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Environmental Protection Agency

40 CFR Parts 9, 141, and 142
National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141, and 142

[WH–FRL–6199–9]

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National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this document, EPA is finalizing the Interim Enhanced Surface Water Treatment Rule (IESWTR). The purposes of the IESWTR are to: Improve control of microbial pathogens, including specifically the protozoan *Cryptosporidium*, in drinking water; and address risk trade-offs with disinfection byproducts. Key provisions established in today's final IESWTR include: A Maximum Contaminant Level Goal (MCLG) of zero for *Cryptosporidium;* 2-log *Cryptosporidium* removal requirements for systems that filter; strengthened combined filter effluent turbidity performance standards and individual filter turbidity provisions; disinfection benchmark provisions to assure continued levels of microbial protection while facilities take the necessary steps to comply with new disinfection byproduct standards; inclusion of *Cryptosporidium* in the definition of ground water under the direct influence of surface water (GWUDI) and in the watershed control requirements for unfiltered public water systems; requirements for covers on new finished water reservoirs; and sanitary surveys for all surface water systems regardless of size. The IESWTR builds upon the treatment technique requirements of the Surface Water Treatment Rule.

EPA believes that implementation of the IESWTR will significantly reduce the level of *Cryptosporidium* in finished drinking water supplies through improvements in filtration. The Agency estimates that the likelihood of endemic illness from *Cryptosporidium* will decrease by 110,000 to 463,000 cases annually. The Agency believes that the rule will also reduce the likelihood of the occurrence of outbreaks of cryptosporidiosis by providing a larger margin of safety against such outbreaks for some systems. In addition, the filtration provisions of the rule are expected to increase the level of protection from exposure to other pathogens (i.e., *Giardia* or other waterborne bacterial or viral pathogens).

The IESWTR applies to public water systems that use surface water or GWUDI and serve 10,000 or more people. The rule also requires primacy States to conduct sanitary surveys for all surface water and GWUDI systems regardless of size.

EFFECTIVE DATE: This regulation is effective February 16, 1999. Compliance dates for specific components of the rule are discussed in the Supplementary Information section.

ADDRESSES: Public comments, the comment/response document, applicable **Federal Register** notices, other major supporting documents, and a copy of the index to the public docket for this rulemaking are available for review at EPA's Drinking Water Docket: 401 M Street, SW., Rm. EB57, Washington, DC 20460 from 9 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. For access to docket materials, please call (202) 260–3027 to schedule an appointment.

FOR FURTHER INFORMATION, CONTACT: For general information contact the Safe Drinking Water Hotline, Telephone (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. Eastern Time. For technical inquiries, contact Elizabeth Corr or Paul S. Berger, Ph.D. (Microbiology), Office of Ground Water and Drinking Water (MC 4607), U.S. Environmental Protection Agency, 401 M Street SW, Washington DC 20460; telephone (202) 260–8907 (Corr) or (202) 260–3039 (Berger). For Regional contacts see Supplementary Information.

SUPPLEMENTARY INFORMATION: This regulation is effective 60 days after publication of FR document for purposes of the Administrative Procedures Act and the Congressional Review Act. Compliance dates for specific components of the rule are discussed below. Solely for judicial review purposes, this final rule is promulgated as of 1 p.m. Eastern Time December 30, 1998 as provided in 40 CFR 23.7.

Regulated entities. Entities potentially regulated by the IESWTR are public water systems that use surface water or ground water under the direct influence of surface water and serve at least 10,000 people. (States are required to carry out sanitary surveys for all surface water and GWUDI systems including those that serve less than 10,000 people.) Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Public Water Systems (PWSs) that use surface water or ground water under the direct influence of surface water and serve at least 10,000 people
State, Local, Tribal or Federal Governments	PWSs that use surface water or ground water under the direct influence of surface water and serve at least 10,000 people.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the IESWTR. This table lists the types of entities that EPA is now aware could potentially be regulated by the rule. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in subpart H (§ 141.70(a)—systems subject to the Surface Water Treatment Rule) and subpart P (§ 141.170(a)—subpart H systems that serve 10,000 or more people) of the final rule. If you have questions regarding the applicability of the IESWTR to a particular entity, consult one of the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

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List of Abbreviations Used in This Document

ASCE: American Society of Civil Engineers
ASDWA: Association of State Drinking Water Administrators
ASTM: American Society for Testing and Materials
AWWA: American Water Works Association
AWWARF: American Water Works Association Research Foundation
°C: Degrees Centigrade
CCP: Composite Correction Program
CDC: Centers for Disease Control
CFE: Combined Filter Effluent
CFR: Code of Federal Regulations
CPE: Comprehensive Performance Evaluation
CT: The Residual Concentration of Disinfectant (mg/L) Multiplied by the Contact Time (in minutes)
CTA: Comprehensive Technical Assistance
DBPs: Disinfection Byproducts
DBPR: Disinfectants/Disinfection Byproducts Rule
ESWTR: Enhanced Surface Water Treatment Rule
FACA: Federal Advisory Committee Act
GAC: Granular Activated Carbon
GAO: Government Accounting Office
GWUDI: Ground Water Under the Direct Influence of Surface Water
HAA5: Haloacetic acids (Monochloroacetic, Dichloroacetic, Trichloroacetic, Monobromoacetic and Dibromoacetic Acids)
HPC: Heterotropic Plate Count
hrs: Hours
ICR: Information Collection Rule
IESWTR: Interim Enhanced Surface Water Treatment Rule
IFA: Individual Filter Assessment
Log Inactivation: Logarithm of (N_0/N_T)
Log: Logarithm (common, base 10)
LTESWTR: Long Term Enhanced Surface Water Treatment Rule
LT1: Long Term 1 Enhanced Surface Water Treatment Rule
MCL: Maximum Contaminant Level
MCLG: Maximum Contaminant Level Goal
M–DBP: Microbial and Disinfectants/Disinfection Byproducts
MPA: Microscopic Particulate Analysis
NODA: Notice of Data Availability
NPDWR: National Primary Drinking Water Regulation
N_T: The Concentration of Surviving Microorganisms at Time T
NTTAA: National Technology Transfer and Advancement Act
NTU: Nephelometric Turbidity Unit
PE: Performance Evaluation
PWS: Public Water System
Reg. Neg.: Regulatory Negotiation
RIA: Regulatory Impact Analysis
RFA: Regulatory Flexibility Act
RSD: Relative Standard Deviation
SAB: Science Advisory Board
SDWA: Safe Drinking Water Act
SWTR: Surface Water Treatment Rule
TC: Total Coliforms
TCR: Total Coliform Rule
TTHM: Total Trihalomethanes
TWG: Technical Work Group
UMRA: Unfunded Mandates Reform Act
x log removal: Reduction to $1/10^x$ of original concentration

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I. Background

A. Statutory Requirements and Legal Authority

The Safe Drinking Water Act (SDWA or the Act), as amended in 1986,

requires USEPA to publish a ''maximum contaminant level goal'' (MCLG) for each contaminant which, in the judgement of the USEPA Administrator, ''may have any adverse effect on the health of persons and which is known or anticipated to occur in public water systems'' (Section 1412(b)(3)(A)). MCLGs are to be set at a level at which ''no known or anticipated adverse effect on the health of persons occur and which allows an adequate margin of safety'' (Section 1412(b)(4)).

The Act was amended in August 1996. As a result of these Amendments, several of these provisions were renumbered and augmented with additional language. Other sections were added establishing new drinking water requirements. These modifications are outlined below.

The Act also requires that at the same time USEPA publishes an MCLG, which is a non-enforceable health goal, it also must publish a National Primary Drinking Water Regulation (NPDWR) that specifies either a maximum contaminant level (MCL) or treatment technique (Sections 1401(l) and 1412(a)(3)). USEPA is authorized to promulgate a NPDWR ''that requires the use of a treatment technique in lieu of establishing a MCL,'' if the Agency finds that ''it is not economically or technologically feasible to ascertain the level of the contaminant'' EPA's general authority to set a maximum contaminant level goal (MCLG) and National Primary Drinking Water Regulation (NPDWR) applies to contaminants that may ''have an adverse effect on the health of persons,'' that are ''known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern,'' and for which ''in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems'' (SDWA Section 1412(b)(1)(A)).

The amendments, also require EPA, when proposing a NPDWR that includes an MCL or treatment technique, to publish and seek public comment on an analysis of health risk reduction and cost impacts. In addition, EPA is required to take into consideration the effects of contaminants upon sensitive subpopulations (i.e. infants, children, pregnant women, the elderly, and individuals with a history of serious illness), and other relevant factors. (Section 1412 (b)(3)(C)).

The amendments established a number of regulatory deadlines, including schedules for a Stage 1 Disinfection Byproduct Rule (DBPR), an Interim Enhanced Surface Water Treatment Rule (IESWTR), a Long Term Final Enhanced Surface Water Treatment Rule (LTESWTR) affecting Public Water Systems (PWSs) that serve under 10,000 people, and a Stage 2 DBPR (Section 1412(b)(2)(C)). The Act as amended also requires EPA to promulgate regulations to address filter backwash (Section 1412(b)(14)) and to promulgate regulations specifying criteria for requiring disinfection ''as necessary'' for ground water systems.

Finally, as part of the 1996 SDWA Amendments, recordkeeping requirements were modified to apply to every person who is subject to a requirement of this title or who is a grantee (Section 1445(a)(1)(A)). Such persons are required to establish and maintain such records, make such reports, conduct such monitoring, and provide such information as the Administrator may reasonably require by regulation.

B. Regulatory History

1. Existing Regulations

Surface Water Treatment Rule (SWTR)

Under the Surface Water Treatment Rule (SWTR) (54 FR 27486, June 29, 1989) (EPA, 1989b), EPA set maximum contaminant level goals of zero for *Giardia lamblia*, viruses, and *Legionella;* and promulgated National Primary Drinking Water Regulations for all PWSs using surface water sources or ground water sources under the direct influence of surface water. The SWTR includes treatment technique requirements for filtered and unfiltered systems that are intended to protect against the adverse health effects of exposure to *Giardia lamblia*, viruses, and *Legionella*, as well as many other pathogenic organisms. Briefly, those requirements include (1) requirements for maintenance of a disinfectant residual in the distribution system; (2) removal and/or inactivation of 3 log (99.9%) for *Giardia* and 4 log (99.99%) for viruses; (3) combined filter effluent turbidity performance standard of 5 NTU as a maximum and 0.5 NTU at the 95th percentile monthly, based on 4-hour monitoring for treatment plants using conventional treatment or direct filtration (with separate standards for other filtration technologies); and (4) watershed protection and other requirements for unfiltered systems.

Total Coliform Rule (TCR)

The Total Coliform Rule (TCR) (54 FR 27544, June 29, 1989) applies to all public water systems (EPA, 1989c). This regulation sets compliance with the Maximum Contaminant Level (MCL) for total coliforms (TC) as follows. For systems that collect 40 or more samples per month, no more than 5.0% of the samples may be TC-positive; for those that collect fewer than 40 samples, no more than one sample may be TC-positive. In addition, if two consecutive samples in the system are TC-positive, and one is also fecal coliform or *E. coli*-positive, then this is defined as an acute violation of the MCL. If a system exceeds the MCL, it must notify the public using mandatory language developed by the EPA. The required monitoring frequency for a system depends on the number of people served and ranges from 480 samples per month for the largest systems to once annually for certain of the smallest systems. All systems must have a written plan identifying where samples are to be collected.

If a system has a TC-positive sample, it must test that sample for the presence of fecal coliforms or *E. coli.* The system must also collect a set of repeat samples, and analyze for TC (and fecal coliform or *E. coli* if necessary) within 24 hours of being notified of a TC-positive sample.

The TCR also requires an on-site inspection (referred to as a sanitary survey) every 5 years for each system that collects fewer than five samples per month. (This requirement is extended to every10 years for non-community systems using only protected and disinfected ground water.)

Total Trihalomethane (TTHM) Rule

In November 1979 (44 FR 68624) (EPA, 1979) EPA set an interim MCL for total trihalomethanes (TTHM) of 0.10 mg/L as an annual average. Compliance is defined on the basis of a running annual average of quarterly averages of all samples. The value for each sample is the sum of the measured concentrations of chloroform, bromodichloromethane, dibromochloromethane and bromoform.

The interim TTHM standard only applies to community water systems using surface water and/or ground water serving at least 10,000 people that add a disinfectant to the drinking water during any part of the treatment process. At their discretion, States may extend coverage to smaller PWSs; however, most States have not exercised this option.

Information Collection Rule (ICR)

The Information Collection Rule (ICR) is a monitoring and data reporting rule that was promulgated on May 14, 1996 (61 FR 24354) (EPA, 1996b). The purpose of the ICR is to collect occurrence and treatment information to

help evaluate the need for possible changes to the current SWTR and existing microbial treatment practices, and to help evaluate the need for future regulation for disinfectants and disinfection byproducts (DBPs). The ICR will provide EPA with additional information on the national occurrence in drinking water of (1) chemical byproducts that form when disinfectants used for microbial control react with naturally occurring compounds already present in source water and (2) disease-causing microorganisms, including *Cryptosporidium, Giardia,* and viruses. The ICR will also provide engineering data on how PWSs currently control for such contaminants. This information is being collected because the 1992 Regulatory Negotiating (Reg. Neg.) Committee on microbial pathogens and disinfectants and DBPs concluded that additional information was needed to assess the potential health problem created by the presence of DBPs and pathogens in drinking water and to assess the extent and severity of risk in order to make sound regulatory and public health decisions. The ICR will also provide information to support regulatory impact analyses for various regulatory options, and to help develop monitoring strategies for cost-effectively implementing regulations.

The ICR pertains to large public water systems serving populations of at least 100,000; a more limited set of ICR requirements pertain to ground water systems serving between 50,000 and 100,000 people. About 300 PWSs operating 500 treatment plants are involved with the extensive ICR data collection. Under the ICR, these PWSs monitor for water quality factors affecting DBP formation and DBPs within the treatment plant and in the distribution system monthly for 18 months. In addition, PWSs must provide operating data and a description of their treatment plant design and surface water systems must monitor for bacteria, viruses, and protozoa. Finally, a subset of PWSs must perform treatment studies, using either granular activated carbon (GAC) or membrane processes, to evaluate DBP precursor removal and control of DBPs. Monitoring for treatment study applicability began in September 1996. The remaining occurrence monitoring began in July 1997.

One initial intent of the ICR was to collect pathogen occurrence data and other information for use in developing the Interim Enhanced Surface Water Treatment Rule (IESWTR) and to estimate national costs for various treatment options. However, because of delays in promulgating the ICR and technical difficulties associated with laboratory approval and review of facility sampling plans, ICR monitoring did not begin until July 1, 1997, which was later than originally anticipated. As a result of this delay and the new statutory deadlines for promulgating the Stage 1 DBPR and IESWTR in November of 1998 (resulting from the 1996 SDWA amendments), ICR data were not available in time to support these rules. In place of the ICR data, the Agency worked with stakeholders to identify other sources of data developed since 1994 that could be used to support the development of the Stage 1 DBPR and IESWTR. EPA will continue to work with stakeholders in analyzing and using the comprehensive ICR data and research for developing future Enhanced Surface Water Treatment requirements and the Stage 2 DBPR.

2. Public Health Concerns To Be Addressed

In 1990, EPA's Science Advisory Board (SAB), an independent panel of experts established by Congress, cited drinking water contamination as one of the most important environmental risks and indicated that disease-causing microbial contaminants (i.e., bacteria, protozoa and viruses) are probably the greatest remaining health risk management challenge for drinking water suppliers (EPA/SAB, 1990). Information on the number of waterborne disease outbreaks from the U.S. Centers for Disease Control and Prevention (CDC) underscores this concern. CDC indicates that, between 1980 and 1996, 401 waterborne disease outbreaks were reported, with over 750,000 associated cases of disease (Craun 1998, 1997a; Kramer et al 1996). During this period, a number of agents were implicated as the cause, including protozoa, viruses and bacteria, as well as several chemicals. Most of the cases (but not outbreaks) were associated with surface water, and specifically with a single outbreak of cryptosporidiosis in Milwaukee (over 400,000 cases) (MacKenzie et al, 1994).

It is important to note that for a number of reasons, the CDC reports may substantially understate the actual number of waterborne disease outbreaks and cases in the U.S. First, few States have an active outbreak surveillance program. Second, disease outbreaks are often not recognized in a community or, if recognized, are not traced to the drinking water source. Third, a large number of people experiencing gastrointestinal illness (predominantly diarrhea) do not seek medical attention. Fourth, physicians may often not have a broad enough community-wide basis of information to attribute gastrointestinal illness to any specific origin such as a drinking water source. Finally, an unknown but probably significant portion of waterborne disease is endemic (i.e., not associated with an outbreak), and thus is even more difficult to recognize.

Waterborne disease is usually acute (i.e., sudden onset and typically lasting a short time in healthy people). Some pathogens (e.g., *Giardia, Cryptosporidium*) may cause extended illness, sometimes lasting months or longer, in otherwise healthy individuals. Most waterborne pathogens cause gastrointestinal illness, with diarrhea, abdominal discomfort, nausea, vomiting, and/or other symptoms. Other waterborne pathogens cause, or at least are associated with, more serious disorders such as hepatitis, gastric cancer, peptic ulcers, myocarditis, swollen lymph glands, meningitis, encephalitis, and a myriad of other diseases.

Gastrointestinal illness may be chronic in vulnerable populations (e.g., immunocompromised individuals). The severity and duration of illness is often greater in immunocompromised persons than in healthy individuals and may be fatal among this population. For instance, a follow-up study of the 1993 Milwaukee waterborne disease outbreak reported that at least 50 *Cryptosporidium*-associated deaths occurred among the severely immunocompromised (Hoxie et al., 1997). Immunocompromised persons include infants, pregnant women, the elderly, and especially those with severely weakened immune systems (e.g., AIDS patients, those receiving treatment for certain types of cancer, organ-transplant recipients and people on immunosuppressant drugs) (Gerba et al., 1996).

With specific reference to cryptosporidiosis, the disease is caused by ingestion of environmentally-resistant *Cryptosporidium* oocysts, which are readily carried by the waterborne route. Humans and other animals may excrete these oocysts. Transmission of this disease often occurs through ingestion of the infective oocysts from contaminated water or food, but may also result from direct or indirect contact with infected persons or animals (Casemore, 1990; Cordell and Addiss, 1994). Symptoms of cryptosporidiosis include typical gastrointestinal symptoms (Current et al., 1983). As noted above, these may persist for several days to several months.

While cryptosporidiosis is generally a self-limiting disease with a complete

recovery in otherwise healthy persons, it can be very serious in immunosuppressed persons. EPA has a particular concern regarding drinking water exposure to *Cryptosporidium*, especially in severely immunocompromised persons, because there is no effective therapeutic drug to cure the disease. There have been a number of waterborne disease outbreaks caused by *Cryptosporidium* in the United States, United Kingdom and many other countries (Rose, 1997). There appears to be an immune response to *Cryptosporidium*, but it is not known if this results in protection (Fayer and Ungar, 1986).

One of the key regulations EPA has developed and implemented to counter pathogens in drinking water is the SWTR. Among its provisions, the rule requires that a surface water system have sufficient treatment to reduce the source water concentration of *Giardia* and viruses by at least 99.9% (3 log) and 99.99% (4 log), respectively. A shortcoming of the SWTR is that the rule does not specifically control for the protozoan *Cryptosporidium*. The first report of a recognized outbreak caused by *Cryptosporidium* was published during the development of the SWTR (D'Antonio et al., 1985).

In terms of occurrence, *Cryptosporidium* is common in the environment. Runoff from unprotected watersheds allows transport of these microorganisms to water bodies used as intake sites for drinking water treatment plants. A particular public health challenge is that simply increasing existing disinfection levels above those most commonly practiced in the United States today does not appear to be an effective strategy for controlling *Cryptosporidium*, because the *Cryptosporidium* oocyst is especially resistant to disinfection practices commonly used at water treatment plants. Today's rule addresses the concern of passage of *Cryptosporidium* through physical removal processes during water treatment. It also strengthens the effectiveness and reliability of physical removal for particulate matter and microorganisms in general, thereby reducing the likelihood of the disinfection barrier being over challenged. Waterborne disease outbreaks have been associated with a high level of particles passing through a water treatment plant (Fox and Lytle, 1996). This presents a significant public health concern. Hence, there is a need to optimize treatment reliability and to enhance physical removal efficiencies to minimize the *Cryptosporidium* levels in finished water. This rule, with tightened turbidity performance criteria and required individual filter monitoring, is formulated to address these public health concerns.

3. Regulatory Negotiation Process

In 1992 EPA initiated a negotiated rulemaking to address public health concerns associated with disinfectants, DBPs and microbial pathogens. The negotiators included representatives of State and local health and regulatory agencies, public water systems, elected officials, consumer groups and environmental groups. The Reg. Neg. Committee met from November 1992 through June 1993.

Early in the process, the negotiators agreed that large amounts of information necessary to understand how to optimize the use of disinfectants to concurrently minimize microbial and DBP risk on a plant-specific basis were unavailable. Nevertheless, the Reg. Neg. Committee agreed that EPA propose a Stage 1 DBPR to extend coverage to all community and nontransient noncommunity water systems that use disinfectants, reduce the current TTHM MCL, regulate additional DBPs, set limits for the use of disinfectants, and reduce the level of organic precursor compounds in the source water that may react with disinfectants to form DBPs.

EPA's most significant concern in developing regulations for disinfectants and DBPs was the need to ensure that adequate treatment be maintained for controlling risks from microbial pathogens. One of the major goals addressed by the Reg. Neg. Committee was to develop an approach that would reduce the level of exposure from disinfectants and DBPs without undermining the control of microbial pathogens. The intention was to ensure that drinking water is microbiologically safe at the limits set for disinfectants and DBPs and that these chemicals do not pose an unacceptable health risk at these limits. Thus, the Reg. Neg. Committee also considered a range of microbial issues and agreed that EPA should also propose a companion microbial rule (IESWTR).

Following months of intensive discussions and technical analysis, the Reg. Neg. Committee recommended the development of three sets of rules: a two-staged approach for the DBPs (proposal: 59 FR 38668, July 29, 1994) (EPA, 1994a), an ''interim'' ESWTR (proposal: 59 FR 38832, July 29, 1994) (EPA, 1994b) and ''long-term'' ESWTR, and an Information Collection Rule (proposal: 59 FR 6332, February 10, 1994) (EPA, 1994c) (promulgation: 61FR24354, May 14, 1996) (EPA, 1996b). The approach used in developing these proposals considered the constraints of simultaneously treating water to control for both microbial contaminants and disinfectants/DBPs.

The Reg. Neg. Committee agreed that the schedules for IESWTR and LTESWTR should be ''linked'' to the schedule for the Stage 1 DBPR to assure simultaneous compliance and a balanced risk-risk based implementation. The Reg. Neg. Committee agreed that additional information on health risk, occurrence, treatment technologies, and analytical methods needed to be developed in order to better understand the risk-risk tradeoff, and how to accomplish an overall reduction in health risks from both pathogens and disinfectants/DBPs.

Finally, the Reg. Neg. Committee agreed that to develop a reasonable set of rules and to understand more fully the limitations of the current SWTR additional field data were critical. Thus, a key component of the regulation negotiation agreement was the promulgation of the ICR previously described.

4. Federal Advisory Committee Process

In May 1996, the Agency initiated a series of public informational meetings to provide an update on the status of the 1994 proposal and to review new data related to microbial and DBP regulations that had been developed since July 1994. In August 1996, Congress enacted the 1996 SDWA Amendments which contained a number of new requirements, as discussed above, as well as specifying deadlines for final promulgation of the IESWTR and Stage 1 DBPR. To meet these deadlines and to maximize stakeholder participation, the Agency established the Microbial-Disinfectants/Disinfection Byproducts (M–DBP) Advisory Committee under the Federal Advisory Committee Act (FACA) in March 1997, to collect, share, and analyze new information and data, as well as to build consensus on the regulatory implications of this new information. The Committee consisted of 17 members representing EPA, State and local public health and regulatory agencies, local elected officials, drinking water suppliers, chemical and equipment manufacturers, and public interest groups.

The M–DBP Advisory Committee met five times in March through July 1997 to discuss issues related to the IESWTR and Stage 1 DBPR. Technical support for these discussions was provided by a Technical Work Group (TWG) established by the Committee at its first meeting in March 1997. The

Committee's activities resulted in the collection, development, evaluation, and presentation of substantial new data and information related to key elements of both proposed rules. The Committee reached agreement on a number of major issues that were discussed in Notices of Data Availability (NODA) for the IESWTR (62 FR 59486, November 3, 1997) (EPA, 1997a) and the Stage 1 DBPR (62 FR 59388, November 3, 1997) (EPA, 1997b). The major issues addressed by the Committee and in the NODAs include: (1) Maintain the proposed MCLs for TTHMs, HAA5 and bromate; (2) modify the enhanced coagulation requirements as part of DBP control; (3) include a microbial benchmarking/profiling to provide a methodology and process by which a PWS and the State, working together, assure that there will be no significant reduction in microbial protection as the result of modifying disinfection practices in order to meet MCLs for TTHM and HAA5; (4) continue credit for compliance with applicable disinfection requirements for disinfection applied at any point prior to the first customer, consistent with the existing SWTR; (5) modify the turbidity performance requirements and add requirements for individual filters; (6) establish an MCLG for *Cryptosporidium*; (7) add requirements for removal of *Cryptosporidium*; (8) provide for mandatory sanitary surveys; and (9) a commitment to additional analysis of the role of *Cryptosporidium* inactivation as part of a multiple barrier concept in the context of a subsequent **Federal Register** microbial proposal. The new data and analysis supporting the technical areas of agreement were summarized and explained at length in EPA's 1997 NODAs. The Committee's recommendations are embodied in an Agreement In Principle document dated July 15, 1997.

