ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[WH–FRL–5915–4]

National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment Rule Notice of Data Availability

AGENCY: U.S. Environmental Protection Agency (USEPA).

ACTION: Notice of Data Availability; request for comments; reopening of comment period.

SUMMARY: USEPA proposed in 1994 to amend the Surface Water Treatment Rule to provide additional protection against disease-causing organisms (pathogens) in drinking water (59 FR 38832: July 29, 1994). This Notice of Data Availability summarizes the 1994 proposal; describes new data and information that the Agency has obtained and analyses that have been developed since the proposal; provides information concerning recommendations of the Microbial-Disinfectants/Disinfection Byproducts (M-DBP) Advisory Committee (chartered in February 1997 under the Federal Advisory Committee Act) on key issues related to the proposal; and requests comment on these recommendations as well as on other regulatory implications that flow from the new data and information. USEPA solicits comment on all aspects of this Notice and the supporting record. The Agency also solicits additional data and information that may be relevant to the issues discussed in the Notice. USEPA is particularly interested in public comment on the Committee's recommendations and whether the Agency should reflect these recommendations in the final rule. In addition, USEPA is hereby providing notice that the Agency is re-opening the comment period for the 1994 proposal for 90 days beginning on the date of publication of today's Notice in the **Federal Register**. USEPA also requests that any information, data or views submitted to the Agency since the close of the comment period on the 1994 proposal that members of the public would like the Agency to consider as part of the final rule development process be resubmitted during this current 90-day comment period unless already in the underlying record in the Docket for this Notice.

The Interim Enhanced Surface Water Treatment Rule (IESWTR) would apply to surface water systems serving 10,000 or more people. USEPA intends to promulgate the final rule in November 1998 as required by the 1996 Amendments to the Safe Drinking Water Act. The Agency plans subsequently to address surface water systems serving fewer than 10,000 people as part of a ''long-term'' Enhanced Surface Water Treatment Rule which may also include additional refinements for larger systems.

Key issues related to the IESWTR that are addressed in this Notice include the establishment of a Maximum Contaminant Level Goal for *Cryptosporidium;* removal of *Cryptosporidium* by filtration; revised 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; sanitary surveys; inclusion of *Cryptosporidium* in the definition of ground water under the direct influence of surface water; and inclusion of *Cryptosporidium* in the watershed control requirements for unfiltered public water systems. Other issues that are discussed include inactivation of *Cryptosporidium*, viruses and *Giardia lamblia;* uncovered finished water reservoirs; cross connection control; and recycling of filter backwash water and filter-to-waste.

Today's **Federal Register** also contains a related Notice of Data Availability for the Stage 1 Disinfectants/Disinfection Byproducts Rule (DBPR). USEPA proposed this rule at the same time as the IESWTR and plans to promulgate it along with the IESWTR in November 1998.

DATES: Comments should be postmarked or delivered by hand on or before February 3, 1998. Comments must be received or post-marked by midnight February 3, 1998.

ADDRESSES: Send written comments to IESWTR NODA Docket Clerk, Water Docket (MC-4101); U.S. Environmental Protection Agency; 401 M Street, SW; Washington, DC 20460. Please submit an original and three copies of your comments and enclosures (including references). If you wish to hand-deliver your comments, please call the Docket between 9:00 a.m. and 4 p.m., Monday through Friday, excluding legal holidays, to obtain the room number for the Docket. Comments may be submitted electronically to ow-docket@epamail.epa.gov.

FOR FURTHER 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 9:00 am to 5:30 pm 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).

Regional Contacts

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X. Wendy Marshall, Drinking Water Unit, 1200 Sixth Avenue (OW–136), Seattle, WA 98101, (206) 553–1890.

SUPPLEMENTARY INFORMATION:

Regulated entities. Entities potentially regulated by the IESWTR are public water systems that use surface water and serve at least 10,000 people. Regulated categories and entities include:

Category	Examples of regulated entities
Public Water System	PWSs that use surface water and serve at least 10,000 people.
State Governments	State government offices that regulate drinking water.

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 USEPA 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 may be regulated by this action, you should carefully examine the applicability criteria outlined under Alternatives A and B in § 141.70 of the proposed rule (59 FR 38832, July 29, 1994).

If you have questions regarding the applicability of the IESWTR to a particular entity, contact one of the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Additional Information for Commenters. The Agency requests that commenters follow the following format: type or print comments in ink, and cite, where possible, the paragraph(s) in this Notice to which each comment refers. Commenters should use a separate paragraph for each method or issue discussed. Electronic comments must be submitted as a WP5.1 or WP6.1 file or as an ASCII file avoiding the use of special characters and any form of name or title of the **Federal Register**. Comments and data will also be accepted on disks in WordPerfect in 5.1 or WP6.1 or ASCII file format. Electronic comments on this Notice may be filed online at many Federal Depository Libraries. Commenters who want EPA to acknowledge receipt of their comments should include a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted.

Availability of Record. The record for this Notice, which includes supporting documentation as well as printed, paper versions of electronic comments, is available for inspection from 9 to 4 p.m., Monday through Friday, excluding legal holidays at the Water Docket, U.S. EPA Headquarters, 401 M. St., S.W. Washington, D.C. 20460. For access to docket materials, please call 202/260–3027 to schedule an appointment and obtain the room number.

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List of Abbreviations Used in This Document

ASCE—American Society of Civil Engineers
ASTM—American Society for Testing Materials
AWWA—American Water Works Association
C—the residual concentration of disinfectant, mg/L
CDC—Centers for Disease Control
CFE—Combined Filter Effluent
CFR—Code of Federal Regulations
CPE—Comprehensive Performance Evaluation
CT—the residual concentration of disinfectant multiplied by the contact time
DOC—dissolved organic carbon
ESWTR—Enhanced Surface Water Treatment Rule
FACA—Federal Advisory Committee Act
gpm/sf—gallons per minute per square foot
HAA5—Haloacetic acids (monochloroacetic, dichloroacetic, trichloroacetic, monobromoacetic, and dibromoacetic acids)
HAV—hepatitis A virus
hrs—hours
ICR—Information Collection Rule
IESWTR—Interim Enhanced Surface Water Treatment Rule
IFA—Individual Filter Assessment
IFE—Individual Filter Effluent
ISO—International Standards Organization
k—the pseudo first-order reaction rate constant
L—liter
Log Inactivation—logarithm of (N_o/N_T)
Log—logarithm (common, base 10)
LTESWTR—Long Term Enhanced Surface Water Treatment Rule
MCL—Maximum Contaminant Level
MCLG—Maximum Contaminant Level Goal
M-DBP—Microbial and Disinfectants/Disinfection Byproducts
mg/L—milligram per liter
mg-min/L—milligram minutes per liter
MMWR—Morbidity and Mortality Weekly Report
mW-s/cm^2—milliwatt seconds per square centimeter
N_o—the initial viable concentration of microorganisms
NPDWR—National Primary Drinking Water Regulation
N_T—the concentration of surviving microorganisms at time T
NTU—nephelometric turbidity unit
°C—degrees centigrade
PE—Performance Evaluation
pH—negative logarithm of the effective hydrogen-ion concentration
PV1—poliovirus 1
PV3—poliovirus 3
PWS—Public Water System
RSD—Relative Standard Deviation
SAB—Science Advisory Board
SDWA—Safe Drinking Water Act
T—the contact time, second or minute
TOC—total organic carbon
TTHM—Total Trihalomethanes
TWG—Technical Work Group
UV—ultraviolet
x—log removal Reduction by 1/10**x

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I. Introduction and Background

A. Existing Regulations

1. Surface Water Treatment Rule

Under the Surface Water Treatment Rule (SWTR)(54 FR 27486, June 29, 1989), USEPA set maximum contaminant level goals of zero for *Giardia lamblia*, viruses, and *Legionella*; and promulgated national primary drinking water regulations for all public water systems (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) removal or inactivation of 3 logs (99.9%) for *Giardia* and 4 logs (99.99%) for viruses; (2) combined filter effluent performance of 5 NTU as a maximum and 0.5 NTU at 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 (3) watershed protection and other requirements for unfiltered systems.

2. Total Trihalomethane MCL

USEPA set an interim Maximum Contaminant Level (MCL) for total trihalomethanes (TTHM) of 0.10 mg/l as an annual average in November 1979 (44 FR 68624). This standard was based on the need to balance the requirement for continued disinfection of water to reduce exposure to pathogenic microorganisms while simultaneously lowering exposure to disinfection byproducts which might be carcinogenic to humans.

The interim TTHM standard only applies to any PWSs (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. About 80 percent of the PWSs, serving populations of less than 10,000, are served by ground water that is generally low in THM precursor content (USEPA, 1979) and which would be expected to have low TTHM levels even if they disinfect.

3. Total Coliform Rule

The Total Coliform Rule (54 FR 27544; June 29, 1989), revised in June 1989 and effective on December 31, 1990 applies to all public water systems (USEPA, 1989b). This regulation sets compliance with the Maximum Contaminant Level (MCL) for total coliforms as follows. For systems that collect 40 or more samples per month, no more than 5.0% of the samples may be total coliform-positive; for those that collect fewer than 40 samples, only one sample may be total coliform-positive. If a system exceeds the MCL for a month, it must notify the public using mandatory language developed by the USEPA. The required monitoring frequency for a system 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. In addition, systems are required to conduct repeat sampling after a positive sample.

The Total Coliform Rule also requires each system that collects fewer than five samples per month to have the system inspected every 5 years (10 years for certain types of systems using only protected and disinfected ground water.) This on-site inspection (referred to as a sanitary survey) must be performed by the State or by an agent approved by the State.

4. Information Collection Rule

The Information Collection Rule (ICR) is a monitoring and data reporting rule that was promulgated on May 14, 1996 (61 FR 24354) (USEPA, 1996b). The purpose of the ICR is to collect occurrence and treatment information to evaluate the need for possible changes to the current Surface Water Treatment Rule and existing microbial treatment practices and to evaluate the need for future regulation for disinfectants and DBPs. The ICR will provide USEPA with additional information on the national occurrence in drinking water of (1) chemical byproducts that form when disinfectants used for microbial control react with compounds already present in source water and (2) disease-causing microorganisms, including *Cryptosporidium, Giardia,* and viruses. The ICR will also collect engineering data on how PWSs currently control such contaminants. This information is being collected because the regulatory negotiation on 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.

B. Public Health Concerns To Be Addressed

In 1990, USEPA'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 (USEPA/SAB 1990). This view was prompted by the SAB's concern about the number of waterborne disease outbreaks in the U.S. Between 1980 and 1994, 379 waterborne disease outbreaks were reported, with over 500,000 cases of disease. 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) (Craun, Pers. Comm. 1997a).

The number of waterborne disease outbreaks and cases is, however, probably much greater than that recorded because the vast majority of waterborne disease is probably not reported. Few States have an active outbreak surveillance program and disease outbreaks are often not recognized in a community or, if recognized, are not traced to the drinking water source. This situation is complicated by the fact that the vast majority of people experiencing gastrointestinal illness (predominantly diarrhea) do not seek medical attention. For those who do, physicians generally cannot attribute gastrointestinal illness to any specific origin such as a drinking water source. 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.

One of the key regulations USEPA has developed and implemented to counter pathogens in drinking water is the SWTR. Among its provisions, the rule requires that a public water system have sufficient treatment to reduce the source water concentration of *Giardia* and viruses by at least 99.9% (3 logs) and 99.99% (4 logs), respectively.

The goal of the SWTR is to reduce risk to less than one infection per year per 10,000 people (10^{-4}). However, one of the SWTR's shortcomings is that the source waters of some systems have high pathogen concentrations that, when reduced by the levels required under the rule, still may not meet a common health goal (e.g., 10^{-4}).

Another 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). Other outbreaks caused by this pathogen have since been reported both in the United States and other countries (Smith et al.,1988; Hayes et al., 1989; Levine and Craun, 1990; Moore et al., 1993; Craun, 1993). 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*.

In addition to these issues, there is another potentially counter-balancing public health concern. The disinfectants used to control microbial pathogens may produce toxic or carcinogenic disinfection byproducts (DBPs) when they react with organic chemicals in the source water. Thus, an important question facing water supply professionals is how to minimize the risk from both microbial pathogens and DBPs simultaneously.

At the time the SWTR was promulgated, USEPA had limited data concerning *Giardia* and *Cryptosporidium* occurrence in source waters and treatment efficiencies. The 3-log removal/inactivation of *Giardia lamblia* and 4-log removal/inactivation of enteric viruses required by the SWTR were developed to provide protection from most pathogens in source waters. However, additional data has become available since promulgation of the SWTR concerning source water occurrence and treatment efficiencies for *Giardia,* as well as for *Cryptosporidium* (LeChevallier et al. 1991 a,b). A major concern is that if systems currently provide four or more logs of removal/inactivation for *Giardia,* such systems might reduce existing levels of disinfection to more easily meet new DBP regulations, and thus only marginally meet the three-log removal/inactivation requirement for *Giardia lamblia* specified in the current SWTR. Depending upon source water *Giardia* concentrations, such treatment changes could lead to significant increases in microbial risk (Regli et al., 1993; Grubbs et al., 1992; USEPA, 1994b).

C. Statutory Provisions

1. SDWA and 1986 Provisions

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 are 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 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(1) 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''.

Section 1414 (c) of the Act requires each owner or operator of a public water system to give notice to the persons served by the system of any failure to comply with an MCL or treatment technique requirement of, or testing procedure prescribed by, a NPDWR and any failure to perform monitoring required by section 1445 of the Act.

Section 1412(b)(7)(C) of the SDWA requires the USEPA Administrator to publish a NPDWR ''specifying criteria under which filtration (including coagulation and sedimentation, as appropriate) is required as a treatment technique for public water systems supplied by surface water sources''. In establishing these criteria, USEPA is required to consider ''the quality of source waters, protection afforded by watershed management, treatment practices (such as disinfection and length of water storage) and other factors relevant to protection of health''. This section of the Act also requires USEPA to promulgate a NPDWR requiring disinfection as a treatment technique for all public water systems and a rule specifying criteria by which variances to this requirement may be granted.

2. Changes to Initial Provisions and New Mandates

In 1996, Congress reauthorized the Safe Drinking Water Act. Several of the 1986 provisions discussed above were renumbered and augmented with additional language, while other sections mandate new drinking water requirements. These modifications, as well as new provisions, are detailed below.

As part of the 1996 amendments to the Safe Drinking Water Act (the Amendments), USEPA's general authority to set a MCLG and NPDWR was modified to apply 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' (1986 SDWA Section 1412 (b)(3)(A) stricken and amended with 1412(b)(1)(A)).

The Amendments also require that USEPA, when proposing a NPDWR that includes an MCL or treatment technique, publish and seek public comment on health risk reduction and cost analyses. The Amendments also require USEPA 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 1996 Amendments also newly require USEPA to promulgate an Interim Enhanced SWTR and a Stage I Disinfectants and Disinfection Byproducts Rule by November 1998. In addition, the 1996 Amendments require USEPA to promulgate a Final Enhanced SWTR and a Stage 2 Disinfection Byproducts Rule by November 2000 and May 2002, respectively (Section 1412(b)(2)(C)).

Under the Amendments of 1996, 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 . . .''.

D. Regulatory Negotiation Process

In 1992 USEPA initiated a negotiated rulemaking to develop a disinfectants/disinfection byproducts rule. The negotiators included representatives of State and local health and regulatory agencies, public water systems, elected officials, consumer groups and environmental groups. The 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 Committee agreed that USEPA propose a disinfectants/disinfection byproducts rule to extend coverage to all community and nontransient noncommunity water systems that use disinfectants. This rule proposed to reduce the current TTHM MCL, regulate additional disinfection byproducts, set limits for the use of disinfectants, and reduce the level of organic compounds in the source water that may react with disinfectants to form byproducts.

One of the major goals addressed by the 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 risk at these limits.

Following months of intensive discussions and technical analysis, the Committee recommended the development of three sets of rules: a two-staged Disinfectants/Disinfection Byproduct Rule (proposal: 59 FR 38668, July 29, 1994) (USEPA, 1994a), an ''interim'' ESWTR (proposal: 59 FR 38832, July 29, 1994) (USEPA, 1994b), and an Information Collection rule (proposal: 59 FR 6332, February 10, 1994) (USEPA, 1994c). The IESWTR would only apply to systems serving 10,000 people or more. The Committee agreed that a ''long-term'' ESWTR (LTESWTR) would be needed for systems serving fewer than 10,000 people when the results of more research and water quality monitoring became available. The LTESWTR could also include additional refinements for larger systems.

