		
(5) Bank filtration	0.5-log credit for 25-foot setback; 1.0-log credit for 50-foot setback; aquifer must be unconsolidated sand containing at least 10 percent fines; average turbidity in wells must be less than 1 NTU. Systems using wells followed by filtration when conducting source water monitoring must sample the well to determine bin classification and are not eligible for additional credit. Specific criteria are in § 141.717(c).		
	Treatment Performance Toolbox Options		
(6) 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. Specific criteria are in § 141.718(a).		
(7) 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. Specific criteria are in § 141.718(b).		
(8) Demonstration of performance	Credit awarded to unit process or treatment train based on a demonstration to the State with a State- approved protocol. Specific criteria are in § 141.718(c).		

MICROBIAL TOOLBOX SUMMARY TABLE: OPTIONS, TREATMENT CREDITS AND CRITERIA—Continued

Toolbox Option	Cryptosporidium treatment credit with design and implementation criteria		
	Additional Filtration Toolbox Options		
(9) Bag or cartridge filters (individual filters)	Up to 2-log credit based on the removal efficiency demonstrated during challenge testing with a 1.0-log factor of safety. Specific criteria are in § 141.719(a).		
(10) Bag or cartridge filters (in series)			
(11) Membrane filtration Log credit equivalent to removal efficiency demonstrated in challenge test for device ported by direct integrity testing. Specific criteria are in § 141.719(b).			
(12) Second stage filtration			
(13) Slow sand filters	2.5-log credit as a secondary filtration step; 3.0-log credit as a primary filtration process. No prior chlorination for either option. Specific criteria are in § 141.719(d).		
	Inactivation Toolbox Options		
(14) Chlorine dioxide	Log credit based on measured CT in relation to CT table. Specific criteria in § 141.720(b)		
(15) Ozone(16) UV	Log credit based on measured CT in relation to CT table. Specific criteria in § 141.720(b). 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. Specific criteria in § 141.720(d).		

§141.716 Source toolbox components.

- (a) Watershed control program.
 Systems receive 0.5-log
 Cryptosporidium treatment credit for implementing a watershed control program that meets the requirements of this section.
- (1) Systems that intend to apply for the watershed control program credit must notify the State of this intent no later than two years prior to the treatment compliance date applicable to the system in § 141.713.
- (2) Systems must submit to the State a proposed watershed control plan no later than one year before the applicable treatment compliance date in § 141.713. The State must approve the watershed control plan for the system to receive watershed control program treatment credit. The watershed control plan must include the elements in paragraphs (a)(2)(i) through (iv) of this section.
- (i) Identification of an "area of influence" outside of which the likelihood of *Cryptosporidium* or fecal contamination affecting the treatment plant intake is not significant. This is the area to be evaluated in future watershed surveys under paragraph (a)(5)(ii) of this section.
- (ii) Identification of both potential and actual sources of *Cryptosporidium* contamination and an assessment of the relative impact of these sources on the system's source water quality.
- (iii) An analysis of the effectiveness and feasibility of control measures that could reduce *Cryptosporidium* loading from sources of contamination to the system's source water.
- (iv) A statement of goals and specific actions the system will undertake to reduce source water *Cryptosporidium* levels. The plan must explain how the

- actions are expected to contribute to specific goals, identify watershed partners and their roles, identify resource requirements and commitments, and include a schedule for plan implementation with deadlines for completing specific actions identified in the plan.
- (3) Systems with existing watershed control programs (*i.e.*, programs in place on January 5, 2006) are eligible to seek this credit. Their watershed control plans must meet the criteria in paragraph (a)(2) of this section and must specify ongoing and future actions that will reduce source water *Cryptosporidium* levels.
- (4) If the State does not respond to a system regarding approval of a watershed control plan submitted under this section and the system meets the other requirements of this section, the watershed control program will be considered approved and 0.5 log Cryptosporidium treatment credit will be awarded unless and until the State subsequently withdraws such approval.
- (5) Systems must complete the actions in paragraphs (a)(5)(i) through (iii) of this section to maintain the 0.5-log credit.
- (i) Submit an annual watershed control program status report to the State. The annual watershed control program status report must describe the system's implementation of the approved plan and assess the adequacy of the plan to meet its goals. It must explain how the system is addressing any shortcomings in plan implementation, including those previously identified by the State or as the result of the watershed survey conducted under paragraph (a)(5)(ii) of

- this section. It must also describe any significant changes that have occurred in the watershed since the last watershed sanitary survey. If a system determines during implementation that making a significant change to its approved watershed control program is necessary, the system must notify the State prior to making any such changes. If any change is likely to reduce the level of source water protection, the system must also list in its notification the actions the system will take to mitigate this effect.
- (ii) Undergo a watershed sanitary survey every three years for community water systems and every five years for noncommunity water systems and submit the survey report to the State. The survey must be conducted according to State guidelines and by persons the State approves.
- (A) The watershed sanitary survey must meet the following criteria: encompass the region identified in the State-approved watershed control plan as the area of influence; assess the implementation of actions to reduce source water *Cryptosporidium* levels; and identify any significant new sources of *Cryptosporidium*.
- (B) If the State determines that significant changes may have occurred in the watershed since the previous watershed sanitary survey, systems must undergo another watershed sanitary survey by a date the State requires, which may be earlier than the regular date in paragraph (a)(5)(ii) of this section.
- (iii) The system must make the watershed control plan, annual status reports, and watershed sanitary survey reports 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. The State may approve systems to withhold from the public portions of the annual status report, watershed control plan, and watershed sanitary survey based on water supply security considerations.