5. Overview of 1994 Proposal and 1997 Notice of Data Availability

EPA proposed to amend the Surface Water Treatment Rule in 1994 to provide additional protection against disease-causing organisms (pathogens) in drinking water (59 FR 38832: July 29, 1994). In November 1997 EPA published a Notice of Data Availability (62 FR 59486) (EPA, 1997a, b) that summarized the 1994 proposal; described new data and information that the Agency had obtained and analyses that had been developed since the proposal; provided information concerning the July 1997 recommendations of the M–DBP Advisory Committee described above on key issues related to the proposal; and requested comment on these recommendations as well as on other regulatory implications that flowed from the new data and information. The Agency also solicited additional data and information that were relevant to the issues discussed in the Notice. In addition, EPA provided notice that the Agency was re-opening the comment period for the 1994 proposal for 90 days. EPA also requested that any information that members of the public would like the Agency to consider as part of the final rule development process regarding data or views submitted to the Agency since the close of the comment period on the 1994 proposal be formally resubmitted during the reopened 90-day comment period unless already in the underlying record in the Docket for the Notice of Data Availability.

II. Summary of the Final Rule

The primary purposes of the IESWTR are (1) to improve control of microbial pathogens in drinking water, particularly for the protozoan *Cryptosporidium*, and (2) to guard against significant increases in microbial risk that might otherwise occur when systems implement the Stage 1 Disinfectants/Disinfection Byproducts Rule. Major components of the IESWTR include the following provisions:

(a) A Maximum Contaminant Level Goal (MCLG) of zero is established for the protozoan genus *Cryptosporidium*.

(b) Surface water systems serving 10,000 or more people, that are required to filter under the SWTR, must achieve at least 2 log removal of *Cryptosporidium*. Systems that use conventional or direct filtration meet this requirement if they comply with strengthened turbidity performance standards for combined filter effluent (described below) and the current requirements under the SWTR (e.g., meet design and operating conditions as specified by the State). Systems that use slow sand filtration or diatomaceous earth meet the 2 log removal requirement if they are in compliance with existing turbidity performance standards under the SWTR (less than or equal to 1 NTU in at least 95% of measurements taken each month or, for slow sand, alternative criteria as approved by the State; and a maximum of 5 NTU).

(c) The rule includes a series of requirements related to turbidity. These address the following:

Strengthened turbidity performance requirements for the combined filter effluent. For all surface water or GWUDI systems that use conventional treatment or direct filtration, serve 10,000 or more people, and are required to filter: (a) The turbidity level of a system's combined filtered water at each plant must be less than or equal to 0.3 NTU in at least 95 percent of the measurements taken each month, and (b) the turbidity level of a system's combined filtered water at each plant must at no time exceed 1 NTU. For both the maximum and the 95th percentile requirements, compliance is determined based on measurements of the combined filter effluent at four-hour intervals.

Individual Filter Requirements. All surface water or GWUDI systems that use conventional or direct filtration, serve 10,000 or more people, and are required to filter must conduct continuous monitoring of turbidity for each individual filter and must provide an exceptions report to the State on a monthly basis. Exceptions reporting must include the following: (1) Any individual filter with a turbidity level greater than 1.0 NTU based on two consecutive measurements fifteen minutes apart; and (2) any individual filter with a turbidity level greater than 0.5 NTU at the end of the first 4 hours of filter operation based on two consecutive measurements fifteen minutes apart. A filter profile (which is a graphical representation of an individual filter performance) must be produced within seven days of the exceedance if no obvious reason for the abnormal filter performance can be identified.

If an individual filter has turbidity levels greater than 1.0 NTU based on two consecutive measurements fifteen minutes apart at any time in each of three consecutive months, the system must make an exceptions report and conduct a self-assessment of the filter. If an individual filter has turbidity levels greater than 2.0 NTU based on two consecutive measurements fifteen minutes apart at any time in each of two consecutive months, the system must make an exception report and arrange for the conduct of a Comprehensive Performance Evaluation (CPE) by the State or a third party approved by the State.

State Authority. States must have rules or other authority to require systems to conduct a Composite Correction Program (CCP) and to assure that systems implement any follow-up recommendations that result as part of the CCP. The CCP consists of two elements—a CPE and Comprehensive Technical Assistance (CTA). The CPE is a thorough review and analysis of a plant's performance-based capabilities and associated administrative, operation and maintenance practices. It is conducted to identify factors that may

be adversely impacting a plant's capability to achieve compliance and emphasizes approaches that can be implemented without significant capital improvements. The CPE must include the following components: (1) Assessment of plant performance; (2) evaluation of major unit processes; (3) identification and prioritization of performance limiting factors; (4) assessment of the applicability of comprehensive technical assistance; and (5) preparation of a CPE report. A CTA is the performance improvement phase that is implemented if the CPE results indicate improved performance potential. During the CTA phase, the system must identify and systematically address plant-specific factors. The CTA is a combination of utilizing CPE results as a basis for follow up, implementing process control priority-setting techniques, and maintaining long-term involvement to systematically train staff and administrators.

(d) Microbial benchmarking/profiling requirements are included to provide a methodology and process by which a public water system and the State, working together, assure that there will be no significant reduction in microbial protection as the result of significant disinfection practice modifications in order to meet MCLs for TTHM and HAA5. The disinfection profiling requirement included in today's rule applies to surface water systems serving 10,000 or more people and which have, based on a one year running annual average of representative samples taken in the distribution system, (1) measured TTHM levels of at least 80% of the MCL (0.064 mg/L) or (2) measured HAA5 levels of at least 80% of the MCL (0.048 mg/L). Those PWSs required to develop a disinfection profile that subsequently decide to make a significant change in disinfection practice must consult with the State prior to implementing such a change.

(e) States are required to conduct sanitary surveys for all public water systems using surface water or ground water under the direct influence of surface water, regardless of system size. Sanitary surveys are required no less frequently than every three years for community systems and no less frequently than every five years for noncommunity systems. For community systems determined by the State to have outstanding performance based on prior sanitary surveys, subsequent sanitary surveys may be conducted no less frequently than every five years. States must have the appropriate rules or other authority to require systems to respond in writing to significant deficiencies outlined in a sanitary survey report within at least 45 days, indicating how and on what schedule the system will address significant deficiencies noted in the survey. States must also have the appropriate rules or other authority to assure that facilities take the steps necessary to address significant deficiencies identified in the survey report that are within the control of the PWS and its governing body.

(f) *Cryptosporidium* is added to the definition of ground water under the direct influence of surface water (for systems serving 10,000 or more people).

(g) *Cryptosporidium* is added to the watershed protection requirements for systems that are avoiding filtration (for systems serving 10,000 or more people).

(h) Surface Water and GWUDI systems serving 10,000 or more people are required to cover all new treated water reservoirs, holding tanks or other storage facilities for which construction begins after the effective date of the rule.

The Surface Water Treatment Rule remains the base rule regulating public water systems that use surface water and ground water under the influence of surface water. All systems, filtered and unfiltered, must continue to comply with all the requirements of the SWTR and, where applicable, meet the new requirements of the IESWTR. The IESWTR's requirements for filtered systems are intended to ensure that where a filtration plant is required to protect public health, as specified in the SWTR, that plant will be operating well for the removal of *Cryptosporidium* and other microorganisms. EPA wishes to emphasize that compliance with today's requirements in no way relieves a public water system of its obligation to comply fully with pre-existing SWTR requirements. With regard to unfiltered systems in particular, development of today's rule was based on the assumption of full compliance with all filtration avoidance criteria in the SWTR.

Finally, EPA notes that today's **Federal Register** also contains the final Stage 1 Disinfectants/Disinfection Byproducts Rule (DBPR). EPA proposed this rule at the same time as the IESWTR and has finalized it along with the IESWTR.

III. Explanation of Today's Action

A. MCLG for *Cryptosporidium*

1. Today's Rule

The Agency is establishing an MCLG of zero for *Cryptosporidium*, as proposed. During the 1997 M–DBP Advisory Committee discussions, the Committee supported the proposed establishment of an MCLG of zero for *Cryptosporidium*. A key issue identified by the Advisory Committee and public commenters was whether the MCLG should be set at the genus level (i.e., *Cryptosporidium*) or at the more specific species level (i.e., C. *parvum*). Because of the uncertainties regarding taxonomy, cross reactions and cross transmission among mammals, EPA believes it is premature to establish the *Cryptosporidium* MCLG at the species level. In addition, the Agency believes that establishing an MCLG for *Cryptosporidium* at the genus level is consistent with the Safe Drinking Water Act, which requires EPA to set the MCLG with an adequate margin of safety (Section 1412(b)(4)(A)).

2. Background and Analysis

In the 1994 proposal of the IESWTR (59 FR 145, p. 38855; July 29, 1994), EPA proposed to establish an MCLG of zero for *Cryptosporidium*. The Agency based its proposal upon concerns about significant health effects on persons consuming inadequately treated surface waters and ground water under the influence of surface waters. Technical justifications for the proposed MCLG relied upon animal studies and human epidemiology studies of waterborne outbreaks of cryptosporidiosis.

Since the proposed rule, results of a human feeding study have become available which further warrant the establishment of an MCLG of zero (1997 NODA 59492). DuPont et al. (1995) fed 29 healthy volunteers single doses ranging from 30 to 1 million *C. parvum* oocysts obtained from a calf. Of the 16 volunteers who received 300 or more oocysts, 88% became infected. Of the five volunteers who received the lowest dose (30 oocysts), one became infected. According to a mathematical model based upon the DuPont et al. data, if an individual ingests a single viable oocyst there is about a 0.5% chance of infection (Haas et al., 1996). The probability of infection from *C. parvum* may be different for different strains.

In the process of further reviewing new information since 1994, EPA has re-examined the issues related to setting an MCLG at the genus level versus the species level. This issue was discussed in some detail during the M–DBP Advisory Committee meetings. Currently, the classification of a number of *Cryptosporidium* species is based, in part, on the animal host from which they were isolated. The Agency is aware that investigators have not found a *Cryptosporidium* species other than *C. parvum* that infects humans (with one highly questionable exception). To the Agency's knowledge, however, no human infectivity studies have been conducted to date with any species

other than *C. parvum*. Moreover, the taxonomy of the genus *Cryptosporidium* is uncertain and changing (Tzipori and Griffiths, 1998; Fayer et al., 1997). As a result, EPA cannot preclude the possibility that a new classification of the species comprising the genus *Cryptosporidium* may include more than one species capable of infecting humans. Recently, for example, Peng et al. (1997) analyzed 39 isolates of *C. parvum* from humans and cattle and found they could be separated into either of two genotypes, one of which could infect humans but not cattle or mice. In the future, these two genotypes may be separated into two different species.

In addition to the taxonomic issue, the current tests for *C. parvum* in stool specimens and water, which involve the microscopic examination of a stained specimen, may give positive results for *Cryptosporidium* species other than *C. parvum*. Often this results because other *Cryptosporidium* species (as well as other microorganisms) may react with the stains used to detect *C. parvum*. This is especially true for the commonly used acid-fast stain. In addition, *C. parvum* oocysts do not differ in size and shape from those of *C. baileyi* and *C. meleagridis* (Arrowood, 1997). As a result, it is not necessarily certain that oocysts in a human fecal specimen identified by a clinical laboratory as *C. parvum* are always *C. parvum*. (In general, clinical labs do not use a stain or other procedure that can distinguish between *C. parvum* and other *Cryptosporidium* species).

The Agency is aware that a few attempts have been made to infect one type of animal (e.g., mammals) with *Cryptosporidium* species isolated from other types of animals (e.g., birds), generally without success (Fayer, 1997). In addition, Graczyk et al. (1996b) found that *C. parvum* was not transmissible to fish, amphibia, or reptiles. Nevertheless, until more cross-species transmission data are available, the Agency cannot foreclose on the possibility that species other than *C. parvum* may be infective to humans. In their review of the literature, Fayer et al. (1990) concluded that the success of transmission studies is contingent upon not only species specificity, but also the condition and age of the oocysts, the route of inoculation of oocysts, and the age and immune status of the recipient. Therefore, negative results to date on transmission are not necessarily conclusive regarding host specificity.

EPA believes that it is prudent to set an MCLG at zero not only for taxonomic reasons but also because of concern that certain populations are at greater risk of waterborne cryptosporidiosis than others. This concern is heightened by the fact that currently there is no cure for cryptosporidiosis (for healthy individuals the disease tends to be self limiting). Thus, the importance of prevention and avoidance of infection becomes even more central to EPA's consideration of this issue. Until the taxonomy of *Cryptosporidium* has been clarified, EPA believes that an MCLG of zero for *Cryptosporidium* at the genus level is appropriate especially in light of the statutory requirement to establish MCLGs with ''an adequate margin of safety''.

3. Summary of Major Comments

Regarding the value of the MCLG most commenters supported the establishment of a MCLG of zero for *Cryptosporidium*. Reasons that were given for their support included: (1) Uncertainty exists in the infective dose for both healthy and vulnerable (immunocompromised) individuals; (2) an MCLG of zero is consistent with the regulatory approach for pathogens under the existing Surface Water Treatment Rule (SWTR); (3) one viable oocyst can cause an infection at least in some people; and (4) *Cryptosporidium* has particularly adverse effects on persons with immune disorders. No commenter proposed an MCLG value other than zero. Some commenters opposed any MCLG for *Cryptosporidium*, arguing that: (1) Current levels of treatment have some level of effectiveness against *Cryptosporidium* transmission to drinking water; (2) uncertainty exists associated with the analytical procedures used to detect *Cryptosporidium*; (3) current technology limits the ability to determine viability, infectivity, and species; and (4) the infectivity threshold has not been determined.

EPA agrees with the commenters who supported an MCLG of zero for *Cryptosporidium* for reasons stated in the previous section. EPA does not agree with comments opposing any MCLG for *Cryptosporidium*. While it is true that current levels of treatment control *Cryptosporidium* to some extent, studies have found *Cryptosporidium* oocysts in filtered water supplies of some treatment plants (LeChevallier, 1991b; LeChevallier, 1995). Therefore, the Agency believes that regulation of *Cryptosporidium* and enhanced treatment practices are warranted. Furthermore, the effectiveness of treatment is irrelevant to the question of setting an MCLG, which asks what is the level of (uncontrolled) *Cryptosporidium* in drinking water that will pose no risk to the health of persons. For the reasons discussed, that level is at zero. The availability of effective treatment merely ensures that EPA can regulate to control the health risk from *Cryptosporidium* reflected by the MCLG.

Comments which address the uncertainty related to the analytical method for *Cryptosporidium* and the fact that current technology does not allow viability, infectivity, and species to be determined may relate to the issue of whether EPA establishes an MCL versus treatment technique requirements for *Cryptosporidium*. However, they are not compelling with regard to the public health goal that should be set for this contaminant.

With regard to the infectivity threshold for *Cryptosporidium*, according to a mathematical model based upon the DuPont et al., 1995 data, if an individual ingests a single viable oocyst there is a 0.5% chance of infection (Haas et al., 1996). It is known that *Cryptosporidium* oocysts are capable of causing an infection in both healthy and seriously ill individuals. Death has been associated with some cryptosporidiosis cases, particularly among sensitive subpopulations (i.e., immunocompromised individuals) (Hoxie et al., 1997). For such reasons, EPA considers an MCLG of zero for *Cryptosporidium* to be appropriate.

EPA also received comments on whether the MCLG for *Cryptosporidium* should be set at the genus or the species level. Commenters offered several reasons for supporting an MCLG for *C. parvum*, as opposed to *Cryptosporidium*. Several professed that only *C. parvum* could infect humans, and therefore EPA should establish an MCLG based on that particular species. Commenters also contended that if, in future regulations, EPA were to establish a treatment technique requirement based on the *Cryptosporidium* density in the source water, publishing an MCLG for *Cryptosporidium* at the genus level might require systems to provide an additional level of treatment for *Cryptosporidium* species that are not known to be infectious to humans. In contrast, other commenters who supported the establishment of an MCLG for *Cryptosporidium* at the genus level stated that, unless further research justifies an MCLG at the species level, the MCLG should be set at the genus level. They reasoned that *Cryptosporidium* method limitations argued for setting the MCLG at the genus level.

In response to comments that did not support establishing an MCLG of zero for *Cryptosporidium* at the genus level,

EPA has carefully considered the issue of genus versus species level for *Cryptosporidium*. As mentioned earlier, EPA concludes that there exists much uncertainty regarding *Cryptosporidium* taxonomy, cross reactions and cross transmissions. Thus, EPA cannot conclude that these other species pose no health risk. For reasons mentioned above, the Agency believes that it is more appropriate to establish an MCLG for *Cryptosporidium* at the genus level at this time. This decision does not affect the level of treatment required under the IESWTR. EPA will revisit the impact of the MCLG in the context of future rules that include consideration of risk-based options.

B. Removal of *Cryptosporidium* by Filtration

1. Today's Rule

Today's final rule establishes a requirement for 2-log removal of *Cryptosporidium* for surface water and GWUDI systems serving 10,000 or more people that must filter under the SWTR. The requirement for at least 99 percent (2-log) removal of *Cryptosporidium* applies between a point where the raw water is not subject to recontamination by surface water runoff and a point downstream before or at the first customer. As discussed below, the data available to EPA indicate that rapid granular filtration systems (i.e., systems using conventional or direct filtration) when operated under appropriate coagulation conditions and optimized to meet the turbidity performance standards of the IESWTR (less than or equal to 0.3 NTU in 95% of the measurements each month and a maximum of 1 NTU) are achieving at least 2-log removal.

2. Background and Analysis

The 1994 proposal to amend the Surface Water Treatment Rule included several proposed treatment alternatives. Two of these alternatives—Alternatives B and C—specifically addressed *Cryptosporidium*. Alternative B envisioned treatment options for *Cryptosporidium* based on levels of source water occurrence. Alternative C called for 99% (2-log) removal of *Cryptosporidium*. EPA was unable to consider Alternative B for the IESWTR because occurrence data and related analysis from the ICR sampling and analysis survey discussed above were not available in time to meet the statutory promulgation deadline of November 1998. For the reasons outlined below and as recommended by the M–DBP Advisory Committee, EPA is proceeding with a 2-log removal requirement for *Cryptosporidium* for surface water and GWUDI systems serving 10,000 or more people that are required to filter under the SWTR.

As part of the 1997 M–DBP Advisory Committee process, substantial new data and information related to removal of *Cryptosporidium* by filtration were collected, evaluated and analyzed. The Committee recommended adoption of a 2-log *Cryptosporidium* removal requirement for all surface water systems that serve more than 10,000 people and are required to filter. The Committee also recommended that systems which use rapid granular filtration (direct filtration or conventional filtration treatment) and meet today's strengthened combined filter effluent turbidity requirements would be in compliance with the requirement for at least a 2-log removal of *Cryptosporidium*. Systems which use slow sand filtration and diatomaceous earth filtration and meet existing SWTR turbidity performance requirements (less than or equal to 1 NTU for the 95th percentile or alternative criteria as approved by the State) also would be in compliance with the requirement for at least a 2-log removal of *Cryptosporidium*.

In November of 1997, EPA issued a Notice of Data Availability (NODA) which discussed new data and information that the Agency had obtained and analyses that had been developed since the 1994 proposal. It also summarized recommendations of the M–DBP Advisory Committee on *Cryptosporidium* removal. The 1997 NODA requested comment on the new information, the Advisory Committee's recommendations, and on other regulatory implications and impacts.

The November 3, 1997 NODA provided new information regarding eight studies (Patania et al., 1995; Nieminski and Ongerth, 1995; Ongerth and Pecoraro, 1995; LeChevallier and Norton, 1992; LeChevallier et al., 1991b; Foundation for Water Research, 1994; Kelley et al., 1995; and West et al., 1994) that indicated that rapid granular filtration when operated under appropriate coagulation conditions and optimized to achieve a filtered water turbidity of less than 0.3 NTU should achieve at least 2-log of *Cryptosporidium* removal. These studies were analyzed as part of the 1997 IESWTR NODA.

3. Summary of Major Comments

In response to the 1994 Proposal, most commenters addressing the issue of treatment alternatives supported Alternative C which would require 2-log physical removal of *Cryptosporidium*. Some opposed any treatment requirement greater than a 2-log removal due to a lack of better understanding of dose-response, effectiveness of treatment and analyses to justify the higher treatment costs involved. Today's rule requires at least 2-log removal for *Cryptosporidium*. EPA will revisit issues related to further control of *Cryptosporidium* in future rulemakings.

The majority of commenters to the November 1997 NODA agreed with the appropriateness of establishing a 2-log removal requirement for *Cryptosporidium* in the IESWTR, although some commenters had additional concerns. One major concern was that a quantitative relationship between removal of *Cryptosporidium* and lowered turbidity was premature and had not been established. EPA believes that the studies identified in the NODA illustrate the removal efficiencies for *Cryptosporidium* by several filtration technologies. While these studies demonstrated a range of *Cryptosporidium* log-removals, it is important to realize that 2-log removal was consistently obtainable at turbidity levels of less than 0.3 NTU when systems were operated under appropriate coagulation conditions and optimized to achieve a filtered water turbidity level of less than 0.3 NTU. EPA will continue to assess data for control of *Cryptosporidium* by physical removal and disinfection as it becomes available, and will consider such data in subsequent regulations.

Another significant issue noted by several commenters was that systems should be provided the opportunity to demonstrate greater log removal of *Cryptosporidium*. Consistent with a key point made during M–DBP Advisory Committee discussions on this issue, EPA takes this opportunity to note the Agency's position that the requirement for at least 2-log removal is not intended to prevent a facility from demonstrating that it can achieve higher than 2-log removal of *Cryptosporidium* on a site-specific basis or States from demonstrating based on site-specific information that a specific facility may actually be achieving less than 2-log removal of *Cryptosporidium* even though it is meeting strengthened turbidity standards of 0.3 NTU for the 95th percentile and a maximum of 1 NTU.

C. Turbidity Control

1. Today's Rule

Today's rule establishes a number of requirements for filtration performance and filter monitoring and reporting, outlined below, which apply to surface

water systems or ground water under the direct influence of surface water (GWUDI) that serve 10,000 or more people and are required to filter under the SWTR. The basis for these provisions is explained at greater length in background sections of the 1997 IESWTR NODA.

Combined Filter Effluent Requirements

For conventional and direct filtration systems, the turbidity level of representative samples of a system's combined filter effluent water must be less than or equal to 0.3 NTU in at least 95 percent of the measurements taken each month. The turbidity level of representative samples of a system's filtered water must at no time exceed 1 NTU. For slow sand and diatomaceous earth filtration, the turbidity level of representative samples of a system's filtered water must be less than or equal to 1 NTU in at least 95 percent of the measurements taken each month and the turbidity level of representative samples of a system's filtered water must at no time exceed 5 NTU (no change from the combined filter effluent turbidity requirements in the 1989 SWTR). For both the maximum and 95th percentile requirements, compliance is determined based on measurements of the combined filter effluent at four-hour intervals.

In carrying out these combined effluent requirements, and the individual filter requirements described below, systems must use methods for turbidity measurement previously approved by EPA. These are Method 2130B, published in Standard Methods for the Examination of Water and Wastewater (19th ed.); Great Lakes Instrument Method 2; and the revised EPA Method 180.1, approved in August 1993 in Methods for the Determination of Inorganic Substances in Environmental Samples (EPA–600/R–93–100). EPA notes that today's rule requires the measurement of turbidity. Turbidity is a method-defined parameter. Turbidity therefore is not a candidate for, and will not be subject to, the performance-based measurements system.

Individual Filter Requirements

Conventional and direct filtration systems must conduct continuous monitoring of turbidity for each individual filter and must provide an exceptions report to the State on a monthly basis as part of the existing combined filter effluent reporting process. Exceptions reporting must include the following: (1) Any individual filter with a turbidity level greater than l.0 NTU based on two consecutive measurements fifteen minutes apart; and (2) any individual filter with a turbidity level greater than 0.5 NTU at the end of the first 4 hours of filter operation based on two consecutive measurements fifteen minutes apart. The system must produce a filter profile for either situation if no obvious reason for the abnormal filter performance can be identified. EPA is including a discussion on filter profiles in its guidance document on turbidity which is currently being developed with input from stakeholders.

Individual Filter Follow-Up Activities

If an individual filter has turbidity levels greater than l.0 NTU based on two consecutive measurements fifteen minutes apart at any time in each of three consecutive months, the system must, in addition to filing an exceptions report, conduct a self-assessment of the filter. The self-assessment must consist of at least the following components: (1) Assessment of filter performance; (2) development of a filter profile; (3) identification and prioritization of factors limiting filter performance; (4) assessment of the applicability of corrections; and (5) preparation of a filter self-assessment report. The system must conduct the self-assessment within 14 days of the exceedance and report to the State that the self-assessment was conducted. If an individual filter has turbidity levels greater than 2.0 NTU based on two consecutive measurements fifteen minutes apart at any time in each of two consecutive months, the system must file an exceptions report and must no later than 30 days following the exceedance arrange for the conduct of a CPE by the State or a third party approved by the State. The CPE must be completed and submitted to the State no later than 90 days following the exceedance.

2. Background and Analysis

A primary focus of the 1994 proposal was the establishment of treatment requirements that would address public health risks from high densities of pathogens in poor quality source waters and from the waterborne pathogen *Cryptosporidium*. Approaches outlined in the 1994 proposal included treatment requirements based on site-specific concentrations of pathogens in source water and a proposed 2-log removal requirement for *Cryptosporidium* by filtration.