The approach in developing these proposals considered the constraints of simultaneously treating water to control for both microbial contaminants and DBPs. As part of this effort, the Negotiating Committee concluded that the SWTR may need to be revised to address health risk from high densities of pathogens in poorer quality source waters and from the protozoan, *Cryptosporidium*. The Committee also agreed that the schedules for IESWTR and LTESWTR should be ''linked'' to the schedule for the Stage 1 DBP Rule to assure simultaneous compliance and a balanced risk-risk based implementation. The 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 risk.

Finally the Negotiating 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 Information Collection Rule (ICR) noted above and described in more detail below.

E. Information Collection Rule

As stated above, the ICR established monitoring and data reporting requirements for large public water systems serving populations over 100,000. About 350 PWSs operating 500 treatment plants are involved in the data collection effort. Under the ICR, these PWSs monitor their source water for bacteria, viruses, and protozoa (surface water sources only); water quality factors affecting DBP formation; and DBPs within the treatment plant and in the distribution system. In addition, PWSs must provide operating data and a description of their treatment plan design. Finally, a subset of PWSs perform treatment studies, using either granular activated carbon or membrane processes, to evaluate DBP precursor removal. Monitoring for treatment study applicability began in September 1996. The remaining occurrence monitoring began in July 1997.

The initial intent of the ICR was to collect monitoring data and other information for use in developing the Stage 2 DBPR and 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, most ICR monitoring did not begin until July 1, 1997. As a result of this delay and the new Stage 1 DBPR and IESWTR deadlines specified in the 1996 SDWA amendments, ICR data will not be available for analysis in connection with these rules. In place of the ICR data, the Agency has worked with stakeholders to identify additional data developed since 1994 that can be used in components of these rules. USEPA intends to continue to work with stakeholders in analyzing and using the comprehensive ICR data and research for developing subsequent revisions to the SWTR and the Stage 2 DBP Rule.

F. Formation of 1997 Federal Advisory Committee

In May 1996, the Agency initiated a series of public informational meetings to exchange information on issues related to microbial and disinfectants/disinfection byproducts regulations. To help meet the deadlines for the IESWTR and Stage 1 DBPR established by Congress in the 1996 SDWA Amendments and to maximize stakeholder participation, the Agency established the Microbial and Disinfectants/Disinfection Byproducts (M-DBP) Advisory Committee under the Federal Advisory Committee Act (FACA) on February 12, 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 consists of 17 members representing USEPA, State and local public health and regulatory agencies, local elected officials, drinking water suppliers, chemical and equipment manufacturers, and public interest groups.

The 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 the following major issues discussed in this Notice and the Notice for the Stage 1 DBPR published elsewhere in today's **Federal Register**: (1) MCLs for TTHMs, HAA5 and bromate; (2) requirements for enhanced coagulation and enhanced softening (as part of DBP control); (3) 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) disinfection credit; (5) turbidity; (6) *Cryptosporidium* MCLG; (7) removal of *Cryptosporidium*; (8) role of *Cryptosporidium* inactivation as part of a multiple barrier concept and (9) sanitary surveys. The Committee's recommendations to USEPA on these issues were set forth in an Agreement In Principle document dated July 15, 1997. This document is included with this notice as Appendix 1.

G. Overview of IESWTR 1994 Proposal

1. Summary of Major Elements

As part of the IESWTR July 29, 1994, **Federal Register** notice (59 FR 38832), USEPA proposed to revise the SWTR to provide additional protection against pathogens in drinking water. USEPA proposed to set the MCLG for *Cryptosporidium* at zero based on animal studies and human epidemiology studies of waterborne outbreaks of cryptosporidiosis. The proposal also focused on treatment requirements for the waterborne pathogens *Giardia lamblia*, *Cryptosporidium*, Legionella and viruses that would apply to all public water systems that use surface water or ground water under the influence of surface water and serve 10,000 people or more. Major features of the proposal included a stricter watershed control requirement for systems using surface water that wish to avoid filtration; a change in the definition of ground water under the influence of surface water to include the presence of *Cryptosporidium*; a periodic sanitary survey requirement for all systems using surface water or ground water under the influence of surface water; and several alternative requirements, described below, for augmenting treatment control of *Giardia lamblia*, *Cryptosporidium*, and viruses. USEPA also requested comment on several supplemental provisions and on other related issues, described below.

2. Alternative Treatment Requirements

USEPA proposed five treatment alternatives for controlling *Giardia lamblia*, *Cryptosporidium*, and viruses. Each alternative included several options. Alternative A addressed enhanced treatment for *Giardia lamblia* only. Alternatives B and C addressed treatment for *Cryptosporidium* only. Alternative D addressed enhanced treatment for viruses only. Alternative E would maintain existing levels of treatment for *Giardia lamblia* and viruses.

a. *Alternative A. Enhanced treatment for Giardia lamblia.* The SWTR currently requires a 99.9 percent (3-log) removal/inactivation of *Giardia lamblia* for all surface waters, regardless of *Giardia lamblia* cyst concentrations in the source water. Under Alternative A, the minimum level of treatment a system would be required to provide (e.g., 3, 4, 5 or 6 log removal/inactivation) would depend on the *Giardia lamblia* density in the source water as determined by monitoring over some specified interval of time. The level of prescribed treatment for a particular system would correspond to providing water below an annual risk level for *Giardia lamblia* infections (e.g. 10^{-4}).

b. *Alternative B. Specific Treatment for Cryptosporidium.* USEPA also proposed a treatment technique for *Cryptosporidium* similar to the proposal for *Giardia* under Alternative A, such that the required level of *Cryptosporidium* treatment for any particular system would depend on the density of *Cryptosporidium* in the source water.

c. *Alternative C. 99% (2-log) removal of Cryptosporidium.* Under this alternative, USEPA would require systems to achieve at least a 99% (2-log) removal of *Cryptosporidium* by filtration (with pretreatment). The 2-log level was based on the premise that a 3-log level (as currently required for *Giardia* removal/inactivation) is not economically or technologically possible, since data suggests that *Cryptosporidium* is consistently more resistant to disinfection than is *Giardia*. USEPA indicated that it would continue to assess new field and laboratory data to control *Cryptosporidium* by physical removal and disinfection for consideration in subsequent microbial regulations.

d. *Alternative D. Specific disinfection treatment for viruses.* The SWTR required systems to achieve a four-log removal/inactivation of viruses. This is to be achieved through a combination of filtration and disinfection or, for systems not required to filter their source waters, by disinfection alone. However, this level of treatment may not be adequate to achieve a particular health risk (e.g., 10^{-4} infections/yr/person) for viruses. Viruses are of particular concern, given that one or several virus particles may be infectious (Regli et al.,1991) and that several enteric viruses are associated with relatively high mortality rates (Bennett et al., 1987). Failure or impairment of filtration performance could allow substantial pathogen contamination of drinking water, particularly if the disinfection barrier following filtration is minimal.

Alternative D would require that systems provide sufficient disinfection such that disinfection alone would achieve at least a 0.5-log inactivation of *Giardia lamblia* or, alternatively, a 4-log inactivation of viruses. This proposed approach would be independent of the level of physical removal or the source water density of viruses. If the filtration process was able to remove three logs of *Giardia lamblia*, a system would still have to provide at least an additional 0.5-log inactivation of *Giardia lamblia* or 4-log inactivation of viruses by disinfection.

e. *Alternative E. No change to existing SWTR treatment requirements for Giardia lamblia and viruses.* Alternative E maintains existing SWTR levels of treatment for *Giardia lamblia* and viruses. USEPA could regulate *Cryptosporidium* directly (e.g., Alternative C above) or make a finding that existing SWTR filtration and disinfection requirements are adequate to control this organism.

3. Possible Supplemental Treatment Requirements

USEPA also requested comment on three supplemental requirements regarding uncovered finished water reservoirs, cross connection control and State notification of turbidity levels.

a. Uncovered Finished Water Reservoirs. As part of the 1994 proposal, USEPA requested comment on possible supplemental requirements for uncovered finished water reservoirs. The Agency noted that USEPA guidelines recommend that all finished water reservoirs be covered (USEPA, 1991a) and that the American Water Works Association (AWWA) also has issued a policy statement that strongly supports the covering of such reservoirs (AWWA, 1993).

b. Cross Connection Control Program. USEPA requested comment on whether to require States or public water systems to have cross connection control programs. Plumbing cross-connections are actual or potential connections between a potable and non-potable water supply (USEPA, 1989a). According to Craun (1991), 24% of the waterborne disease outbreaks that occurred during 1981–1990 were caused by water contamination in the distribution system, primarily as the result of cross-connections and main repairs.

c. State Notification of High Turbidity Levels. USEPA also requested comment on whether to require systems to notify the State as soon as possible for persistent turbidity levels above the performance standards or for any other situation that is not now a violation of the turbidity standards. Under the SWTR, any time the turbidity of a treatment plant's combined filter effluent exceeds 5 NTU the system must notify the State as soon as possible, but no later than the end of the next business day. In addition, the system must notify the public as soon as possible, but in no case later than 14 days after the violation.

USEPA indicated in the proposal that it was considering broadening the requirement for State notification. The Agency suggested it might, for example, require systems to notify the State as soon as possible if at any point during the month it becomes apparent that a system will violate the monthly 95th percentile turbidity performance standard specified in the SWTR, rather than wait to the end of the month.

USEPA outlined a number of public health reasons for requiring swift State notification for persistent turbidity levels. Pathogens may accompany the turbidity particles that exit the filters, especially with poor quality source waters. High turbidity levels in the filtered water, even for a limited time, may represent a significant risk to the public. USEPA's proposed approach was intended to allow States to respond in controlling a potentially serious problem more quickly.

4. Other related issues. The Agency also requested comments on other issues related to possible IESWTR options. A number of these are listed below.

(a) To what extent should the ESWTR address the issue of recycling filter backwash, given its potential for increasing the densities of *Giardia lamblia* and *Cryptosporidium* on the filter?

(b) Should the ESWTR define minimum certification criteria for surface water treatment plant operators? Currently the SWTR (40 CFR 141.70) requires such systems to be operated by ''qualified personnel who meet the requirements specified by the State.''

(c) What criteria, if any, should the ESWTR include to ensure that systems optimize treatment plant performance?

(d) Should turbidity performance criteria be modified? Should criteria pertain to individual filters?

(e) Should the rule include a performance standard for particle removal?

(f) Should the rule include a requirement for an early warning for high turbidity?

(g) Under what conditions could systems be allowed different log removal credits than is currently recommended in the SWTR Guidance Manual?

(h) How should USEPA decide, in developing a Notice of Data Availability, what treatment approach(es) is most suitable for additional public comment?

II. New Information and Key Issues to be Addressed

A. MCLG for Cryptosporidium

1. Summary of 1994 Proposal and Public Comments

The July 29, 1994, **Federal Register** notice proposed to set the MCLG for Cryptosporidium at zero. The purpose of the MCLG is to protect public health. The reasons for this determination were based upon animal studies and human epidemiology studies of waterborne outbreaks of cryptosporidiosis.

Most commenters supported an MCLG of zero for *Cryptosporidium*. Those who provided reasons stated that (1) a single cell could infect, and data do not support a threshold dose below which an outbreak or disease will not occur, (2) the organism is present in water and has caused major waterborne disease outbreaks, and (3) it is consistent with the goals set under the SWTR and Total Coliform Rule. Commenters who opposed the proposed MCLG stated that USEPA needed more health risk and organism/disease transmission data and better analytical methods before setting an MCLG and regulating *Cryptosporidium*.

2. New data and Perspectives

Since publication of the proposed rule, results of a human feeding study have become available. 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. The median infective dose was 132 oocysts. According to a mathematical model based upon the Dupont et al. data, 0.5% of a population exposed to an average dose of one oocyst, would be expected to become infected. (Haas et al., 1996).

An important concern is that certain populations are at greater risk of waterborne disease infection than others. These vulnerable populations include the immunocompromised; children, especially the very young; the elderly; and pregnant women (Gerba et al. 1996; Fayer and Ungar 1986). The most significant segment within these vulnerable populations with regard to cryptosporidiosis is people who are immunocompromised. In patients with severely weakened immune systems, (e.g cancer, AIDS patients), cryptosporidiosis can be serious, long-lasting and sometimes fatal. There is concern about cryptosporidiosis in immunocompromised individuals because currently there is no cure for the disease.

C. parvum is the only *Cryptosporidium* species known for certain to infect humans. One controversial report (the only one of its kind) found evidence that *C. baileyi*, which infects birds, was present in the stools and other autopsied organs of an immunodeficient patient (Ditrich et al., 1991). There was no indication that *Cryptosporidium* had been responsible in this instance for any adverse health effects. *C. parvum* also infects many other mammals. While *C. parvum* is a well-documented human pathogen, strain variation may occur and one strain may cause infection and/or disease at a higher or lower concentration than other strains. USEPA is currently funding research [*Cryptosporidium* virulence study using different strains, Herbert Dupont] to examine this issue.

There is some question about the taxonomy (i.e., classification) of species within the genus *Cryptosporidium*. Up until 1980, classification was based on the assumption that a particular species only infected one type of animal. This assumption appears to be incorrect; hence other appropriate taxonomy schemes have been suggested.

An important issue not directly related to the MCLG involves the measurement of *C. parvum* in water. With current technology, it is often very difficult to distinguish between viable and non-viable oocysts. When *Cryptosporidium* is identified it is often not clear whether it is *C. parvum* or another species. Several *Cryptosporidium* species look similar to *C. parvum* and react to ''specific'' *C. parvum* stains in a like manner (cross-reactions). In addition, it can be difficult to distinguish *Cryptosporidium* from alga and invertebrate eggs (Clancy et al. 1994)

3. Advisory Committee Recommendations and Related Issues

The M-DBP Federal Advisory Committee supported the proposed establishment of a *Cryptosporidium* MCLG at zero. However, a key issue identified by the Committee and public commenters is whether the MCLG should be set at the genus level (i.e., *Cryptosporidium*), as proposed, or at the more specific species level (i.e., *C. parvum*). Setting the MCLG at the genus level would automatically include any *Cryptosporidium* species other than *C. parvum* that is later found to be pathogenic to humans. In contrast, setting an MCLG at the species level would indicate that only *C. parvum* infects humans, and would also be consistent with the approach taken under the SWTR for *Giardia* where the MCLG is set at the species level (i.e., *G. lamblia*). USEPA has not decided which approach is most appropriate and seeks public comment on this issue.

As indicated above, USEPA's intent in establishing this MCLG at zero is to protect public health. The Agency believes there is adequate research data to support this determination. However, as noted above, the Agency recognizes that there is scientific uncertainty on the issue of *Cryptosporidium* taxonomy and on the question of cross reactions between species. USEPA expects further clarification on this issue as research continues, *Cryptosporidium* analytical methods improve, and more is learned about the circumstances under which cross-reactivity between species occurs. The Agency also wishes to emphasize that the scope or specificity of the MCLG may be modified in the future to reflect new research and additional information about particular species that represent a significant risk to human health.

As part of this notice, USEPA requests comment on whether to establish a *Cryptosporidium* MCLG at the genus level as proposed or at the species level (i.e., *Cryptosporidium* vs. *Cryptosporidium parvum*). USEPA also requests copies of any additional research, data or other information related to this issue.

B. Removal of Cryptosporidium by Filtration

1. Summary of 1994 Proposal and Public Comments Received

One of USEPA's proposed treatment Alternatives (Alternative C) would require filtered systems to achieve at least a 2 log removal of *Cryptosporidium* oocysts. USEPA recognized that the proposed removal level was based on limited data and therefore solicited comment on whether other minimum removal levels might be appropriate.

Most commenters addressing the issue of treatment alternatives supported Alternative C. Some commenters 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.

Other commenters referred to specific studies (Nieminski 1995; Patania et al., 1995) that provided additional information on *Cryptosporidium* removal. One commenter cited a study (Parker and Smith, 1993), where oocyst damage was observed after agitation with sand. This study postulated that oocysts may be damaged as they pass through the filtration media. This commenter also pointed to the lack of data on cyst removal by full-scale plants and recommended that additional research be conducted. Some commenters recognized the need to regulate *Cryptosporidium*, but opposed having the level of treatment based upon source water pathogen density (alternative B). One commenter indicated that further implementation and evaluation of the adequacy of the SWTR needs to occur before modifying it.

2. New Data and Perspectives

a. Rapid Granular Filtration. Table 1 summarizes research pertinent to *Cryptosporidium* and *Giardia lamblia* removal efficiencies by rapid granular filtration. Brief descriptions of these studies and a summary of key points follow.