(6) If the State determines that a system is not carrying out the approved watershed control plan, the State may withdraw the watershed control

program treatment credit.

- (b) Alternative source. (1) A system may conduct source water monitoring that reflects a different intake location (either in the same source or for an alternate source) or a different procedure for the timing or level of withdrawal from the source (alternative source monitoring). If the State approves, a system may determine its bin classification under § 141.710 based on the alternative source monitoring results.
- (2) If systems conduct alternative source monitoring under paragraph (b)(1) of this section, systems must also monitor their current plant intake concurrently as described in § 141.701.
- (3) Alternative source monitoring under paragraph (b)(1) of this section must meet the requirements for source monitoring to determine bin classification, as described in §§ 141.701 through 141.706. Systems must report the alternative source monitoring results to the State, along with supporting information documenting the operating conditions under which the samples were collected.
- (4) If a system determines its bin classification under § 141.710 using alternative source monitoring results that reflect a different intake location or a different procedure for managing the timing or level of withdrawal from the source, the system must relocate the intake or permanently adopt the withdrawal procedure, as applicable, no later than the applicable treatment compliance date in § 141.713.

§ 141.717 Pre-filtration treatment toolbox components.

- (a) Presedimentation. Systems receive 0.5-log Cryptosporidium treatment credit for a presedimentation basin during any month the process meets the criteria in this paragraph.
- (1) The presedimentation basin must be in continuous operation and must treat the entire plant flow taken from a surface water or GWUDI source.
- (2) The system must continuously add a coagulant to the presedimentation basin.

(3) The presedimentation basin must achieve the performance criteria in paragraph (3)(i) or (ii) of this section.

(i) 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: log₁₀(monthly mean of daily influent turbidity) – \log_{10} (monthly mean of daily effluent turbidity).

(ii) Complies with State-approved performance criteria that demonstrate at least 0.5-log mean removal of micronsized particulate material through the

presedimentation process.

(b) Two-stage lime softening. Systems receive an additional 0.5-log Cryptosporidium treatment credit for a two-stage lime softening plant if chemical addition and hardness precipitation occur in two separate and sequential softening stages prior to filtration. Both softening stages must treat the entire plant flow taken from a surface water or GWUDI source.

(c) Bank filtration. Systems receive Cryptosporidium treatment credit for bank filtration that serves as pretreatment to a filtration plant by meeting the criteria in this paragraph. Systems using bank filtration when they begin source water monitoring under § 141.701(a) must collect samples as described in § 141.703(d) and are not eligible for this credit.

(1) 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 paragraph

(c)(4) of this section.

(2) 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 aguifer 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.

(3) Only horizontal and vertical wells are eligible for treatment credit.

(4) 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

(5) 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.

(6) Springs and infiltration galleries are not eligible for treatment credit under this section, but are eligible for

credit under § 141.718(c).

(7) Bank filtration demonstration of performance. The State may approve Cryptosporidium treatment credit for bank filtration based on a demonstration of performance study that meets the criteria in this paragraph. This treatment credit may be greater than 1.0-log and may be awarded to bank filtration that does not meet the criteria in paragraphs (c)(1)–(5) of this section.

(i) The study must follow a Stateapproved 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.

(ii) 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).

§ 141.718 Treatment performance toolbox components.

(a) Combined filter performance. Systems using conventional filtration treatment or direct filtration treatment receive an additional 0.5-log Cryptosporidium treatment credit during any month the system meets the criteria in this paragraph. Combined filter effluent (CFE) turbidity must be less than or equal to 0.15 NTU in at least 95 percent of the measurements. Turbidity must be measured as described in § 141.74(a) and (c).

(b) Individual filter performance. Systems using conventional filtration treatment or direct filtration treatment receive 0.5-log Cryptosporidium treatment credit, which can be in