EPA specifically requested comment on what criteria, if any, should be included to ensure that systems optimize treatment plant performance and on whether any of the existing turbidity performance criteria should be modified (e.g., should systems be required to base compliance with the turbidity standards on individual filter effluent monitoring in lieu of or in addition to monitoring the confluence of all filters; and should any performance standard value be changed). In addition, the Agency also requested comment in the 1994 proposal on possible supplemental requirements for State notification of persistent high turbidity levels (e.g., broadening the requirements for State notification of turbidity exceedances).

The 1997 M-DBP Advisory Committee meetings resulted in the collection, development, evaluation, and presentation of substantial data and information related to turbidity control. The Committee's recommendations are reflected in today's rule.

The November 3, 1997 IESWTR NODA discussed new data and information regarding turbidity control with respect to three areas: (1) Current turbidity levels at systems throughout the country; (2) individual filter performance; and (3) turbidity measurement.

Current Turbidity Levels

The November 3, 1997 NODA discussed three data sets that summarized the historical turbidity performance of various filtration plants (AWWSC, 1997; Bissonette, 1997; SAIC, 1997b). These were evaluated to assess the national impact of modifying existing turbidity requirements. Each of the data sets was analyzed to assess the current performance of plants with respect to the number of months in which selected 95th percentile and maximum turbidity levels were exceeded. The data show that upwards of 90% of the systems are currently meeting the new requirements of a maximum turbidity limit of 1 NTU. With respect to the 95th percentile turbidity limit, roughly 78% of the systems are currently meeting the new requirement of 0.3 NTU. Estimates for systems needing to make changes to meet a turbidity performance limit of 0.3 NTU were based on the ability of systems currently to meet a 0.2 NTU. This assumption was intended to take into account a utility's concern with possible turbidity measurement error and to reflect the expectation that a number of utilities will ''aim'' lower than the regulatory performance level to assure compliance. The percentage of systems estimated to modify treatment practices to meet the revised turbidity requirements (i.e., 0.3 NTU 95th percentile and 1 NTU maximum combined filter effluent levels) is

approximately 50%. Based on the turbidity performance data, EPA assumed that for systems serving less than 100,000 people, 51.2 percent of the systems can be expected to make treatment changes to consistently comply with a monthly 95th percentile limit of 0.3 NTU. Similarly, for systems serving over 500,000 people, EPA assumed that 41.7 percent can be expected to make treatment changes to comply with a 0.3 NTU regulatory limit. For systems serving 100,000 to 500,000 people, EPA assumed that 46.5 percent of systems can be expected to make changes. As discussed in greater detail in the November 3, 1997 NODA, the tighter turbidity performance criteria for combined filter effluent in today's rule reflect actual current performance for a substantial percentage of systems nationally. Revising the turbidity criteria effectively ensures that these systems continue to perform at these levels (in addition to improving performance of systems that currently meet existing SWTR criteria but operate at turbidity levels higher than those in today's final rule).

Individual Filter Performance

Several of the studies published since 1994, considered by both EPA and the M-DBP Advisory Committee and outlined in the 1997 NODA, note that the greatest potential for a peak in turbidity (and thus, pathogen break-through) is near the beginning of the filter run after filter backwash or start up of operation (Amirtharajah 1988; Bucklin et al. 1988; Cleasby 1990; and Hall and Croll 1996). During a turbidity spike, significant amounts of particulate matter (including oocysts, if present) may pass through the filter. Various factors affect the duration and amplitude of filter spikes, including sudden changes to the flow rate through the filter, treatment of the filter backwash water, filter-to-waste capability, and site-specific water quality conditions. As discussed in the 1997 IESWTR NODA, these issues highlighted the need to ensure that systems have a greater understanding of individual filter performance and thus for establishment of individual filter monitoring and reporting requirements.

Turbidity Measurement

The November 3, 1997 NODA discussed several issues relating to measurement of turbidity. It was noted that issues exist concerning the accuracy and precision of turbidity measurement due to design criteria, calibration methods, calibration standards, and sampling technique. Performance evaluation (PE) studies conducted by EPA provide an indication of the current level of accuracy and precision for turbidity measurements among different laboratories for a common synthetically prepared water. In PE studies, PE samples with known turbidity levels are sent to participating laboratories (which are not informed of the turbidity level). Laboratories participating in these studies used turbidimeters from various manufacturers and conducted their analysis in accordance with calibration and analytical procedures they are familiar with. Thus, the variability of the results reflects differences resulting from using different turbidimeter models and methods and the effects of different laboratory procedures. Four PE studies were discussed in the NODA with turbidities in the range of 0.35 to 0.72 NTU. The Relative Standard Deviations (RSD) at turbidity levels considered in these PE studies are slightly below 20%.

3. Summary of Major Comments

In response to the 1994 proposal, EPA received a range of comments both in support of and in opposition to optimizing existing water treatment processes to address *Cryptosporidium* removal. Several commenters supported tighter turbidity standards as well as monitoring of individual filters. Other commenters suggested no modifications be made to turbidity standards until further implementation of the SWTR and/or further supporting data was gathered.

Commenters on the 1997 NODA provided additional views on the general subject of filtration performance and turbidity. Commenters generally supported tightening combined filter effluent performance standards as well as the establishment of individual filter monitoring requirements. EPA agrees with these comments, as reflected in today's rule. EPA also notes that turbidity performance data that reflects implementation of the SWTR was analyzed as part of the M–DBP Advisory Committee discussions and was considered by the Committee in developing the recommendations for turbidity which are reflected in today's rule.

Several commenters discussed the ability of systems to measure turbidity at low levels (<0.3 NTU) with accuracy and consistency. EPA believes that the performance evaluation (PE) studies cited in the NODA provide an indication of the precision and accuracy of turbidity measurements at low levels. While turbidities in these studies only ranged from 0.35 to 0.72 NTU, they provided an understanding of the ability to measure at such levels. EPA recognizes that accurate and consistent measurements are not only a function of available technology but also a function of a range of operator/technician factors including calibration, maintenance, training, and adherence to manufacturer instructions. In conjunction with the IESWTR, EPA is currently developing guidance, with stakeholder input, targeted at assisting owners/operators with understanding turbidity as well as focusing on the importance of accuracy and consistency in turbidity measurement, including the low level measurement concerns noted by the commenters.

Many commenters discussed the issue of lime-softening plants and how the new requirements would affect such plants which, because of the softening processes, have artificially elevated levels of turbidity. The IESWTR allows acidification of samples for the combined filter effluent at lime softening plants. In addition, EPA is allowing systems that use lime softening to apply to States for alternative exceedance reporting levels for individual filters if they can demonstrate that higher turbidity levels in individual filters are due to lime carryover and not due to degraded filter performance.

Several commenters noted that special filters would present difficulties in complying with the individual filter monitoring requirements. While EPA realizes that variations exist in filter configurations and filters in use at systems throughout the country, the IESWTR will not seek to address the specific requirements of each and every one. EPA intends to provide States the flexibility and the tools necessary to effectively deal with special filters discussed by the commenters on a more appropriate case-by-case basis.

Another issue raised in public comments was the need to clarify how public notice requirements in the IESWTR would be integrated with future public notice requirements under the SDWA. EPA notes that today's action addresses public notification by using the existing public notification language for microbiological contaminants in 40 CFR 141.32 (e)(10) for violations of treatment technique requirements under the IESWTR. EPA takes this opportunity to note that the 1996 amendments to the SDWA require the Agency to make certain technical changes to the public notice regulations. EPA intends to propose changes to the public notice requirements in the **Federal Register** shortly after promulgation of the IESWTR. Applicable changes in the public notice

requirements, when they become effective, will supersede today's provisions. EPA also takes this opportunity to note that today's rule amends the Consumer Confidence Report Regulation (CCR) to extend the CCR requirements to apply to Subpart P violations.

Several respondents indicated that it would be necessary to provide guidance materials to systems to aid in compliance with these rules. EPA is currently developing a number of guidance manuals, with stakeholder input, to aid systems in understanding and complying with requirements. One such manual will address issues of turbidity control and filter performance.

D. Disinfection Benchmark for Stage 1 DBPR MCLs

1. Today's Rule

Today's rule establishes the disinfection benchmark as a procedure requiring certain PWSs to evaluate the impact on microbial risk of proposed changes in disinfection practice. It reflects the recommendation of the M–DBP Advisory Committee to develop a mechanism that allows utilities and States working together to assure that pathogen control is maintained while the Stage 1 DBPR provisions are implemented. In essence, this procedure involves a PWS charting daily levels of *Giardia lamblia* inactivation for a period of at least one year to create a profile of inactivation performance. The PWS must then use this profile to determine a baseline or benchmark of inactivation against which proposed changes in disinfection practices can be measured. However, only certain systems are required to develop a profile and keep it on file for State review during sanitary surveys. When those systems required to develop a profile plan a significant change in disinfection practice, they must submit the profile, along with an analysis of how the proposed change will affect the current disinfection benchmark, to the State for review. The disinfection benchmark provisions, then, contain three major components: applicability requirements, characterization of disinfection practice, and State review of proposed changes in disinfection practice. Each of these components is discussed in turn below.

Applicability

Systems are required to prepare a disinfection profile if at least one of the following criteria is met:

(1) TTHM levels are at least 80% of the MCL (0.064 mg/L) as an annual average

(2) Haloacetic acid (HAA5) levels are at least 80% of the MCL (0.048 mg/L) as an annual average

In connection with TTHM and HAA5 monitoring to create a disinfection profile, the following provisions apply:

First, the TTHM annual average must be the annual average during the same period as is used for the HAA5 annual average. Second, systems that have collected TTHM and HAA5 data under the ICR must use the results of samples collected during the last 12 months of monitoring unless the State determines that there is a more representative annual data set. Third, systems not required to collect data under the ICR but which have collected four consecutive quarters of TTHM and HAA5 data that substantially meet the sample location, handling, and analytical methods requirements of the ICR may use those data if approved by the State. (Systems must coordinate with the State to confirm acceptability of the existing data). Fourth, if the system does not have four quarters of acceptable HAA5 and TTHM data by the end of 90 days following the IESWTR promulgation date, the PWS must conduct HAA5 and TTHM monitoring to determine an annual average. Alternatively, the system may elect to conduct profiling, as described below, and forego TTHM/HAA5 monitoring to determine applicability. This monitoring must be completed no later than 15 months after promulgation of this rule and conform to the monitoring location requirements of the 1979 TTHM Rule and the analytical methods in the May 1996 Information Collection Rule.

Today's rule applies profiling requirements to systems with TTHM or HAA5 concentrations of at least 80% of the MCL, based upon the M–DBP Advisory Committee technical recommendation that this level will cover most systems that might be expected to modify their disinfection practices to comply with the Stage 1 DBPR. Also, EPA previously considered this 80% target level at the recommendation of the 1992 Reg Neg Committee to evaluate Stage 1 DBPR compliance forecasts and costs, based upon the judgment that most facilities will take additional steps to ensure continuing MCL compliance if they are at or above this level.

Developing the Profile and Benchmark

Profiling is the characterization of a system's disinfection practice over a one year period. The system can create the profile by conducting new daily monitoring and also by using ''grandfathered'' data (as explained below). A disinfection profile consists of a compilation of daily *Giardia lamblia* log inactivations (plus virus inactivations for systems using either chloramines or ozone for primary disinfection), computed over the period of a year, based on daily measurements of operational data (disinfectant residual concentration(s), contact time(s), temperature(s), and, where necessary, pH).

Grandfathered data are those operational data that a system has previously collected at a treatment plant during the course of normal operation. These data may or may not have been used previously for compliance determinations with the SWTR. Those systems that have all necessary data to determine profiles using existing operational data collected prior to promulgation of the IESWTR may use these data in developing profiles. However, grandfathered data must be substantially equivalent to operational data that would be collected under this rule. These data must be representative of inactivation through the entire treatment plant and not just of certain treatment segments. The State determines whether grandfathered data are acceptable. (EPA believes that grandfathered data used in constructing profiles should be the most recent data available, unless the State determines that there is a more representative data.)

Systems required to develop disinfection profiles under this rule must exercise one of the following three options:

Option 1—Systems must conduct daily monitoring as described below. This monitoring must begin no later than 15 months after IESWTR promulgation and must continue for a period of one year. The data collected from this monitoring must be used to develop a one year disinfection profile;

Option 2—Systems that conduct monitoring under this rule, as described under Option 1, may also use one or two years of acceptable grandfathered data, in addition to the one year of new operational data, in developing the disinfection profile;

Option 3—Systems that have three years of acceptable existing operational data are not required to conduct monitoring to develop the disinfection profile under this rule. Instead, they may use grandfathered data to develop a three year disinfection profile. Systems must coordinate with the State to confirm acceptability of grandfathered data no later than 15 months after promulgation of this rule, but must conduct the required monitoring until the State approves the system's request to use grandfathered

data. In order to develop the profile, a system must:

—Measure disinfectant residual concentration (C, in mg/L) before or at the first customer and just prior to each additional point of disinfectant addition, whether with the same or a different disinfectant.
—Determine contact time (T, in minutes) for each residual disinfectant monitoring point during peak flow conditions. T can be based on either a tracer study or assumptions based on contactor basin geometry and baffling. However, systems must use the same method for both grandfathered data and new data.
—Measure water temperature (°C).
—Measure pH (for chlorine only).

The system must then convert daily operational data to daily log inactivation values for *Giardia* (and viruses when chloramines or ozone is used for primary disinfection) as follows:

—Determine CTcalc for each disinfection segment.
—Determine $CT_{99.9}$ (i.e., 3-log inactivation) from tables in the SWTR using temperature (and pH for chlorine) for each disinfection segment. Alternatively, States may allow an alternate calculation procedure (e.g. use of spreadsheet).
—For each segment, log inactivation = $(CTcalc/CT_{99.9})\times 3.0$.
—Sum the log inactivations for each segment to get the daily log inactivation.

A log inactivation benchmark is then calculated as follows:

1. Calculate the average log inactivation of all the days for each calendar month.
2. Determine the calendar month with the lowest average log inactivation.
3. The lowest average month becomes the critical period for that year.
4. If acceptable data from multiple years are available, the average of critical periods for each year becomes the benchmark.
5. If only one year of data is available, the critical period (lowest monthly average inactivation level) for that year is the benchmark.

State Review

If a system that is required to produce a disinfection profile decides to make a significant change in disinfection practice after the profile is developed, it must consult with the State before implementing such a change. Significant changes in disinfection practice are defined as: (1) Moving the point of disinfection (this is not intended to) include routine seasonal changes already approved by the State), (2) changing the type of disinfectant or (3) changing the disinfection process, (4) making other modifications designated as significant by the State. Supporting materials for such consultation with the State must include a description of the proposed change, the disinfection profile developed under this rule for *Giardia lamblia* (and, if necessary, viruses), and an analysis of how the proposed change will affect the current disinfection benchmark. In addition, the State is required to review disinfection profiles as part of its periodic sanitary survey.

EPA is currently developing, with stakeholder input, the *Disinfection Benchmarking Guidance Manual* for States and systems. This manual will provide instruction on the development of disinfection profiles, identification and evaluation of significant changes in disinfection practices, and considerations for setting an alternative benchmark. This manual will also provide guidance for systems that are required to develop a profile based on virus inactivation instead of *Giardia lamblia* inactivation.

2. Background and Analysis

A fundamental principle of the 1992–93 regulatory negotiation reflected in the 1994 proposal for the IESWTR was that new standards for control of disinfection byproducts must not result in significant increases in microbial risk. This principle was also one of the underlying premises of the 1997 M-DBP Advisory Committee's deliberations, i.e., that existing microbial protection must not be significantly reduced or undercut as a result of systems taking the necessary steps to comply with the Stage 1 DBPR. The Advisory Committee reached agreement on the use of microbial profiling and benchmarking as a process by which a PWS and the State, working together, assure that there will be no significant reduction in microbial protection as the result of modifying disinfection practices in order to meet MCLs for TTHM and HAA5.

The strategy of disinfection profiling and benchmarking stemmed from data provided to the EPA and M-DBP Advisory Committee by PWSs and reviewed by stakeholders, in which the baseline of microbial inactivation (expressed as logs of *Giardia lamblia* inactivation) demonstrated high variability. Inactivation varied by several log on a day-to-day basis at any particular treatment plant and by as much as tens of logs over a year due to changes in water temperature, flow rate (and, consequently, contact time), seasonal changes in residual disinfectant, pH, and disinfectant demand (and, consequently, disinfectant residual). There were also differences between years at individual plants. To address these variations, M-DBP stakeholders developed the procedure of profiling a plant's inactivation levels over a period of at least one year, and then establishing a benchmark of minimum inactivation as a way to characterize disinfection practice. This approach makes it possible for a plant that may need to change its disinfection practice in order to meet DBP MCLs to determine the impact the change would have on its current level of disinfection and, thereby, to assure that there is no significant increase in microbial risk.

3. Summary of Major Comments

In the 1997 IESWTR NODA, EPA requested public comment on all aspects of the benchmarking procedure, along with any alternative suggestions, from stakeholders and other interested parties. EPA specifically requested comment on the following issues: Applicability requirements; characterization of disinfection practices and components; use of TTHM and HAA5 data from the same time period instead of TTHM data from one year and HAA5 data from another; definition of significant changes to disinfection practice; different approaches to evaluating possible changes in disinfection practice against a disinfection profile; and whether the use of grandfathered data, if available, should be mandatory for profiling and benchmarking.

The majority of comments on the overall benchmarking procedure outlined in the 1997 IESWTR NODA were positive. Commenters acknowledged the procedure as a way to maintain microbial control in systems changing their disinfection practices to comply with DBP MCLs. However, a significant area of concern expressed in comments was that if PWSs believe they will be held to a relatively higher regulatory standard as a result of maintaining a greater level of disinfection than is currently required, then some PWSs may reduce log inactivation during profiling in order to lower their benchmarks. EPA emphasizes that benchmarking is not intended to function as a regulatory standard. Rather, the objective of the disinfection benchmark is to facilitate interactions between the States and PWSs for the purpose of assessing the impact on microbial risk of proposed significant changes to existing disinfection practices. Final decisions regarding levels of disinfection beyond

those required by the SWTR that are necessary to protect public health will continue to be left to the States. For this reason EPA has not mandated specific evaluation protocols or decision matrices for analyzing changes in disinfection practice. EPA is, however, providing support to the States in making these analyses through the issuance of guidance. This approach is consistent with a majority of comments on this issue which requested that EPA not require specific procedures for the setting of alternative benchmarks but, rather, provide guidance to States.

Several commenters suggested that instead of requiring profiling and benchmarking in regulations, EPA should place these procedures in guidance and allow the States to implement them at their discretion. EPA considers benchmarking to be an important measure in preventing significant increases in microbial risk during implementation of the M-DBP rule cluster. Moreover, States have different statutory authorities governing what they can mandate and some State agencies are prohibited by State law from adopting procedures not required by federal regulations. Consequently, EPA believes the inclusion of benchmarking as a regulation is warranted.

Commenters were concerned that the benchmarking procedure would not take into account source water characteristics and that benchmarking would not be accurate for systems switching from one disinfectant to another (e.g. chlorine to ozone). EPA will cover both of these topics in the *Disinfection Benchmarking Guidance Manual* in sections that address setting an alternative benchmark. Commenters also asked EPA to provide instruction on awarding disinfection credits taking into account possible synergistic effects for different sequential disinfectants. However, as discussed in other parts of this preamble, research in this area is not adequate for a disinfection credit scheme to be developed based on synergistic inactivation.

Most comments submitted to EPA on the issue of applicability favored using 80% of the MCLs for TTHM and HAA5 as threshold levels for profiling. Commenters agreed with the EPA and M-DBP Advisory Committee that these values would capture most of the PWSs likely to change their disinfection processes to meet DBP MCLs. One commenter proposed that using TTHM and HAA5 data from two different years would not present a problem because either one of these parameters can trigger the profiling requirement. However, the majority of comments on this subject supported requiring TTHM and HAA5 data to be collected during the same period since changes in water quality and treatment conditions influence not only the total quantity of DBPs but also the relative formation of different DBP species. In today's rule EPA requires that TTHM and HAA5 data used in determining applicability be collected during the same period. A few commenters recommended that the applicability requirements for profiling should also include ozonation systems with bromate concentrations at least 80% of the MCL (i.e. 8μg/L). EPA has elected not to include bromate levels in the profiling requirements because operational changes, such as dropping the pH during ozonation, can decrease bromate formation without reducing disinfection efficacy.

Certain commenters felt that disinfection profiling should only be required in the event that a system planned to change disinfection practice and that requiring plants which meet water quality standards to perform additional studies is unwarranted. EPA believes, however, that a profile should span all seasons of at least one year to show how seasonal variations impact the log inactivation provided. Consequently, waiting to profile until a disinfection change is needed is not practical because at least one year of monitoring is required and this could significantly delay the desired modifications. Accordingly, EPA maintains that profiling in advance of a decision to change disinfection practices will allow systems to comply with TTHM and HAA5 MCLs in a timely manner without increasing microbial risk. For this reason, EPA requires profiling of those PWSs most like to modify their disinfection procedures (i.e. those with TTHM and HAA5 concentrations at or above 80% of the MCLs).

Many comments advocated allowing the use of grandfathered data in developing disinfection profiles. However, commenters were predominantly against making the use of existing operational data mandatory. They expressed concern that such a requirement would be inherently inequitable, could entail significant retrieval costs, and that the data might not be representative of a system's current operations. EPA believes that grandfathered data will often provide the most accurate picture of historic levels of microbial disinfection and encourages its use in constructing the disinfection profile. However, EPA recognizes that certain problems, such as those identified by commenters, may justify the exclusion of grandfathered data and, therefore, has made the use of such data optional. EPA notes that States may consider issues related to profiling data when determining whether a proposed change in disinfection practice is acceptable.

The benchmarking procedure in today's rule, therefore, reflects the concerns of commenters in many respects. On issues such as the use of grandfathered data, applicability requirements, and evaluating proposed changes in disinfection practice, the disinfection benchmark requirements conform to the majority view of comments. In cases where the rule is at variance with certain commenters' suggestions, such as making the disinfection benchmarking procedure discretionary and requiring profiling only in advance of a proposed change in disinfection practice, EPA has acted in accordance with the need to achieve risk-risk balancing, which is a central objective of the M–DBP rule cluster.

E. Definition of Ground Water Under the Direct Influence of Surface Water

1. Today's Rule

In today's rule, EPA includes *Cryptosporidium* in the definition of ground water under the direct influence of surface water (GWUDI). This change in definition applies only to public water systems that serve 10,000 or more people.

2. Background and Analysis

EPA issued guidance in October 1992 as the *Consensus Method for Determining Groundwater Under the Direct Influence of Surface Water Using Microscopic Particulate Analysis* (MPA). As part of this method, a microscopic examination is made of the ground water to determine whether insect parts, plant debris, rotifers, nematodes, protozoa, and other material associated with the surface or near surface environment are present. Additional guidance for making GWUDI determinations is also available (EPA, 1994d, e). Since 1990, States have acquired substantial experience in making GWUDI determinations and have documented their approaches (Massachusetts Department of Environmental Protection, 1993; Maryland, 1993; Sonoma County Water Agency, 1991). Guidance on existing practices undertaken by States in response to the SWTR may also be found in the *State Sanitary Survey Resource Directory*, jointly published in December 1995 by EPA and the Association of State Drinking Water Administrators. AWWARF has also

published guidance (Wilson et al., 1996).

In the existing MPA guidance (EPA, 1992), *Cryptosporidia* oocysts are included under the general category of coccidian protozoans, a more encompassing grouping, some of which are pathogenic to humans. The score assigned to an occurrence of a coccidian is equivalent to the score assigned to an occurrence of a *Giardia* cyst. Thus, it not anticipated that any change is needed in the MPA scoring methodology to accommodate the regulation of *Cryptosporidium* by this rule.

The 1997 NODA summarized the available guidance and additional information provided by the States and regulated community. Most recently, Hancock et al. (1998) summarized some of the available data on parasitic protozoan occurrence in ground water and EPA compiled additional data on such occurrence in wells (SAIC, 1997a).

3. Summary of Major Comments

The July 29, 1994, **Federal Register** notice proposed to amend the SWTR by including *Cryptosporidium* in the definition of a GWUDI system. Under the 1994 IESWTR proposal, a system using ground water considered vulnerable to *Cryptosporidium* contamination would be subject to the provisions of the SWTR. EPA proposed that this determination be made by the State for individual sources using State-established criteria. The 1994 proposed IESWTR also requested comment on revisions to EPA's guidance on this issue.

Commenters generally agreed that *Cryptosporidium* should be added to the definition.

F. Inclusion of Cryptosporidium in Watershed Control Requirements

1. Today's Rule

In today's final rule, EPA is extending the existing watershed control regulatory requirements for unfiltered systems serving 10,000 or more people to include the control of *Cryptosporidium*. *Cryptosporidium* will be included in the watershed control provisions for these systems wherever *Giardia lamblia* is mentioned.

2. Background and Analysis

Watershed control requirements were initially established in 1989 (EPA, 1989b, 54 FR 27496, June 29, 1989) as one of a number of preconditions that a public water system using surface water must meet to avoid filtration. As part of its 1994 IESWTR proposal (EPA, 1994b, 59 FR 38839, July 29, 1994), EPA requested comment on extending these existing watershed control requirements for unfiltered systems at 40 CFR 141.71(b)(2) to include the control of *Cryptosporidium*. This was intended to be analogous to and build upon the existing requirements for *Giardia lamblia* and viruses; *Cryptosporidium* would be included in the watershed control provisions wherever *Giardia lamblia* is mentioned. In the November 3, 1997 NODA (EPA, 1997a, 62 FR 59506), the Agency also requested comment on issues pertaining to monitoring for *Giardia* and *Cryptosporidium* for unfiltered systems serving 10,000 or more people.