TABLE 1.—CRYPTOSPORIDIUM AND GIARDIA LAMBLIA REMOVAL EFFICIENCIES BY RAPID GRANULAR FILTRATION

Type of treatment plant	Log removal	Experimental design	Researcher
Conventional filtration plants	*Crypt* 2.7–5.9	Pilot Plants	Patania et al. 95.
Do	*Giardia* 3.4–5.8	......do	Do.
Do	*Crypt* 2.3–3.0	Pilot scale plant	Nieminski/Ongerth 95.
Do	*Giardia* 3.3–3.4	+full scale plant with seeded cysts/ oocysts.	Do.
Do	*Crypt* 2.7–3.1	Pilot Plants	Ongerth/Pecaroro 95.
Do	*Giardia* 3.1–3.5	......do	Do.
Do	*Crypt* 2–2.5	Full scale plants	LeChevallier et al. 91b.
Do	*Giardia* 2–2.5	Full scale plants	LeChevallier et al. 91b.
Do	*Crypt* 2.3–2.5	Full scale plants	LeChevallier/Norton 92.
Do	*Giardia* 2.2–2.8	......do	Do.
Do	*Crypt* 2–3	Pilot scale plant	Foundation for Water. Research 94.
Do	*Giardia* and	Full scale plant	Kelley et al. 95.
Do*Crypt 1.5–2*	operation considered ot optimized).		
Direct filtration plants	*Crypt* 1.5–4.0	Pilot Plants	Patania et al. 1995.
Do	*Giardia* 1.5–4.8	......do	Do.

TABLE 1.—CRYPTOSPORIDIUM AND GIARDIA LAMBLIA REMOVAL EFFICIENCIES BY RAPID GRANULAR FILTRATION—Continued

Type of treatment plant	Log removal	Experimental design	Researcher
Do	*Crypt* 2.8–3.0	......do	Nieminski/Ongerth 95.
Do	*Giardia* 3.3–3.9	......do	Do.
Do	*Crypt* 2–3	......do	West et al. 1994.

Patania, Nancy L; et al. 1995

Raw water turbidities were between 0.2 and 13. When treatment conditions were optimized for turbidity and particle removal at four different sites, *Cryptosporidium* removal ranged from 2.7 to 5.9 log and *Giardia* removal ranged from 3.4 to 5.1 log during stable filter operation. The median turbidity removal was 1.4 log, whereas the median particle removal was 2 log. Median oocyst and cyst removal was 4.2 log. A filter effluent turbidity of 0.1 NTU or less resulted in the most effective cyst removal, by up to l log greater than when filter effluent turbidities were greater than 0.1 NTU (within the 0.1 to 0.3 NTU range) (see Figures 1 and 2 below). *Cryptosporidium* removal rates of less than 2.0 log (indicated in Figures 1 and 2) occurred at the end of the filtration cycle.

Blackened data points in these figures represent data in which oocysts were not detected in the filtered water. The log removal values shown would be greater than indicated had the influent oocyst concentration been sufficiently high to show oocyst detection in the filtered water. The researchers also noted that removal of *Cryptosporidium* was 0.4 to 0.9 log lower during filter ripening than during stable filter operation; *Giardia* removal was generally 0.4 to 0.5 log lower during ripening. *Cryptosporidium* removal was 1.4 to 1.8 log higher for conventional treatment (including sedimentation) as compared to direct filtration. Similarly, *Giardia* removal was 0.2 to 1.8 log higher. Figures 1 and 2 below show the log removal rates discussed above.

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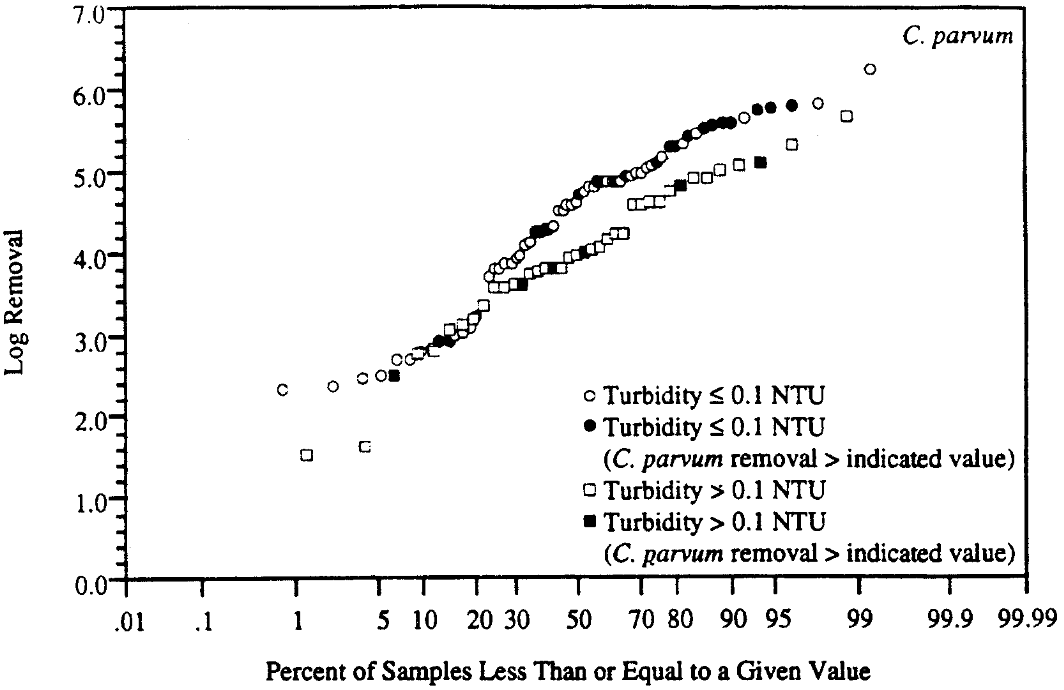

Figure 1: Cumulative probability distribution of aggregate pilot plant data for *C. parvum* removal when filtered water turbidity was ≤ 0.1 NTU and > 0.1 NTU (extracted from Patania et al. 1995). Reprinted from *Optimization of Filtration for Cyst Removal*, by permission. Copyright ©1995, American Water Works Association and AWWA Research Foundation.

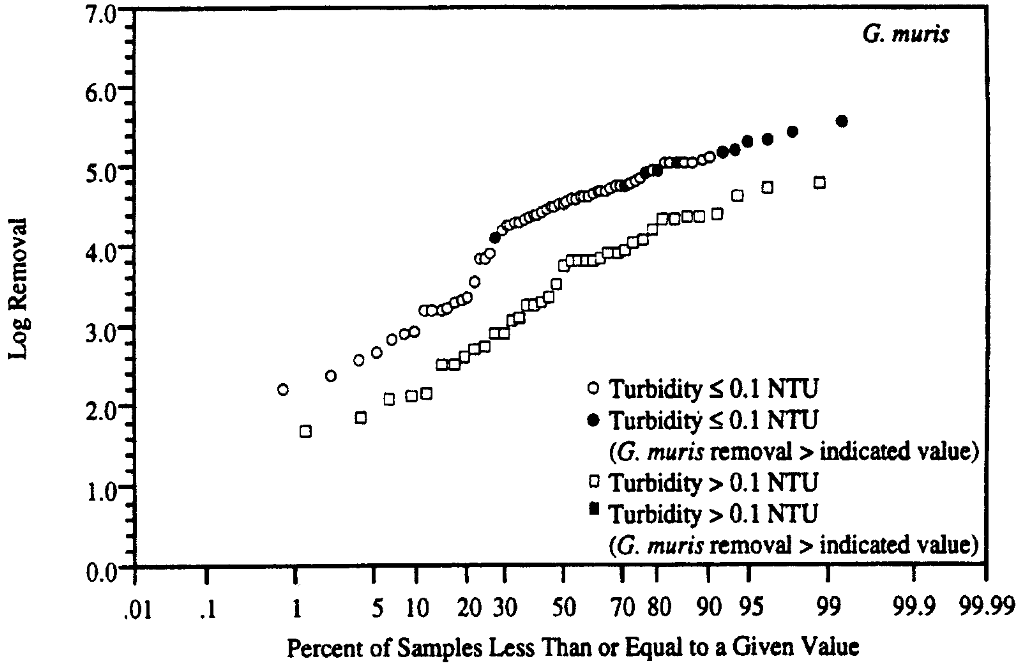

Figure 2: Cumulative probability distribution of aggregate pilot plant data for *G. muris* removal when filtered water turbidity was ≤ 0.1 NTU and > 0.1 NTU (extracted from Patania et al. 1995). Reprinted from *Optimization of Filtration for Cyst Removal*, by permission.

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Nieminski, Eva C. and Ongerth, Jerry E. 1995

This study evaluated performance in a pilot plant and in a full scale plant (not in operation during the time of the study) and considered two treatment modes: direct filtration and conventional treatment. The source water of the full scale plant had turbidities typically between 2.5 and 11 NTU with a peak level of 28 NTU. The source water of the pilot plant typically had turbidities of 4 NTU with a maximum of 23 NTU. For the pilot plant, achieving filtered water turbidities between 0.1–0.2 NTU, *Cryptosporidium* removals averaged 3.0 log for conventional treatment and 3.0 log for direct filtration, while the respective *Giardia* removals averaged 3.4 log and 3.3 log. For the full scale plant, achieving similar filtered water turbidities, *Cryptosporidium* removal averaged 2.25 log for conventional treatment and 2.8 log for direct filtration, while the respective *Giardia* removals averaged 3.3 log for conventional treatment and 3.9 log for direct filtration. Differences in performance between direct filtration and conventional treatment by the full scale plant were attributed to different source water quality during the filter runs.

Ongerth, Jerry E. and Pecoraro, J.P. 1995

This project used very low turbidity source waters (0.35 to 0.58 NTU). With optimal coagulation, 3 log removal for both cysts were obtained. In one test run, where coagulation was intentionally suboptimal, the removals were only 1.5 log for *Cryptosporidium* and 1.3 log for *Giardia.* This emphasized the importance of proper coagulation for cyst removal even though the effluent turbidity was less than 0.5 NTU.

LeChevallier, Mark W. and Norton, William D. 1992

Source water turbidities ranged from less than 1 to 120 NTU. Removals of *Giardia* and *Cryptosporidium* (2.2–2.8 log) were slightly less than those reported by other researchers, possibly because full scale plants were studied, under less ideal conditions than the pilot plants. The participating treatment plants were in varying stages of treatment optimization. Removal achieved a median of 2.5 log for *Cryptosporidium* and *Giardia.*

LeChevallier, Mark W.; Norton, William D.; and Lee, Raymond G. 1991b

This study evaluated removal efficiencies for *Giardia* and *Cryptosporidium* in 66 surface water treatment plants in 14 States and 1 Canadian province. Most of the utilities achieved between 2 and 2.5 log removals for both *Giardia* and *Cryptosporidium.* When no cysts were detected on the finished water below detection protozoan levels were set at the detection limit for calculating removal efficiencies.

Foundation for Water Research 1994

Raw water turbidity ranged from 1 to 30 NTU. *Cryptosporidium* oocyst removal was between 2 and 3 log. Investigators concluded that any measure which reduced filter effluent turbidity should reduce risk from *Cryptosporidium*. The importance in selecting coagulants, dosages, and pH should not be overlooked. Apart from turbidity, indicators of possible reduced efficiency for oocyst removal would be increased color and dissolved metal ion coagulant concentration in the effluent, for these are indications of reduced efficiency of coagulation/ flocculation.

Kelley, M.B. et al. 1995

Protozoa removal was between 1.5 and 2 log. The authors speculated that this low *Cryptosporidium* removal occurred because the coagulation process was not optimized, though the finished water turbidity was less than 0.5 NTU. Also, when cysts were not detected in the finished water below detection values were assumed as filtered water concentration levels.

West, Thomas; et al. 1994

Pilot scale direct filtration was used with anthracite mono-media at filtration rates of 6 and 14 gpm/sq ft. Raw water turbidity was 0.3 to 0.7 NTU. Removal efficiencies for *Cryptosporidium* at both filtration rates were 2 log during filter ripening (despite turbidity exceeding 0.2 NTU), and 2 to 3 log for the stable filter run, declining significantly during particle breakthrough. When effluent turbidity was less than 0.1 NTU, removal typically exceeded 2 log. Log removal of *Cryptosporidium* generally exceeded that for particle removal.

Summary of Studies

The studies described above indicate that rapid granular filtration, when operated under appropriate coagulation conditions and optimized to achieve a filtered water turbidity level of less than 0.3 NTU, should achieve at least 2 log of *Cryptosporidium* removal. Removal rates vary widely, up to almost 6 log, depending upon water matrix conditions, filtered water turbidity effluent levels, and where and when removal efficiencies are measured within the filtration cycle. The highest log pathogen removal rates occurred in those pilot plants and systems which achieved very low finished water turbidities (less than 0.1 NTU).

Members of the M–DBP Advisory Committee discussed that tighter turbidity performance criteria would increase the likelihood of systems achieving higher oocyst removal rates. As a general principle, members of the M–DBP Advisory Committee indicated that if a utility were required to achieve less than 0.3 NTU 95% of the time, it would target substantially lower turbidity levels in order to have confidence that it will not exceed the 0.3 level. This principle was also recognized by the M–DBP Advisory Committee's Technical Work Group and served as a technical basis for much of the Committee's discussion of turbidity (i.e., that if the performance standard is 0.3 NTU systems would target achieving less than 0.2 NTU 95 percent of the time).

The Patania and Nieminski/Ongerth studies as they relate to finished water turbidity levels and log removal are particularly relevant to this point. These particular studies involve finished water turbidity at low levels in the same range as the finished water target identified by the Committee. The associated removal of *Cryptosporidium* at these turbidity levels was reliably in the range of 2 log or greater.

Other key points discussed during the Advisory Committee's deliberations related to the studies include:

- As turbidity performance improves for treatment of a particular water, there tends to be greater removal of *Cryptosporidium*.
- Pilot plant study data in particular indicate high likelihood of achieving at least 2 log removal when plant operation is optimized to achieve low turbidity levels. Moreover, pilot studies represented in the table tend to be for low-turbidity waters, which are considered to be the most difficult to treat regarding particulate removal and associated protozoan removal. Since high removal rates have been demonstrated in pilot studies using lower-turbidity source waters, it is likely that similar or higher removal rates would be achieved for higher-turbidity source waters.
- The evaluation of *Cryptosporidium* removal in full-scale plants can be difficult in that this data includes many non-detects in the finished water. In these cases, values assigned at the detection limit will likely result in over-estimation of oocysts in the finished water. This in turn means that removal levels will tend to be under-estimated.
- Another factor that contributes to differences among the data is that some of the full-scale plant data comes from plants that are not optimized, but that still meet existing SWTR requirements. In such cases, oocyst removal may be less than 2 log. In those studies that indicate that full-scale plants are achieving greater than 2 log removal (LeChevallier studies in particular), the following characteristics pertain:
  - —Substantial numbers of filtered water measurements resulted in oocyst detections;
  - —Source water turbidity tended to be relatively high compared to some of the other studies;
  - —A significant percentage of these systems were also achieving low filtered water turbidities, substantially less than 0.5 NTU.
- Removal of *Cryptosporidium* can vary significantly in the course of the filtration cycle (i.e., at the start-up and end of filter operations versus the stable period of operation, which is the predominant period).

b. Other Filtration Technologies. Other filtration technologies include slow sand and diatomaceous earth filtration. ''Technologies and Costs for the Treatment of Microbial Contaminants in Potable Water Supplies, October 1988'' by USEPA (1988) listed research studies indicating that a well designed and operated plant using these technologies is capable of 3- to 4-log removal of *Giardia* and viruses. Recent findings appear in Table 2 below.

TABLE 2.—CRYPTOSPORIDIUM AND GIARDIA LAMBLIA REMOVAL EFFICIENCIES

Type of treatment plant	Log removal	Experimental design	Researcher
Slow Sand	*Giardia* >3	Pilot plant at 4.5 to	Schuller and Ghosh, 91.
	Crypt >3	16.5 degrees C.	
	Crypt 4.5	Full scale plant	Timms et al., 1995
Diatomaceous Earth	*Giardia* >3	Pilot plant, addition of	Schuler and Ghosh, 90.
	Crypt >3	coagulant increased.	
		removal beyond.	
		values shown.	

c. Multiple Barrier Approach.

The M–DBP Advisory Committee engaged in extensive discussion regarding the adequacy of relying solely on physical removal to control *Cryptosporidium* in drinking water supplies and on the need for inactivation. There was a substantial absence of technical consensus on how to or whether it is currently possible to adequately measure *Cryptosporidium* inactivation efficiencies for various disinfection technologies. This issue emerged as a significant impediment to addressing inactivation in the IESWTR.

As part of the original 1994 proposal, USEPA included control strategies that would entail the development of a map of inactivation efficiencies for *Cryptosporidium*. As discussed later in Section M. of this Notice, adequate information to develop such a map is not available at this time. The Advisory Committee discussion recognized, however, that inactivation requirements may be appropriate and necessary under future regulatory scenarios and that physical removal by filtration may not be sufficient under all circumstances or for all source waters.