- addition to the 0.5-log credit under paragraph (a) of this section, during any month the system meets the criteria in this paragraph. Compliance with these criteria must be based on individual filter turbidity monitoring as described in § 141.174 or § 141.560, as applicable.
- (1) The filtered water turbidity for each individual filter must be less than or equal to 0.15 NTU in at least 95 percent of the measurements recorded each month.
- (2) No individual filter may have a measured turbidity greater than 0.3 NTU in two consecutive measurements taken 15 minutes apart.
- (3) Any system that has received treatment credit for individual filter performance and fails to meet the requirements of paragraph (b)(1) or (2) of this section during any month does not receive a treatment technique violation under § 141.711(c) if the State determines the following:
- (i) The failure was due to unusual and short-term circumstances that could not reasonably be prevented through optimizing treatment plant design, operation, and maintenance.
- (ii) The system has experienced no more than two such failures in any calendar year.
- (c) Demonstration of performance. The State may approve Cryptosporidium treatment credit for drinking water treatment processes based on a demonstration of performance study that meets the criteria in this paragraph. This treatment credit may be greater than or less than the prescribed treatment credits in § 141.711 or §§ 141.717 through 141.720 and may be awarded to treatment processes that do not meet the criteria for the prescribed credits.
- (1) Systems cannot receive the prescribed treatment credit for any toolbox box option in §§ 141.717 through 141.720 if that toolbox option is included in a demonstration of performance study for which treatment credit is awarded under this paragraph.
- (2) The demonstration of performance study must follow a State-approved protocol and must demonstrate the level of *Cryptosporidium* reduction the treatment process will achieve under the full range of expected operating conditions for the system.
- (3) Approval by the State must be in writing and may include monitoring and treatment performance criteria that the system must demonstrate and report on an ongoing basis to remain eligible for the treatment credit. The State may designate such criteria where necessary to verify that the conditions under which the demonstration of

performance credit was approved are maintained during routine operation.

§ 141.719 Additional filtration toolbox components.

- (a) Bag and cartridge filters. Systems receive Cryptosporidium treatment credit of up to 2.0-log for individual bag or cartridge filters and up to 2.5-log for bag or cartridge filters operated in series by meeting the criteria in paragraphs (a)(1) through (10) of this section. To be eligible for this credit, systems must report the results of challenge testing that meets the requirements of paragraphs (a)(2) through (9) of this section to the State. The filters must treat the entire plant flow taken from a subpart H source.
- (1) The Cryptosporidium treatment credit awarded to bag or cartridge filters must be based on the removal efficiency demonstrated during challenge testing that is conducted according to the criteria in paragraphs (a)(2) through (a)(9) of this section. A factor of safety equal to 1-log for individual bag or cartridge filters and 0.5-log for bag or cartridge filters in series must be applied to challenge testing results to determine removal credit. Systems may use results from challenge testing conducted prior to January 5, 2006 if the prior testing was consistent with the criteria specified in paragraphs (a)(2) through (9) of this section.
- (2) Challenge testing must be performed on full-scale bag or cartridge filters, and the associated filter housing or pressure vessel, that are identical in material and construction to the filters and housings the system will use for removal of *Cryptosporidium*. Bag or cartridge filters must be challenge tested in the same configuration that the system will use, either as individual filters or as a series configuration of filters.
- (3) Challenge testing must be conducted using *Cryptosporidium* or a surrogate that is removed no more efficiently than *Cryptosporidium*. The microorganism or surrogate used during challenge testing is referred to as the challenge particulate. The concentration of the challenge particulate must be determined using a method capable of discreetly quantifying the specific microorganism or surrogate used in the test; gross measurements such as turbidity may not be used.
- (4) The maximum feed water concentration that can be used during a challenge test must be based on the detection limit of the challenge particulate in the filtrate (i.e., filtrate detection limit) and must be calculated using the following equation:

- Maximum Feed Concentration = 1×10^4 × (Filtrate Detection Limit)
- (5) Challenge testing must be conducted at the maximum design flow rate for the filter as specified by the manufacturer.
- (6) Each filter evaluated must be tested for a duration sufficient to reach 100 percent of the terminal pressure drop, which establishes the maximum pressure drop under which the filter may be used to comply with the requirements of this subpart.
- (7) Removal efficiency of a filter must be determined from the results of the challenge test and expressed in terms of log removal values using the following equation:

 $LRV = LOG_{10}(C_f) - LOG_{10}(C_p)$

Where:

- LRV = log removal value demonstrated during challenge testing; C_f = the feed concentration measured during the challenge test; and C_p = the filtrate concentration measured during the challenge test. In applying this equation, the same units must be used for the feed and filtrate concentrations. If the challenge particulate is not detected in the filtrate, then the term C_p must be set equal to the detection limit.
- (8) Each filter tested must be challenged with the challenge particulate during three periods over the filtration cycle: within two hours of start-up of a new filter; when the pressure drop is between 45 and 55 percent of the terminal pressure drop; and at the end of the cycle after the pressure drop has reached 100 percent of the terminal pressure drop. An LRV must be calculated for each of these challenge periods for each filter tested. The LRV for the filter (LRV_{filter}) must be assigned the value of the minimum LRV observed during the three challenge periods for that filter.
- (9) If fewer than 20 filters are tested, the overall removal efficiency for the filter product line must be set equal to the lowest LRV_{filter} among the filters tested. If 20 or more filters are tested, the overall removal efficiency for the filter product line must be set equal to the 10th percentile of the set of LRV_{filter} values for the various filters tested. The percentile is defined by (i/(n+1)) where i is the rank of n individual data points ordered lowest to highest. If necessary, the 10th percentile may be calculated using linear interpolation.
- (10) If a previously tested filter is modified in a manner that could change the removal efficiency of the filter product line, challenge testing to demonstrate the removal efficiency of

the modified filter must be conducted and submitted to the State.