As noted above, the SWTR specifies the conditions under which a system can avoid filtration (40 CFR 141.71). These conditions include good source water quality, as measured by concentrations of coliforms and turbidity; disinfection requirements; watershed control; periodic on-site inspections; the absence of waterborne disease outbreaks; and compliance with the Total Coliform Rule and the MCL for TTHMs. This watershed control program under the SWTR must include a characterization of the watershed hydrology characteristics, land ownership, and activities which may have an adverse effect on source water quality, and must minimize the potential for source water contamination by *Giardia lamblia* and viruses. The SWTR Guidance Manual (EPA, 1991a) identifies both natural and human-caused sources of contamination to be controlled. These sources include wild animal populations, wastewater treatment plants, grazing animals, feedlots, and recreational activities. The Guidance Manual recommends that grazing and sewage discharges not be permitted within the watershed of unfiltered systems, but indicates that these activities may be permissible on a case-by-case basis where there is a long detention time and a high degree of dilution between the point of activity and the water intake. Although there are no specific monitoring requirements in the watershed protection program, the non-filtering utility is required to develop State-approved techniques to eliminate or minimize the impact of identified point and non-point sources of pathogenic contamination. The guidance already suggests identifying sources of microbial contamination, other than *Giardia*, transmitted by animals, and points out specifically that *Cryptosporidium* may be present if there is grazing in the watershed.

As discussed in the 1997 IESWTR NODA, the Seattle Water Department summarized the *Giardia* and *Cryptosporidium* monitoring results from several unfiltered water systems (Montgomery Watson, 1995). The central tendency of this data is approximately 1 oocyst/100L. In light of data previously discussed that indicates that at least 2-log removal of *Cryptosporidium* is achievable with filtration, and considering the Seattle data analysis, it appears that unfiltered water systems that comply with the source water requirements of the SWTR have a risk of cryptosporidiosis equivalent to that of a water system with a well-operated filter plant using a water source of average quality. EPA plans to continue to evaluate this issue when additional data becomes available.

3. Summary of Major Comments

Commenters generally supported specific inclusion of *Cryptosporidium* in the watershed control requirements for unfiltered systems. Some commenters supported watershed control programs in general without specifically offering an opinion on *Cryptosporidium*. A few commenters specifically opposed the inclusion of *Cryptosporidium* in the watershed control program, maintaining that other avenues of watershed control could be promoted without including this organism in the control plan and that environmental sources of *Giardia* and *Cryptosporidium* were not sufficiently understood.

In response, EPA believes that the environmental sources of *Cryptosporidium* are sufficiently understood, as described above, to support rule requirements. *Cryptosporidium* cannot be easily controlled with conventional disinfection practices, and therefore its presence in source water serving unfiltered surface water systems must be addressed. EPA also believes that *Cryptosporidium* poses a potential hazard to public health and, as noted above, is establishing in today's rule an MCLG of zero for this pathogenic protozoan. EPA is therefore amending the existing watershed control requirements for unfiltered systems to include *Cryptosporidium* in order to protect public health. EPA believes that an effective watershed protection program will help to improve source water quality. Existing guidance already references the need to guard against pathogenic protozoa including specifically *Cryptosporidium*. EPA is proceeding on the presumption that existing watershed programs already consider and State reviews have evaluated the adequacy of watershed provisions to assure that raw drinking water supplies are adequately protected against *Cryptosporidium* contamination.

To the extent this is not the case, however, EPA expects that unfiltered systems, and States in their annual review, will reassess their program with regard to this concern and take whatever steps are necessary to ensure that potential vulnerability to *Cryptosporidium* contamination is considered and adequately addressed.

With regard to monitoring, many NODA commenters supported some form of routine monitoring for *Giardia* and *Cryptosporidium* in unfiltered watershed systems serving 10,000 or more people. A few NODA commenters supported event monitoring (i.e., an occasion where the raw water turbidity and/or fecal/total coliform concentration exceeds a specific value or possibly a site-specific 90th percentile value) for large unfiltered systems while others were silent on the issue or against event monitoring. In response, today's final rule does not include monitoring requirements for unfiltered systems for several reasons. The IFA method is the only method currently and widely available to evaluate the presence or absence of *Cryptosporidium* in a water supply. However, EPA does not believe this method is appropriate for regulatory compliance purposes because of its low recovery and variability. EPA therefore believes that monitoring is most appropriately handled through guidance at this time. EPA is working with stakeholders to develop a guidance document for unfiltered systems which will describe possible monitoring programs. Moreover, the Agency is supporting and participating in the development of improved *Cryptosporidium* analytical methods, including a draft interim method 1622. At the moment, it is unclear when prototype *Cryptosporidium* methods (both method 1622, as well as methods under development to determine viability and infectivity) will be adequate for regulatory use and compliance determinations at low concentration levels, but ongoing research appears promising in this area. As a result, establishment of *Cryptosporidium* monitoring requirements for unfiltered systems will be considered during the development of future microbial rules when EPA has more information on which to base a regulation (e.g. availability of better methods, ICR monitoring data, and research characterizing the relationship between watershed control and pathogen occurrence).

G. Covered Finished Water Reservoirs

1. Today's Rule

In today's final rule EPA is requiring surface water and GWUDI systems that serve 10,000 or more people to cover all new reservoirs, holding tanks or other storage facilities for finished water for which construction begins after the effective date of this rule, February 16, 1999. Today's final rule does not apply these requirements to existing uncovered finished water reservoirs.

2. Background and Analysis

The proposed IESWTR (EPA, 1994b, 59 FR 38841) indicated that EPA was considering whether to issue regulations requiring systems to cover finished water reservoirs and storage tanks, and requested public comment. The IESWTR Notice of Data Availability (EPA, 1997a, 62 FR 59509) indicated that EPA was considering a requirement that systems cover all new reservoirs, holding tanks or other storage facilities for finished water for which construction begins after the effective date of the rule and invited comment on this issue. The IESWTR NODA also invited further comment on whether there should be a requirement that all finished water reservoirs, holding tanks and other storage facilities be covered as part of the development of future regulations.

As discussed in the 1997 IESWTR Notice of Data Availability, when a finished water reservoir is open to the atmosphere it may be subject to some of the environmental factors that surface water is subject to, depending upon site-specific characteristics and the extent of protection provided. Potential sources of contamination to uncovered reservoirs and tanks include airborne chemicals, surface water runoff, animal carcasses, animal or bird droppings and growth of algae and other aquatic organisms due to sunlight that results in biomass (Bailey and Lippy, 1978). In addition, uncovered reservoirs may be subject to contamination by persons tossing items into the reservoir or illegal swimming (Pluntze 1974; Erb, 1989). Increases in algal cells, heterotrophic plate count (HPC) bacteria, turbidity, color, particle counts, biomass and decreases in chlorine residuals have been reported (Pluntze, 1974, AWWA Committee Report, 1983, Silverman et al., 1983, LeChevallier et al. 1997a).

Small mammals, birds, fish, and the growth of algae may contribute to the microbial degradation of an open finished water reservoir (Graczyk et al., 1996a; Geldreich, 1990; Fayer and Ungar, 1986; Current, 1986). In one study, sea gulls contaminated a 10 million gallon reservoir and increased bacteriological growth, and in another study waterfowl were found to elevate coliform levels in small recreational lakes by twenty times their normal levels (Morra, 1979). Algal growth increases the biomass in the reservoir, which reduces dissolved oxygen and thereby increases the release of iron, manganese, and nutrients from the sediments. This, in turn, supports more growth (Cooke and Carlson, 1989). In addition, algae can cause drinking water taste and odor problems as well as impact water treatment processes.

EPA suggested in the proposal that covering reservoirs and storage tanks would reduce the potential for contamination of the finished water by pathogens and hazardous chemicals, as well as limit the potential for taste and odor problems and increased operation and maintenance costs resulting from algal blooms associated with environmental factors such as sunlight. Because of these concerns, EPA guidelines recommend that all finished water reservoirs and storage tanks be covered (EPA, 1991a,b). The American Water Works Association (AWWA) also has issued a policy statement strongly supporting the covering of reservoirs that store potable water (AWWA, 1993). In addition, a survey of nine States was conducted in the summer of 1996 (Montgomery Watson, 1996). The States which were surveyed included several in the West (Oregon, Washington, California, Idaho, Arizona, and Utah), two States in the East known to have water systems with open reservoirs (New York and New Jersey), and one midwestern State (Wisconsin). Seven of the nine States which were surveyed require by direct rule that all new finished water reservoirs and tanks be covered.

EPA is currently developing, with stakeholder input, an Uncovered Finished Water Reservoir Guidance Document. The manual will discuss methods to maintain water quality, control aquatic and microbial growths, describe methods to cover and line reservoirs, and discuss the use of sampling and sampling points to monitor reservoir water quality.

3. Summary of Major Comments

Most commenters on the proposed rule supported either federal or State requirements for covered finished water reservoirs. Some commenters on the proposed rule suggested that regulations apply only to new reservoirs while other commenters opposed any requirement, citing high cost, the notion that ''one size does not fit all,'' and aesthetic benefits of an open reservoir. Nearly all

the commenters on the NODA supported regulatory requirements for covered finished water reservoirs in order to protect human health. Many commenters on the NODA supported requirements for covered finished water reservoirs for both new and existing reservoirs. Some commenters on the NODA supported requirements for new reservoirs only to be covered and believed that requirements for existing uncovered reservoirs should be included in a future regulation rather than in today's rule. Several commenters on the NODA were against a federal requirement for covered finished reservoirs. One commenter thought that EPA should provide States with sufficient flexibility to make the final decision on this issue while another commenter suggested that any future regulatory action for existing reservoirs should take the form of guidance to States. One commenter believes that EPA does not have enough information to require covered finished reservoirs.

In response, EPA believes, in light of the substantial information summarized above, that microbial contamination risks are posed by uncovered finished water reservoirs and therefore is requiring that all new reservoirs be covered. The final rule requires that finished water reservoirs for which construction begins after the effective date of today's rule be built with covers. With respect to existing reservoirs, EPA needs more time to collect and analyze additional information to evaluate regulatory impacts on systems with existing uncovered reservoirs on a national basis. EPA needs this information in order to carry out the cost benefit analysis for a requirement that existing reservoirs be covered. The IESWTR therefore does not require that existing reservoirs have covers installed. EPA will further consider whether to require the covering of existing reservoirs during the development of subsequent microbial regulations when additional data and analysis to develop the national costs of coverage are available.

H. Sanitary Survey Requirements

1. Today's Rule

The State must complete sanitary surveys for all surface water and GWUDI systems no less frequently than every three years for community systems and no less frequently than every five years for noncommunity systems. The State may ''grandfather'' sanitary surveys conducted after December 1995 for the first set of required sanitary surveys if the surveys address the eight survey components of the 1995 EPA/State guidance. The rule also provides that for community systems determined by the State to have outstanding performance based on prior sanitary surveys, successive sanitary surveys may be conducted no less frequently than every five years. In its primacy application, the State must include: (1) How it will decide whether a system has outstanding performance and is thus eligible for sanitary surveys at a reduced frequency, and (2) how it will decide whether a deficiency identified during a survey is significant.

In the IESWTR, a sanitary survey is defined as an onsite review of the water source (identifying sources of contamination using results of source water assessments where available), facilities, equipment, operation, maintenance, and monitoring compliance of a public water system to evaluate the adequacy of the system, its sources and operations and the distribution of safe drinking water.

Components of a sanitary survey may be completed as part of a staged or phased State review process within the established frequency interval set forth below. A sanitary survey must address each of the following eight elements: Source; treatment; distribution system; finished water storage; pumps, pump facilities, and controls; monitoring and reporting and data verification; system management and operation; and operator compliance with State requirements. In addition, sanitary surveys include review of disinfection profiles for systems required to comply with the disinfection benchmarking requirements discussed elsewhere in today's notice.

States must have the appropriate rules or other authority to assure that facilities take the steps necessary to address any significant deficiencies identified in the survey report that are within the control of the public water system and its governing body. As noted above, a State must also, as part of its primary application, include how it will decide; (1) Whether a system has outstanding performance and is thus eligible for sanitary surveys at a reduced frequency, and (2) whether a deficiency identified during a survey is significant for the purposes of this rule. In addition, a State must have appropriate rules or other authority to ensure that a public water system responds to significant deficiencies outlined in a sanitary survey report within 45 days of receipt of the report, indicating how and on what schedule the system will address significant deficiencies noted in the survey.

EPA notes that it will consider sanitary surveys that meet IESWTR requirements to also meet the requirements for sanitary surveys under the Total Coliform Rule (TCR), since the definition of a sanitary survey under the IESWTR is broader than that for the TCR (i.e., a survey as defined under the IESWTR includes all the elements, and more, of a sanitary survey as required under the TCR). Moreover, with regard to TCR sanitary survey frequency, the IESWTR requires that surveys be conducted at least as frequently, or, in some cases, possibly more often than required under the TCR.

2. Background and Analysis

The July 29, 1994, **Federal Register** proposed to amend the SWTR to require periodic sanitary surveys for all public water systems that use surface water, or ground water under the direct influence of surface water, regardless of whether they filter or not. States would be required to review the results of each sanitary survey to determine whether the existing monitoring and treatment practices for that system are adequate, and if not, what corrective measures are needed to provide adequate drinking water quality.

The July 1994 notice proposed that only the State or an agent approved by the State would be able to conduct the required sanitary survey, except in the unusual case where a State has not yet implemented this requirement, i.e., the State had neither performed the required sanitary survey nor generated a list of approved agents. The proposal suggested that under exceptional circumstances the sanitary survey could be conducted by the public water system with a report submitted to the State within 90 days. EPA also requested comment on whether sanitary surveys should be required every three or every five years.

In 1993, the Government Accounting Office (GAO) issued a report summarizing the findings of a survey conducted to examine sanitary survey programs as well as GAO's key observations (GAO, 1993). ''On the basis of a nationwide questionnaire and a review of 200 sanitary surveys conducted in four States (Illinois, Montana, New Hampshire and Tennessee), GAO found that sanitary surveys are often deficient in how they are conducted, documented and/or interpreted.''

The GAO survey found that 45 States omit one or more of the key elements of surveys that EPA recommends be evaluated. The report also indicated that, ''regardless of a system's size,

deficiencies previously disclosed frequently went uncorrected.''

In summary, GAO observed that problems with sanitary survey programs are compounded by the lack of any minimum requirements on how surveys are to be conducted and documented. The GAO report notes that the result ''has been that a key benefit of surveys—identifying and correcting problems before they become larger problems affecting water quality— has often not been realized.''

Sanitary surveys have historically been conducted by State drinking water programs as a preventive tool to identify water system deficiencies that could pose a threat to public health. The general requirements for State primacy in § 142.10(b)(2) of subpart B include a provision that the State have a systematic program for conducting sanitary surveys for public water systems, with priority given to those systems not in compliance with the State's primary drinking water regulations. In addition, the TCR includes regulatory requirements for systems to have a periodic on-site sanitary survey (54 FR 27544–27568, 29 June 1989). This rule requires all systems that collect fewer than 5 total coliform samples each month to undergo such surveys. These sanitary surveys must be conducted by the State or an agent approved by the State. Community water systems were to have had the first sanitary survey conducted by June 29, 1994, and every five years thereafter while non-community water systems are to have the first sanitary survey conducted by June 29, 1999, and every five years thereafter unless the system is served by a protected and disinfected ground water supply, in which case, a survey must be conducted every 10 years. The TCR does not specify in detail what must be addressed in a sanitary survey or how such a survey should be conducted.

The SWTR does not specifically require water systems to undergo a sanitary survey. Instead, it requires that unfiltered water systems, as one criterion to remain unfiltered, have an annual on-site inspection to assess the system's watershed control program and disinfection treatment process. The on-site survey must be conducted by the State or a party approved by the State. This on-site survey is not a substitute for a more comprehensive sanitary survey, but the information can be used to supplement a full sanitary survey.

EPA's SWTR Guidance Manual (EPA, 1991a), Appendix K, suggests that, in addition to the annual on-site inspection, a sanitary survey be conducted every three to five years by both filtered and unfiltered systems. This time period is suggested ''since the time and effort needed to conduct the comprehensive survey makes it impractical for it to be conducted annually.''

Since the publication of the proposed ESWTR and GAO report, EPA and the States (through the Association of State Drinking Water Authorities) have issued a joint guidance on sanitary surveys entitled *EPA/State Joint Guidance on Sanitary Surveys* (1995). The Guidance outlines the following elements as integral components of a comprehensive sanitary survey:

- Source
—Protection
—Physical Components and Condition
- Treatment
- Distribution System
- Finished Water Storage
- Pumps/Pump Facilities and Controls
- Monitoring/Reporting/Data Verification
- Water System Management/ Operations
- Operator Compliance with State Requirements

The guidance also addresses the qualifications for sanitary survey inspectors, the development of assessment criteria, documentation, follow-up after the survey, tracking and enforcement.

As discussed earlier, EPA published a NODA (62 FR 59485) in November 1997 discussing new information the Agency has received since the 1994 IESWTR proposal as well as recommendations of the M-DBP Advisory Committee. The Advisory Committee made recommendations on the definition and frequency of surveys, as well as on survey components based on the 1995 EPA/State Guidance, and follow-up activities. In the 1997 Notice, EPA requested comment on the Advisory Committee recommendations. In addition, the Agency requested comment on whether systems should be required to respond in writing to a State's sanitary survey report. EPA also requested comment on (1) what would constitute ''outstanding performance'' for purposes of allowing sanitary surveys for a community water system to be conducted every five years and (2) how to define ''significant deficiencies.''

3. Summary of Major Comments

Commenters on the 1994 proposal generally voiced support for requiring a periodic sanitary survey for all systems. One commenter suggested that EPA develop sanitary survey guidance for administration by the States, while another commenter suggested that sanitary surveys by the private sector be certified by States or national associations using EPA-defined criteria. Commenters recommended that surveys be conducted either by the State or a private independent party/contractor. One respondent contended that sanitary surveys, as presently conducted, were insufficient to assess operational effectiveness in surface water systems.

With regard to sanitary survey frequency, commenters on the 1994 proposal were nearly evenly divided between every three years and every five years. Some commenters argued that the frequency should depend on: (1) Whether a system's control is effective or marginal, (2) system size (less frequent for small systems), (3) source water quality, (4) whether the State believes a system's water quality is likely to change over time, (5) results of the previous survey, and (6) population density on the watershed. One commenter suggested an annual sanitary survey.

In terms of the frequency of conducting a sanitary survey, commenters on the 1997 notice generally voiced support for the frequencies recommended by the M–DBP Advisory Committee. One commenter suggested that all public water systems should have a sanitary survey no less often than once every three years and that systems with unsatisfactory or provisional ratings should be surveyed annually or more often. Another commenter suggested that even outstanding systems should be surveyed on a three year cycle because personnel or management changes can impact plant performance. One respondent recommended that sanitary surveys be required at a maximum frequency of every five years for all public water systems using surface water or ground water under the direct influence of surface water as a source. One commenter suggested that three and five year schedules be given as targets rather than requirements to allow States flexibility in deploying resources.

EPA believes that the frequencies in today's rule allow States the flexibility to prioritize and carry out the sanitary survey process, while also ensuring that these surveys will be conducted as an effective preventive tool to identify and correct water system deficiencies that could pose a threat to public health. Given these considerations and recognizing that there are many more non-community than community water systems, EPA believes that the required frequencies for sanitary surveys are reasonable.

With respect to the definition of outstanding performance, most commenters on the 1997 notice suggested some combination of both a history of no rule or public health violations and past surveys without significant deficiencies. One commenter suggested that a system with no rule violations in a year meeting 0.1 NTU ninety-five percent of the time and practicing filter to waste should get some type of formal recognition from EPA and be considered to have outstanding performance. Another respondent pointed out that in addition to performance, other factors such as management, emergency preparedness and backup structures are critical to maintain outstanding performance.

EPA believes that today's rule provides State flexibility to work within their existing programs in addressing how to define outstanding performance and significant deficiencies as part of their primacy application. The Agency will discuss these issues in further detail in Sanitary Survey Guidance which is currently under development with stakeholder input.

I. Compliance Schedules

1. Today's rule

Today's action establishes revised compliance deadlines for States to adopt and for public water systems to implement the requirements in this rulemaking. Central to the determination of these deadlines are the principles of simultaneous compliance between the Stage 1 DBPR and the corresponding rules (Interim Enhanced Surface Water Treatment Rule, Long Term Enhanced Surface Water Treatment Rule, and Ground Water Rule) to ensure continued microbial protection, and minimization of risk-risk tradeoffs. These deadlines also reflect new legislative provisions enacted as part of 1996 SDWA amendments. Section 1412 (b)(10) of the SDWA as amended provides PWSs must comply with new regulatory requirements 36 months after promulgation (unless EPA or a State determines that an earlier time is practicable or that additional time up to two years is necessary for capital improvements). In addition, section 1413(a)(1) provides that States have 24 instead of the previous 18 months from promulgation to adopt new drinking water standards.

Applying the 1996 SDWA Amendments to today's action, this rulemaking provides that States have two years from promulgation to adopt and implement the requirements of this regulation. Simultaneous compliance will be achieved as follows.

Subpart H water systems that serve a population of 10,000 or more generally have three years from promulgation to comply with all requirements of this rule, except for profiling and benchmarking, which require systems to begin sampling after three months. In cases where capital improvements are needed to comply with the rule, States may grant such systems up to an additional two years to comply. These deadlines were consistent with those for the Stage 1 DBPR.

While only subpart H systems serving at least 10,000 people are affected by today's rule, EPA has included information on the compliance requirements for other system categories for the reader. Subpart H systems that serve a population of less than 10,000 and all ground water systems will be required to comply with applicable Stage 1 DBPR requirements within five years from promulgation. Since the Long Term 1 Enhanced Surface Water Treatment Rule (LT1) requirements that apply to systems under 10,000 and the Ground Water Rule (GWR) are scheduled to be promulgated two years after today's rule or in November 2000, the net result of this staggered deadline is that these systems will be required to comply with both Stage 1 DBPR and LT1/GWR requirements three years after promulgation of LT1/GWR at the same end date of November 2003. For reasons discussed in more detail below, EPA believes this is both consistent with the requirements of section 1412(b)(10) as well as with legislative history affirming the Reg. Neg. objectives of simultaneous compliance and minimization of risk-risk tradeoff.

2. Background and Analysis

The background, factors, and competing concerns that EPA considered in developing the compliance deadlines in today's rule are explained in detail in both the Agency's IESWTR and Stage 1 DBPR November 1997 NODAs. As explained in those NODAs, EPA identified four options to implement the requirements of the 1996 SDWA Amendments. The requirements outlined above reflect the fourth option that EPA requested comment upon in November 1997.

By way of background, the SDWA 1996 Amendments affirmed several key principles underlying the M–DBP compliance strategy developed by EPA and stakeholders as part of the 1992 regulatory negotiation process. First, under section 1412(b)(5)(A), Congress recognized the critical importance of addressing risk/risk tradeoffs in establishing drinking water standards and gave EPA the authority to take such risks into consideration in setting MCL or treatment technique requirements. The technical concerns and policy objectives underlying M–DBP risk-risk tradeoffs are referred to in the initial sections of today's rule and have remained a key consideration in EPA's development of appropriate compliance requirements. Second, Congress explicitly adopted the phased M–DBP regulatory development schedule developed by the Negotiating Committee. Section 1412(b)(2)(C) requires that the M–DBP standard setting intervals laid out in EPA's proposed ICR rule be maintained even if promulgation of one of the M–DBP rules is delayed. As explained in the 1997 NODA, this phased or staggered regulatory schedule was specifically designed as a tool to minimize risk/risk tradeoff. A central component of this approach was the concept of ''simultaneous compliance'', which provides that a PWS must comply with new microbial and DBP requirements at the same time to assure that in meeting a set of new requirements in one area, a facility does not inadvertently increase the risk (i.e., the risk ''tradeoff'') in the other area.

A complicating factor that EPA took into account in developing today's deadlines is that the SDWA 1996 Amendments changed two statutory provisions that elements of the 1992 Negotiated Rulemaking Agreement were based upon. The 1994 Stage 1 DBPR and ICR proposals provided that 18 months after promulgation large PWS would comply with the rules and States would adopt and implement the new requirements. As noted above, Section 1412(b)(10) of the SDWA as amended now provides that drinking water rules shall become effective 36 months after promulgation (unless the Administrator determines that an earlier time is practicable or that additional time for capital improvements is necessary—up to two years). In addition, section 1413(a)(1) now provides that States have 24 instead of the previous 18 months to adopt new drinking water standards that have been promulgated by EPA.

Today's compliance deadline requirements reflect the principle of simultaneous compliance and the concern with risk-risk tradeoffs. Subpart H systems serving a population of at least 10,000 will be required to comply with the key provisions of this rule on the same schedule as they will be required to comply with the parallel requirements of the accompanying Stage 1 DBPR that is also included in today's **Federal Register**.

With regard to subpart H systems serving fewer than 10,000, EPA believes that providing a five year compliance period under Stage 1 DBPR is appropriate and warranted under section 1412(b)(10), which expressly allows five years where necessary for capital improvements. As discussed in more detail in the 1997 IESWTR NODA, capital improvements require, of necessity, preliminary planning and evaluation. An essential prerequisite of such planning is a clear understanding of final compliance requirements that must be met. In the case of the staggered M–DBP regulatory schedule established as part of the 1996 SDWA Amendments, LT1 microbial requirements for systems under 10,000 are required to be promulgated two years after the final Stage 1 DBPR. As a result, small systems will not even know what their final combined compliance obligations are until promulgation of the LT 1 rule. Thus, an additional two year period reflecting the two year Stage 1 DBPR/LT 1 regulatory development interval established by Congress is required to allow for the preliminary planning and design steps which are inherent in any capital improvement process.