As part of the development process for the long term ESWTR, the Advisory Committee recommended that USEPA request comment on a risk-based proposal for *Cryptosporidium* embodying the multiple barrier approach (e.g., source water protection, physical removal, inactivation, etc.), including, where risks suggest appropriate, inactivation requirements. In establishing the LTESWTR, the Committee recommended that the following issues be evaluated:

—Data and research needs and limitations (e.g., occurrence, treatment, viability, active disease surveillance, etc.);
—Technology and methods capabilities and limitations;
—Removal and inactivation effectiveness;
—Risk tradeoffs including risks of significant shifts in disinfection practices;
—Cost considerations consistent with the SDWA;
—Reliability and redundancy of systems; and
—Consistency with the requirements of the Act.

3. Advisory Committee Recommendations and Related Issues

USEPA reiterates its request for comment on the following recommendations of the M–DBP Advisory Committee.

All surface water systems that serve more than 10,000 people and are required to filter must achieve at least a 2-log removal of *Cryptosporidium*. Systems which use rapid granular filtration (direct filtration or conventional filtration treatment-as currently defined in the SWTR), and meet the turbidity requirements described in section II.C. are assumed to achieve at least a 2-log removal of *Cryptosporidium*. Systems which use slow sand filtration and diatomaceous earth filtration and meet existing turbidity performance requirements under the SWTR (less than 1 NTU for the 95th percentile or alternative criteria as approved by the State) are assumed to achieve at least 2-logs removal of *Cryptosporidium*.

Systems may demonstrate that they achieve higher levels of physical removal.

C. Turbidity Control

1. Summary of 1994 Proposal as it Relates to Turbidity Issues and Public Comments

Finished water turbidity levels are currently regulated by USEPA under the SWTR as a treatment technique to ensure removal of *Giardia* and viruses. The SWTR requires systems to monitor the turbidity of the combined filter effluent every four hours at each treatment plant. Systems using direct filtration or conventional treatment must achieve a combined filter effluent turbidity level of no more than 0.5 NTU in 95% of the measurements in each month and never exceed 5 NTU. Failure of individual filters may allow pathogens to enter the distribution system. However, the SWTR does not presently require systems to monitor the effluent of individual filters.

As a treatment technique, turbidity is an indicator of filtration performance. Treatment plants are, as noted above, required to meet certain turbidity levels to meet the removal requirements for Giardia. Although turbidity is not a direct indicator of health risk, a very low turbidity level of the treated water is in general a good indicator of effective *Cryptosporidium* and *Giardia* oocyst and cyst removal by rapid granular filtration. USEPA continues to believe that turbidity is the most readily measurable parameter to indicate filtration treatment effectiveness.

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*. As discussed earlier in this Notice, waterborne pathogens have caused significant disease outbreaks in the United States. 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.

USEPA also 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 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).

Some comments suggested and supported a revised approach to the IESWTR that would focus on optimizing existing water treatment processes to provide insurance against microbial disease outbreak in the absence of source water occurrence data. Another comment suggested that current levels of treatment, including filtration, have a sufficient degree of effectiveness in preventing transmission of *Cryptosporidium* in drinking water.

One commenter suggested that turbidity performance standards should not be modified until the SWTR has been further implemented. One commenter suggested that decreases in turbidity standards or monitoring after each filter should be voluntary unless scientific data demonstrate otherwise. Another commenter suggested that individual filters can be evaluated during sanitary surveys. Several commenters supported tighter turbidity standards and monitoring of individual filters. Suggested turbidity performance levels included 0.1 or less, or 0.2 NTU as revised standards. Several commenters supported monitoring of individual filters, with one suggesting backwashing of filters when turbidity levels increase.

2. New Data and Perspectives

As presented in detail below, the M-DBP Advisory Committee's recommendations to the Agency included tighter turbidity performance criteria and individual filter monitoring requirements as part of the IESWTR. These revised performance criteria, along with the individual filter monitoring requirements, would better enable systems to demonstrate that they meet a 2 log removal requirement for *Cryptosporidium*. Because *Cryptosporidium* is exceptionally resistant to inactivation using chlorine, physical removal by filtration is extremely important in controlling this organism. Data presented in the previous section of this Notice support modifications to the existing turbidity requirements under the SWTR to enable systems to demonstrate that they meet the proposed 2 log requirement.

The revised turbidity performance criteria would also contribute to another of the IESWTR's key objectives, which is to establish a microbial backstop to prevent significant increases in microbial risk when systems implement new disinfection byproduct standards under the Stage 1 DBPR. As indicated by data presented below, tighter turbidity performance criteria would reflect actual current performance for a substantial percentage of systems nationally. Revising the turbidity criteria would effectively ensure that these systems continue to perform at these levels (in addition to resulting in improved performance by systems that currently meet the existing criteria but that operate at levels higher than those suggested in the Advisory Committee's recommendations). The other major component of a microbial backstop would be provisions for disinfection profiling and benchmarking, which are discussed in Section D. of this Notice.

The revisions to the turbidity provisions (including the individual filter provisions) recommended by the Committee would also contribute to the microbial backstop objective in direct relationship to the treatment process itself. The reliability of the disinfection barrier as a means for preventing waterborne disease should increase substantially as a result of these tighter turbidity provisions because:

—There would be fewer and shorter periods of elevated turbidity during which the disinfection barrier could be compromised; and

—The removal of particulate matter achieved by the filtration process will both be higher on average and more consistent throughout the treatment cycle, thus putting less burden on the disinfection barrier.

a. 95th Percentile and Maximum Turbidity Levels of Composite Filtered Water.

Three data sets, summarizing the historical turbidity performance of various filtration plants, were evaluated to assess the national impact of modifying existing turbidity requirements. This included turbidity information from the American Water Works Service Company (AWWSC, 1997), a multi-State data set (which was analyzed in two sets) (SAIC, 1997), and information from plants participating in the Partnership for Safe Water program (Bissonette, 1997). Only turbidity data from plants serving populations greater than 10,000 persons were used. The analyses also included only plants that met the current 95th percentile turbidity standard, 0.5 NTU, and the current maximum turbidity standard, 5 NTU, in all months. 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 AWWSC is a privately-held company that owns and operates for profit about 70 water treatment facilities located across the country. For this analysis, the AWWSC data set (AWWSC, 1997) included one year's data for 45 plants in 10 States. The States, with number of plants in each state listed in parentheses, are as follows: California (1), Connecticut (3), Iowa (2), Indiana (6), Maryland (1), Missouri (2), Pennsylvania (24), Tennessee (1), Virginia (2), and West Virginia (3). USEPA analyzed the composite filtered effluent turbidity data obtained from the AWWSC plants measured every 4-hours.

The analyses examined two variations of turbidity data obtained from the multi-State data set (SAIC, 1997). The multi-State data set included 86 plants in 11 states. The States, with number of plants in each state listed in parentheses, are as follows: California (10), Georgia (5), Kansas (9), New Jersey (5), Ohio (12), Oregon (10), Rhode Island (6), Texas (9), Wisconsin (8), West Virginia (6), Wyoming (6). The State data was analyzed as two data sets, denoted as State 1 and State 2. The State 1 data set included only plant information with measurements every 4 hours, comprising slightly more than half of the State data (47 plants in CA (10), OR (10), TX (9), WI (6), WY (6), WV (6)). The State 2 data set was comprised of both the State 1 data and other data including plant information consisting of daily maximum turbidity values only, altogether 86 plants.

The State 1 data set was expected to provide a more accurate picture of typical plant performance among the plants in the entire State data set because there were more data points per plant. However, the State 2 data set increased regional coverage by incorporating data from five additional States (GA, KS, NJ, OH, RI) to reflect additional geographic variation that may not have been captured in the State 1 data set.

In order to determine how many of the systems met lower 95th percentile turbidity levels based on turbidity measurements every four hours, the data from those States in which systems only report maximum daily values had to be statistically adjusted. The adjustment is necessary to take into account the difference in the number of reported measurements in a month that can exceed a particular level (e.g., 0.3 NTU) without exceeding the monthly 95th percentile for that level. (Systems that report measurements every four hours can have up to 9 of 180 measurements (5%) that exceed the level in a month; however, there is no way to directly calculate an equivalent value for systems that only report daily maximum values without making some adjustment.) No adjustment was necessary for assessing monthly maximum turbidity levels.

The State 2 analyses adjusted the monthly 95th percentile turbidity levels for plants with only daily maximum data. This was done because the 95th percentile based on 31 daily turbidity maximums a month will overestimate the 95th percentile based on 186 daily measures (or measurements every 4 hours). To assess the magnitude of the bias, the State 1 data were used to examine the relationship between the 95th percentile of the daily maximums and the 95th percentile of the daily measurements.

The State 2 monthly 95th percentile analyses were obtained by dividing the estimated monthly 95th percentiles of those systems reporting only daily maximums by a factor of 1.2 to account for bias. This factor was derived as follows. The daily maximum was determined for each day in the State 1 data set and a monthly 95th percentile (of the 30 or 31 daily maximums) was determined, i.e., the second largest daily maximum. The corresponding monthly 95th percentile based on the daily data was also determined. The ratio of these two values was then calculated and summarized across months. The median ratio across all months was 1.2, with 90 percent of the ratios ranging between 1.0 and 1.9. The analysis used to derive the adjustment factor examined only plants that reported six values per day.

The remaining data set included in the turbidity analysis was of plants participating in the Partnership for Safe Water. The Partnership for Safe Water is a joint venture of several organizations, including the American Water Works Association, the Association of State Drinking Water Administrators, the Association of Metropolitan Water Agencies, the National Association of Water Companies, the American Water Works Association Research Foundation and USEPA. These organizations entered into a voluntary ''partnership'' with the nation's drinking water filtration plants treating surface water to tighten treatment practices and operational controls to reduce the risk from *Cryptosporidium* and other waterborne pathogens. The Partnership approach, described in the ''Partnership for Safe Water Voluntary Water Treatment Plant Performance Improvement Program Self-Assessment Procedures'' (USEPA et al. 1995), is based on USEPA's Composite Correction Program (CCP). The CCP is a voluntary program which is described in detail in the handbook Optimizing Water Treatment Plant Performance Using the Composite Correction Program—USEPA/625/6–91/027. The Partnership for Safe Water utility membership consists of 199 utilities representing almost 280 water treatment plants. These plants serve approximately 80 million persons. The Partnership consists of four phases with each phase providing tools and methodologies to assist utilities in progressing toward a higher quality finished water. The following data summarizes turbidity performance based on 4-hour measurements reported by the Partnership utilities for 12 months overlapping 1995 and 1996. The data represents a composite of Partnership utilities that have completed varying phases of Partnership activities, ranging from having just joined to having progressed well into the self-assessment phase (phase 3). All data were derived from the 1997 Partnership for Safe Water Annual report (Bissonette, 1997).

The results of the analyses of all of the data sets are shown in Tables 3 and 4.

Tables 3 and 4 indicate the extent to which plants, as currently operated, are meeting different turbidity levels. Conversely the data indicate the portion of utilities which might need to alter existing practice in order to meet lower turbidity limits, if such limits were required through regulation.

Table 3 is organized to reflect the extent to which utilities are currently meeting monthly 95th percentile turbidity limits, assuming that compliance with such limits is determined as currently done under the existing monthly 95th percentile standard of < 0.5 NTU. For example, Table 3 indicates that 19.1 percent (based on the Partnership data set) and 34.9 percent (based on the State 2 data set) exceed a monthly 95th percentile turbidity limit of 0.3 NTU at least one month during the year for which data were collected. Table 3 also indicates the extent to which utilities meet a particular limit for multiple months of the year (i.e., for at least 3 months and for at least 6 months). The frequency in months by which utilities exceed a particular monthly turbidity limit could influence the extent of treatment that might be needed to achieve compliance through out the year.

The Technical Work Group (TWG) which provided technical advice to the Advisory Committee made the following recommendations for estimating national compliance forecasts.

(1) The State 2 data set could be used as a reference point for estimating potential compliance burdens for systems serving less than 100,000 people. The Partnership data could be used as a reference point for estimating potential compliance burdens for systems serving greater than 500,000 people. For systems serving between 100,000 and 500,000 people, the average of the percentages of systems not meeting a particular limit reflected by the Partnership and State 2 data could be used for estimating compliance burdens.

(2) Estimates for systems needing to make changes to meet a turbidity performance limit of < 0.3 NTU should be based on the ability of systems currently being able to meet a 0.2 NTU as reflected in Table 3. This assumption would also take into account a utility's concern with possible turbidity measurement error.

For example, for systems serving less than 100,000 people, the TWG assumed that 51.7 percent of the systems could 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, the TWG assumed that 41.7 percent could be expected to make treatment changes to comply with a 0.3 NTU regulatory limit.

Table 4 is organized to reflect the extent to which utilities meet different monthly maximum turbidity limits (i.e., all measurements taken during the month must be below the indicated limit). For example, Table 4 indicates that 6 percent of the plants (based on State 2 Partnership data) are currently exceeding a monthly maximum limit of 1.0. The data in Table 4 were considered for evaluating possible national impacts of lowering the current maximum limit of 5 NTU to some lower value.

Regarding maximum turbidity levels, the Advisory Committee also discussed filtered water turbidity levels with respect to the cryptosporidiosis outbreak in Milwaukee in 1993. Some members indicated concern that filtered water turbidities associated with the outbreak apparently were significantly lower than the current maximum turbidity level of 5 NTU. Indications are that the turbidity levels were at about 2 NTU (MacKenzie et al., 1994; Fox and Lytle., 1996).

TABLE 3.—NUMBER AND PERCENT OF PLANTS THAT EXCEEDED MONTHLY 95TH PERCENTILE TURBIDITY LIMITS IN AT LEAST N MONTHS OUT OF 12

Turbidity limit	Data source	At least 1 month		At least 3 months		At least 6 months	
		Num	Pct	Num	Pct	Num	Pct
0.1	State 1	34	72.3	28	59.6	24	51.1
State 2	69	80.2	59	68.6	51	59.3	
AWWSC	33	73.3	24	53.3	15	33.3	
Partnership	177	75.3	136	57.9	100	42.6	
0.2	State 1	17	36.2	9	19.1	2	4.3
State 2	44	51.2	29	33.7	15	17.4	
AWWSC	12	26.7	7	15.6	2	4.4	
Partnership	98	41.7	51	21.7	27	11.5	
0.3	State 1	10	21.3	3	6.4	0	0.0
State 2	30	34.9	11	12.8	3	3.5	
AWWSC	6	13.3	1	2.4	0	0.0	
Partnership	45	19.1	17	7.2	7	3.0	
0.4	State 1	3	6.4	0	0.0	0	0.0
State 2	9	10.5	1	1.2	0	0.0	
AWWSC	3	6.7	0	0.0	0	0.0	

TABLE 3.—NUMBER AND PERCENT OF PLANTS THAT EXCEEDED MONTHLY 95TH PERCENTILE TURBIDITY LIMITS IN AT LEAST N MONTHS OUT OF 12—Continued

Turbidity limit	Data source	At least 1 month		At least 3 months		At least 6 months	
		Num	Pct	Num	Pct	Num	Pct
Partnership	22	9.4	5	2.1	3	1.3	

Population served ≥10,000. State 1 (4-hour daily data from 47 plants): 10 CA, 10 OR, 9 TX, 6 WI, 6 WV, 6 WY. State 2 (86 plants including State 1 data and daily maximums * from additional plants) : 10 CA, 5 GA, 9 KS, 5 NJ, 12 OH, 10 OR, 6 RI, 9 TX, 8 WI, 6 WV, 6 WY. AWWSC: 45 plants: 1 CA, 3 CT, 2 IA, 6 IN, 1 MD, 2 MO, 24 PA, 1 TN, 2 VA, 3 WV. Partnership for Safe Water 235 plants. *For plants with only daily maximums, the monthly 95th percentile was estimated as the 95th percentile of the daily maximums divided by 1.2. The adjustment was done to account for the potential bias of taking the 95th percentile of daily maximums, and was based on the relationship observed in the State 1 data between the 95th percentile of the daily maximums and the 95th percentile of the 4-hour data.