(b) Membrane filtration. (1) Systems receive Cryptosporidium treatment credit for membrane filtration that meets the criteria of this paragraph. Membrane cartridge filters that meet the definition of membrane filtration in § 141.2 are eligible for this credit. The level of treatment credit a system receives is equal to the lower of the values determined under paragraph (b)(1)(i) and (ii) of this section.

(i) The removal efficiency demonstrated during challenge testing conducted under the conditions in paragraph (b)(2) of this section.

- (ii) The maximum removal efficiency that can be verified through direct integrity testing used with the membrane filtration process under the conditions in paragraph (b)(3) of this section
- (2) Challenge Testing. The membrane used by the system must undergo challenge testing to evaluate removal efficiency, and the system must report the results of challenge testing to the State. Challenge testing must be conducted according to the criteria in paragraphs (b)(2)(i) through (vii) of this section. Systems may use data from challenge testing conducted prior to January 5, 2006 if the prior testing was consistent with the criteria in paragraphs (b)(2)(i) through (vii) of this section.
- (i) Challenge testing must be conducted on either a full-scale membrane module, identical in material and construction to the membrane modules used in the system's treatment facility, or a smaller-scale membrane module, identical in material and similar in construction to the full-scale module. A module is defined as the smallest component of a membrane unit in which a specific membrane surface area is housed in a device with a filtrate outlet structure.
- (ii) Challenge testing must be conducted using *Cryptosporidium* oocysts or a surrogate that is removed no more efficiently than *Cryptosporidium* oocysts. The organism or surrogate used during challenge testing is referred to as the challenge particulate. The concentration of the challenge particulate, in both the feed and filtrate water, must be determined using a method capable of discretely quantifying the specific challenge particulate used in the test; gross measurements such as turbidity may not be used.
- (iii) The maximum feed water concentration that can be used during a challenge test is based on the detection limit of the challenge particulate in the

filtrate and must be determined according to the following equation: Maximum Feed Concentration = $3.16 \times 10^6 \times \text{(Filtrate Detection Limit)}$

- (iv) Challenge testing must be conducted under representative hydraulic conditions at the maximum design flux and maximum design process recovery specified by the manufacturer for the membrane module. 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).
- (v) Removal efficiency of a membrane module must be calculated from the challenge test results and expressed as a log removal value according to the following equation:

 $LRV = LOG_{10}(C_f) \times LOG_{10}(C_p)$

Where

Where: LRV = log removal value demonstrated during the challenge test; C_f = the feed concentration measured during the challenge test; and C_p = the filtrate concentration measured during the challenge test. Equivalent units must be used for the feed and filtrate concentrations. If the challenge particulate is not detected in the filtrate, the term C_p is set equal to the detection limit for the purpose of calculating the LRV. An LRV must be calculated for each membrane module evaluated during the challenge test.

(vi) The removal efficiency of a membrane filtration process demonstrated during challenge testing must be expressed as a log removal value (LRV $_{C-Test}$). If fewer than 20 modules are tested, then LRV_{C-Test} is equal to the lowest of the representative LRVs among the modules tested. If 20 or more modules are tested, then LRV_{C-Test} is equal to the 10th percentile of the representative LRVs among the modules tested. The percentile is defined by (i/(n+1)) where i is the rank of n individual data points ordered lowest to highest. If necessary, the 10th percentile may be calculated using linear interpolation.

(vii) The challenge test must establish a quality control release value (QCRV) for a non-destructive performance test that demonstrates the *Cryptosporidium* removal capability of the membrane filtration module. This performance test must be applied to each production membrane module used by the system

that was not directly challenge tested in order to verify *Cryptosporidium* removal capability. Production modules that do not meet the established QCRV are not eligible for the treatment credit demonstrated during the challenge test.

(viii) If a previously tested membrane is modified in a manner that could change the removal efficiency of the membrane or the applicability of the non-destructive performance test and associated QCRV, additional challenge testing to demonstrate the removal efficiency of, and determine a new QCRV for, the modified membrane must be conducted and submitted to the State

(3) Direct integrity testing. Systems must conduct direct integrity testing in a manner that demonstrates a removal efficiency equal to or greater than the removal credit awarded to the membrane filtration process and meets the requirements described in paragraphs (b)(3)(i) through (vi) of this section. A direct integrity test is defined as a physical test applied to a membrane unit in order to identify and isolate integrity breaches (i.e., one or more leaks that could result in contamination of the filtrate).

(i) The direct integrity test must be independently applied to each membrane unit in service. A membrane unit is defined as a group of membrane modules that share common valving that allows the unit to be isolated from the rest of the system for the purpose of integrity testing or other maintenance.

(ii) The direct integrity method must have a resolution of 3 micrometers or less, where resolution is defined as the size of the smallest integrity breach that contributes to a response from the direct

integrity test.

(iii) The direct integrity test must have a sensitivity sufficient to verify the log treatment credit awarded to the membrane filtration process by the State, where sensitivity is defined as the maximum log removal value that can be reliably verified by a direct integrity test. Sensitivity must be determined using the approach in either paragraph (b)(3)(iii)(A) or (B) of this section as applicable to the type of direct integrity test the system uses.