In the case of ground water systems, the statutory deadline for promulgation of the GWR is May 2002. However, EPA intends to promulgate this rule by November 2000, in order to allow three years for compliance and still ensure simultaneous compliance by ground water systems with the Stage 1 DBPR and the GWR. As in the case of subpart H systems serving fewer than 10,000, system operators will not know until November 2000 what the final compliance requirements for both rules are. EPA thus believes it appropriate to grant the additional two years for compliance with the Stage 1 DBPR allowed by the statute.

EPA has been very successful in meeting all of the new statutory deadlines and is on track for the LT1 Rule and GWR. While EPA fully intends to meet the schedule discussed earlier, if those rules are delayed the Agency will evaluate all available options to protect against unacceptable risk-risk trade-offs. Part of this effort is the extensive outreach to systems already underway to fully inform water supplies of the likely elements in the upcoming rules. In addition, EPA would consider including provisions for streamlined variance and/or exemption processing in these rules if they were delayed, in order to enhance State flexibility in ensuring that compliance with the Stage 1 DBPR is not required before the corresponding microbial protection rule.

Under today's Stage 1 DBPR, EPA has already provided small subpart H systems and ground water systems the two-year extension for capital improvements since these systems will not know with certainty until November 2000 if capital improvements will be needed for simultaneous compliance with the Stage 1 DBPR and LT1/GWR. States considering whether to grant a two-year capital improvement extension for compliance with the GWR or LT1 will also need to consider the impact of such extensions on compliance with today's rule, since the two-year extension for the Stage 1 DBPR has already been used. EPA believes, however, that these systems will generally not require extensive capital improvements that take longer than three years to install to meet Stage 1 DBPR, GWR, and LT1 requirements, or will require no capital improvements at all. However if needed, EPA will work with States and utilities to address systems that require time beyond November 2003 to comply. This strategy may include exemptions. In addition, EPA will provide guidance and technical assistance to States and systems to facilitate timely compliance with both DBP and microbial requirements. EPA will request comment on how best to do this when the Agency proposes the LTESWTR and GWR.

3. Summary of Major Comments

Commenters were in general agreement that the compliance deadline strategy contained in the fourth option of the 1997 NODA did the best job of complying with the requirements to 1996 SDWA Amendments and meeting the objectives of the 1993 Reg. Neg. Agreement that Congress affirmed as part of the 1996 Amendments. Nonetheless, a number of commenters expressed concern about the ability of large surface water systems that had to make capital improvements to comply with all requirements of the Stage 1 DBPR and IESWTR. They pointed out that capital improvements include more than just the construction, but also financing, design, and approval.

EPA believes that the provisions of section 1412(b)(10) of the SDWA as amended allow systems the flexibility needed to comply. As noted earlier in this section, States may grant up to an additional two years compliance time for an individual system if capital improvements are necessary. Moreover, as both of these rules have been under negotiation since 1992, proposed in 1994 and further clarified in 1997, EPA believes that most systems have had substantial time to consider how to proceed with implementation and to initiate preliminary planning. Several commenters also supported delaying the promulgation of the Stage 1 DBPR for ground water systems until the GWR is promulgated, in order to ensure simultaneous compliance with both rules. EPA believes that this option would not be consistent with the reg-neg agreement, as endorsed by Congress, because the agreement specifies that the Stage 1 DBPR will apply to all community and nontransient noncommunity water systems. Moreover, EPA has committed to the LT1 and GWR promulgation schedule outlined above precisely to address this issue.

In conclusion EPA believes that the compliance deadlines outlined above for systems covered by this rule are appropriate and consistent with the requirements of the 1996 SDWA amendments. The Agency notes, however, that some elements of Option 4 outlined in the 1997 NODA apply to systems that may be covered by future Long Term Enhanced and Ground Water rules. EPA intends to follow the deadline strategy outlined in Option 4 for these future rules. However, as today's action only relates to the IESWTR, the Agency will defer final action on deadlines associated with future rules until those rules, themselves, are finalized.

IV. State Implementation

This section describes the regulations and other procedures and policies States have to adopt, or have in place, to implement today's final rule. States must continue to meet all other conditions of primacy in section 142.

Section 1413 of the SDWA establishes requirements that a State or eligible Indian tribe must meet to maintain primary enforcement responsibility (primacy) for its public water systems. These include (1) adopting drinking water regulations that are no less stringent than Federal NPDWRs in effect under sections 1412(a) and 1412(b) of the Act, (2) adopting and implementing adequate procedures for enforcement, (3) keeping records and making reports available on activities that EPA requires by regulation, (4) issuing variances and exemptions (if allowed by the State) under conditions no less stringent than allowed by sections 1415 and 1416, and (5) adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the public water supply supervision

program, as authorized under section 1413 of the Act. In addition to adopting the basic primacy requirements, States may be required to adopt special primacy provisions pertaining to a specific regulation. These regulation-specific provisions may be necessary where implementation of the NPDWR involves activities beyond those in the generic rule. States are required by 40 CFR 142.12 to include these regulation-specific provisions in an application for approval of their program revisions. These State primacy requirements apply to today's final rule, along with the special primacy requirements discussed below.

To implement today's final rule, States are required to adopt revisions to § 141.2—definitions; § 141.32—public notification; § 142.14—records kept by States; § 142.15—reports by States; § 142.16—special primacy requirements; § 141.52—maximum contaminant level goals for microbiological contaminants; § 141.70—general requirements; § 141.71—criteria for avoiding filtration; § 141.73—filtration; § 141.153—content of the reports; and a new subpart P, consisting of § 141.170 to § 141.175.

A. Special State Primacy Requirements

In addition to adopting drinking water regulations at least as stringent as the Federal regulations listed above, EPA requires that States adopt certain additional provisions related to this regulation to have their program revision application approved by EPA. This information advises the regulated community of State requirements and helps EPA in its oversight of State programs. States which require without exception all public water systems using a surface water source or a ground water source under the direct influence of surface water to provide filtration need not demonstrate that the State program has provisions that apply to systems which do not provide filtration treatment. However, such States must provide the text of the State statutes or regulations which specifies that public water systems using a source water must provide filtration.

EPA is currently developing, with stakeholder input, several guidance documents to aid the States and water systems in implementing today's final rule. This includes guidance for the following topics: Enhanced coagulation, disinfection benchmark and profiling, turbidity, alternative disinfectants, M–DBP simultaneous compliance, sanitary survey, unfiltered systems and uncovered finished water reservoirs. In addition, upon promulgation of the IESWTR, EPA will work with States to develop a State implementation guidance manual.

To ensure that the State program includes all the elements necessary for a complete enforcement program, the State's application must include the following in order to obtain EPA's approval for implementing this rule:

(1) Adoption of the promulgated IESWTR.

(2) Description of how the State will implement its sanitary survey program and how the State will assure that a system responds in writing to a sanitary survey report within 45 days indicating how and on what schedule the system will address significant deficiencies noted in the survey. The description must also identify the appropriate rules or other authority of the State to assure that PWSs respond to significant deficiencies. The State must conduct sanitary surveys that include eight specified components (described below) for all surface water and GWUDI systems no less frequently than every 3 years for community systems and no less frequently than every five years for noncommunity systems. The State may ''grandfather'' sanitary surveys conducted after December 1995 for the first set of required sanitary surveys if the surveys address the eight sanitary survey components (source; treatment; distribution system; finished water storage; pumps, pump facilities and controls; monitoring and reporting and data verification; system management and operation; and operator compliance with State requirements). For community systems determined by the State to have outstanding performance based on prior sanitary surveys, subsequent sanitary surveys may be conducted no less than every five years. The State must include how it will decide whether a system has outstanding performance in its primacy application. Components of a sanitary survey may be completed as part of a staged or phased State review process within the established frequency. The State must also describe how it will decide whether a deficiency identified during a sanitary survey is significant.

(3) Description of the procedures the State will use to determine the adequacy of changes in disinfection process by systems required to profile and benchmark under § 141.172 and how the State will consult with PWSs to evaluate modifications to disinfection practice.

(4) Description of existing or adoption of appropriate rules or other authority to assure PWSs to conduct a Composite Correction Program (CCP) and to require that PWSs implement any follow up recommendations that results as part of the CCP.

(5) Description of how the State will approve a more representative annual data set than the data set determined under § 141.172(a)(1) or (2) for the purpose of determining applicability of the requirements of § 141.172 (disinfection benchmarking/profiling).

(6) Description of how the State will approve a method to calculate the logs of inactivation for viruses for a system that uses either chloramines or ozone for primary disinfection.

(7) For filtration technologies other than conventional filtration treatment, direct filtration, slow sand filtration or diatomaceous earth filtration, a description of how the State will determine that a public water system may use a filtration technology if the PWS demonstrates to the State, using pilot plant studies or other means, that the alternative filtration technology, in combination with the disinfection treatment that meets the requirements of § 141.172(b) of this title, consistently achieves 99.9 percent removal and/or inactivation of *Giardia lamblia* cysts and 99.99 percent removal and/or inactivation of viruses, and 99 percent removal of *Cryptosporidium* oocysts; and a description of how, for the system that makes this demonstration, the State will set turbidity performance requirements that the system must meet 95 percent of the time and that the system may not exceed at any time at a level that consistently achieves 99.9 percent removal and/or inactivation of *Giardia lamblia* cysts, 99.99 percent removal and/or inactivation of viruses, and 99 percent removal of *Cryptosporidium* oocysts.

B. State Recordkeeping Requirements

Today's rule includes changes to the existing record-keeping provisions to implement the requirements in today's final rule. States must maintain records of the following: (1) Turbidity measurements must be kept for not less than one year, (2) disinfectant residual measurements and other parameters necessary to document disinfection effectiveness must be kept for not less than one year, (3) decisions made on a system-by-system basis and case-by-case basis under provisions of part 141, subpart H or subpart P, (4) a list of systems consulting with the State concerning a modification of disinfection practice (including the status of the consultation), (5) a list of decisions that a system using alternative filtration technologies can consistently achieve a 99 percent removal of *Cryptosporidium* oocysts as well as the required levels of removal and/or

inactivation of *Giardia* and viruses for systems using alternative filtration technologies, including State-set enforceable turbidity limits for each system. A copy of the decision must be kept until the decision is reversed or revised and the State must provide a copy of the decision to the system, (6) a list of systems required to do filter self-assessments, CPE or CCP. These decision records must be kept for 40 years (as currently required by § 142.14 for other State decision records) or until a subsequent determination is made, whichever is shorter.

C. State Reporting Requirements

Currently States must report to EPA information under 40 CFR 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of State public water supply programs. Today's rule requires States to provide additional information to EPA within the context of the existing special report requirements for the SWTR (§ 142.15(c)(1)). States must report a list of Subpart H systems that have had a sanitary survey completed during the previous year and an evaluation of the State's program for conducting sanitary surveys.

D. Interim Primacy

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

As a result, States that have primacy for every existing NPDWR already in effect may obtain interim primacy for this rule, beginning on the date that the State submits its complete and final application for primacy for this rule to EPA, or the effective date of its revised regulations, whichever is later. In addition, a State which wishes to obtain interim primacy for future NPDWRs must obtain primacy for this rule. After the effective date of today's rule, any State that does not have primacy for this rule cannot obtain interim primacy for future rules.

V. Economic Analysis

A. Today's Rule

EPA has estimated that the total annualized cost for implementing the IESWTR is $307 million, in 1998 dollars, at 7 percent rate cost of capital. This estimate includes annualized treatment costs to utilities ($192 million), start-up and annualized monitoring costs to utilities ($99 million), and start-up and annualized monitoring costs to States ($16 million). Annualized treatment costs to utilities includes annual operation and maintenance costs ($106 million) and annualized capital costs assuming 7 percent cost of capital ($86 million). The two cost elements which have the greatest impact on total annualized costs are treatment ($192 million), which for the most part reflects turbidity treatment costs, and turbidity monitoring ($96 million). More detail including the basis for these estimates and alternate cost estimates using different cost of capital assumptions are described later in this section. The benefits resulting from this rule range from $0.263 billion to $1.240 billion per year using a valuation of $2,000 in health damages avoided per cryptosporidiosis illness prevented (based on the mean of a distribution of values ascribed to health damages avoided, as discussed below). Based on this analysis, EPA has determined that the benefits of today's rule justify the costs.

B. Overview of RIA for Proposed Rule

The Regulatory Impact Analysis (RIA) (EPA, 1994f) for the proposed IESWTR (59 FR 38832, July 29, 1994) only considered one of the rule options that were proposed: that which would require systems to provide enough treatment to achieve less than a 10^{-4} risk level from giardiasis while meeting the Stage 1 DBPR. Other rule options were not considered for the RIA because of insufficient data at the time of proposal. The RIA for the proposed 1994 IESWTR estimated national capital and annualized costs (amortized capital and annual operating costs) for surface water systems serving at least 10,000 people at $4.4 billion and $468 million (in 1998 dollars at a 10% cost of capital) respectively. In estimating these costs, it was assumed that additional *Giardia* reduction beyond the requirements of the SWTR to achieve the 10^{-4} risk level would be achieved solely by using chlorine as the disinfectant and providing additional contact time by increasing the disinfectant contact basin size. Under the 1994 RIA, EPA also estimated that 400,000 to 500,000 *Giardia* infections per year that could be avoided would have an economic value of $1.4 to $1.7 billion per year (in 1998 dollars at a 10% cost of capital), suggesting under this rule option, the benefit nationwide of avoiding *Giardia* infections would be as much as three or four times greater than the estimated $468 million national annual cost of providing additional contact time. Development of the proposed rule option was based on the availability of an analytical method to quantify *Giardia* source water concentrations and prescribe appropriate levels of treatment to achieve the 10^{-4} risk level. This rule option was dropped from consideration of a final IESWTR since adequate methods for measuring *Giardia* were not available during the final development phase of this rule. Also, ICR data was not available to evaluate the validity of assumed national *Giardia* source water concentration levels under the RIA for the proposed rule.

C. What's Changed Since the Proposed Rule

National source water occurrence data for *Giardia* and *Cryptosporidium* are being collected as part of the ICR but this data will not become available until after promulgation of the IESWTR. Since February 1997, the Agency worked with stakeholders to identify additional data available since 1994 to support the RIA for the IESWTR published today. USEPA established the Microbial and Disinfectants/ Disinfection Byproducts Advisory Committee to collect, share and analyze new information and data, as well as to build consensus on the regulatory implications of this new information.

D. Summary of Cost Analysis

The IESWTR will result in increased costs to public water systems for improved turbidity treatment, monitoring, disinfection benchmarking and covering new finished water reservoirs, as well as State implementation costs. As discussed earlier in this Notice, the rule will only apply to systems using surface water or ground water under the direct influence of surface water that serve 10,000 or more persons. (EPA notes that the rule does include provisions for primacy States to conduct sanitary surveys for all surface water and GWUDI systems regardless of size.) EPA intends to address systems serving less than 10,000 people, under the Long Term 1

Enhanced Surface Water Treatment Rule.

Table V.1 indicates estimated annual costs associated with implementing the IESWTR in 1998 dollars for different cost of capital assumptions. A cost of capital rate of 7 percent was used to calculate the unit costs for the national compliance cost model. This rate represents the standard discount rate preferred by the Office of Management and Budget (OMB) for benefit-cost analyses of government programs and regulations. The 3 percent rate and 10 percent rate are provided as a sensitivity analysis. The 10 percent rate also provides a link to the 1994 Stage 1 DBPR cost analysis which was based on a 10 percent rate.

Estimated costs are presented as either public water system (utility) or State costs. Utility costs include all costs associated with improved turbidity treatment, start-up and annual costs for turbidity monitoring, the one-time cost of performing disinfection benchmarking, and costs for covering new finished water reservoirs. State costs include program start-up and ongoing implementation costs, including sanitary surveys.

The 1994 proposal, in 1998 dollars, is equivalent to $4.370 billion for total capital costs, a difference of $3.611 billion (in 1998 dollars) from the capital costs estimated for today's final rule. The difference is accounted for primarily by rule criteria evaluated in the benefit-cost analysis, i.e., changes in the level of disinfection required. Under the final IESWTR virtually no systems would need to install additional disinfection contact basins. Also, the capital costs associated with physical removal under the final IESWTR are substantially lower than those estimated in the 1994 RIA.

To comply with the IESWTR, systems would be expected to employ treatment enhancement and/or modifications. These activities were grouped into 10 decision tree categories based on general process descriptions as follows: chemical addition, coagulant improvements, rapid mixing, flocculation improvements, settling improvements, filtration improvements, hydraulic improvements, administration culture improvements, laboratory modifications and process control testing modifications. Descriptions of how systems were expected to evaluate these activities are included in the document *Technologies and Costs for the Interim Enhanced Surface Water Treatment Rule* (USEPA, 1998b).

The decision tree stratifies public water systems into groups or categories based on the number of people served and the range of treatment choices available to them to achieve compliance. The decision tree incorporates estimates of the percent of public water systems in each category selecting a particular approach to achieve compliance. These percentages were factors in the national cost model and represent the percentage of systems needing to modify treatment to meet the limits. Further description of the compliance decision tree and methodology are included in the *Regulatory Impact Analysis for the Interim Enhanced Surface Water Treatment Rule* (USEPA, 1998a). Based on this decision tree analysis and the total costs indicated in Table V.1, the two cost elements which have the greatest impact on national costs are Total Treatment, which for the most part reflects turbidity treatment costs, and Turbidity Monitoring. The percent of systems estimated to modify treatment practices to meet the revised turbidity requirements (i.e., 0.3 NTU 95 percentile and 1 NTU maximum combined filter effluent levels) is 50 percent (or 691 out of a possible 1,381 systems), as shown in Table V.2. Turbidity monitoring is required of all systems covered by the rule and using rapid granular filtration (i.e., conventional or direct filtration). As shown in table V.3, total annual cost to utilities for turbidity monitoring are $96 million.

E. Household Costs

Household costs are a way to represent water system treatment costs as costs to the system customer. Under the IESWTR, households will face the increases in annual costs displayed in Figure V.1. All households served by large surface water systems will incur additional costs under the IESWTR since all systems are required to perform turbidity monitoring activities. However, as shown in the cumulative distribution of households affected by the rule, 92 percent of households (60 million) will incur less than a cost of $1 per month. 7 percent of households (5 million) will face an increase in cost of between $1 and $5 per month. The highest cost faced by 23,000 households is approximately $100 per year ($8 per month).

The assumptions and structure of this analysis, in describing the curve, tend to overestimate the highest costs. To be on the upper bound of the curve, a system would have to implement all, or almost all, of the treatment activities. These systems, however, might seek less costly alternatives, such as connecting into a larger regional water system.

F. Summary of Benefits Analysis

The economic benefits of the IESWTR derive from the increased level of protection to public health. The primary goal of these provisions is to improve public health by increasing the level of protection from exposure to *Cryptosporidium* and other pathogens (i.e., *Giardia*, or other waterborne bacterial or viral pathogens) in drinking water supplies through improvements in filtration at water systems. The IESWTR is expected to reduce the level of *Cryptosporidium* and other pathogen contamination in finished drinking water supplies through improvements in filtration at water systems (i.e., revised turbidity requirements). In this case, benefits will accrue due to the decreased likelihood of endemic incidences of cryptosporidiosis, giardiasis and other waterborne disease, and the avoidance of resulting health costs. In addition to reducing the endemic disease, the provisions are expected to reduce the likelihood of the occurrence of *Cryptosporidium* outbreaks and their associated economic costs, by providing a larger margin of safety against such outbreaks for some systems.

The benefit analysis attempts to take into account some of the uncertainties in the analysis by estimating benefits under two different current treatment assumptions and three improved removal assumptions. The benefit analysis also used Monte Carlo simulations to derive a distribution of estimates, rather than a single point estimate.

The benefits analysis focused on estimating changes in incidence of cryptosporidiosis that would result from the rule. The analysis included estimating the baseline (pre-IESWTR) levels of exposure from *Cryptosporidium* in drinking water, reductions in such exposure resulting from treatment changes to comply with the IESWTR, and resultant reductions of risk.

Baseline levels of *Cryptosporidium* in finished water were estimated by assuming national source water occurrence distribution (based on data by LeChevallier and Norton 1995) and a national distribution of *Cryptosporidium* removal by treatment.

In the IESWTR RIA, the following two assumptions were made about the performance of current treatment in removing oocysts to estimate finished water *Cryptosporidium* concentrations. Based on treatment removal efficiency data presented in the 1997 IESWTR NODA, EPA assumed a national distribution of physical removal

efficiencies with a mean of 2.5 logs and a standard deviation of ±0.63 logs. Under this assumption, average log removal for different plants would generally range from 1.25 logs to 3.75 logs. Because the finished water concentrations of oocysts represent the baseline against which improved removal from the IESWTR is compared, variations in the log removal assumption could have considerable impact on the risk assessment. To evaluate the impact of the removal assumptions on the baseline and resulting improvements, an alternative mean log removal/inactivation assumption of 3.0 logs and a standard deviation of ±0.63 logs was also used to calculate finished water concentrations of *Cryptosporidium*. Under this assumption average log removal for different plants would generally range from 1.75 to 4.25 logs.

For each of the two baseline assumptions, USEPA assumed that a certain number of plants would show low, mid or high improved removal, depending upon factors such as water matrix conditions, filtered water turbidity effluent levels, and coagulant treatment conditions. As a result, the RIA considers six scenarios that encompass the range of endemic health damages avoided based on the rule.

The finished water *Cryptosporidium* distributions that would result from additional log removal with the turbidity provisions were derived assuming that additional log removal was dependent on current removal, i.e., that sites currently operating at the highest filtered water turbidity levels would show the largest improvements or high improved removal assumption (e.g., plants now failing to meet a 0.4 NTU limit would show greater removal improvements than plants now meeting a 0.3 NTU limit).

Table V.4 indicates estimated annual benefits associated with implementing the IESWTR. The benefits analysis quantitatively examines endemic health damages avoided based on the IESWTR for each of the six scenarios mentioned above. For each of these scenarios, EPA calculated the mean of the distribution of the number of illnesses avoided. The assessment also discusses, but does not quantify, other economic benefits that may result from the provisions, including the avoided health damage costs associated with reduced risk of outbreaks and avoided costs of averting behavior such as boiling water or use of an alternative water source during outbreaks or periods of high turbidity.

According to the RIA performed for the IESWTR published today, the rule is estimated to reduce the mean annual number of illnesses caused by *Cryptosporidium* in water systems improving filtration by 110,000 to 463,000 cases depending upon which of the six baseline and improved *Cryptosporidium* removal assumptions was used. Based on these values, the mean estimated annual benefits of reducing the illnesses ranges from $0.263 billion to $1.240 billion per year. This calculation is based on a valuation of $2,000 per incidence of cryptosporidiosis prevented which is the mean of a distribution of values ascribed to health damages avoided. The RIA also indicated that the rule could result in a mean reduction of 14 to 64 fatalities each year, depending upon the varied baseline and improved removal assumptions. Using a mean value of $5.6 million per statistical life saved, reducing these fatalities could produce benefits in the range of $0.085 billion to $0.363 billion.

G. Comparison of Costs and Benefits

Given the costs summarized in Table V.1 and the benefits summarized in Table V.4, the IESWTR results in positive net benefits under all three improved removal scenarios (low, mid, and high) assuming that current treatment as a national average achieves 2.5 log of *Cryptosporidium* removal, taking into account only the value of cost of illness avoided. Using a current national average treatment removal assumption of 3.0 logs, net benefits are positive under the high and mid improved removal scenarios. Net benefits using the 3.0 log current removal assumption are negative under the low improved removal scenario using only the value of cost of illness avoided, however, when the value of mortalities prevented is added into the benefits, all scenarios have positive net benefits at the mean.

Thus, the monetized net benefits are positive across most of the range of current treatment assumptions, improved log removal scenarios, and discount rates. The benefits due to the illnesses avoided may be slightly overstated when aggregated with benefits due to mortalities avoided, because the mortalities were not netted out of the number of illnesses. This value is minimal and would not be captured at the level of significance of the analysis. Several categories of benefits, including reducing the risk of outbreaks, reducing exposure to other pathogens such as *Giardia*, and avoiding the cost of averting behavior have not been quantified for this analysis, but could represent substantial additional economic value. In addition, the estimates for avoided costs of illness do not include the value for pain and suffering or the risk premium.

TABLE V.1.—ANNUAL COSTS OF THE INTERIM ENHANCED SURFACE WATER TREATMENT RULE ($000S)

	Final Rule (1998 dollars)			1994 Proposal	
	3% Cost of Capital	7% Cost of Capital	10% Cost of Capital	10% Cost of Capital 1992 dollars	10% Cost of Capital 1998 dollars
Utility Costs					
Utility Treatment Capital	$758,965	$758,965	$758,965	$3,665,568	$4,370,389
Annual Costs					
Annualized Capital†	65,999	85,611	103,437		
Annual O&M	105,943	105,943	105,943		
Total Treatment	171,942	191,554	209,380	391,702	466,891
Turbidity Monitoring	95,924	95,924	95,924		
Turbidity Exceptions*	195	195	195		
Disinfection Benchmarking	2,841	2,841	2,841		
Subtotal	270,902	290,514	308,340	391,702	466,891
Annualized One-Time Costs**					
Turbidity Monitoring Start-Up	289	405	504	.....	.....