TABLE 4.—NUMBER AND PERCENT OF PLANTS THAT EXCEEDED MONTHLY MAXIMUM TURBIDITY LIMITS IN AT LEAST N MONTHS OUT OF 12

Maximum turbidity limit	Data source	At least 1 month		At least 3 months		At least 6 months	
		Num	Pct	Num	Pct	Num	Pct
0.3	State 1	36	76.6	15	31.9	6	12.8
State 2	69	80.2	36	41.9	15	7.4	
AWWSC	24	53.3	10	22.2	4	8.9	
Partnership	129	54.9	72	30.6	37	15.7	
0.5	State 1	18	38.3	3	6.4	1	2.1
State 2	35	40.7	7	8.1	1	1.2	
AWWSC	12	26.7	3	6.7	0	0.0	
Partnership	65	27.7	20	8.5	5	2.1	
1.0	State 1	1	2.1	0	0.0	0	0.0
State 2	6	7.0	0	0.0	0	0.0	
AWWSC	4	8.9	0	0.0	0	0.0	
Partnership	16	6.8	4	1.7	2	0.9	
2.0	State 1	1	2.1	0	0.0	0	0.0
State 2	2	2.3	0	0.0	0	0.0	
AWWSC	0	0.0	0	0.0	0	0.0	
Partnership	7	3.0	2	0.9	1	0.4	

b. Individual Filter Performance.

During a turbidity spike, significant amounts of particulate matter (including oocysts, if present) may pass through the filter. Figure 3 presents the turbidity levels over time of a typical filter. The greatest potential for a peak (and thus, pathogen break-through) is near the beginning of the filter run after filtered backwash or start up of operation (Amirtharajah 1988; Bucklin et al. 1988; Cleasby 1990; and Hall and Croll 1996).

Various factors effect 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. The M–DBP Advisory Committee also discussed the need to control turbidity spikes in order to limit the number of oocysts passing through the filter.

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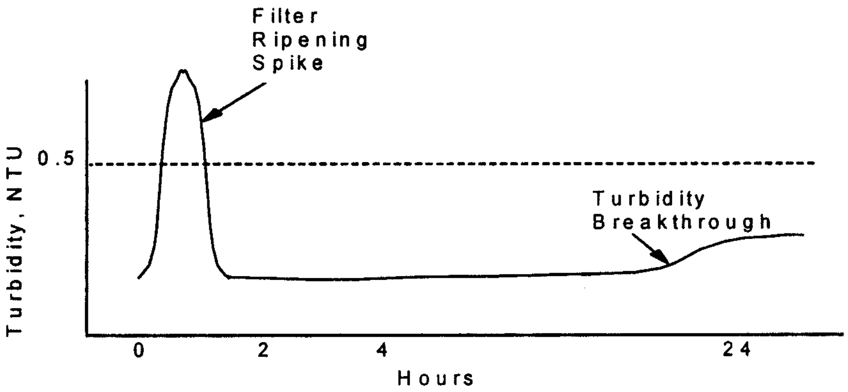

Figure 3. Plot of Turbidity Profile

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c. Turbidity Measurement.

Turbidity is a measure of light scatter that is affected by the size distribution and shape of suspended particles in the water. Four methods are commonly used to measure turbidity and all are approved for use under the SWTR. They include the Nephelometric Method listed in 2130B of the *Standard Methods for the Examination of Water and Wastewater,* Standard Test Method for Turbidity of Water ASTM (1990) D1889–94, the Nephelometric Method in 180.1 of USEPA–600/R–93–100 and the Great Lakes Instruments Method 2 (see section 141.74(a)(1)).

Turbidimeters which measure turbidity commonly consist of the following components: (1) a light source and lenses and other optical devices to project the light beam at the sample container and to direct the scattered light to the detector; (2) a transparent cell that contains the water to be measured; (3) light traps within the sample chamber that minimize the amount of stray light that reaches the detector; and (4) a meter that indicates the intensity of the light reaching the detector. While turbidity measurement has long been recognized as a means for evaluating treatment performance for removal of particulate matter (which include microorganisms), issues remain pertinent to the accuracy and precision of the measurement (Hart et al. 1992; Sethi et al. 1997).

Large tolerances in instrument design criteria, intended to promote competition among instrument manufacturers, have lead to turbidimeters with significantly different design features being available on the market. Turbidimeters with different designs (but within the design specifications of Standard Methods), calibrated according to manufacturer's recommendations, have been shown to provide different turbidity readings for a given suspension (Hart et al. 1992). The significance of this phenomenon as it might pertain to the same water with changing turbidities over time or different waters in the U.S. is not known. Therefore, narrowing instrument design criteria could reduce variation of turbidity measurement but the best direction that such change should take is not yet apparent.

Calibration procedures also affect turbidity measurements. Calibration typically involves placing a quantity of a standard suspension in the turbidimeter and then adjusting the response so that the meter gives a reading equal to the turbidity value assigned to the standard. Instruments that are calibrated with currently approved different standard suspensions can yield different turbidity measurements on the same water (Hart et al. 1992). The significance of this phenomenon as it might pertain to the same water with changing turbidities over time or different waters in the U.S. is also not known. While narrowing specifications for current calibration procedures could reduce variation of turbidity measurements, the best direction that such change should take is not yet apparent.

Other factors that may affect turbidity measurement include procedures used to prepare and wipe the sample cell and use of sample degassing procedures. The extent to which all of the above factors, collectively, affect turbidity measurement is not known. However, past performance evaluation (PE) studies conducted by USEPA provide some indication of accuracy and precision of 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 (who 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 reflect differences resulting from using different turbidimeter models and methods and the effects of different laboratory procedures. Table 5 summarizes results from PE studies conducted at turbidity levels close to the SWTR turbidity performance limit of 0.5 NTU. The Relative Standard Deviation (RSD) is the Standard Deviation divided by the mean. It appears that the RSD at turbidity levels considered in these PE studies are slightly below 20%. (A RSD of 20% implies that 95% of one-time turbidity measurements made by different laboratories would fall within 40% of the mean. The RSD for an individual laboratory, making numerous measurements on a given sample water would be expected to be significantly less than that achieved among different laboratories (using a variety of turbidimeters as indicated in Table 5).

TABLE 5.—USEPA PERFORMANCE EVALUATION RESULTS OF TURBIDITY MEASUREMENTS (USEPA 1997d)

[Turbidity readings are expressed in NTU, and Relative Standard Deviation in %]

Study No.	True Turb.	No. of samples	Mean	Relative S D
34 USEPA/State	.720	54	.752	16.0
34 All Lab	.720	1503	.744	15.8
23 USEPA/State	.650	24	.659	10.1
25 USEPA/State	.600	28	.585	13.8
25 All Lab	.600	708	.597	16.0
25 USEPA/State	.450	29	.463	20.5
25 All Lab	.450	707	.481	19.5
22 USEPA/State	.350	52	.406	16.1

No data is yet available on measurement performance from PE studies at levels less than 0.3 NTU. A major concern expressed by participants among the Advisory Committee is the ability to reliably measure low turbidity levels. The TWG assumed that if systems operated to achieve a turbidity limit of less than 0.2 NTU 95 percent of the time, this would provide an adequate margin of safety from variability in treatment performance and turbidity measurement error, to consistently meet a turbidity limit of 0.3 NTU.

USEPA intends to conduct two PE studies with true turbidities ranging from 0.1 to 0.3 NTU. One study is planned to begin no later than the end of January 1998 and the other study within 6 months thereafter. These new studies will provide an indication of accuracy and precision of turbidity measurements at lower levels than previously examined. Measurements by on-line turbidimeters will also be evaluated.

On-line monitoring issues: For expedience, on-line turbidimeters are often calibrated against a bench instrument that has been accurately calibrated by comparing the turbidity level in a water sample. However, at regular intervals they need to be taken off line and calibrated, as for bench instruments, by pouring the prepared standard suspension into the chamber of the instrument. On-line instruments must be inspected regularly to remove air bubbles and accumulated debris. Fluctuations in continuous measurements do not necessarily signify a decrease in water treatment performance. Fluctuations in continuous measurements should be investigated since they may be due to air bubbles, debris or a temporary disturbance due to a change in the flow rate of sample water flow through the turbidimeter. To address the contingency of such phenomenon, the Advisory Committee recommended, based on advice from the Technical Work Group, that turbidity spikes should be defined on the basis of at least 2 consecutive measurements taken over some interval of time (e.g., 15 minutes).

There is no standard design specification for on-line turbidimeters regarding chamber size and recommended flow rate. Thus, turbidity spikes of the treated water will be reflected with a delay of a few seconds to a few minutes, depending on chamber volume and flow rate of the turbidimeter. A turbidity peak measured by a turbidimeter with a large chamber volume and small flow rate will result in slightly reduced peak.

3. Advisory Committee Recommendations and Related Issues

USEPA reiterates its request for comment on the following recommendations of the M–DBP Advisory Committee.

1. Turbidity Performance Requirements. For all surface water systems that use conventional treatment or direct filtration, serve more than 10,000 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 shall be determined based on measurements of the combined filter effluent at four-hour intervals.

2. Individual Filter Requirements. All surface water systems that use rapid granular filtration, serve more than 10,000 people, and are required to filter shall conduct continuous monitoring of turbidity for each individual filter and shall provide an exceptions report to the State on a monthly basis. Exceptions reporting shall include the following: (1) any individual filter with a turbidity level greater than 1.0 NTU based on 2 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 2 consecutive measurements fifteen minutes apart. A filter profile will be produced 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 2 consecutive measurements fifteen minutes apart at any time in each of 3 consecutive months, the system shall conduct a self-assessment of the filter utilizing as guidance relevant portions of guidance issued by the Environmental Protection Agency for Comprehensive Performance Evaluation (CPE). If an individual filter has turbidity levels greater than 2.0 NTU based on 2 consecutive measurements fifteen minutes apart at any time in each of two consecutive months, the system will arrange for the conduct of a CPE by the State or a third party approved by the State.

3. 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.

In reference to the above recommendations, EPA also requests comment on what would or would not constitute an obvious reason for abnormal filter performance. The Agency also requests comment on how much time a system should have to conduct a self-assessment of the filter and how much time a system should have to arrange for the conduct of a CPE under circumstances such as described in the recommendations.

USEPA also requests comment on whether there are particular filters currently in operation in the United States for which specific guidance may be needed with regard to individual filter monitoring. For example, some members of the M-DBP Advisory Committee suggested that special guidance be developed for unique filtration devices made by Infilco Degremeont (previously made by Aldridge). These devices consist of multi-celled filters with a traveling bridge-automated back washing unit that are not conducive to individual cell monitoring.

USEPA also requests comment regarding existing SWTR provisions for lime softening plants that have very low turbidity in source waters. The existing SWTR allows States to set numerically higher standards up to 1 NTU in 95 percent of samples taken per month for conventional treatment and direct filtration plants if the State determines that on-site studies demonstrate at least 99.9 percent overall removal and/or inactivation of Giardia cysts. (54 FR 27503). In the SWTR (54 FR 27486), the Agency notes that actual demonstrations ''(e.g. with pilot plant study results)'' are not required for the State to determine when minimum performance requirements at the higher turbidity level might be appropriate for a particular system. The SWTR states:

> Instead, the State's determination may be based upon an analysis of existing design and operating conditions (e.g. adequacy of treatment prior to filtration, percent turbidity removal across the entire treatment train, stringency of disinfection) and/or performance relative to certain water quality characteristics (e.g. microbiological analysis of the filtered water, particle size counts in water before and after filtration). The State may wish to consider such factors as source water quality and system size in determining the extent of analysis necessary. (54 FR 27503).

Committee members raised situations where filtration plants have been designed for specific source water quality characteristics such as high alkalinity and extremely low turbidity water (e.g. 0.1 to 0.5 NTU). In systems with such source waters, turbidity levels from the filters may actually be higher than in the source waters due to reactions from chemicals added mainly for purposes other than source water particle removal. Lime softening plants operating under certain conditions, depending upon process configuration and raw water characteristics or when flocculation conditions change, may periodically experience a carry over of extremely fine calcium carbonate or magnesium hydroxide particles. These fine particles may pass through filters thereby resulting in artificially elevated effluent turbidity levels. If turbidity performance criteria are tightened under the IESWTR some plants may have difficulty meeting these criteria but still achieve substantial removal of *Giardia lamblia, Cryptosporidium parvum*, and viruses. As reflected in the 1989 SWTR, USEPA believes that in cases where lime softening is practiced and source water turbidity levels are low, provisions for alternative treatment performance criteria (i.e., in lieu of turbidity) may be appropriate.

As in the present SWTR, USEPA believes that demonstrations of equivalent protection need not be based on actual demonstrations (e.g. pilot plant study results). Instead the State's determination can be based on the factors cited at 54 FR 27503 as quoted above. Other factors related to source water microbial quality (e.g. pristine source water, source water protection programs, microbial monitoring results, bank filtration) may be appropriate for such determinations.

USEPA requests comment on the appropriateness of continuing existing provisions that provide States the flexibility of approving higher turbidity levels up to 1 NTU in 95 percent of samples per month and up to 2 NTU maximum turbidity for such plants, and additionally seeks comments on:

- What types of plants might fall in this category (e.g. softening plants designed for color and hardness removal with very low turbidity source waters);
- What demonstrations of equivalent protection from Giardia lamblia, Cryptosporidium parvum, and viruses are appropriate (e.g. microbiological analysis of the filtered water, monitoring results for protozoans, watershed control, wellhead protection programs);
- What additional or alternative requirements States might place on such systems to insure the objective of equivalent protection from Giardia lamblia, Cryptosporidium parvum, and viruses (e.g. regular monitoring for protozoans in source and or filtered water, or for other water quality parameters, watershed control, well head protection programs);
- Allowing systems to acidify turbidity samples when calcium carbonate carry-over exists to obtain true turbidity readings; and
- The appropriateness of including source water microbial quality measurements or surrogates as part of a State determination of equivalent protection when considering whether to authorize higher operating turbidity levels.

D. Disinfection Benchmark for Stage 1 DBP MCLS

A fundamental principle of the 1992–93 regulatory negotiation which was reflected in the 1994 proposal for the IESWTR was that new standards for control of byproducts must not result in significant increases in microbial risk. This principle was also one of the underlying premises of the 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's recommendations to meet this key objective are discussed in this section.

The approach outlined below represents the recommendation of the Advisory Committee to develop a mechanism that is designed to assure that pathogen control is maintained while the Stage 1 DBPR provisions are implemented. Briefly, the disinfection benchmark addresses the three issues of who must gather the necessary information to evaluate current practices, how the benchmark operates, and finally, how the system and the State work together to assure that microbial control is maintained.

Based on data provided by systems and reviewed by the TWG, the baseline of microbial inactivation (expressed as logs of *Giardia lamblia* inactivation) demonstrated high variability. Inactivation varied by several logs 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, the TWG developed an approach for a system to use to characterize disinfection practice; the procedure is called profiling. In essence, this approach allows a plant to chart or plot its daily levels of *Giardia* inactivation on a graph which, when viewed on a seasonal or annual basis, represents a ''profile'' of the plant's inactivation performance. The system can use the profile to develop a baseline or benchmark of inactivation against which to measure possible changes in disinfection practice. This approach makes it possible for a plant that may need to change practice to meet DBP MCLs to assure no significant increase in microbial risk. It provides the necessary tool to allow plants to project or measure the possible impacts of potential changes in disinfection. Only certain systems would be required to develop a profile and keep it on file for State review during sanitary surveys, and only a subset of those required to develop a profile would be required to submit it to the State as part of a package submitted when the system is making significant changes to its disinfection practice.

USEPA reiterates its request for comment on the following recommendations of the M-DBP Advisory Committee that address the three questions outlined above: (1) who should develop a profile, (2) how a profile is actually generated, and (3) how the profile will be used.

1. Applicability

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

(1) TTHM levels are at least 80% of the MCL (0.064 mg/l) as an annual average for the most recent 12 month compliance period for which compliance data are available prior to November 1998 (or some other period designated by the State). Monitoring would be in accordance with current TTHM requirements.

(2) Haloacetic acid (HAA5) levels are at least 80% of the MCL (0.048 mg/l) as an annual average for the most recent 12 month period for which data are available (or some other period designated by the State). In connection with HAA5 monitoring, the following provisions apply:

(a) Systems that have collected HAA5 data under the ICR must use those data to determine the HAA5 level, unless the State determines that there is a more representative annual data set.

(b) If the system does not have four quarters of HAA5 data by the end of 90 days following the IESWTR promulgation date, the PWS must conduct HAA5 monitoring for four quarters. This monitoring must comply with the monitoring requirements included in the DBP Stage 1 rule.

(The Advisory Committee recommended a value of 80% of the MCL because available data indicated that DBP levels varied from year to year due to many factors (e.g., changes in source water quality, changes in water demand). The Committee believed that targeting a level 20% below the MCL would include most systems that would be expected to make changes to comply with the TTHM and HAA5 MCLs on a continuing basis. Also, USEPA previously considered this target level at the recommendation of the 1992 reg-neg committee, to evaluate DBP Stage 1 compliance forecasts and costs, based upon the judgement that most facilities will take additional steps to ensure continuing MCL compliance if they are at or above these levels.)