(A) For direct integrity tests that use an applied pressure or vacuum, the direct integrity test sensitivity must be calculated according to the following equation:

 $LRV_{DIT} = LOG_{10} (Q_p / (VCF \times Q_{breach}))$

Where:

 LRV_{DIT} = the sensitivity of the direct integrity test; Q_p = total design filtrate flow from the membrane unit; Q_{breach} = flow of water from an

integrity breach associated with the smallest integrity test response that can be reliably measured, and VCF = volumetric concentration factor. The volumetric concentration factor is the ratio of the suspended solids concentration on the high pressure side of the membrane relative to that in the feed water.

(B) For direct integrity tests that use a particulate or molecular marker, the direct integrity test sensitivity must be calculated according to the following equation:

 $LRV_{DIT} = LOG_{10}(C_f) - LOG_{10}(C_p)$

Where:

- LRV_{DIT} = the sensitivity of the direct integrity test; C_f = the typical feed concentration of the marker used in the test; and C_p = the filtrate concentration of the marker from an integral membrane unit.
- (iv) Systems must establish a control limit within the sensitivity limits of the direct integrity test that is indicative of an integral membrane unit capable of meeting the removal credit awarded by the State.
- (v) If the result of a direct integrity test exceeds the control limit established under paragraph (b)(3)(iv) of this section, the system must remove the membrane unit from service. Systems must conduct a direct integrity test to verify any repairs, and may return the membrane unit to service only if the direct integrity test is within the established control limit.
- (vi) Systems must conduct direct integrity testing on each membrane unit at a frequency of not less than once each day that the membrane unit is in operation. The State may approve less frequent testing, based on demonstrated process reliability, the use of multiple barriers effective for *Cryptosporidium*, or reliable process safeguards.
- (4) Indirect integrity monitoring. Systems must conduct continuous indirect integrity monitoring on each membrane unit according to the criteria in paragraphs (b)(4)(i) through (v) of this section. Indirect integrity monitoring is defined as monitoring some aspect of filtrate water quality that is indicative of

- the removal of particulate matter. A system that implements continuous direct integrity testing of membrane units in accordance with the criteria in paragraphs (b)(3)(i) through (v) of this section is not subject to the requirements for continuous indirect integrity monitoring. Systems must submit a monthly report to the State summarizing all continuous indirect integrity monitoring results triggering direct integrity testing and the corrective action that was taken in each case.
- (i) Unless the State approves an alternative parameter, continuous indirect integrity monitoring must include continuous filtrate turbidity monitoring.
- (ii) Continuous monitoring must be conducted at a frequency of no less than once every 15 minutes.
- (iii) Continuous monitoring must be separately conducted on each membrane unit.
- (iv) If indirect integrity monitoring includes turbidity and if the filtrate turbidity readings are above 0.15 NTU for a period greater than 15 minutes (i.e., two consecutive 15-minute readings above 0.15 NTU), direct integrity testing must immediately be performed on the associated membrane unit as specified in paragraphs (b)(3)(i) through (v) of this section.
- (v) If indirect integrity monitoring includes a State-approved alternative parameter and if the alternative parameter exceeds a State-approved control limit for a period greater than 15 minutes, direct integrity testing must immediately be performed on the associated membrane units as specified in paragraphs (b)(3)(i) through (v) of this section.
- (c) Second stage filtration. Systems receive 0.5-log Cryptosporidium treatment credit for a separate second stage of filtration that consists of sand, dual media, GAC, or other fine grain media following granular media filtration if the State approves. To be eligible for this credit, the first stage of filtration must be preceded by a coagulation step and both filtration stages must treat the entire plant flow

- taken from a surface water or GWUDI source. A cap, such as GAC, on a single stage of filtration is not eligible for this credit. The State must approve the treatment credit based on an assessment of the design characteristics of the filtration process.
- (d) Slow sand filtration (as secondary filter). Systems are eligible to receive 2.5-log *Cryptosporidium* treatment credit for a slow sand filtration process that follows a separate stage of filtration if both filtration stages treat entire plant flow taken from a surface water or GWUDI source and no disinfectant residual is present in the influent water to the slow sand filtration process. The State must approve the treatment credit based on an assessment of the design characteristics of the filtration process. This paragraph does not apply to treatment credit awarded to slow sand filtration used as a primary filtration process.

§ 141.720 Inactivation toolbox components.

- (a) Calculation of CT values. (1) CT is the product of the disinfectant contact time (T, in minutes) and disinfectant concentration (C, in milligrams per liter). Systems with treatment credit for chlorine dioxide or ozone under paragraph (b) or (c) of this section must calculate CT at least once each day, with both C and T measured during peak hourly flow as specified in §§ 141.74(a) through (b).
- (2) Systems with several disinfection segments in sequence may calculate CT for each segment, where a disinfection segment is defined as a treatment unit process with a measurable disinfectant residual level and a liquid volume. Under this approach, systems must add the *Cryptosporidium* CT values in each segment to determine the total CT for the treatment plant.
- (b) CT values for chlorine dioxide and ozone. (1) Systems receive the Cryptosporidium treatment credit listed in this table by meeting the corresponding chlorine dioxide CT value for the applicable water temperature, as described in paragraph (a) of this section.