TABLE V.1.—ANNUAL COSTS OF THE INTERIM ENHANCED SURFACE WATER TREATMENT RULE ($000S)—Continued

	Final Rule (1998 dollars)			1994 Proposal	
	3% Cost of Capital	7% Cost of Capital	10% Cost of Capital	10% Cost of Capital 1992 dollars	10% Cost of Capital 1998 dollars
HAA Benchmarking	175	246	306	.....	.....
Subtotal	464	651	810	.....	.....
Total Annual Utility Costs	271,366	291,165	309,150	.....	.....
State Costs					
Annual Costs					
Turbidity Monitoring	5,256	5,256	5,256	.....	.....
Turbidity Exceptions***	409	409	409	.....	.....
Sanitary Survey	6,979	6,979	6,979	867	1,034
Disinfection Benchmarking	2,789	2,789	2,789	.....	.....
Subtotal	15,433	15,433	15,433	867	1,034
Annualized One-Time Costs**					
Turbidity Monitoring Start-Up	27	38	48	.....	.....
Disinfection Benchmarking Start-Up	22	30	38	.....	.....
Sanitary Survey Start-Up	39	55	69	.....	.....
Subtotal	88	123	155	.....	.....
Total Annual State Costs	15,521	15,556	15,588	.....	.....
Total Annual Costs	286,887	306,721	324,738	392,569	467,925

*Costs associated with Individual Filter Effluent Turbidity Requirements for exceptions reporting, Individual Filter Assessments.
**All one-time costs are annualized over 20 years.
***Costs associated with Reporting Exceptions and Comprehensive Performance Evaluations.
†Most costs are annualized over 20 years. Some costs, including turbidimeters and process control monitoring, are annualized over 7 years.

TABLE V.2.—FINAL ANNUAL COST ESTIMATES FOR TURBIDITY TREATMENT REQUIREMENTS

[0.3 NTU CFE 95th percentile, 1 NTU CFE Maximum 1998 $000s]

System Size (population served)	Number of Systems	Systems Modifying Treatment	3 Percent Cost of Capital	7 Percent Cost of Capital	10 Percent Cost of Capital
10,000–25,000	594	303	$ 33,946	$ 37,624	$40,932
25,000–50,000	316	161	29,316	31,862	35,304
50,000–75,000	124	63	15,450	17,143	18,564
75,000–100,000	52	27	7,958	8,861	9,508
100,000–500,000	259	122	56,895	63,544	69,080
500,000–1 Million	26	11	16,310	18,381	20,092
>1 Million	10	4	10,130	11,641	12,927
Total	1,381	691	170,005	189,056	206,407

TABLE V.3.—UTILITY TURBIDITY START-UP AND MONITORING ANNUAL COSTS

Compliance Activities	Respondents Affected	Unit Costs	CF*	Annual Costs
Utility Start-Up Costs**	1,381 Systems	$3,108	0.09439	$405,136
Utility Plant Monitoring Costs	1,728 Plants	52,644		90,968,832
Utility System Monitoring Costs	1,381 Systems	3,588		4,955,028
Total Annual Utility Costs for Turbidity Monitoring and Start-Up.	.....			96,328,996

*The Capitalization Factor (CF) is calculated using the cost of capital (7%), the number of years of capitalization (20 years), and the current value of money ($1).
**Start-up costs are annualized over 20 years with a CF of 0.09439.

TABLE V.4.—SUMMARY OF POTENTIAL ANNUAL BENEFITS

	Baseline Assumes			
	2.5 Log Cryptosporidium Removal		3.0 Log Cryptosporidium Removal	
	Mean	Range	Mean	Range
Cryptosporidiosis Illness Avoided Annually				
Low Estimate of Number of Illnesses Avoided.	338,000	0–1,029,000	110,000	0–322,500
Cost of Illness Avoided	$0.950 billion	0–1.883 billion	0.263 billion	0–0.585 billion
Mid Number of Illnesses Avoided.	432,000	0–1,074,000	141,000	0–333,000
Cost of Illness Avoided	1.172 billion	0–1.960 billion	0.327 billion	0–0.608 billion
High Number of Illnesses Avoided.	463,000	0–1,080,000	152,000	0–338,000
Cost of Illness Avoided	1.240 billion	0–1.999 billion	0.359 billion	0–0.620 billion
Value of Cryptosporidiosis Mortalities Avoided Annually				
Low Number of Mortalities Avoided.	48	0–129	14	0–40
Value of Mortalities Avoided.	0.272 billion	0–0.674 billion	0.085 billion	0–0.209 billion
Mid Number of Mortalities Avoided.	60	0–135	18	0–42
Value of Mortalities Avoided.	0.341 billion	0–0.706 billion	0.107 billion	0–0.219 billion
High Number of Mortalities Avoided.	64	0–136	20	0–42
Value of Mortalities Avoided.	0.363 billion	0–0.708 billion	0.115 billion	0–0.221 billion
Reduced Risk of Cryptosporidiosis Outbreaks				
Cost of Illness Avoided Emergency Expenditures Liability Costs	Benefits not quantified, but could be substantial for large outbreak ($0.800 billion cost of illness avoided for a Milwaukee-level outbreak).			
Reduced Risk from Other Pathogens.	Benefits not quantified.			
Enhanced Aesthetic Water Quality.	Difference may not be noticeable to consumer.			
Averting Behavior	Benefits not quantified, but could be substantial for large outbreak ($0.020 billion to $0.062 billion for a Milwaukee-level outbreak).			

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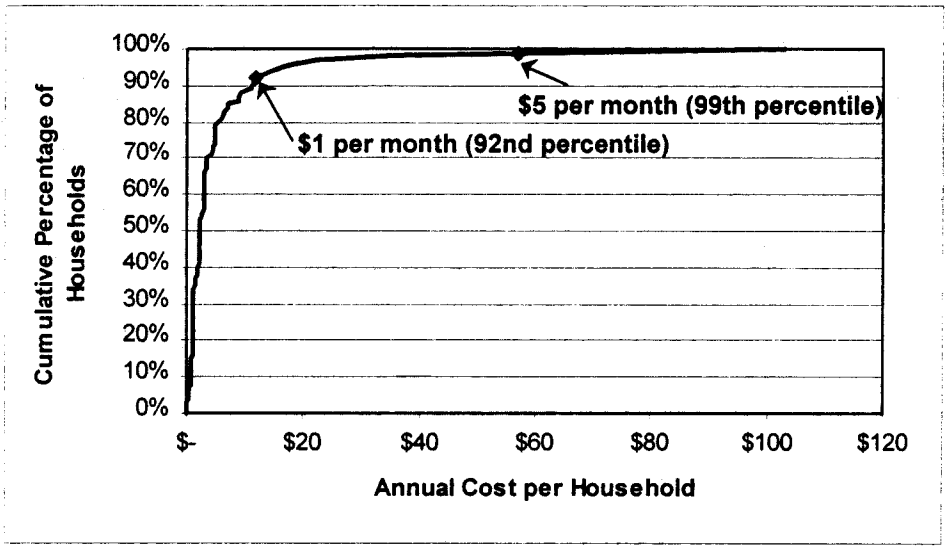
Figure V.1: Cumulative Distribution of Annual Cost per Household of the IESWTR



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VI. Additional Issues Discussed in 1994 Proposal and 1997 NODA

A. Inactivation of Cryptosporidium

When the IESWTR was proposed in 1994, EPA recognized that chlorine disinfectants were relatively ineffective in inactivating *Cryptosporidium*, but was not certain if alternative disinfectants might be more effective than chlorine. In the NODA for the IESWTR, EPA discussed the present data on *Cryptosporidium* disinfection for a variety of disinfectants. Many commenters thought that sufficient data was not available to develop guidelines for estimating inactivation of *Cryptosporidium* in water. Several commenters pointed out the inconsistency of inactivation data from different studies. Some commenters also supported the use of *Giardia* as the target organism for defining the disinfection benchmark required by today's rule. EPA believes that variability in inactivation results is not surprising, given the absence of standard testing protocol and methodology, and agrees that the existing data is not sufficient to enable the development of guidelines for estimating inactivation efficiencies for *Cryptosporidium* in water. The Agency also notes that research is underway to better clarify inactivation efficiencies for *Cryptosporidium* and anticipates that new research results will be available for consideration during the development of the Long Term 2 Enhanced Surface Water Treatment Rule which EPA plans to promulgate simultaneously with the Stage 2 DBPR.

B. Giardia Inactivation CT Values for Profiling/Benchmarking

In the 1997 NODA for the IESWTR, EPA requested comment on developing CT tables for free chlorine at pH levels above 9, which are not currently available in EPA's guidance to the SWTR. This effort was intended to support implementation of the microbial profiling/benchmarking required in the today's rule. Under the profiling/benchmarking requirement, certain utilities must determine CT values and compute daily average log inactivation of *Giardia*.

While some commenters supported the CT tables for high pHs presented in the NODA, other commenters opposed them because they thought that the literature data were not sufficient for development of these CT tables. Commenters also noted that for the systems with pH levels higher than 9, States currently provide guidelines by which utilities can estimate inactivation levels for the purpose of compliance with the SWTR. State guidelines are to use inactivation levels at pH 9 for above pH 9 conditions. EPA believes these guidelines, along with existing CT tables, are sufficient for implementing the benchmark/profiling requirements and therefore no additional CT tables have been developed at this time.

As explained previously, in conjunction with today's rule, EPA is also concurrently promulgating the Stage 1 DBPR under which the maximum disinfectant residual level for free chlorine is 4 mg/L. However, the CT tables for free chlorine that appear in the SWTR Guidance Manual only cover the chlorine residual up to 3 mg/L. Some commenters expressed a need for CT values for higher chlorine residuals. Since it has been observed that the free chlorine residual concentration (C) is not as significant as the contact time (T) in terms of inactivation kinetics for *Giardia* cysts and no data are currently available to support the development of additional CT tables for the range of chlorine residuals between 3 and 4 mg/L, EPA recommends that for the purpose of microbial profiling/benchmarking the value of 3 mg/L as Cl_2 be used for estimating log inactivation when the chlorine residual level is higher than 3 mg/L.

C. Cross Connection Control

Today's Rule

EPA is not establishing requirements for cross connection control in today's final rule. The Agency does plan to consider cross connection control issues during the development of subsequent microbial regulations, in the context of a broad range of issues related to distribution systems. At that time the results of research currently in progress should be available to the Agency and enable EPA to make regulatory decisions.

Background and Analysis

The proposed IESWTR (EPA, 1994b, 59 FR 38841, July 29, 1994) requested

public comment on whether the Agency should require States and/or systems to have a cross-connection control program. In addition, the Agency solicited comment on a number of associated issues, including (1) what specific criteria, if any, should be included in such a requirement, (2) how often such a program should be evaluated, (3) whether EPA should limit any requirement to only those connections identified as a cross connection by the public water system or the State, and (4) conditions under which a waiver from this requirement would be appropriate. The Agency also requested commenters to identify other regulatory measures EPA should consider to prevent contamination of drinking water in the distribution system (e.g., minimum pressure requirements in the distribution system).

Historically, a significant portion of waterborne disease outbreaks reported by CDC are caused by distribution system deficiencies. Distribution system deficiencies are defined in CDC's publication *Morbidity and Mortality Weekly Report* as cross connections, contamination of water mains during construction or repair, and contamination of a storage facility. Between 1971–1994, approximately 53 waterborne disease outbreaks reported were associated with cross connections or backsiphonage. Fifty-six outbreaks were associated with other distribution system deficiencies (Craun, Pers. Comm. 1997b). Some outbreaks have resulted from water main breaks or repairs.

There is no centralized repository where backflow incidents are reported or recorded. The vast majority of backflow incidents are probably not reported. Examples of specific backflow incidents are described in detail in EPA's *Cross-Connection Control Manual* (EPA, 1989a).

Where cross connections exist, some protection is still afforded to the distribution system by the maintenance of a positive water pressure in the system. Adequate maintenance of pressure provides a net movement of water out through breaks in the distribution pipes and prevents contaminated water outside of the pipes from entering the drinking water supply. The loss of pressure in the distribution system, less than 20 psi, can cause a net movement of water from outside the pipe to the inside, possibly allowing the introduction of fecal contamination into the system. This problem is of special concern where wastewater piping is laid in the same street as the water pipes, creating a potential threat to public health whenever there is low or no pressure.

A number of States have cross connection control programs, although the extent to which they vary is unclear. A Florida Department of Environmental Protection survey evaluated cross-connection control regulations in the 50 States (Florida DEP 1996). The survey results showed that 29 of the 40 States that responded to the survey request have programs. The rigor of the programs and the extent to which they are enforced was not addressed by the survey. An EPA report suggests that the responsibility for administration and enforcement of the State programs is generally at the local level (EPA, 1995a).

Summary of Major Comments

Most commenters supported either a federal or State cross connection control program in order to prevent disease outbreaks and injury to the public. Some commenters suggested EPA update its guidance document on cross connection control. Commenters opposed to a cross connection control program indicated that (1) a federally-mandated program would be impractical, burdensome, and would fail, (2) a State or local program would be more appropriate than an EPA-mandated program, (3) most States already have a comprehensive program, thus negating need for federal regulations, (4) EPA should publish general guidelines only, and (5) there should be a separate regulation because a cross connection control program would affect both surface water and ground water.

As noted above, EPA plans to consider cross connection control in the context of future microbial rules rather than in the IESWTR. The Agency will consider cross connection control issues in connection with a broad range of issues related to distribution systems as it develops these microbial rules. Issues to be considered include biofilm growth and the potential for biofilm associated with pathogens, water treatment and distribution system operations to minimize microbial growth, and causes of pathogen intrusion into the distribution system. These are all areas that are the focus of a significant research effort, most of which is still in progress. The American Water Works Association Research Foundation (AWWARF) presently has 17 projects pertaining to maintenance of water quality in the distribution system that are not yet complete. EPA's laboratories are also working on important research questions in these areas. EPA intends to evaluate this large body of distribution system research as well as data on State and local government requirements and their impact in order to develop comprehensive regulations and guidance on distribution system maintenance and operations, including the prevention of cross-connections.

EPA has previously published guidance on cross connection control entitled the Cross Connection Control Manual (EPA, 1989a, EPA 570/9–89–007, June 1989). This guidance describes methods, devices, etc. for prevention of backflow and back-siphonage, testing procedures for backflow preventers, administration of cross-connection programs and cross-connection control ordinance provisions. The Agency plans to update this Cross Connection Control Manual during the development of future microbial rules that address cross connection. The Agency will request public comment on issues related to cross connection control at that time. EPA would also like to point out that a number of States and local governments have existing cross connection control programs and strongly encourages States and local governments to implement effective cross connection control programs.

D. Filter Backwash Recycling

The SDWA Amendments of 1996 require that the EPA promulgate a regulation governing the recycle of filter backwash water within the treatment process by August 2000. The Agency is currently developing data and collecting information to consider these issues in a separate rule rather than in the IESWTR. The Agency held a public meeting in Denver, Colorado, in July 1998 and plans to hold another meeting in early 1999 to discuss available data and possible regulatory options, and intends to propose a rule in August of 1999.

E. Certification Criteria for Water Plant Operators

The July 29, 1994 notice requested comment on whether the ESWTR should define minimum certification criteria for surface water treatment plant operators. Currently, the SWTR (141.70) requires such systems to be operated by ''qualified personnel who meet the requirements specified by the State''. EPA is not further defining ''qualified'' in the IESWTR as the operator certification requirements discussed below will address this issue. The 1996 Amendments to the SDWA direct the Administrator, EPA, in cooperation with the States, to publish guidelines in the **Federal Register** specifying minimum standards for certification and recertification of operators of

community and nontransient noncommunity public water systems. Draft guidelines were published in the **Federal Register** Friday, March 27, 1998 (EPA 1998f) with a 90-day public comment period. Final guidelines are required to be published by February 1999. States then have two years to adopt and implement an operator certification program that meets these guidelines. After that date, if a State has not adopted and implemented an approved program, the Administrator must withhold 20 percent of the funds a State is otherwise entitled to receive in its Drinking Water State Revolving Fund (DWSRF) capitalization grants under section 1452 of SDWA. Questions regarding the draft guidelines may be directed to Jenny Jacobs (202–260–2939) or Richard Naylor (202–260–5135) of EPA's Office of Ground Water and Drinking Water. Their e-mail addresses are: jacobs.jenny@epamail.epa.gov and naylor.richard@epamail.epa.gov. In light of the 1996 Amendments and the draft guidelines, certification criteria need not be included in today's rule.

VII. Other Requirements

A. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA is generally required to prepare a regulatory flexibility analysis describing the impact of the regulatory action on small entities as part of the rulemaking. However, under section 605(b) of the RFA, if EPA certifies that the rule will not have a significant economic impact on a substantial number of small entities, EPA is not required to prepare a regulatory flexibility analysis. Pursuant to section 605(b) of the RFA, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities.

The RFA authorizes use of an alternative definition to that of the Small Business Administration for a small water utility. Throughout the 1992–93 negotiated rulemaking process for the Stage 1 DBPR and IESWTR and in the July 1994 proposals for these rules, a small public water system (PWS) was defined as a system serving fewer than 10,000 persons. This definition reflects the fact that the original 1979 standard for total trihalomethanes applied only to systems serving at least 10,000 people. The definition thus recognizes that baseline conditions from which systems serving fewer than 10,000 people will approach disinfection byproduct control and simultaneous control of microbial pathogens is different than that for systems serving 10,000 or more persons. EPA again discussed this approach to the definition of a small system for these rules in the March 1998 Disinfectants/Disinfection Byproducts Notice of Data Availability (63 FR 15676, March 31, 1998). EPA is continuing to define ''small system'' for purposes of this rule and the Stage 1 DBPR as a system which serves fewer than 10,000 people. The IESWTR applies only to systems serving at least 10,000 people and accordingly does not have a significant economic impact on a substantial number of small entities. Accordingly EPA has not completed a regulatory flexibility analysis for the IESWTR or a small entity compliance guide.

The Agency has since proposed and taken comment on its intent to define ''small entity'' as a public water system that serves 10,000 or fewer persons for purposes of its regulatory flexibility assessments under the RFA for all future drinking water regulations. (See Consumer Confidence Reports Rule, 63 FR 7620, Feb. 13, 1998.) In that proposal, the Agency discussed the basis for its decision to use this definition and to use a single definition of small public water system whether the system was a ''small business'', ''small nonprofit organization'', or ''small governmental jurisdiction.'' EPA also consulted with the Small Business Administration on the use of this definition as it relates to small businesses. Subsequently, the Agency has used this definition in developing its regulations under the Safe Drinking Water Act. This approach is virtually identical to the approach used in the IESWTR and Stage 1 DBPR.

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 2040–0205.

The information collected as a result of this rule will allow the States and EPA to evaluate PWS compliance with the rule. For the first three years after promulgation of this rule, the major information requirements pertain to monitoring, compliance reporting and sanitary surveys. Responses to the request for information are mandatory (Part 141). The information collected is not confidential.

EPA is required to estimate the burden on PWS for complying with the final rule. 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.

EPA estimates that the annual burden on PWS and States for reporting and recordkeeping will be 150,557 hours. This is based on an estimate that there will be 998 respondents per year who will each, on average, need to provide 3,803 responses and that the average response will take 40 hours. The total annual cost burden is $27,448,013. This includes total annual labor costs of $4,615,791 for the following activities: reading and understanding the rule, planning, training, data collection, data review, data reporting, recordkeeping, compliance tracking and making determinations. The cost burden also includes capital costs of $17,137,222 for turbidimeter installation by PWS, and an operations and maintenance cost of $5,695,000 for turbidimeters.

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 are listed in 40 CFR part 9 and 48 CFR chapter 15. EPA is amending the table in 40 CFR part 9 of currently approved ICR control numbers issued by OMB for various regulations to list the information requirements contained in this final rule. This ICR was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is ''good cause'' under section 553 (b) (B) of the Administrative Procedures Act (5 U.S.C. 553 (b) (B) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

C. Unfunded Mandates Reform Act

1. Summary of UMRA requirements

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 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 UMRA section 202, 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 cost-effective 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 an explanation why that alternative was not adopted with the final rule.

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.

2. Written Statement for Rules With Federal Mandates of $100 Million or More

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 and the private sector in any one year. Accordingly, EPA has prepared under section 202 of the UMRA a written statement which is summarized below. The written statement addresses the following areas: (a) Authorizing legislation; (b) cost-benefit analysis including an analysis of the extent to which the costs of State, local and Tribal governments will be paid for by the Federal government; (c) estimates of future compliance costs and disproportionate budgetary effects; (d) macro-economic effects; and (e) a summary of EPA's consultation with State, local, and Tribal governments and their concerns, including a summary of the Agency's evaluation of those comments and concerns; (f) identification and consideration of regulatory alternatives; and (g) selection of the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The major points of this written statement are summarized below. A more detailed description of this analysis is presented in EPA's *Unfunded Mandates Reform Act Analysis for the IESWTR* (EPA,1998c) which is included in the docket for this rule.

a. Authorizing Legislation

Today's rule is promulgated pursuant to (section 1412(b)(2)(C)) of the 1996 amendments to the SDWA; paragraph C of this section establishes a statutory deadline of November 1998 to promulgate this rule. In addition, the Interim Enhanced Surface Water Treatment Rule (IESWTR) is closely integrated with the Stage 1 DBPR, which also has a statutory deadline of November 1998.

b. Cost Benefit Analysis

Section V of this preamble discusses in detail the cost and benefits associated with the IESWTR. Also, the EPA's *Regulatory Impact Analysis of the Interim Enhanced Surface Water Treatment Rule* (EPA, 1998a) contains a detailed cost benefit analysis. The analysis includes both qualitative and monetized benefits for improvements to health and safety. Because of scientific uncertainty regarding the exposure assessment and the risk assessment for *Cryptosporidium*, the Agency calculated partial monetary benefit estimates for three different scenarios (low, medium, high) of improved removal of *Cryptosporidium* concentrations assuming two different levels of current inactivation (2.5 log baseline or 3.0 log baseline). Potential monetized annual benefits for illness avoided associated with *Cryptosporidium* ranged from a mean of $0.263 billion (3.0 log) to a mean of $1.24 billion (2.5 log) for this rule depending upon varied baseline and improved *Cryptosporidium* removal assumptions. The benefits from reduction in exposure to *Cryptosporidium* have been compared with the aggregate annualized costs to State, local, and tribal governments and the private sector that totaled approximately $307 million (annualized at 7%).

Using a current national average treatment removal assumption of 3.0 logs, net benefits are positive under the high and mid improved removal scenarios. Net benefits using the 3.0 log current removal assumption are negative near and below the mean associated with the low improved removal assumption using only the value of cost of illness avoided; however, when the value of mortalities prevented is added with the benefits, all scenarios have positive net benefits at the mean.

Thus, the monetized net benefits are positive across most of the range of current treatment assumptions, improved log removal scenarios, and discount rates. The benefits due to the illnesses avoided may be slightly overstated because mortalities were not netted out of the number of illnesses avoided. This value is minimal and would not be captured at the level of significance of the analysis. Other possible benefits considered in the analysis but not monetized are reducing the risk of outbreaks, reducing the exposure to other pathogens, enhancing aesthetic water quality, avoiding the cost of averting behavior, and reducing the cost of pain and suffering. These benefits could add substantial economic value to this rule.

Various Federal programs exist to provide financial assistance to State, local, and Tribal governments in complying with this rule. The Federal government provides funding to States that have primacy enforcement responsibility for their drinking water programs through the Public Water Systems Supervision Grants program. Additional funding is available from other programs administered either by EPA or other Federal agencies. These include the Drinking Water State Revolving Fund (DWSRF) and Housing and Urban Development's Community Development Block Grant Program.

For example, SDWA authorizes the Administrator of the EPA to award capitalization grants to States, which in turn can provide low cost loans and other types of assistance to eligible public water systems. The DWSRF assists public water systems with financing the costs of infrastructure needed to achieve or maintain compliance with SDWA requirements. Each State will have considerable flexibility to determine the design of its program and to direct funding toward its most pressing compliance and public health protection needs. States may also, on a matching basis, use up to ten percent of their DWSRF allotments for each fiscal year to assist in running the State drinking water program.

c. Estimates of Future Compliance Costs and Disproportionate Budgetary Effects

EPA believes that the cost estimates indicated above in Section V to be a fairly accurate assessment of future

compliance costs and generally does not anticipate any disproportionate budgetary effects. In general, the costs that a public water system, whether publicly or privately owned, will incur to comply with this rule will depend on many factors that are not generally based on location. However, the data needed to confirm this assessment and to analyze other impacts of this problem are not available; therefore, EPA looked at three other factors: The impacts of the regulation on small versus large systems, the costs to public versus private water systems, and the costs to households. First, EPA notes that the IESWTR does not have a significant impact on a substantial number of small entities, as discussed previously in Section VII.A. These small systems are the subject of a subsequent rulemaking planned for 2000.

Second, the review of costs to public versus private systems is based on estimates of the allocation of the systems across size categories and can only be viewed as an indication of possible impacts. More important, implementation of the rule affects both public and private water systems equally, with the variance in total cost by system size merely a function of the number of affected systems. This analysis is presented in further detail in the *IESWTR UMRA Analysis Document* (EPA, 1998c).

Finally, the highest estimated household costs would be for those households served by systems that would have to implement all proposed combined filter effluent alternative treatment activities to meet the 0.3 NTU requirement for 95 percent of samples in a given month and a maximum of 1 NTU. However, this analysis may overstate costs because these systems may choose a less costly alternative such as point-of-use devices, selecting alternative water sources, or connecting to a larger regional water system.

d. Macro-economic Effects

As required under UMRA Section 202, EPA is required to estimate the potential macro-economic effects of the regulation. 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 1997, real GDP was $7,188 billion so a rule would have to cost at least $18 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 IESWTR should be negligible based on the fact that the total annual costs are about $307 million per year (at a 7 percent cost of capital) and the costs are not expected to be highly focused on a particular geographic region or sector.

e. Summary of EPA's Consultation With State, Local, and Tribal Government and Their Concerns

Under UMRA section 202, EPA is to provide a summary of its consultation with elected representatives (or their designated authorized employees) of affected State, local and Tribal governments in this rulemaking. Although this rule was proposed before UMRA became a statutory requirement, EPA initiated consultations with governmental entities and the private sector affected by this rule through various means. This included participation on a Regulatory Negotiation Committee, chartered under the Federal Advisory Committee Act (FACA), in 1992–93 that included stakeholders representing State and local governments, public health organizations, public water systems, elected officials, consumer groups, and environmental groups.