2. Developing the Profile and Benchmark

As outlined above, profiling is the characterization of a system's disinfection practice over a period of time. The system can create the profile by conducting new daily monitoring or by using ''grandfathered'' data (as explained below). A disinfection profile consists of a compilation of daily *Giardia lamblia* log inactivations (or virus inactivations under conditions to be specified in the final rule), 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(s)).

Grandfathered data are those operational data that a system 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 operational data collected prior to promulgation of the IESWTR, would be able to use up to three years of operational data in developing profiles. Grandfathered operational data should be substantially equivalent to operational data that would be collected under this rule.

Those systems that do not have three years of operational data to develop profiles would have to conduct monitoring to develop the profile for one year beginning no later than 15 months after IESWTR promulgation. If the PWS has existing operational data to develop profiles, it would have to use those data to develop profiles for the years prior to the IESWTR promulgation.

In order to develop the profile, a system would have to:

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

The system would then have to convert operational data to log inactivation values for *Giardia* (and viruses when chloramines or ozone used as primary disinfectant).

—Determine CT_{actual} for each disinfection segment.
—Determine $CT_{99.9}$ (i.e., 3-logs inactivation) from tables in the SWTR/IESWTR using temperature (and pH for chlorine) for each disinfection segment. [NOTE: USEPA may redesign the tables so that no conversion is necessary (i.e., the tables will reflect a CT_{90} (1-log) value.]
—For each segment, log inactivation = $(CT_{act}/CT_{99.9}) \times 3.0$.

A log inactivation benchmark would then be calculated as follows:

1. Calculate the average log inactivation 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 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 for that year is the benchmark.

3. State Review

The State would review disinfection profiles as part of its periodic sanitary survey. If a system that is required to develop a disinfection profile subsequently decides to make a significant change in disinfection practice, it would have to consult with the State before implementing such a change. Significant changes would be defined as: (1) moving the point of disinfection, (2) changing the type of disinfectant, (3) changing the disinfection process, or (4) making any other change designated as significant by the State. Supporting materials for such consultation would have to include a description of the proposed change, the disinfection profile, and an analysis of how the proposed change will affect the current disinfection benchmark.

4. Guidance

USEPA, in consultation with interested stakeholders, will develop guidance for States and systems on how to develop and evaluate disinfection profiles, how to identify and evaluate significant changes in disinfection practices, and guidance on moving the point of disinfection from before the point of coagulant addition to after the point of coagulant addition. USEPA will also develop guidance for systems that would be required to develop a profile based on virus inactivation instead of *Giardia lamblia* inactivation. Guidance will be available when the IESWTR is promulgated.

5. Request for Public Comment

USEPA requests comment on all aspects of the recommendation outlined above and any alternative suggestions that stakeholders or other interested parties may have. Commenters may want to focus particular attention on the following issues:

—Applicability requirements,
—Characterization of disinfection practices and components (e.g., monitoring, analysis),
—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.

E. Definition of Ground Water Under the Direct Influence of Surface Water (GWUDI)—Inclusion of Cryptosporidium in the Definition

1. Summary of 1994 Proposal and Public 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 rule, a system using ground water considered vulnerable to *Cryptosporidium* contamination would be subject to the provisions of the SWTR. USEPA 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 USEPA's guidance on this issue. *Cryptosporidium* oocysts are smaller than *Giardia* cysts and may have substantially different hydrodynamic behavior in ground water due to their smaller size and perhaps also due to a difference in charge distribution on the outer surface of the oocyst. USEPA guidance for the determination of GWUDI suggests methods that may be insensitive to this differing hydrodynamic behavior in ground water.

Almost all commenters agreed that *Cryptosporidium* should be added to the definition. Only one commenter clearly opposed the addition without caveat, maintaining that problems with the analytical methods for the recovery and enumeration of viable organisms and uncertainties associated with risk assessment should preclude its addition. One commenter contended that *Cryptosporidium* should be included only if USEPA addresses the amount of natural disinfection at each site and defines treatment effectiveness, especially coagulant use, for GWUDI systems. One commenter believed that the definition of *Cryptosporidium* should be made at the species level, e.g. *Cryptosporidium parvum*, because other species were not pathogenic to humans.

One commenter was concerned about the Microscopic Particulate Analysis (MPA), one of the methods that USEPA identifies in guidance as being suitable for making GWUDI determinations. As part of this method, a microscopic examination is made of the ground water to determine whether insect parts, plant debris, rotifers, nematodes, *Giardia lamblia*, and other material associated with the surface or near surface environment are present. The commenter claimed that the MPA has analytical method problems similar to those associated with the recovery of cysts and oocysts from environmental samples and suggested that the method should undergo additional testing with positive and negative controls and with performance evaluation samples.

2. Overview of Existing Guidance

USEPA issued guidance on the MPA in October 1992 as the Consensus Method for Determining Groundwater Under the Direct Influence of Surface Water Using Microscopic Particulate Analysis. Additional guidance for making GWUDI determinations is also available (USEPA, 1994e,f). 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 USEPA and the Association of State Drinking Water Administrators. AWWARF has also published guidance (Wilson et al., 1996).

3. Summary of New Data and Perspectives

Most recently, Hancock et al. (1997) used the MPA test to study the occurrence of *Giardia* and *Cryptosporidium* in the subsurface. They found that, in a study of 383 ground water samples, the presence of *Giardia* correlated with the presence of *Cryptosporidium*. The presence of both pathogens correlated with the amount of sample examined but not with the month of sampling. There was a correlation between source depth and occurrence of *Giardia* but not *Cryptosporidium*. The investigators also found no correlation between the distance of the ground water source from adjacent surface water and the occurrence of either *Giardia* or *Cryptosporidium*. However, they did find a correlation between distance from a surface water source and generalized MPA risk ratings of high (high represents an MPA score of 20 or greater), medium or low, but no correlation was found with the specific numerical values that are calculated by the MPA scoring system.

USEPA is interested in an expanded discussion of MPA performance. The work cited here is preliminary information and represents the only data provided to USEPA so far. USEPA is considering several analytical activities to address possible changes in the GWUDI determination guidance. These changes are as follows:

- Change the MPA methodology to include a score for *Cryptosporidium* oocysts in the risk rating method.
- Conduct additional comparison of MPA scores with cyst and oocyst recovery to evaluate the performance of MPA as an indicator method (e.g., Schulmeyer, 1995).
- Conduct additional MPA performance evaluation testing (with both positive and negative controls).
- Compare MPA scores and cyst/oocyst recovery in horizontal collector wells and vertical wells to determine if additional guidance for horizontal collector wells is needed.

4. Request for Public Comment

USEPA is continuing to consider inclusion of *Cryptosporidium* in the definition of GWUDI. USEPA requests further comment on this issue as well as on issues outlined above pertaining to guidance for GWUDI determinations.

F. Inclusion of Cryptosporidium in Watershed Control Requirements

1. Summary of 1994 Proposal and Public Comments

USEPA proposed to extend the existing watershed control requirements for unfiltered systems to include the control of *Cryptosporidium*. This would 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. USEPA also proposed requiring a State, as a condition of primacy, to describe how it would judge the adequacy of watershed control programs for *Cryptosporidium* as well as *Giardia lamblia* and viruses in the source water.

Several commenters to the proposed rule specifically supported inclusion of *Cryptosporidium* in watershed control. Others supported watershed control programs in general without specifically articulating an opinion on *Cryptosporidium*. One commenter specifically opposed the inclusion of *Cryptosporidium* in watershed control program, maintaining that other avenues of watershed control could be promoted without including this organism in the control plan. Another commenter opposed including *Cryptosporidium* because environmental sources of *Giardia* and *Cryptosporidium* were not sufficiently understood. This commenter also opposed the requirement to include *Cryptosporidium* in State watershed control program protocols as a condition of primacy.

Other comments included: (1) Systems need to be informed of the nature of upstream pathogen sources and changes in upstream water quality in a timely manner, (2) watershed characteristics should not be the sole basis for determining water treatment strategies, (3) upstream sewage discharges should be prohibited and cattle farming and feedlots prohibited or substantially limited in a watershed, and (4) watershed control programs should be scientifically based, educational, and voluntary. One commenter contended that the burden of contamination on the watershed should not fall to the drinking water systems, and that better coordination on regulations is needed between the USEPA's drinking water and wastewater programs.

2. Overview of Existing Guidance

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.

The watershed control program under the SWTR must minimize the potential for source water contamination by Giardia lamblia and viruses. This program must include a characterization of the watershed hydrology characteristics, land ownership and activities which may have an adverse effect on source water quality. The SWTR Guidance Manual (USEPA, 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.

3. Summary of New Data and Perspectives

Since proposal of the IESWTR in July 1994, several new outbreaks of waterborne cryptosporidiosis have occurred in the United States. A recent summary of these outbreaks (Solo-Gabriele and Neumeister, 1996) identified raw sewage, surface runoff from livestock grazing areas, septic tank effluent, cattle wastes, treated wastewater, and backflow of contaminated water in the distribution system as the suspected sources of *Cryptosporidium* contamination of the water supplies in these outbreaks. Cattle grazing, feedstocks and in particular, calves and other young livestock, appear to be of greater concern for *Cryptosporidium* contamination than for *Giardia*. Some outbreaks of cryptosporidiosis have been related to upsets in the treatment process of filtered water systems or have occurred on occasions when spikes in turbidity have occurred in those systems. However, little information is available for unfiltered water systems as to whether spikes in raw water turbidity increase the likelihood that elevated levels of *Cryptosporidium* are present in the source water. Because *Cryptosporidium* cannot easily be controlled with conventional disinfection practices, there is particular concern about the presence of this organism in the source waters of systems that do not filter.

Data from the ICR may be useful in providing information on the relative *Giardia* and *Cryptosporidium* levels in the raw water sources of unfiltered and filtered water systems. In one comprehensive study on *Giardia* and *Cryptosporidium* densities in ambient water and drinking water, investigators (LeChevallier and Norton, 1995) found *Cryptosporidium* oocyst levels in ambient water ranging from 0.065/L to 65.1/L, with a geometric mean of 2.4 oocysts/L. In drinking water, the level of *Cryptosporidium* oocysts ranged from 0.29–57 oocysts/100L, with a mean of 3.3 oocysts/100L.

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 about 1 oocyst/100L. Thus, depending upon what removal efficiencies are achieved by filtration for *Cryptosporidium* (for example, 2 logs), it appears that unfiltered water systems that comply with the source water requirements of the SWTR may 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.

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. USEPA is considering adding specific monitoring requirements to the IESWTR for the unfiltered supplies serving 10,000 or more people to ensure the continued effectiveness of the watershed control program. The monitoring would be similar to the requirements under the ICR for *Giardia* and *Cryptosporidium* although the sampling frequency may be modified. As with the ICR, a USEPA-approved method and laboratory for *Giardia* and *Cryptosporidium* analyses would be required.

At a minimum, such a monitoring program might require some level of routine sampling (e.g., on a weekly, biweekly or monthly basis). The program may also include ''event'' sampling. An ''event'' would constitute an occasion when the raw water turbidity and/or fecal/total coliform concentration exceeded a specific value or possibly exceeded a site-specific 90th percentile value. At least one sample during an event might be required in addition to routine sampling. Results of all protozoa and related analyses would be made available to the State at a minimum as part of the annual on-site inspection required under the SWTR for non-filtering supplies.

USEPA is continuing to consider extending the existing watershed control requirements for unfiltered systems to include the control of *Cryptosporidium*. USEPA requests further comment on this issue. The Agency also requests comment on issues pertaining to monitoring for unfiltered systems serving 10,000 or more people, including comment on the following approaches:

Routine Source Water *Giardia* and *Cryptosporidium* Monitoring:

Option 1. Weekly *Giardia* and *Cryptosporidium* Monitoring
Option 2. Bi-Weekly *Giardia* and *Cryptosporidium* Monitoring
Option 3. Monthly *Giardia* and *Cryptosporidium* Monitoring

The Agency also requests comments on whether the frequency of monitoring should depend on system size, e.g., should requirements differ for systems serving between 10–100,000 people versus those serving more than 100,000 people.

''Event'' Source Water *Giardia* and *Cryptosporidium* Monitoring:

Option 1. No event sampling required.

Option 2. Collect sample(s) for *Giardia* and *Cryptosporidium* when source water turbidity exceeds 1.0 NTU or some alternative value such as a site-specific 90th percentile which might be lower than 1.0 NTU.

Option 3. Collect sample(s) for *Giardia* and *Cryptosporidium* when source water fecal coliform concentration exceeds 20 per 100 mL or total coliform level exceeds 100 per 100 mL, depending on which class of coliforms is used under the individual systems filtration avoidance agreement. Alternatively, the trigger could be some other coliform or fecal coliform value.

Option 4. Individual utility develops turbidity frequency distribution (e.g., based on previous 1 to 3 years of daily historical data) and collects sample(s) for *Giardia* and *Cryptosporidium* when turbidity exceeds 90th percentile level.

Option 5. Some combination of Options 2, 3, or 4.

The Agency also requests comment on whether any of the above options should depend on system size.

G. Sanitary Survey Requirements

1. Summary of 1994 Proposal and Public Comments

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. USEPA also requested comment on whether sanitary surveys should be required every three or every five years.

Most commenters on this issue voiced support for requiring a periodic sanitary survey for all systems. One commenter suggested that USEPA 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 USEPA-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 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.

Regarding criteria for sanitary survey inspectors, some commenters suggested that the State should decide what requirements to use. Others suggested some combination of education and working experience related to water plant operations, including (1) professional engineering certificate and water plant operator license for at least five years, (2) knowledge of surface water contaminants, source and fate of contaminants, and both removal capabilities of existing treatment technologies and ability to evaluate their performance, (3) a BS degree (preferably MS degree) in sanitary or environmental engineering with two years experience in evaluating water treatment plants and valid plant operator's license, (4) five years experience in water system operation, evaluation, and/or design, and a BS in engineering or environmental science, (5) a BS degree in science or engineering and five years experience in the drinking water field.

2. Overview of Existing Regulations and Guidance

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 first regulatory requirement for systems to have a periodic on-site sanitary survey appeared in the final TCR (54 FR 27544–27568). This rule requires all systems that collect less 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 SWTR did not specifically require water systems to undergo a sanitary survey. Instead, it required 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.

USEPA's SWTR Guidance Manual (USEPA, 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.''

3. New Developments

Since the publication of the proposed ESWTR in 1994, USEPA and the States (through the Association of State Drinking Water Authorities) have issued a joint guidance on sanitary surveys entitled USEPA/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.

USEPA is aware that a number of States have independently developed their own sanitary survey criteria. For instance, the American Water Works Association California-Nevada Section, Source Water Quality Committee in conjunction with the California Department of Health Services, Division of Drinking Water and Environmental Management (DHS) have published a document entitled Watershed Sanitary Survey Guidance Manual (AWWA California -Nevada Section 1993) to assist domestic water suppliers in defining the scope of their watershed sanitary surveys and to provide information on the methods and sources of information for conducting sanitary surveys.

4. Advisory Committee Recommendations and Related Issues

USEPA reiterates its request for comment on the following recommendations of the M–DBP Advisory Committee.

> A sanitary survey would be 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 system to evaluate the adequacy of the system, its sources and operations and the distribution of safe drinking water. Included in this definition is the concept that 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. Finally, for a sanitary survey to fall within this definition, it must address each of the eight elements in the December 1995 USEPA/State Guidance on Sanitary Surveys.
>
> In terms of frequency, this approach would provide that sanitary surveys must be conducted for all surface water systems (including ground water under the influence) no less frequently than every three years for community systems and no less frequently than every five years for noncommunity systems. Any sanitary survey conducted after December 1995, that addresses the eight sanitary survey components of the 1995 EPA/State guidance, may be counted or ‘‘grandfathered’’ for purposes of completing the round of surveys. This approach would also provide 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 than every five years.
>
> Finally, under this approach, as part of follow-up activity for sanitary surveys, systems must respond to deficiencies outlined in the State’s sanitary survey report within 45 days, indicating how and on what schedule the system will address significant deficiencies noted in the survey. In addition, States must 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.

USEPA also requests comment on whether systems should be required to respond in writing to a State’s sanitary survey report discussed in the paragraph above. USEPA also requests 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.’’

H. Covered Finished Water Reservoirs

1. Summary of the 1994 Proposal and Public Comments Received

The July 29, 1994, **Federal Register** indicated that USEPA was considering whether to issue regulations requiring systems to cover finished water reservoirs and storage tanks, and requested public comment. The rationale for this position was given in the proposed rule.

Most commenters supported either federal or State requirements. Some commenters suggested that regulations apply only to new reservoirs. Some commenters opposed any requirement, citing high cost, the notion that ‘‘one size does not fit all’’, and aesthetic benefits of an open reservoir.