CT Values (MG·MIN/L) FOR Cryptosporidium INACTIVATION BY CHLORINE DIOXIDE 1

Log prodit		Water Temperature, °C									
Log credit	<=0.5	1	2	3	5	7	10	15	20	25	30
(i) 0.25	159	153	140	128	107	90	69	45	29	19	12
(ii) 0.5	319	305	279	256	214	180	138	89	58	38	24
(iii) 1.0	637	610	558	511	429	360	277	179	116	75	49
(iv) 1.5	956	915	838	767	643	539	415	268	174	113	73
(v) 2.0	1275	1220	1117	1023	858	719	553	357	232	150	98
(vi) 2.5	1594	1525	1396	1278	1072	899	691	447	289	188	122

CT VALUES (MG·MIN/L) FOR Cryptosporidium INACTIVATION BY CHLORINE DIOXIDE 1—Continued

Log gradit		Water Temperature, °C									
Log credit	<=0.5	1	2	3	5	7	10	15	20	25	30
(vii) 3.0		1830	1675	1534	1286	1079	830	536	347	226	147

¹ Systems may use this equation to determine log credit between the indicated values: Log credit = (0.001506 × (1.09116) Temp) × CT.

(2) Systems receive the *Cryptosporidium* treatment credit listed in this table by meeting the

corresponding ozone CT values for the applicable water temperature, as

described in paragraph (a) of this section.

CT VALUES (MG·MIN/L) FOR Cryptosporidium INACTIVATION BY OZONE 1

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

¹ Systems may use this equation to determine log credit between the indicated values: Log credit = (0.0397 × (1.09757)^{Temp}) × CT.

(c) Site-specific study. The State may approve alternative chlorine dioxide or ozone CT values to those listed in paragraph (b) of this section on a site-specific basis. The State must base this approval on a site-specific study a system conducts that follows a State-approved protocol.

(d) *Ultraviolet light*. Systems receive *Cryptosporidium, Giardia lamblia*, and virus treatment credits for ultraviolet

(UV) light reactors by achieving the corresponding UV dose values shown in paragraph (d)(1) of this section. Systems must validate and monitor UV reactors as described in paragraphs (d)(2) and (3) of this section to demonstrate that they are achieving a particular UV dose value for treatment credit.

(1) *UV dose table.* The treatment credits listed in this table are for *UV* light at a wavelength of 254 nm as

produced by a low pressure mercury vapor lamp. To receive treatment credit for other lamp types, systems must demonstrate an equivalent germicidal dose through reactor validation testing, as described in paragraph (d)(2) of this section. The UV dose values in this table are applicable only to post-filter applications of UV in filtered systems and to unfiltered systems.

UV DOSE TABLE FOR Cryptosporidium, Giardia lamblia, AND VIRUS INACTIVATION CREDIT

Log credit	Cryptosporidium	Giardia lamblia	Virus
	UV dose (mJ/cm²)	UV dose (mJ/cm²)	UV dose (mJ/cm²)
(i) 0.5 (ii) 1.0 (iii) 1.5 (iv) 2.0 (v) 2.5 (vi) 3.0 (vii) 3.5 (viii) 4.0	1.6 2.5 3.9 5.8 8.5 12 15	1.5 2.1 3.0 5.2 7.7 11 15 22	39 58 79 100 121 143 163 186

- (2) Reactor validation testing. Systems must use UV reactors that have undergone validation testing to determine the operating conditions under which the reactor delivers the UV dose required in paragraph (d)(1) of this section (i.e., validated operating conditions). These operating conditions must include flow rate, UV intensity as measured by a UV sensor, and UV lamp status.
- (i) When determining validated operating conditions, systems must account for the following factors: UV
- absorbance of the water; lamp fouling and aging; measurement uncertainty of on-line sensors; UV dose distributions arising from the velocity profiles through the reactor; failure of UV lamps or other critical system components; and inlet and outlet piping or channel configurations of the UV reactor.
- (ii) Validation testing must include the following: Full scale testing of a reactor that conforms uniformly to the UV reactors used by the system and inactivation of a test microorganism whose dose response characteristics
- have been quantified with a low pressure mercury vapor lamp.
- (iii) The State may approve an alternative approach to validation testing.
- (3) Reactor monitoring. (i) Systems must monitor their UV reactors to determine if the reactors are operating within validated conditions, as determined under paragraph (d)(2) of this section. This monitoring must include UV intensity as measured by a UV sensor, flow rate, lamp status, and other parameters the State designates

based on UV reactor operation. Systems must verify the calibration of UV sensors and must recalibrate sensors in accordance with a protocol the State approves.

(ii) To receive treatment credit for UV light, systems must treat at least 95 percent of the water delivered to the public during each month by UV reactors operating within validated conditions for the required UV dose, as described in paragraphs (d)(1) and (2) of this section. Systems must demonstrate compliance with this condition by the monitoring required under paragraph (d)(3)(i) of this section.

Reporting and Recordkeeping Requirements

§141.721 Reporting requirements.