After the amendments to SDWA in 1996, the Agency initiated a second FACA process, similarly involving a broad range of stakeholders, and held meetings during 1997 to address the expedited deadline for promulgation of the IESWTR in November 1998. EPA established the M–DBP Advisory Committee to collect, share, and analyze new data reviewed since the earlier Reg. Neg. process and also to build a consensus on the regulatory implications of this new information. The M–DBP Advisory Committee established a technical working group to assist them with the many scientific issues surrounding this rule. The Committee included representatives from organizations such as the National League of Cities, the National Association of City and County Health Officials, the Association of Metropolitan Water Agencies, the Association of State Drinking Water Administrators, and the National Association of Water Companies. In addition, the Agency invited the Native American Water Association to participate in the FACA process to develop this rule. Although they eventually decided not to take part, the Association continued to be informed of meetings and developments through a stakeholders mailing list. Stakeholders who participated in the FACA processes, as well as all other interested members of the public, were invited to comment on the proposed rule and NODA. Also, as part of the Agency's Communication Strategy, EPA sent copies of the proposed rule and NODA to many stakeholders, including six tribal associations.

In addition, the Agency notified governmental entities and the private sector of opportunities to provide input on this rule in the **Federal Register** on July 29, 1994 (59 FR 38832) and on November 3, 1997 (62 FR 59485). EPA received written comments from approximately 37 commenters on the July 29, 1994 notice and from approximately 157 commenters on the November 3, 1997 notice. Of the 37 commenters on the 1994 proposed rule, approximately 22% were States and 35% were local governments. Of the 157 commenters on the 1997 Notice of Data Availability, approximately 8% were States and 27% were local governments.

The public docket for this rulemaking contains all comments received by the Agency and provides details about the nature of State and local governments' concerns. Issues addressed by State and local government commenters included concerns about the cost and feasibility of proposed regulatory alternatives to require treatment levels based on *Giardia* and/or *Cryptosporidium* occurrence in a public water system's source water; preferences for requiring 2 log removal of *Cryptosporidium* for filtered systems; and concerns about the feasibility of requiring source water monitoring for unfiltered systems. A number of commenters on the issue of sanitary survey frequencies supported the three and five years frequencies for community and non-community water systems, respectively, as recommended by the M–DBP Advisory Committee. Some State commenters, however, expressed concern about resources for carrying out the surveys on such a schedule. On the issue of flexibility in implementing the Stage 1 DBPR and IESWTR to ensure that the rules are implemented simultaneously, most commenters preferred option four (discussed in the November 1997 IESWTR NODA) that calls for simultaneous implementation of both the IESWTR and the Stage 1 DBPR.

EPA understands the State and local government concerns noted above. EPA agrees that of the regulatory alternatives proposed, the appropriate alternative is the 2 log removal requirement for *Cryptosporidium* included in the final rule; the rule does not include treatment requirements based on microbial occurrence in source water. Nor does it require source water monitoring for unfiltered systems, based in part on concerns about current availability of

analytical methods. With respect to sanitary survey frequencies, the final IESWTR reflects the M–DBP Advisory Committee's recommendations, including provisions that allow States to (1) grandfather surveys done after December 1995 if they address eight elements that are currently part of existing State/EPA guidance; (2) do sanitary surveys on a five-year instead of a three-year schedule for community water systems that the State determines to be outstanding performers; and (3) carry out survey components in a staged or phased manner within the established frequency. EPA believes that these frequencies and associated provisions in the final rule allow States the flexibility to prioritize and carry out the sanitary survey process as an effective tool to identify and correct water system deficiencies that could pose a threat to public health. EPA agrees that concurrent implementation of the Stage 1 DBPR and IESWTR, as described in option 4 and reflected in the final Stage 1 DBPR compliance schedules, is the most effective means of implementing both rules. Finally, the Agency believes that the final IESWTR will provide public health benefits that justify the costs of the rule by reducing the public's exposure to microbial pathogens, including *Cryptosporidium*. EPA notes that, as discussed in Section V. above, over 90% of affected households will incur costs of less than $1 per month.

f. Regulatory Alternatives Considered

As required under section 205 of the UMRA, EPA considered several regulatory alternatives that developed from the Regulatory Negotiation process, M–DBP Advisory Committee, and stakeholder comments. These approaches sought to improve microbial protection and balance the risk/risk tradeoff of controlling microbial pathogens while simultaneously limiting the formation of disinfection byproducts. EPA proposed core requirements related to ground water under the direct influence of surface water, watershed control for unfiltered systems and sanitary surveys for all surface water systems, as well as five treatment alternatives for controlling pathogens, including a number of sub-options. In addition, the Agency requested comment on possible supplemental treatment requirements for requiring covers on finished water reservoirs, cross connection control programs and State notification of high turbidity levels and other issues related to turbidity control. Among these various approaches, the Agency was unable to pursue certain ones in the final IESWTR because additional data was needed.

Additional analysis of the regulatory alternatives was provided by the M–DBP Advisory Committee. The M–DBP Advisory Committee assessed tightening turbidity performance criteria and monitoring individual filtration performance. The Committee discussed at least one alternative that would have required the use of membrane technology to improve turbidity performance but concluded that utilities could more affordably achieve sufficient performance levels through changes in operation and administrative practices. The Committee considered three different turbidity standards as well as some existing State requirements for individual filter monitoring. A more detailed description of these alternatives is discussed in Chapter V of the *IESWTR Regulatory Impact Analysis* (EPA, 1998a).

g. Selection of the Least Costly, Most Cost-Effective or Least Burdensome Alternative That Achieves the Objectives of the Rule

As discussed above, EPA considered various regulatory options that would reduce exposures to pathogens and disinfectant byproducts that are the objectives of the SDWA. For instance, the M–DBP Committee analyzed the cost for three different levels of turbidity performance for the combined filter effluent turbidity requirements (measured in NTUs). The three NTU limits considered at the 95th percentile were 0.1, 0.2, and 0.3 and their cost estimates show a clear distinction among the three different levels. At the 0.1 NTU, the total annual costs of treatment were estimated to be $3,213 million. At 0.2 NTU and 0.3 NTU, the total annual costs of treatment were estimated to be $317 million and $174 million, respectively. The costs of the 0.1 NTU requirement were roughly 20 times the 0.3 NTU scenario and 10 times the 0.2 NTU scenario.

The large increase in costs for the 1.0 NTU scenario occurs because it was assumed that 95 percent of systems would need to install costly membrane technology to comply with this level. Most of the difference between the 0.2 and 0.3 levels is attributable to twice as many systems having to install coagulant aid polymer feed and filter aid polymer feed capabilities in complying with the 0.2 NTU limit as compared with the 0.3 NTU limit. The Committee recommended the 0.3 option because they felt that this level would provide adequate health protection at the least cost. The 0.3 NTU limit was the option that was eventually adopted as part of this rule and is the least costly option that accomplishes the objectives of the IESWTR.

3. Impacts on Small Governments

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely effect small governments. Thus this rule is not subject to the requirements of section 203 of UMRA. For purposes of the IESWTR, EPA has defined small public water systems as those that serve a population of fewer than 10,000, as discussed above in Section VIIA. Consequently, section 203 of UMRA does not apply because, as discussed above, the IESWTR applies to systems serving 10,000 or more people. As noted above, EPA plans to address surface water systems serving fewer than 10,000 people in the Long Term 1 Enhanced Surface Water Treatment Rule.

Even though section 203 does not apply, the FACA processes gave a variety of stakeholders, including small governments, the opportunity for timely and meaningful participation in the regulatory development process. Groups such as the National Association of City and County Health Officials and the National League of Cities participated in the rule making process. Through such participation and exchange, EPA notified small governments of requirements under consideration and provided officials of these small governments with an opportunity to have meaningful and timely input into the development of regulatory proposals.

D. National Technology Transfer and Advancement Act

Under section 12(d) of the National Technology Transfer and Advancement Act (''ANTTAA''), the Agency is required 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, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. Where available and potentially applicable voluntary consensus standards are not used by EPA, the Act requires the Agency to provide Congress, through the Office of Management and Budget, an explanation of the reasons for not using such standards.

Today's rule requires the use of previously approved technical standards for the measurement of turbidity. In previous rulemakings, EPA

approved three methods for measuring turbidity in drinking water. Turbidity is a method-defined parameter and therefore modifications to any of the three approved methods requires prior EPA approval. One of the approved methods was published by the Standard Methods Committee of American Public Health Association, the American Water Works Association, and the Water Environment Federation, a voluntary consensus standard body. That method, Method 2130B is published in Standard Methods for the Examination of Water and Wastewater (19th ed.). Standard Methods is a widely used reference which has been peer-reviewed throughout the scientific community. In addition to this voluntary consensus standard, EPA approved Great Lakes Instrument Method 2 as an alternate test procedure for the measurement of turbidity. Finally, the Agency approved a revised EPA Method 180.1 for turbidity measurement in August 1993 in Methods for the Determination of Inorganic Substances in Environmental Samples (EPA–600/R–93–100).

In 1994, EPA reviewed and rejected an additional technical standard for the measurement of turbidity, the ISO 7027 standard, which measures turbidity at a higher wavelength than the approved test measurement standards. The ISO 7027 is an analytical method for the measurement of turbidity. ISO 7027 measures turbidity using either 90° scattered or transmitted light depending on the turbidity concentration evaluated. Although instruments conforming to ISO 7027 specifications are similar to the GLI instrument, only the GLI instrument uses pulsed, multiple detectors to simultaneously read both 90° scattered and transmitted light. EPA has no data upon which to evaluate whether the separate 90° scattered or transmitted light measurement evaluations according to the ISO 7027 method would produce results that are equivalent to results produced using GLI Method 2, Standard Method 2130B, or EPA Method 180.1.

Today's final rule also requires continuous individual filter monitoring for turbidity and requires PWSs to calibrate the individual turbidimeter according to the turbidimeter manufacturer's instructions. These calibration instructions may constitute technical standards as that term is defined in the NTTAA. EPA has looked for voluntary consensus standards with regard to calibration of turbidimeter. The American Society for Testing and Materials (ASTM) is developing such voluntary consensus standards; however, there do not appear to be any voluntary consensus standards available at this time.

E. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51,735 (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 will have an annual effect on the economy of $100 million or more. 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.

F. Executive Order 12898: Environmental Justice

Executive Order 12898 (59 FR 7629) 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. The Agency has considered environmental justice related issues concerning the potential impacts of this action and has consulted with minority and low-income stakeholders.

Three aspects of today's rule comply with the Environmental Justice Executive Order and they can be classified as follows: (1) The overall nature of the rule; (2) the inclusion of sensitive sub-populations in the regulatory development process; and (3) the convening of a stakeholder meeting specifically to address environmental justice issues. The IESWTR applies uniformly to all surface water and GWUDI systems that serve a population of at least 10,000 and consequently, the health protection benefits this rule provides are equal across all income and minority groups within these communities. A complementary regulation is under development that will address similar issues for systems serving fewer than 10,000 people.

In addition, concerns of the sensitive sub-populations were included in the IESWTR through the Reg. Neg. and M-DBP Advisory Committee process undertaken to craft the regulation. Both Committees were chartered under the FACA authorization, and included a broad cross-section of regulators, regulated communities, industry, public interest groups, and State and local public health officials. Representatives of sensitive sub-populations, in particular people with AIDS, participated in the regulatory development process. Extensive discussion on setting treatment requirements that provide the maximum feasible protection took place, and the final consensus that resulted in the rule considered issues of affordability, equity, and safety.

Finally, as part of EPA's responsibilities to comply with E.O. 12898, the Agency held a stakeholder meeting on March 12, 1998 (EPA 1998e) to address various components of pending drinking water regulations; and how they may impact sensitive sub-populations, minority populations, and low-income populations. Topics discussed included treatment techniques, costs and benefits, data quality, health effects, and the regulatory process. Participants included national, State, tribal, municipal, and individual stakeholders. EPA conducted the meetings by video conference call between eleven cities. This meeting was a continuation of stakeholder meetings that started in 1995 to obtain input on the Agency's Drinking Water Programs. The major objectives for the March 12, 1998 (EPA 1998e) meeting were:

- Solicit ideas from Environmental Justice (EJ) stakeholders on known issues concerning current drinking water regulatory efforts;
- Identify key issues of concern to EJ stakeholders; and
- Receive suggestions from EJ stakeholders concerning ways to increase representation of EJ communities in OGWDW regulatory efforts.

In addition, EPA developed a plain-English guide specifically for this

meeting to assist stakeholders in understanding the multiple and sometimes complex issues surrounding drinking water regulation.

Overall, EPA believes this rule will equally protect the health of all minority and low income populations within communities served by public water systems regulated under this rule.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule initiated after April 21, 1997, or proposed after April 21, 1998, that (1) is determined to be ''economically significant'' as defined under E.O. 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.

The final rule is not subject to the Executive Order because EPA published a notice of proposed rulemaking before April 21, 1998. However, EPA's policy since November 1, 1995, is to consistently and explicitly consider risks to infants and children in all risk assessments generated during its decision making process including the setting of standards to protect public health and the environment.

In promulgating the IESWTR the Agency recognizes that the health risks associated with exposure to the protozoan *Cryptosporidium* are of particular concern for certain sensitive subpopulations, including children and immunocompromised individuals. These concerns were considered as part of the regulatory development process, particularly in the establishment of the MCLG for *Cryptosporidium* in drinking water, and are reflected in the final rule. The IESWTR establishes a Maximum Contaminant Level Goal (MCLG) of zero for *Cryptosporidium* at the genus level, taking into account the need to protect sensitive populations (e.g., children) and providing for an adequate margin of safety. For public water systems that use surface water, filter and serve at least 10,000 people, the Agency is establishing physical removal treatment requirements for *Cryptosporidium*. For systems that use conventional or direct filtration, the Agency is strengthening the existing turbidity standards for finished water and is also requiring individual filter monitoring to assist in controlling pathogen breakthrough during the treatment process.

H. Executive Order 12875: Enhancing the Intergovernmental Partnership

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

EPA has concluded that this rule will create a mandate on State, local, and tribal governments and that the Federal government will not provide all of the funds necessary to pay the direct costs incurred by the State, local, and tribal governments in complying with the mandate. In developing this rule, EPA consulted with State and local governments to enable them to provide meaningful and timely input in the development of this rule. EPA also invited the Native American Water Association to participate in the FACA process to develop this rule. Although they decided not to take part in the deliberations, the Association continued to be informed of meetings and developments through a stakeholders mailing list.

As described above in Section VII. C.2(e), EPA held extensive meetings with a variety of State and local representatives who provided meaningful and timely input in the development of the proposed rule. State and local representatives were part of the FACA committees involved in the development of this rule. Summaries of the meetings have been included in the public docket for this rulemaking. See section VII.C.2(e) for summaries of the extent of EPA's consultation with State, local, and tribal governments; the nature of the government concerns; and EPA's position supporting the need to issue the rule.

I. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. There are very few Tribal surface water systems that serve 10,000 or more people. Moreover, the rule does not impose requirements on the Tribal systems that differ from those required for other water systems covered under the rule. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

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

In accordance with section 1412(d) and (e) of SDWA, EPA consulted with the Science Advisory Board, National Drinking Water Council, and Secretary of Health and Human Services, and requested and considered their comments in developing this rule.

K. Likely Effect of Compliance With the IESWTR on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of the SDWA as amended requires that, in promulgating a NPDWR, the Administrator shall

include an analysis of the likely effect of compliance with the regulation on the technical, financial, and managerial capacity of public water systems. The following analysis has been performed to fulfill this statutory obligation.

Overall water system capacity is defined in EPA guidance (EPA 816–R–98–006) (EPA 1998g) as the ability to plan for, achieve, and maintain compliance with applicable drinking water standards. Capacity has three components: technical, managerial, and financial.

Technical capacity is the physical and operational ability of a water system to meet SDWA requirements. Technical capacity 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. A water system's technical capacity can be determined by examining key issues and questions, including:

- *Source water adequacy.* Does the system have a reliable source of drinking water? Is the source of generally good quality and adequately protected?
- *Infrastructure adequacy.* Can the system provide water that meets SDWA standards? What is the condition of its infrastructure, including well(s) or source water intakes, treatment, storage, and distribution? What is the infrastructure's life expectancy? Does the system have a capital improvement plan?
- *Technical knowledge and implementation.* Is the system's operator certified? Does the operator have sufficient technical knowledge of applicable standards? Can the operator effectively implement this technical knowledge? Does the operator understand the system's technical and operational characteristics? Does the system have an effective operation and maintenance program?

Managerial capacity is the ability of a water system to conduct its affairs in a manner enabling the system to achieve and maintain compliance with SDWA requirements. Managerial capacity refers to the system's institutional and administrative capabilities.

Managerial capacity can be assessed through key issues and questions, including:

- *Ownership accountability.* Are the system owner(s) clearly identified? Can they be held accountable for the system?
- *Staffing and organization.* Are the system operator(s) and manager(s) 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? 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 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.

Financial capacity can be assessed through key issues and questions, including:

- *Revenue sufficiency.* Do revenues cover costs? Are water rates and charges adequate to cover the cost of water?
- *Credit worthiness.* Is the system financially healthy? Does it have access to capital through public or private sources?
- *Fiscal management and controls.* Are adequate books and records maintained? Are appropriate budgeting, accounting, and financial planning methods used? Does the system manage its revenues effectively?

1,381 systems are affected by the IESWTR. Of these, 691 may need to modify their treatment process and undertake turbidity monitoring, and will need to meet the disinfection benchmarking and turbidity exceptions reporting requirements. The other 690 systems will need to do turbidity monitoring and will need to meet the disinfection benchmarking and turbidity exceptions reporting requirements as applicable, but will not need to modify their treatment process.

Systems not modifying treatment will need to do turbidity monitoring, disinfection benchmarking, and turbidity exceptions reporting, These systems are not generally expected to require significantly increased technical, financial, or managerial capacity to comply with these new requirements. Some individual facilities may have weaknesses in one or more of these areas, but overall surface water systems should have or be able to easily obtain the capacity needed for these activities.

Systems needing to modify treatment will employ one or more of a variety of steps. The steps expected to be employed by 25% or more of systems in virtually all size categories covered by the rule are: install backwash water polymer feed capability; install individual filter turbidimeters; account for recycle flow in process control decisions; implement a policy and commitment to lower water quality goals; utilize alternative process control testing equipment; modify/implement process control monitoring and control; and designate a process control strategy facilitator.

Furthermore, there are a number of actions that are expected to be taken disproportionately by the smaller sized systems covered under the IESWTR (that is to say, a greater percentage of smaller sized systems will undertake these activities than will larger sized systems). These steps include: Structural and mechanical rapid mix improvements; filter underdrain retrofits and gravel media; filter rate-of-flow controller replacement; hydraulic improvements in flow distribution/control/measurement; increase plant staffing; replace obsolete bench top turbidimeters; purchase jar test apparatus; and train staff to understand process control strategy.

For many systems serving between 10,000 and 100,000 persons which need to make treatment modifications an enhancement of technical, financial, and managerial capacity may likely be needed. As the preceding paragraph makes clear, these systems will be making structural improvements and enhancing laboratory and staff capacity. Larger sized systems have typically already made these improvements as part of normal operations. Meeting the requirements of the IESWTR will require operating at a higher level of sophistication and in a better state of repair than some plants in the 10,000–100,000 person size category have considered acceptable in the past.

Certainly there will be exceptions both between 10,000 and 100,000 persons and above. Some larger plants are expected to find that their technical, managerial, and financial capacity needs to be upgraded to support the system in meeting the new requirements. Likewise, some plants serving 10,000–100,000 persons will already have more than adequate technical, financial, and managerial capacity to meet these requirements. However, in general, the systems serving 10,000–100,000 persons needing to make treatment modifications will be the ones most needing to enhance their capacity.

L. Submission to Congress and the General Accounting Office

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 rule is a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective February 16, 1999.

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List of Subjects

40 CFR Parts 9

Reporting and recordkeeping requirements.

40 CFR Parts 141 and 142

Drinking water, Environmental protection, Public utilities, Reporting and recordkeeping requirements, Reservoirs, Utilities, Water supply, Watersheds.

Dated: November 30, 1998.

Carol M. Browner,

Administrator.

For the reasons set out 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; E.O. 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 by adding under the indicated heading the new entries in numerical order to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control no.
* * * * *	
National Primary Drinking Water Regulations	
* * * * *	
141.170	2040–0205
141.172	2040–0205
141.174–141.175	2040–0205
* * * * *	

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 revising the definition of ''ground water under the direct influence of surface water'' and adding the following definitions in alphabetical order to read as follows:

§ 141.2 Definitions.

* * * * *

Comprehensive performance evaluation (CPE) is a thorough review and analysis of a treatment plant's performance-based capabilities and associated administrative, operation and maintenance practices. It is conducted to identify factors that may be adversely impacting a plant's capability to achieve compliance and emphasizes approaches that can be implemented without significant capital improvements. For purposes of compliance with subpart P of this part, the comprehensive performance evaluation must consist of at least the following components: Assessment of plant performance; evaluation of major unit processes; identification and prioritization of performance limiting factors; assessment of the applicability of comprehensive technical assistance; and preparation of a CPE report.

* * * * *

Disinfection profile is a summary of daily *Giardia lamblia* inactivation through the treatment plant. The procedure for developing a disinfection profile is contained in § 141.172.

* * * * *

Filter profile is a graphical representation of individual filter performance, based on continuous turbidity measurements or total particle counts versus time for an entire filter run, from startup to backwash inclusively, that includes an assessment of filter performance while another filter is being backwashed.

* * * * *

Ground water under the direct influence of surface water means any water beneath the surface of the ground with significant occurrence of insects or other macroorganisms, algae, or large-diameter pathogens such as *Giardia lamblia* or (for subpart H systems serving at least 10,000 people only) *Cryptosporidium*, or significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlate to climatological or surface water conditions. Direct influence must be determined for individual sources in accordance with criteria established by the State. The State determination of direct influence may be based on site-specific measurements of water quality and/or documentation of well construction characteristics and geology with field evaluation.

* * * * *

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

* * * * *

5. Section 141.32 is amended by revising paragraph (e)(10) to read as follows:

§ 141.32 Public notification.

* * * * *

(e) * * *

(10) *Microbiological contaminants* (for use when there is a violation of the treatment technique requirements for filtration and disinfection in subpart H or subpart P of this part). The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that the presence of microbiological contaminants are a health concern at certain levels of exposure. If water is inadequately treated, microbiological contaminants in that water may cause disease. Disease symptoms may include diarrhea, cramps, nausea, and possibly jaundice, and any associated headaches and fatigue. These symptoms, however, are not just associated with disease-causing organisms in drinking water, but also may be caused by a number of factors other than your drinking water. EPA has set enforceable requirements for treating drinking water to reduce the risk of these adverse health effects. Treatment such as filtering and disinfecting the water removes or destroys microbiological contaminants. Drinking water which is treated to meet EPA requirements is associated with little to none of this risk and should be considered safe.

* * * * *

6. In § 141.52, the table is amended by adding a new entry, in numerical order, to read as follows:

§ 141.52 Maximum contaminant level goals for microbiological contaminants.

* * * * *

Contaminant	MCLG
* * * * *	
(5) *Cryptosporidium*	zero.

7. Section 141.70 is amended by adding paragraph (d) to read as follows:

§ 141.70 General requirements.

* * * * *

(d) *Additional requirements for systems serving at least 10,000 people.* In addition to complying with requirements in this subpart, systems serving at least 10,000 people must also comply with the requirements in subpart P of this part.

8. Section 141.71 is amended by revising paragraph (b)(6) to read as follows:

§ 141.71 Criteria for avoiding filtration.

* * * * *

(b) * * *

(6) The public water system must comply with the requirements for trihalomethanes in §§ 141.12 and 141.30 until December 17, 2001. After December 17, 2001, the system must comply with the requirements for total trihalomethanes, haloacetic acids (five), bromate, chlorite, chlorine, chloramines, and chlorine dioxide in subpart L of this part.

* * * * *

9. Section 141.73 is amended by adding paragraph (a)(3) and revising paragraph (d) to read as follows:

§ 141.73 Filtration.

* * * * *

(a) * * *

(3) Beginning December 17, 2001, systems serving at least 10,000 people must meet the turbidity requirements in § 141.173(a).

* * * * *

(d) *Other filtration technologies.* A public water system may use a filtration technology not listed in paragraphs (a) through (c) of this section if it demonstrates to the State, using pilot plant studies or other means, that the alternative filtration technology, in combination with disinfection treatment that meets the requirements of § 141.72(b), consistently achieves 99.9 percent removal and/or inactivation of *Giardia lamblia* cysts and 99.99 percent removal and/or inactivation of viruses. For a system that makes this demonstration, the requirements of paragraph (b) of this section apply. Beginning December 17, 2001, systems serving at least 10,000 people must meet the requirements for other filtration technologies in § 141.173(b).

10. Section 141.153 is amended by revising the first sentence of paragraph (d)(4)(v)(C) to read as follows:

§ 141.153 Content of the reports.

* * * * *

(d) * * *

(4) * * *

(v) * * *

(C) When it is reported pursuant to §§ 141.73 or 141.173: The highest single measurement and the lowest monthly percentage of samples meeting the turbidity limits specified in §§ 141.73 or 141.173 for the filtration technology being used. * * *

* * * * *

11. Part 141 is amended by adding a new subpart P to read as follows:

Subpart P—Enhanced Filtration and Disinfection

Sec.