Some commenters suggested elements for such regulations or guidance, including (1) applying the same criteria to finished water reservoirs as exists for unfiltered surface water systems, (2) using engineering measures to minimize contamination, (3) disinfecting the effluent to maintain residual in distribution system, (4) monitoring reservoirs routinely for water quality indicators, (5) covering all storage tanks, (6) fencing reservoirs with signs warning against swimming, trespassing, and tampering, and (7) adding notices in the annual water quality report that the reservoir is not in compliance with current waterworks standards. A few commenters suggested a number of other elements.

2. Overview of Existing Information

Possible Health Concerns: 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. It may be subject to contamination by persons tossing items into the reservoir or illegal swimming (Pluntze 1974; Erb, 1989).

Microscopic and other organisms may proliferate in open finished water reservoirs. 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., 1996; Geldreich, 1990; Fayer and Ungar, 1986; Current, 1986). Mammals, birds and fish and their carcasses seed the water and the sediment with total and fecal coliforms, *E. coli* and pathogens. 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). Seagulls are a source of numerous coliforms and can also be a source for several human pathogens, (Geldreich and Shaw, 1993). 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). Plants, macrophytes and organic debris will add to the biomass and nutrient supply.

State Regulations: In order to assess regulatory requirements at the State level, it is necessary to contact individual drinking water programs and collect and evaluate specific regulatory language obtained from those programs. 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.

Survey of Ten Utilities: There is no comprehensive information available on the number or size of open finished water reservoirs in water systems around the country; however, there is one recent survey of ten utilities which either have open finished water reservoirs or which had them in the past and covered or replaced them (E&S Environmental Chemistry, 1997). The existing open reservoirs which were operated by these systems varied greatly in size, from 5.5 million gallons (MG) to 900 MG. The systems with open finished reservoirs also had closed reservoirs within their service area, but for some of the systems the open reservoirs represent the largest component of total storage volume in the systems.

Most of the reservoirs in the systems in this survey were excavated and lined, but several of the larger ones were formed by dams or natural lakes that had been converted to water supply use. Many of these reservoirs have irregular geometry and configurations which make covering very difficult or impossible. Others are so large that covering them would be impractical. For some of these reservoirs, it is impractical to find locations for replacement with the proper hydraulic characteristics and size. To partially solve this problem in some cases, systems have chosen to leave large existing open reservoirs off-line, except for emergency supply purposes.

None of the systems had comprehensive evidence about the effect of open reservoirs on water quality. These water systems had instituted a number of measures at open reservoirs to control potential sources of contamination; these measures included fencing setbacks, security cameras, on-site surveillance, rechlorination, wire canopies to control bird activity, and other measures.

3. Request for Public Comment

USEPA is considering as part of the IESWTR 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. The Agency intends to further consider this issue, including 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 the Long-Term ESWTR. The Agency requests further comment on this issue and whether provisions should be established to require all new reservoirs, holding tanks, or other storage facilities to be covered.

I. Cross Connection Control Program

1. Summary of 1994 Proposal and Public Comments

The July 29, 1994, **Federal Register** 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 USEPA 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 USEPA should consider to prevent contamination of drinking water in the distribution system (e.g., minimum pressure requirements in the distribution system).

Most commenters supported either a federal or State cross connection control program. Various commenters recommended that such a program include a backflow prevention program with approved backflow preventer lists, categorization of all service connections with respect to potential risk of backflow, requirement for periodic testing and maintenance of backflow prevention devices, periodic review of program by State, establishment of an annual backflow device testing program, establishment of a backflow device inspector certification program, enforcement authority, and other suggestions. Commenters also recommended national disinfection procedures for repair of water lines and for placing new lines into service, a provision for at least one person trained in cross-connection control to carry out the program, and other suggestions.

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 program would be more appropriate than an USEPA-mandated program, (3) most States already have a comprehensive program, thus negating need for federal regulations, (4) USEPA 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.

2. Overview of Existing Information

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 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. Specific backflow incidents are described in detail in USEPA's Cross-Connection Control Manual (USEPA, 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.

Many States have cross connection control programs. 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 USEPA report suggests that the responsibility for administration and enforcement of the State programs is generally at the local level (USEPA, 1995a).

3. Request for Public Comment

USEPA does not plan to address cross connection control in the IESWTR. As noted above, many States currently have programs, although the extent to which these vary is unclear. The Agency does plan to consider cross connection control issues during the development of the Long-Term ESWTR, in the context of a broad range of issues related to distribution systems. USEPA continues to request comments or additional information related to cross connection control or other distribution system issues.

J. Recycling Filter Backwash Water and Filtering to Waste

The July 29, 1994, notice requested comment on the extent to which the ESWTR should address the issue of recycling filter backwash water, given its potential for increasing the densities of *Giardia* and *Cryptosporidium* on the filters. The 1996 Amendments to the SDWA require USEPA to promulgate a regulation for filter backwash recycling not later than August 2000, (SDWA 1412(b)(14)).

Most commenters who addressed this issue contended that backwash water should not be recycled or that, if it is recycled, it should be treated first. One commenter suggested that this decision should be based on the pathogen density in the backwash water. Another commenter suggested that the rule should include criteria for assessing the extent of backwash recycling, depending on raw water quality, size of filters, and water volume. Another commenter maintained that this issue should be left to the State and system. One commenter suggested that the impacts of recycling needed additional research and that any rule addressing this issue needed to incorporate the results of the latest research.

1. Filter Backwash Recycle Configurations

Treatment plants can be configured into several general categories but the variation within each category is significant.

One aspect of this treatment variation is how recycling of waste streams from plant processes are handled. Figure 4 shows a general schematic of a conventional treatment plant and how recycle streams may be developed and treated. Note that backwash water treatment is carried out in a miniature coagulation-flocculation-sedimentation treatment facility. Some utilities are considering microfiltration to replace these unit processes.

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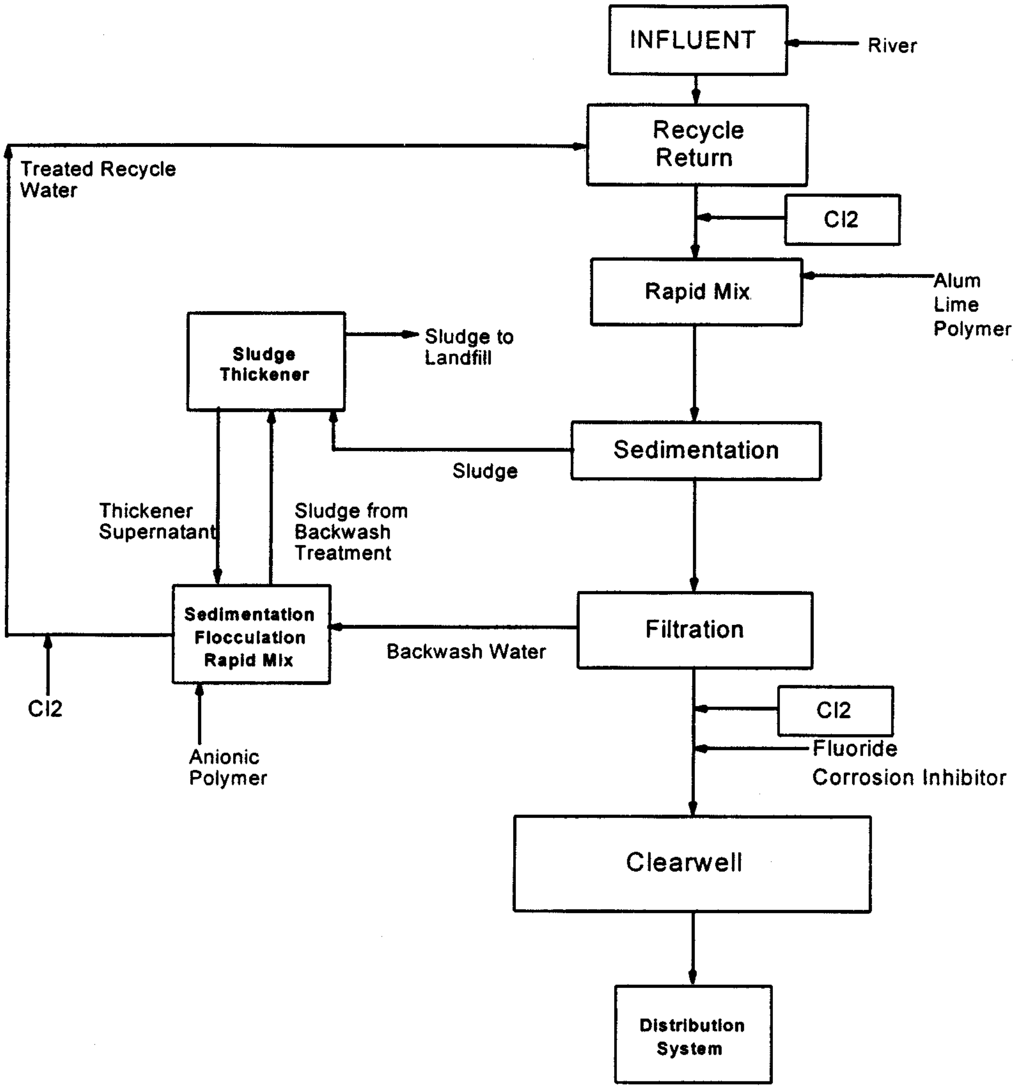

Figure 4. Schematic of Typical Waste Stream Recycle with Treatment

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Figure 5 shows an alternate view for some water treatment facilities that do not practice treatment of their recycled waste streams. There is an almost infinite variety between these two examples. In addition, waste streams can be recycled to many different points in the treatment train. The most common recycle points are at the plant influent or rapid mix. However, there are several known examples of recycle streams being introduced into the treatment process as late as the filter influent.

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Figure 5. Schematic of Typical Waste Stream Recycle without Treatment

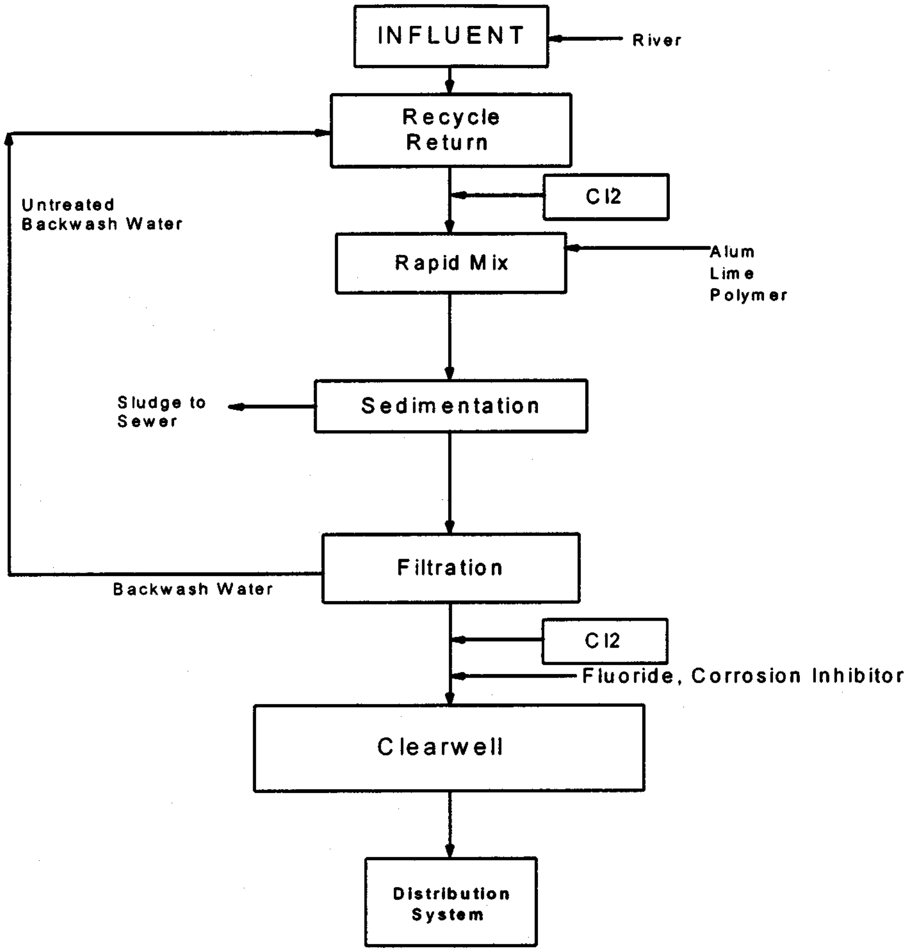

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Figure 6 shows a typical plot of turbidity over time from a filter from reintroduction into service after backwash to breakthrough of turbidity at the end of the filter run. Some plants have installed filter-to-waste facilities which allow the discharge of the first minutes of a filter's operation after backwashing usually into the backwash reclamation system. In California, the State drinking water regulations define filter-to-waste as: ' "Filter-to-waste" means a provision in a filtration process to allow the first filtered water, after backwashing a filter, to be wasted or reclaimed.' (McGuire, 1994)

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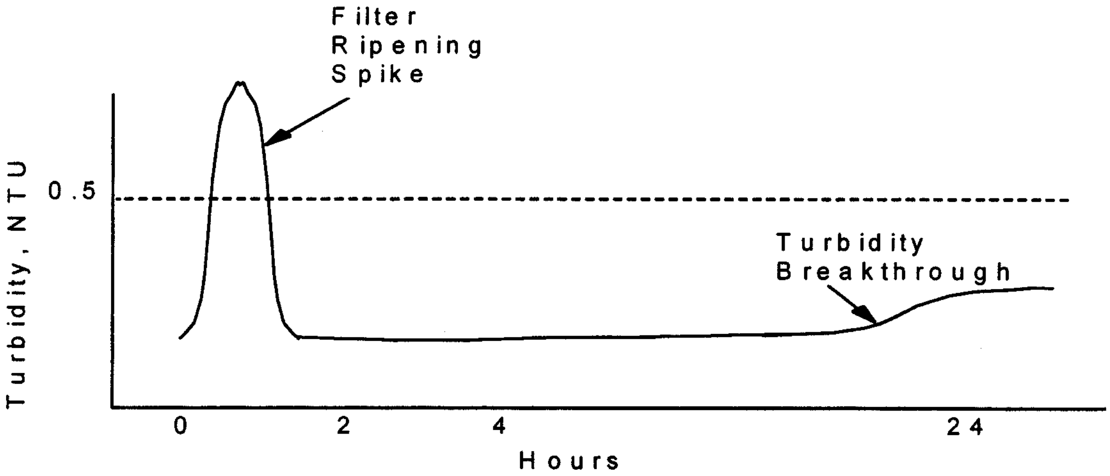

Figure 6. Plot of Turbidity Profile

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Figure 7 shows a general schematic of a filter-to-waste operation. After the backwash process is complete and the filter influent water is allowed to enter the filter, Valve A is operated so that all of the filter effluent water is sent to waste. After a specified period of time or when it is determined that the ripening spike is largely over, Valve A is operated so that the filtered water becomes part of the product water of the treatment plant.