- (a) Systems must report sampling schedules under § 141.702 and source water monitoring results under § 141.706 unless they notify the State that they will not conduct source water monitoring due to meeting the criteria of § 141.701(d).
- (b) Systems must report the use of uncovered finished water storage facilities to the State as described in § 141.714.
- (c) Filtered systems must report their *Cryptosporidium* bin classification as described in § 141.710.

- (d) Unfiltered systems must report their mean source water *Cryptosporidium* level as described in § 141.712.
- (e) Systems must report disinfection profiles and benchmarks to the State as described in §§ 141.708 through 141.709 prior to making a significant change in disinfection practice.
- (f) Systems must report to the State in accordance with the following table for any microbial toolbox options used to comply with treatment requirements under § 141.711 or § 141.712. Alternatively, the State may approve a system to certify operation within required parameters for treatment credit rather than reporting monthly operational data for toolbox options.

MICROBIAL TOOLBOX REPORTING REQUIREMENTS

Toolbox option	Systems must submit the following information	On the following schedule
(1) Watershed control program (WCP).	(i) Notice of intention to develop a new or continue an existing watershed control program.	No later than two years before the applicable treatment compliance date in § 141.713
	(ii) Watershed control plan	No later than one year before the applicable treatment compliance date in § 141.713.
	(iii) Annual watershed control program status report	Every 12 months, beginning one year after the applicable treatment compliance date in § 141.713.
	(iv) Watershed sanitary survey report	For community water systems, every three years beginning three years after the applicable treatment compliance date in § 141.713. For noncommunity water systems, every five years beginning five years after the applicable treatment compliance date in § 141.713.
(2) Alternative source/intake management.	Verification that system has relocated the intake or adopted the intake withdrawal procedure reflected in monitoring results.	No later than the applicable treatment compliance date in § 141.713.
(3) Presedimentation	Monthly verification of the following: (i) Continuous basin operation (ii) Treatment of 100% of the flow (iii) Continuous addition of a coagulant (iv) At least 0.5-log mean reduction of influent turbidity or compliance with alternative State-approved performance criteria.	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(4) Two-stage lime softening	Monthly verification of the following: (i) Chemical addition and hardness precipitation occurred in two separate and sequential softening stages prior to filtration (ii) Both stages treated 100% of the plant flow.	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(5) Bank filtration	 (i) Initial demonstration of the following: (A) Unconsolidated, predominantly sandy aquifer (B) Setback distance of at least 25 ft. (0.5-log credit) or 50 ft. (1.0-log credit). 	No later than the applicable treatment compliance date in § 141.713.
	(ii) If monthly average of daily max turbidity is greater than 1 NTU then system must report result and sub- mit an assessment of the cause	Report within 30 days following the month in which the monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(6) Combined filter performance.	Monthly verification of combined filter effluent (CFE) turbidity levels less than or equal to 0.15 NTU in at least 95 percent of the 4 hour CFE measurements taken each month.	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(7) Individual filter performance.	Monthly verification of the following: (i) Individual filter effluent (IFE) turbidity levels less than or equal to 0.15 NTU in at least 95 percent of samples each month in each filter (ii) No individual filter greater than 0.3 NTU in two consecutive readings 15 minutes apart.	Monthly reporting within 10 days following the month in which the monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.]
(8) Demonstration of per- formance.	(i) Results from testing following a State approved protocol.	No later than the applicable treatment compliance date in § 141.713.
	(ii) As required by the State, monthly verification of op- eration within conditions of State approval for dem- onstration of performance credit.	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.

MICROBIAL TOOLBOX REPORTING REQUIREMENTS—Continued

Toolbox option	Systems must submit the following information	On the following schedule
	Cystems must submit the following mornation	On the following schedule
(9) Bag filters and cartridge filters.	(i) Demonstration that the following criteria are met: (A) Process meets the definition of bag or cartridge filtra- tion; (B) Removal efficiency established through chal- lenge testing that meets criteria in this subpart.	No later than the applicable treatment compliance date in § 141.713.
	(ii) Monthly verification that 100% of plant flow was filtered.	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(10) Membrane filtration	lowing: (A) Removal efficiency established through challenge testing that meets criteria in this subpart; (B) Integrity test method and parameters, including resolution, sensitivity, test frequency, control limits, and associated baseline.	No later than the applicable treatment compliance date in § 141.713.
	(ii) Monthly report summarizing the following: (A) All direct integrity tests above the control limit; (B) If applicable, any turbidity or alternative state-approved indirect integrity monitoring results triggering direct integrity testing and the corrective action that was taken.	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(11) Second stage filtration	Monthly verification that 100% of flow was filtered through both stages and that first stage was preceded by coagulation step.	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(12) Slow sand filtration (as secondary filter).	Monthly verification that both a slow sand filter and a preceding separate stage of filtration treated 100% of flow from subpart H sources	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(13) Chlorine dioxide	Summary of CT values for each day as described in §141.720	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(14) Ozone	Summary of CT values for each day as described in § 141.720	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.
(15) UV	(i) Validation test results demonstrating operating conditions that achieve required UV dose.	No later than the applicable treatment compliance date in § 141.713.
	(ii) Monthly report summarizing the percentage of water entering the distribution system that was not treated by UV reactors operating within validated conditions for the required dose as specified in 141.720(d)	Within 10 days following the month in which monitoring was conducted, beginning on the applicable treatment compliance date in § 141.713.