§ 141.170 General requirements.

(a) The requirements of this subpart P constitute national primary drinking water regulations. These regulations establish requirements for filtration and disinfection that are in addition to criteria under which filtration and disinfection are required under subpart H of this part. The requirements of this subpart are applicable to subpart H systems serving at least 10,000 people, beginning December 17, 2001 unless otherwise specified in this subpart. The regulations in this subpart establish or extend treatment technique requirements in lieu of maximum contaminant levels for the following contaminants: *Giardia lamblia,* viruses, heterotrophic plate count bacteria, *Legionella, Cryptosporidium,* and turbidity. Each subpart H system serving at least 10,000 people must provide treatment of its source water that complies with these treatment technique requirements and are in addition to those identified in § 141.70. The treatment technique requirements consist of installing and properly operating water treatment processes which reliably achieve:

(1) At least 99 percent (2-log) removal of *Cryptosporidium* between a point where the raw water is not subject to recontamination by surface water runoff and a point downstream before or at the first customer for filtered systems, or *Cryptosporidium* control under the watershed control plan for unfiltered systems.

(2) Compliance with the profiling and benchmark requirements under the provisions of § 141.172.

(b) A public water system subject to the requirements of this subpart is considered to be in compliance with the requirements of paragraph (a) of this section if:

(1) It meets the requirements for avoiding filtration in §§ 141.71 and 141.171 and the disinfection requirements in §§ 141.72 and 141.172; or

(2) It meets the applicable filtration requirements in either § 141.73 or § 141.173 and the disinfection requirements in §§ 141.72 and 141.172.

(c) Systems are not permitted to begin construction of uncovered finished water storage facilities beginning February 16, 1999.

§ 141.171 Criteria for avoiding filtration.

In addition to the requirements of § 141.71, a public water system subject to the requirements of this subpart that does not provide filtration must meet all of the conditions of paragraphs (a) and (b) of this section.

(a) *Site-specific conditions.* In addition to site-specific conditions in § 141.71(b), systems must maintain the watershed control program under § 141.71(b)(2) to minimize the potential for contamination by *Cryptosporidium* oocysts in the source water. The watershed control program must, for *Cryptosporidium*:

(1) Identify watershed characteristics and activities which may have an adverse effect on source water quality; and

(2) Monitor the occurrence of activities which may have an adverse effect on source water quality.

(b) During the onsite inspection conducted under the provisions of § 141.71(b)(3), the State must determine whether the watershed control program established under § 141.71(b)(2) is adequate to limit potential contamination by *Cryptosporidium* oocysts. The adequacy of the program must be based on the comprehensiveness of the watershed review; the effectiveness of the system's program to monitor and control detrimental activities occurring in the watershed; and the extent to which the water system has maximized land ownership and/or controlled land use within the watershed.

§ 141.172 Disinfection profiling and benchmarking.

(a) *Determination of systems required to profile.* A public water system subject to the requirements of this subpart must determine its TTHM annual average using the procedure in paragraph (a)(1) of this section and its HAA5 annual average using the procedure in

paragraph (a)(2) of this section. The annual average is the arithmetic average of the quarterly averages of four consecutive quarters of monitoring.

(1) The TTHM annual average must be the annual average during the same period as is used for the HAA5 annual average.

(i) Those systems that collected data under the provisions of subpart M (Information Collection Rule) must use the results of the samples collected during the last four quarters of required monitoring under § 141.142.

(ii) Those systems that use ''grandfathered'' HAA5 occurrence data that meet the provisions of paragraph (a)(2)(ii) of this section must use TTHM data collected at the same time under the provisions of §§ 141.12 and 141.30.

(iii) Those systems that use HAA5 occurrence data that meet the provisions of paragraph (a)(2)(iii)(A) of this section must use TTHM data collected at the same time under the provisions of §§ 141.12 and 141.30.

(2) The HAA5 annual average must be the annual average during the same period as is used for the TTHM annual average.

(i) Those systems that collected data under the provisions of subpart M (Information Collection Rule) must use the results of the samples collected during the last four quarters of required monitoring under § 141.142.

(ii) Those systems that have collected four quarters of HAA5 occurrence data that meets the routine monitoring sample number and location requirements for TTHM in §§ 141.12 and 141.30 and handling and analytical method requirements of § 141.142(b)(1) may use those data to determine whether the requirements of this section apply.

(iii) Those systems that have not collected four quarters of HAA5 occurrence data that meets the provisions of either paragraph (a)(2)(i) or (ii) of this section by March 16, 1999 must either:

(A) Conduct monitoring for HAA5 that meets the routine monitoring sample number and location requirements for TTHM in §§ 141.12 and 141.30 and handling and analytical method requirements of § 141.142(b)(1) to determine the HAA5 annual average and whether the requirements of paragraph (b) of this section apply. This monitoring must be completed so that the applicability determination can be made no later than March 16, 2000, or

(B) Comply with all other provisions of this section as if the HAA5 monitoring had been conducted and the results required compliance with paragraph (b) of this section.

(3) The system may request that the State approve a more representative annual data set than the data set determined under paragraph (a)(1) or (2) of this section for the purpose of determining applicability of the requirements of this section.

(4) The State may require that a system use a more representative annual data set than the data set determined under paragraph (a)(1) or (2) of this section for the purpose of determining applicability of the requirements of this section.

(5) The system must submit data to the State on the schedule in paragraphs (a)(5)(i) through (v) of this section.

(i) Those systems that collected TTHM and HAA5 data under the provisions of subpart M (Information Collection Rule), as required by paragraphs (a)(1)(i) and (a)(2)(i) of this section, must submit the results of the samples collected during the last 12 months of required monitoring under § 141.142 not later than December 16, 1999.

(ii) Those systems that have collected four consecutive quarters of HAA5 occurrence data that meets the routine monitoring sample number and location for TTHM in §§ 141.12 and 141.30 and handling and analytical method requirements of § 141.142(b)(1), as allowed by paragraphs (a)(1)(ii) and (a)(2)(ii) of this section, must submit those data to the State not later than April 16, 1999. Until the State has approved the data, the system must conduct monitoring for HAA5 using the monitoring requirements specified under paragraph (a)(2)(iii) of this section.

(iii) Those systems that conduct monitoring for HAA5 using the monitoring requirements specified by paragraphs (a)(1)(iii) and (a)(2)(iii)(A) of this section, must submit TTHM and HAA5 data not later than March 16, 2000.

(iv) Those systems that elect to comply with all other provisions of this section as if the HAA5 monitoring had been conducted and the results required compliance with this section, as allowed under paragraphs (a)(2)(iii)(B) of this section, must notify the State in writing of their election not later than December 16, 1999.

(v) If the system elects to request that the State approve a more representative annual data set than the data set determined under paragraph (a)(2)(i) of this section, the system must submit this request in writing not later than December 16, 1999.

(6) Any system having either a TTHM annual average ≥0.064 mg/L or an HAA5 annual average ≥0.048 mg/L during the period identified in paragraphs (a)(1) and (2) of this section must comply with paragraph (b) of this section.

(b) *Disinfection profiling.* (1) Any system that meets the criteria in paragraph (a)(6) of this section must develop a disinfection profile of its disinfection practice for a period of up to three years.

(2) The system must monitor daily for a period of 12 consecutive calendar months to determine the total logs of inactivation for each day of operation, based on the CT99.9 values in Tables 1.1–1.6, 2.1, and 3.1 of § 141.74(b), as appropriate, through the entire treatment plant. This system must begin this monitoring not later than March 16, 2000. As a minimum, the system with a single point of disinfectant application prior to entrance to the distribution system must conduct the monitoring in paragraphs (b)(2)(i) through (iv) of this section. A system with more than one point of disinfectant application must conduct the monitoring in paragraphs (b)(2)(i) through (iv) of this section for each disinfection segment. The system must monitor the parameters necessary to determine the total inactivation ratio, using analytical methods in § 141.74(a), as follows:

(i) The temperature of the disinfected water must be measured once per day at each residual disinfectant concentration sampling point during peak hourly flow.

(ii) If the system uses chlorine, the pH of the disinfected water must be measured once per day at each chlorine residual disinfectant concentration sampling point during peak hourly flow.

(iii) The disinfectant contact time(s) (''T'') must be determined for each day during peak hourly flow.

(iv) The residual disinfectant concentration(s) (''C'') of the water before or at the first customer and prior to each additional point of disinfection must be measured each day during peak hourly flow.

(3) In lieu of the monitoring conducted under the provisions of paragraph (b)(2) of this section to develop the disinfection profile, the system may elect to meet the requirements of paragraph (b)(3)(i) of this section. In addition to the monitoring conducted under the provisions of paragraph (b)(2) of this section to develop the disinfection profile, the system may elect to meet the requirements of paragraph (b)(3)(ii) of this section.

(i) A PWS that has three years of existing operational data may submit those data, a profile generated using those data, and a request that the State approve use of those data in lieu of monitoring under the provisions of

paragraph (b)(2) of this section not later than March 16, 2000. The State must determine whether these operational data are substantially equivalent to data collected under the provisions of paragraph (b)(2) of this section. These data must also be representative of *Giardia lamblia* inactivation through the entire treatment plant and not just of certain treatment segments. Until the State approves this request, the system is required to conduct monitoring under the provisions of paragraph (b)(2) of this section.

(ii) In addition to the disinfection profile generated under paragraph (b)(2) of this section, a PWS that has existing operational data may use those data to develop a disinfection profile for additional years. Such systems may use these additional yearly disinfection profiles to develop a benchmark under the provisions of paragraph (c) of this section. The State must determine whether these operational data are substantially equivalent to data collected under the provisions of paragraph (b)(2) of this section. These data must also be representative of inactivation through the entire treatment plant and not just of certain treatment segments.

(4) The system must calculate the total inactivation ratio as follows:

(i) If the system uses only one point of disinfectant application, the system may determine the total inactivation ratio for the disinfection segment based on either of the methods in paragraph (b)(4)(i)(A) or (b)(4)(i)(B) of this section.

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

(B) 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. Under this alternative, 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 ($\Sigma(CTcalc/CT_{99.9})$).

(ii) If the system uses more than one point of disinfectant application before the first customer, the system 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 (($CTcalc/CT_{99.9}$)) must be calculated using the method in paragraph (b)(4)(i) of this section.

(iii) The system must determine the total logs of inactivation by multiplying the value calculated in paragraph (b)(4)(i) or (ii) of this section by 3.0.

(5) A system that uses either chloramines or ozone for primary disinfection must also calculate the logs of inactivation for viruses using a method approved by the State.

(6) The system must retain disinfection profile data in graphic form, as a spreadsheet, or in some other format acceptable to the State for review as part of sanitary surveys conducted by the State.

(c) *Disinfection benchmarking.* (1) Any system required to develop a disinfection profile under the provisions of paragraphs (a) and (b) of this section and that decides to make a significant change to its disinfection practice must consult with the State prior to making such change. Significant changes to disinfection practice are:

(i) Changes to the point of disinfection;

(ii) Changes to the disinfectant(s) used in the treatment plant;

(iii) Changes to the disinfection process; and

(iv) Any other modification identified by the State.

(2) Any system that is modifying its disinfection practice must calculate its disinfection benchmark using the procedure specified in paragraphs (c)(2)(i) through (ii) of this section.

(i) For each year of profiling data collected and calculated under paragraph (b) of this section, the system must determine the lowest average monthly *Giardia lamblia* inactivation in each year of profiling data. The system must determine the average *Giardia lamblia* inactivation for each calendar month for each year of profiling data by dividing the sum of daily *Giardia lamblia* of inactivation by the number of values calculated for that month.

(ii) The disinfection benchmark is the lowest monthly average value (for systems with one year of profiling data) or average of lowest monthly average values (for systems with more than one year of profiling data) of the monthly logs of *Giardia lamblia* inactivation in each year of profiling data.

(3) A system that uses either chloramines or ozone for primary disinfection must also calculate the disinfection benchmark for viruses using a method approved by the State.

(4) The system must submit information in paragraphs (c)(4)(i) through (iii) of this section to the State as part of its consultation process.

(i) A description of the proposed change;

(ii) The disinfection profile for *Giardia lamblia* (and, if necessary, viruses) under paragraph (b) of this section and benchmark as required by paragraph (c)(2) of this section; and

(iii) An analysis of how the proposed change will affect the current levels of disinfection.

§ 141.173 Filtration.

A public water system subject to the requirements of this subpart that does not meet all of the criteria in this subpart and subpart H of this part for avoiding filtration must provide treatment consisting of both disinfection, as specified in § 141.72(b), and filtration treatment which complies with the requirements of paragraph (a) or (b) of this section or § 141.73 (b) or (c) by December 17, 2001.

(a) *Conventional filtration treatment or direct filtration.* (1) For systems using conventional filtration or direct filtration, the turbidity level of representative samples of a system's filtered water must be less than or equal to 0.3 NTU in at least 95 percent of the measurements taken each month, measured as specified in § 141.74(a) and (c).

(2) The turbidity level of representative samples of a system's filtered water must at no time exceed 1 NTU, measured as specified in § 141.74(a) and (c).

(3) A system that uses lime softening may acidify representative samples prior to analysis using a protocol approved by the State.

(b) *Filtration technologies other than conventional filtration treatment, direct filtration, slow sand filtration, or diatomaceous earth filtration.* A public water system may use a filtration technology not listed in paragraph (a) of this section or in § 141.73(b) or (c) if it demonstrates to the State, using pilot plant studies or other means, that the alternative filtration technology, in combination with disinfection treatment that meets the requirements of § 141.72(b), consistently achieves 99.9 percent removal and/or inactivation of *Giardia lamblia* cysts and 99.99 percent removal and/or inactivation of viruses, and 99 percent removal of *Cryptosporidium* oocysts, and the State approves the use of the filtration technology. For each approval, the State will set turbidity performance requirements that the system must meet at least 95 percent of the time and that the system may not exceed at any time at a level that consistently achieves 99.9 percent removal and/or inactivation of *Giardia lamblia* cysts, 99.99 percent removal and/or inactivation of viruses,

and 99 percent removal of *Cryptosporidium* oocysts.

§ 141.174 Filtration sampling requirements.

(a) Monitoring requirements for systems using filtration treatment. In addition to monitoring required by § 141.74, a public water system subject to the requirements of this subpart that provides conventional filtration treatment or direct filtration must conduct continuous monitoring of turbidity for each individual filter using an approved method in § 141.74(a) and must calibrate turbidimeters using the procedure specified by the manufacturer. Systems must record the results of individual filter monitoring every 15 minutes.

(b) If there is a failure in the continuous turbidity monitoring equipment, the system must conduct grab sampling every four hours in lieu of continuous monitoring, but for no more than five working days following the failure of the equipment.

§ 141.175 Reporting and recordkeeping requirements.

In addition to the reporting and recordkeeping requirements in § 141.75, a public water system subject to the requirements of this subpart that provides conventional filtration treatment or direct filtration must report monthly to the State the information specified in paragraphs (a) and (b) of this section beginning December 17, 2001. In addition to the reporting and recordkeeping requirements in § 141.75, a public water system subject to the requirements of this subpart that provides filtration approved under § 141.173(b) must report monthly to the State the information specified in paragraph (a) of this section beginning December 17, 2001. The reporting in paragraph (a) of this section is in lieu of the reporting specified in § 141.75(b)(1).

(a) Turbidity measurements as required by § 141.173 must be reported within 10 days after the end of each month the system serves water to the public. Information that must be reported includes:

(1) The total number of filtered water turbidity measurements taken during the month.

(2) The number and percentage of filtered water turbidity measurements taken during the month which are less than or equal to the turbidity limits specified in § 141.173(a) or (b).

(3) The date and value of any turbidity measurements taken during the month which exceed 1 NTU for systems using conventional filtration treatment or direct filtration, or which exceed the maximum level set by the State under § 141.173(b).

(b) Systems must maintain the results of individual filter monitoring taken under § 141.174 for at least three years. Systems must report that they have conducted individual filter turbidity monitoring under § 141.174 within 10 days after the end of each month the system serves water to the public. Systems must report individual filter turbidity measurement results taken under § 141.174 within 10 days after the end of each month the system serves water to the public only if measurements demonstrate one or more of the conditions in paragraphs (b)(1) through (4) of this section. Systems that use lime softening may apply to the State for alternative exceedance levels for the levels specified in paragraphs (b)(1) through (4) of this section if they can demonstrate that higher turbidity levels in individual filters are due to lime carryover only and not due to degraded filter performance.

(1) For any individual filter that has a measured turbidity level of greater than 1.0 NTU in two consecutive measurements taken 15 minutes apart, the system must report the filter number, the turbidity measurement, and the date(s) on which the exceedance occurred. In addition, the system must either produce a filter profile for the filter within 7 days of the exceedance (if the system is not able to identify an obvious reason for the abnormal filter performance) and report that the profile has been produced or report the obvious reason for the exceedance.

(2) For any individual filter that has a measured turbidity level of greater than 0.5 NTU in two consecutive measurements taken 15 minutes apart at the end of the first four hours of continuous filter operation after the filter has been backwashed or otherwise taken offline, the system must report the filter number, the turbidity, and the date(s) on which the exceedance occurred. In addition, the system must either produce a filter profile for the filter within 7 days of the exceedance (if the system is not able to identify an obvious reason for the abnormal filter performance) and report that the profile has been produced or report the obvious reason for the exceedance.

(3) For any individual filter that has a measured turbidity level of greater than 1.0 NTU in two consecutive measurements taken 15 minutes apart at any time in each of three consecutive months, the system must report the filter number, the turbidity measurement, and the date(s) on which the exceedance occurred. In addition, the system must conduct a self-assessment of the filter within 14 days of the exceedance and report that the self-assessment was conducted. The self assessment must consist of at least the following components: assessment of filter performance; development of a filter profile; identification and prioritization of factors limiting filter performance; assessment of the applicability of corrections; and preparation of a filter self-assessment report.

(4) For any individual filter that has a measured turbidity level of greater than 2.0 NTU in two consecutive measurements taken 15 minutes apart at any time in each of two consecutive months, the system must report the filter number, the turbidity measurement, and the date(s) on which the exceedance occurred. In addition, the system must arrange for the conduct of a comprehensive performance evaluation by the State or a third party approved by the State no later than 30 days following the exceedance and have the evaluation completed and submitted to the State no later than 90 days following the exceedance.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

12. 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.

13. Section 142.14 is amended by revising paragraphs (a)(3), (a)(4)(i), and (a)(4)(ii) introductory text, and adding paragraph (a)(7) to read as follows:

§ 142.14 Records kept by States.

(a) * * *

(3) Records of turbidity measurements must be kept for not less than one year. The information retained must be set forth in a form which makes possible comparison with the limits specified in §§ 141.71, 141.73, 141.173 and 141.175 of this chapter. Until June 29, 1993, for any public water system which is providing filtration treatment and until December 30, 1991, for any public water system not providing filtration treatment and not required by the State to provide filtration treatment, records kept must be set forth in a form which makes possible comparison with the limits contained in § 141.13 of this chapter.

* * * * *

(4)(i) Records of disinfectant residual measurements and other parameters necessary to document disinfection effectiveness in accordance with §§ 141.72 and 141.74 of this chapter and

the reporting requirements of §§ 141.75 and 141.175 of this chapter must be kept for not less than one year.

(ii) Records of decisions made on a system-by-system and case-by-case basis under provisions of part 141, subpart H or subpart P of this chapter, must be made in writing and kept at the State.

* * * * *

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

(i) Records of systems consulting with the State concerning a modification to disinfection practice under § 141.172(c) of this chapter, including the status of the consultation.

(ii) Records of decisions that a system using alternative filtration technologies, as allowed under § 141.173(b) of this chapter, can consistently achieve a 99.9 percent removal and/or inactivation of *Giardia lamblia* cysts, 99.99 percent removal and/or inactivation of viruses, and 99 percent removal of *Cryptosporidium* oocysts. The decisions must include State-set enforceable turbidity limits for each system. A copy of the decision must be kept until the decision is reversed or revised. The State must provide a copy of the decision to the system.

(iii) Records of systems required to do filter self-assessment, CPE, or CCP under the requirements of § 141.175 of this chapter.

* * * * *

14. Section 142.15 is amended by adding paragraph (c)(5) to read as follows:

§ 142.15 Reports by States.

* * * * *

(c) * * *

(5) Sanitary surveys. A list of subpart H systems that have had a sanitary survey completed during the previous year and an annual evaluation of the State's program for conducting sanitary surveys under § 141.16(b)(3) of this chapter.

* * * * *

15. Section 142.16 is amended by redesignating paragraph (b)(1) as (b)(1)(i), and adding paragraphs (b)(1)(ii), (b)(3), and (g) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(b) * * *

(1) Enforceable requirements. (i)

* * *

(ii) States must have the appropriate rules or other authority to assure that PWSs respond in writing to significant deficiencies outlined in sanitary survey reports required under paragraph (b)(3) of this section 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.

(iii) States must have the appropriate rules or other authority to assure that PWSs take necessary steps to address significant deficiencies identified in sanitary survey reports required under paragraph (b)(3) of this section, if such deficiencies are within the control of the PWS and its governing body.

* * * * *

(3) Sanitary survey. In addition to the general requirements for sanitary surveys contained in § 142.10(b)(2), an application must describe how the State will implement a sanitary survey program that meets the requirements in paragraphs (b)(3)(i) through (v) of this section. For the purposes of this paragraph, ''sanitary survey'' means an onsite review of the water source (identifying sources of contamination using results of source water assessments where available), facilities, equipment, operation, maintenance, and monitoring compliance of a public water system to evaluate the adequacy of the system, its sources and operations and the distribution of safe drinking water.

(i) The State must conduct sanitary surveys for all surface water systems (including groundwater under the influence) that address the eight sanitary survey components listed in paragraphs (b)(3)(i)(A) through (H) of this section no less frequently than every three years for community systems and no less frequently than every five years for noncommunity systems. The State may allow sanitary surveys conducted after December 1995 to serve as the first set of required sanitary surveys if the surveys address the eight sanitary survey components listed in paragraphs (b)(3)(i)(A) through (H) of this section.

(A) Source.

(B) Treatment.

(C) Distribution system.

(D) Finished water storage.

(E) Pumps, pump facilities, and controls.

(F) Monitoring and reporting and data verification.

(G) System management and operation.

(H) Operator compliance with State requirements.

(ii) For community systems determined by the State to have outstanding performance based on prior sanitary surveys, subsequent sanitary surveys may be conducted no less than every five years. In its primacy application, the State must describe how it will decide whether a system has outstanding performance and is thus eligible for sanitary surveys at a reduced frequency.

(iii) Components of a sanitary survey may be completed as part of a staged or phased state review process within the established frequency.

(iv) When conducting sanitary surveys for systems required to comply with the disinfection profiling requirements in § 141.172 of this chapter, the State must also review the disinfection profile as part of the sanitary survey.

(v) In its primacy application, the State must describe how it will decide whether a deficiency identified during a sanitary survey is significant for the purposes of paragraph (b)(1)(ii) of this section.

* * * * *

(g) Requirements for States to adopt 40 CFR part 141, subpart P Enhanced Filtration and Disinfection. In addition to the general primacy requirements enumerated elsewhere in this part, including the requirement that State provisions are no less stringent than the federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subpart P Enhanced Filtration and Disinfection, must contain the information specified in this paragraph:

(1) *Enforceable requirements.* States must have the appropriate rules or other authority to require PWSs to conduct a Composite Correction Program (CCP) and to assure that PWSs implement any followup recommendations that result as part of the CCP. The CCP consists of two elements—a Comprehensive Performance Evaluation (CPE) and Comprehensive Technical Assistance (CTA). A CPE is a thorough review and analysis of a plant's performance-based capabilities and associated administrative, operation and maintenance practices. It is conducted to identify factors that may be adversely impacting a plant's capability to achieve compliance and emphasizes approaches that can be implemented without significant capital improvements. A CTA is the performance improvement phase that is implemented if the CPE results indicate improved performance potential. During the CTA phase, the system must identify and systematically address plant-specific factors. The CTA is a combination of utilizing CPE results as a basis for followup, implementing process control priority-setting techniques and maintaining long-term involvement to systematically train staff and administrators.

(2) *State practices or procedures.* (i) Section 141.172(a)(3) of this chapter—How the State will approve a more representative annual data set than the data set determined under § 141.172 (a)(1) or (2) of this chapter for the purpose of determining applicability of the requirements of § 141.172 of this chapter.

(ii) Section 141.172(b)(5) of this chapter—How the State will approve a method to calculate the logs of inactivation for viruses for a system that uses either chloramines or ozone for primary disinfection.

(iii) Section 141.172(c) of this chapter—How the State will consult with PWSs to evaluate modifications to disinfection practice.

(iv) Section 141.173(b) of this chapter—For filtration technologies other than conventional filtration treatment, direct filtration, slow sand filtration, or diatomaceous earth filtration, how the State will determine that a public water system may use a filtration technology if the PWS demonstrates to the State, using pilot plant studies or other means, that the alternative filtration technology, in combination with disinfection treatment that meets the requirements of § 141.172(b) of this chapter, consistently achieves 99.9 percent removal and/or inactivation of *Giardia lamblia* cysts and 99.99 percent removal and/or inactivation of viruses, and 99 percent removal of *Cryptosporidium* oocysts. For a system that makes this demonstration, how the State will set turbidity performance requirements that the system must meet 95 percent of the time and that the system may not exceed at any time at a level that consistently achieves 99.9 percent removal and/or inactivation of *Giardia lamblia* cysts, 99.99 percent removal and/or inactivation of viruses, and 99 percent removal of *Cryptosporidium* oocysts.

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