§ 141.722 Recordkeeping requirements.

- (a) Systems must keep results from the initial round of source water monitoring under § 141.701(a) and the second round of source water monitoring under § 141.701(b) until 3 years after bin classification under § 141.710 for filtered systems or determination of the mean *Cryptosporidium* level under § 141.710 for unfiltered systems for the particular round of monitoring.
- (b) Systems must keep any notification to the State that they will not conduct source water monitoring due to meeting the criteria of § 141.701(d) for 3 years.
- (c) Systems must keep the results of treatment monitoring associated with microbial toolbox options under §§ 141.716 through 141.720 and with uncovered finished water reservoirs under § 141.714, as applicable, for 3 years.

Requirements for Sanitary Surveys Performed by EPA

§ 141.723 Requirements to respond to significant deficiencies identified in sanitary surveys performed by EPA.

- (a) A sanitary survey is an onsite review of the water source (identifying sources of contamination by using results of source water assessments where available), facilities, equipment, operation, maintenance, and monitoring compliance of a PWS to evaluate the adequacy of the PWS, its sources and operations, and the distribution of safe drinking water.
- (b) For the purposes of this section, a significant deficiency includes a defect in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that EPA determines to be causing, or has the potential for causing the introduction of contamination into the water delivered to consumers.
- (c) For sanitary surveys performed by EPA, systems must respond in writing to significant deficiencies identified in sanitary survey reports no later than 45 days after receipt of the report,

- indicating how and on what schedule the system will address significant deficiencies noted in the survey.
- (d) Systems must correct significant deficiencies identified in sanitary survey reports according to the schedule approved by EPA, or if there is no approved schedule, according to the schedule reported under paragraph (c) of this section if such deficiencies are within the control of the system.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

■ 8. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9 and 300j-11.

■ 9. Section 142.14 is amended by adding paragraph (a)(9) to read as follows:

§ 142.14 Records kept by States.

* * * *

(a) * * *

(9) Any decisions made pursuant to the provisions of part 141, subpart W of this chapter.

(i) Results of source water *E. coli* and *Cryptosporidium* monitoring.

(ii) The bin classification after the initial and after the second round of source water monitoring for each filtered system, as described in § 141.710 of this chapter.

(iii) Any change in treatment requirements for filtered systems due to watershed assessment during sanitary surveys, as described in § 141.711(d) of

this chapter.

- (iv) The determination of whether the mean *Cryptosporidium* level is greater than 0.01 oocysts/L after the initial and after the second round of source water monitoring for each unfiltered system, as described in § 141.712(a) of this chapter.
- (v) The treatment processes or control measures that systems use to meet their *Cryptosporidium* treatment requirements under § 141.711 or § 141.712 of this chapter.
- (vi) A list of systems required to cover or treat the effluent of an uncovered finished water storage facility, as specified in § 141.714 of this chapter.
- 10. Section 142.15 is amended by adding paragraph (c)(6) to read as follows:

§142.15 Reports by States.

(c) * * *

- (6) Subpart W. (i) The bin classification after the initial and after the second round of source water monitoring for each filtered system, as described in § 141.710 of this chapter.
- (ii) Any change in treatment requirements for these systems due to watershed assessment during sanitary surveys, as described in § 141.711(d) of this chapter.
- (iii) The determination of whether the mean *Cryptosporidium* level is greater than 0.01 oocysts/L both after the initial and after the second round of source water monitoring for each unfiltered system, as described in § 141.712(a) of this chapter.
- 11. Section 142.16 is amended by adding paragraph (n) to read as follows:

§ 142.16 Special primacy conditions.

(n) Requirements for States to adopt 40 CFR part 141, subpart W. In addition to the general primacy requirements elsewhere in this part, including the requirements that State regulations be at least as stringent as Federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subpart W, must contain a description of how the

- State will accomplish the following program requirements where allowed in State programs.
- (1) Approve an alternative to the *E. coli* levels that trigger *Cryptosporidium* monitoring by filtered systems serving fewer than 10,000 people, as described in § 141.701(a)(5).
- (2) Assess significant changes in the watershed and source water as part of the sanitary survey process and determine appropriate follow-up action for systems, as described in § 141.711(d) of this chapter.
- (3) Approve watershed control programs for the 0.5-log treatment credit in the microbial toolbox, as described in § 141.716(a) of this chapter.
- (4) Approve protocols for demonstration of performance treatment credits in the microbial toolbox, as allowed under § 141.718(c) of this chapter.
- (5) Approve protocols for alternative ozone and chlorine dioxide CT values in the microbial toolbox, as allowed under § 141.720(c) of this chapter.
- (6) Approve an alternative approach to UV reactor validation testing in the microbial toolbox, as allowed under § 141.720(d)(2)(iii) of this chapter.

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