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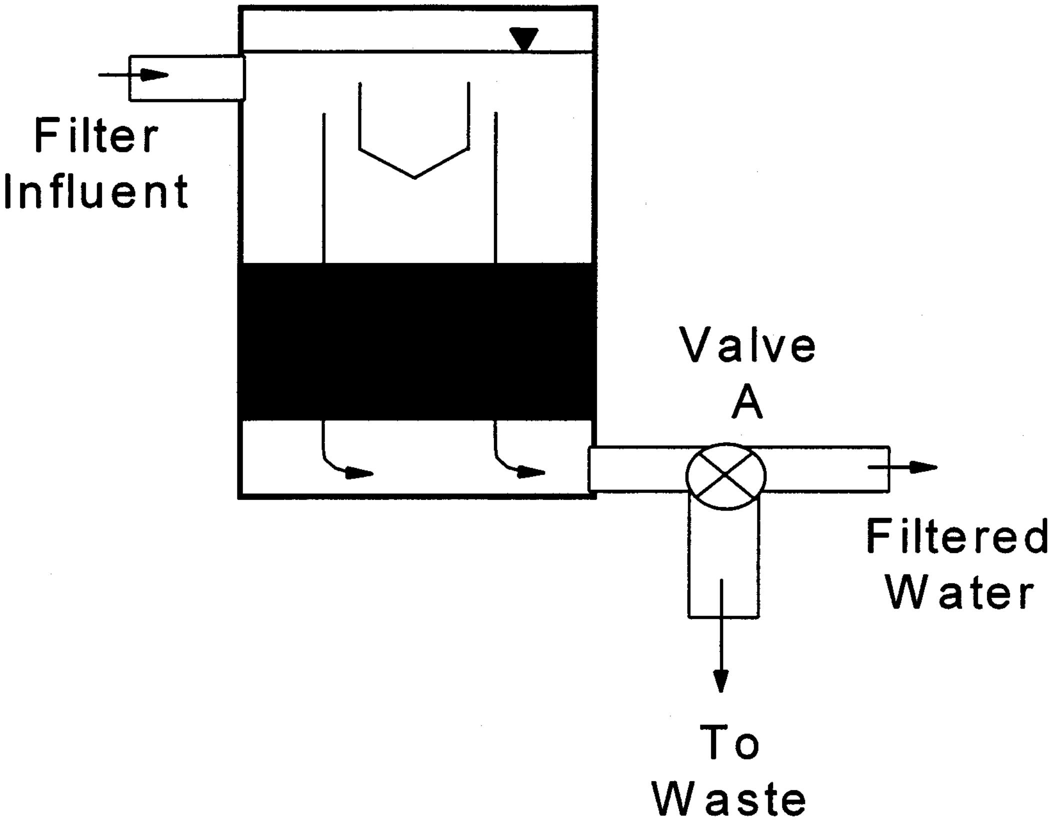
Figure 7. Filter-to-Waste Operation



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2. State Drinking Water Regulations

California has specific regulations that deal with backwash recycle and filter-to-waste. Treatment of backwash recycle flows is covered in the design of treatment facilities section. For new construction, utilities are required to install solids removal treatment for recycled filter backwash water. Also, treated backwash water must be returned to the ‘‘headworks’’ (i.e., the plant influent) of the treatment plant. Solids removal treatment unit processes are not specified in the regulation, but new construction must be approved by the California Department of Health Services (California Health and Safety Code, Sections 646658 & 64660).

To minimize the filter ripening spike, the California Department of Health specifies operational requirements such that filtration rates are increased gradually when filters are placed back into service following backwashing or any other interruption in the operation of the filter. When any individual filter is placed back into service following backwashing or other interruption event, the filtered water turbidity from that filter cannot exceed any of the following criteria:

- 2.0 NTU.
- 1.0 NTU in at least 90 percent of the interruption events during any consecutive 12-month period.
- 0.5 NTU after the filter has been in operation for 4 hours.

For new construction, utilities are required to provide filter-to-waste or add additional coagulant chemicals to backwash water.

3. Literature Overview of Standard of Practice

a. Treatment Reference Texts. The joint ASCE/AWWA (1990) water treatment plant design book includes one section on page 182 dealing with washwater disposal and recovery. The section lists several possibilities including recycling without treatment, equalization and treatment, and lagoons to provide for both equalization and sedimentation. On page 188, the backwash recycle facility at the Duluth, Minnesota plant is described. Chemical addition, flocculation and clarification comprise the backwash treatment system.

The fourth edition of Water Quality and Treatment contains one section on pages 988–989 dealing with filter backwash residuals. The section notes that recovery of ‘‘dirty’’ backwash water is becoming increasingly common and that the volume of backwash water is typically one to five percent of total plant production. Flow equalization is listed as the most common approach to dealing with recycling of backwash water. The section states that ‘‘For conventional plants, solid separation before return is not common, and some holding tanks are mixed to keep solids in suspension.’’ Direct filtration plants are noted for needing solids separation treatment of backwash water, because there is no sedimentation facility in a direct filtration plant. Concerns are expressed in the section about increasing the concentrations of *Giardia* cysts in the plant influent with the recycle of untreated backwash water.

A handbook of practice was published in 1987 dealing with water treatment plant waste management. Backwash water was described as a major waste stream on page 5 and flow equalization was listed as an important requirement. The handbook gives specific examples of the size of backwash basins needed based on the number of filters backwashed and the backwash frequency. The example discusses tankage volumes that would allow a maximum 10 percent recycle rate of the backwash water to the plant influent. Neither clarification nor polymer addition were mentioned in this early reference (Cornwell et al., 1987).

b. ICR Treatment Plants. Of the 523 treatment plants subject to the ICR, 282 use conventional treatment. Of the conventional treatment plants, 146 (or 52%) practice recycling of their backwash water. Additionally, 15 direct filtration plants and 3 in-line filter plants recycle their backwash water. These data show that a large fraction of the surface water treatment plants recycle their backwash water.

The ICR will provide the first detailed data on the number of treatment plants that treat their recycled backwash water and the technologies they use and some limited data on backwash water quality. Until the initial sampling plan data is available for analysis sometime in early 1998, the only information available on the ICR utilities is from their Initial Sampling Schematics and that will only show the addition of a treatment chemical. The Initial Sampling Schematics do not indicate if coagulation, flocculation or sedimentation is used for washwater recycle treatment.

An inspection of those schematics revealed the following information on treatment of recycled backwash water. A total of 164 schematics for plants using conventional treatment, direct filtration or in-line filtration were examined. Only 12 of the plants indicated that they provided any chemical treatment. Addition of a polymer was practiced at 5 plants. Chlorination as the only treatment of the recycled washwater was found at 2 plants. A total of 5 plants provided both chlorination and polymer treatment of the backwash water.

c. Cornwell and Lee 1993 Report. Another source of information on waste stream quality and the impact of recycling of these streams on treated water quality is found in an American Water Works Association Research Foundation (AWWARF) 1993 report authored by Cornwell and Lee. They studied the quality characteristics of waste streams from 24 treatment plants and investigated the treatment characteristics in some detail at 8 plants.

Among the contaminants analyzed were *Giardia* and *Cryptosporidium*. The study found that filter backwash water could have very high cyst/oocyst concentrations and chemical loads. However, the researchers found no finished water quality problems as a result of recycling.

The study found that backwash water sedimentation was effective in reducing particle and pathogen concentrations in the used filter backwash water. However, very low overflow rates (less than 0.05 gpm/sf) of the sedimentation basin were required to achieve the solids removal unless a polymer was used. Using an anionic polymer increased the particle removals and allowed sedimentation overflow rates of 0.2 to 0.3 gpm/sf. The last two sentences of the Executive Summary of the report provide insight into the overall findings.

> ‘‘The use of equalized, continuous recycle, proper waste stream treatment prior to recycle, and characterization of waste stream quality through proper monitoring should be used in conjunction with recycle operations. If these recommendations are used, recycle can be an appropriate part of water treatment operations (Cornwell and Lee, 1993).’’

In a paper which summarized the report findings, the authors stated a general rule that the recycle streams should be flow equalized and blended in to the plant flow over the entire 24 hour plant operating cycle. The rule of thumb that the amount of recycle should be less than 10 percent of the plant flow may not be sufficient, and a lower percentage of recycle may have to be practiced depending on the quality of the recycled water (Cornwell and Lee, 1994).

d. Other Studies. In 1996, AWWA conducted a survey of treatment plants to determine the extent of backwash water recycling and the treatment provided to that water (McGuire, 1997). A total of 400 plants from utilities serving more than 100,000 people were contacted. About 40 percent of those plants responded. Of those responding, about 60 percent of the plants recycled their filter backwash water. The other 40 percent appeared to discharge the backwash water to a surface water supply or to a sanitary sewer. Of the plants that recycled their backwash water, 27 percent responded that they treated the recycle water. The important point to note from this limited survey is that recycle of backwash water appears to be a common practice among water treatment plants.

4. Filter-to-Waste

One possible concern is the discharge of large number of particles from filters that are put back into service after backwashing. Work done on *Giardia* removal by filtration at Fort Collins, Colorado, indicated that a filter-to-waste period was not necessary to produce low *Giardia* filter effluent levels as long as proper chemical preconditioning of the filter was practiced (Gertig et al. 1988). Logsdon et al. studied sedimentation and several different filter media from removing *Giardia* cysts at McKeesport, Pennsylvania. *Giardia* cyst concentrations were found to be higher at the beginning of the filter run, indicating that filter-to-waste may be needed to reduce the levels of *Giardia* in the finished water (Logsdon et al, 1985).

One study (Amirtharajah, 1988) indicated that more than 90% of the particles that pass through a filter do so during the initial stages of filtration. Another study (Logsdon et al., 1981) found that initial cyst concentrations in the effluent, after backwash, were from 10 to 25 times higher than those in the stabilized filter run, even though the difference in turbidity was less than 0.1 NTU. One British study (Hall and Croll 1996) found that in one test filter run, calculation of the total number of particles released during the whole run showed that up to 30% of the particles were released during the first hour of filter ripening. The turbidity during this peak was 0.4 NTU. Gradual start of the filter after backwashing reduced the peak particle count in the effluent. Effectiveness of practicing filter-to-waste in reducing the passing of oocysts depends on the duration of the ripening period. For example, a 15 minute filter-to-waste period will not be very effective for a ripening period of 2 hours. Mid and end-of-run turbidity spikes can also pass large number of particles (including pathogen oocysts) into the effluent. However, these latter spikes can be controlled by avoidance of flow changes and by timely backwashing the filter.

5. Request for Public Comment

USEPA does not plan to include separate provisions for recycling of filter backwash water and filter-to-waste issues in the IESWTR. The Agency anticipates that some systems will address these issues as part of their efforts to comply with revised turbidity performance standards of 0.3 NTU for the 95th percentile of monthly measurements and a maximum turbidity level of 1 NTU. As previously discussed in this Notice, USEPA is required under the 1996 Amendments to the SDWA to issue a regulation to address filter backwash recycling by August 2000. USEPA plans to develop these regulations in conjunction with the development of the Long-Term ESWTR. USEPA continues to request comments or additional information related to recycling of filter backwash water or filter-to-waste issues.

K. 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.’’ The 1996 Amendments to the SDWA require USEPA to undertake several actions with regard to operator certification, including the publication of guidelines specifying minimum standards.

Of the few commenters who addressed this issue most asserted that minimum certification criteria for water operators should be left to the States. One commenter contended that certified operator(s) should be on site at all times and that a non-certified operator should never be in charge. Another respondent noted that rewording § 141.70 to read ‘‘personnel who are certified by the State, or can obtain certification within one year of date of employment’’ will adequately define certification criteria.

Consistent with the 1996 SDWA amendments, USEPA appointed an Operator Certification Working Group of the National Drinking Water Advisory Council (NDWAC) to form a partnership with States, water systems and the public to develop information on recommended operator certification requirements. USEPA will publish guidelines specifying minimum standards for certification (and recertification) of operators of community and nontransient noncommunity public water systems. USEPA is developing the draft guidelines based on recommendations from the NDWAC. The draft guidelines, when available, will be published in the **Federal Register** for public review and comment. Members of the public who are interested in further information regarding this effort may contact Richard Naylor of USEPA's Office of Ground Water and Drinking Water at 202–260–5135 or at e-mail address: naylor.richard@epamail.epa.gov.

L. Regulatory Compliance Schedule and Other Compliance-Related Issues

A. Regulatory Compliance Schedule

Background

During the 1992 Disinfectants/Disinfection Byproducts Regulatory Negotiation (reg-neg) that resulted in the 1994 proposed Stage 1 DBPR and proposed IESWTR, there was extensive discussion of the compliance schedule and applicability to different groups of systems and coordination of timing with other regulations.

In addition to the Stage 1 DBPR, the Negotiating Committee agreed that EPA would (a) propose an interim ESWTR which would apply to surface water systems serving 10,000 or more people, and (b) at a later date, propose a long-term ESWTR applying primarily to small systems under 10,000. Both of these microbial rules would be proposed and promulgated so as to be in effect at the same time that systems of the respective size categories would be required to comply with new regulations for disinfectants and DBPs. Finally, although the GWDR was not specifically addressed during the reg-neg, EPA anticipated that it would be promulgated at about the same time as the IESWTR and Stage 1 DBPR.

EPA proposed a staggered compliance schedule, based on the reg-neg results. The Negotiating Committee and EPA believed that such a process was needed for the rules to be properly implemented by both States and PWSs. Also, EPA proposed a staggered schedule to achieve the greatest risk reduction by providing that larger water systems were to come into compliance earlier than small systems (to cover more people earlier), and surface water systems were to come into compliance earlier than ground water systems (since the potential risks of both pathogens and DBPs were considered generally higher for surface water systems). Large and medium size surface water PWSs (serving at least 10,000 people) constitute less than 25% of community water systems using surface water and less than 3% of the total number of community water systems, but serve 90% of the population using surface water and over 60% of the population using water from community water systems. These large PWSs are also those with experience in simultaneous control of DBPs and microbial contaminants. EPA proposed that these systems be required to comply with the Stage 1 DBPR and IESWTR 18 months after promulgation of the rules and that States would be required to adopt the rules no later than 18 months after promulgation. These 18 month periods were prescribed in the 1986 SDWA Amendments.

Surface water PWSs serving fewer than 10,000 people were to comply with the Stage 1 DBPR requirements 42 months after promulgation, to allow such systems to simultaneously come into compliance with the LTESWTR. This compliance date reflected a schedule that called for the LTESWTR to be promulgated 24 months after the IESWTR was promulgated and for PWSs then to have 18 months to come into compliance. Such a simultaneous compliance schedule was intended to provide the necessary protection from any downside microbial risk that might otherwise result when systems of this size attempted to achieve compliance with the Stage 1 DBPR.

Ground water PWSs serving at least 10,000 people would also be required to achieve compliance with the Stage 1 DBPR 42 months after promulgation. A number of these systems, due to recently installing or upgrading to meet the GWDR (which EPA planned to promulgate at about the same time as the Stage 1 DBPR), were expected to need some period of monitoring for DBPs in order to adjust their treatment processes to also meet the Stage 1 DBPR standards.

1996 Safe Drinking Water Act Amendments

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. Second, Congress explicitly adopted the staggered M–DBP regulatory development schedule developed by the Negotiating Committee. Section 1412(b)(2)(C) requires that the standard setting intervals laid out in EPA's proposed ICR rule be maintained even if promulgation of one of the M–DBP rules was delayed. As noted above, this 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.

The SDWA 1996 Amendments also changed two statutory provisions that elements of the 1992 Negotiated Rulemaking Agreement were based upon. As outlined above, the 1994 Stage 1 DBPR and ICR proposals provided that 18 months after promulgation large PWSs would comply with the rules and States would adopt and implement the new requirements. 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.

Discussion

In light of the 1996 SDWA amendments, developing a compliance deadline strategy that encompasses both the Stage 1 DBPR and IESWTR, as well the related LTESWTR and Stage 2 DBPR, is a complex challenge. On the one hand, such a strategy needs to reflect new statutory provisions. On the other, it needs to continue to embody key reg-neg principles reflected in both the 1994 ICR and Stage 1 DBPR proposals; principles that both Congressional intent and the structure of the new Amendments, themselves, indicate must be maintained.

An example of the complexity that must be addressed is the relationship between the principles of risk/risk tradeoff, simultaneous compliance, and the staggered regulatory schedule adopted by Congress. Under the 1996 SDWA amendments, the staggered regulatory deadlines under Section 1412(b)(2)(C) call for the IESWTR and Stage 1 DBPR to be promulgated in November 1998 and the LTESWTR in November of 2000. However, a complicating factor reflected in the Negotiated Rulemaking Agreement of 1992 and contained in the 1994 ICR, IESWTR, and Stage 1 DBPR proposals, is that Stage 1 applies to all PWSs, while IESWTR applies only to PWSs over 10,000, and the LTESWTR covers remaining surface water systems under 10,000.

One approach might be to simply provide that each M–DBP rule becomes effective 3 years after promulgation in accordance with the new SDWA provisions. For surface water systems over 10,000, each plant would be required to comply with related microbial and DBP requirements at the same time thereby minimizing potential risk/risk tradeoffs. For surface water systems under 10,000, however, this approach would result in a very large number of smaller plants complying with DBP requirements two years before related LTESWTR microbial provisions became effective, thereby creating an unbalanced risk tradeoff situation that the Negotiating Committee, EPA, and Congress each sought to avoid.

As this example suggests, given the staggered regulatory development schedule developed by stakeholders in the reg-neg process and adopted by Congress, there is a difficult inconsistency between the principle of avoiding risk tradeoffs, simultaneous compliance, and simply requiring all facilities to comply with applicable M–DBP rules three years after their respective promulgation. The challenge, then, is to give the greatest possible meaning to each of the new SDWA provisions while adhering to the fundamental principles also endorsed by Congress of addressing risk-risk tradeoffs and assuring simultaneous compliance.

A further question that must be factored into this complex matrix is how to address the relationship between promulgation of a particular rule, its effective date, and its adoption by a primacy State responsible for implementing the Safe Drinking Water Act. Under the 1994 IESWTR and Stage 1 DBPR proposals, the rule's 18 month effective date was the same as the 18 month date by which a State was required to adopt it. This approach reflected the 18 month SDWA deadlines applicable during reg-neg negotiations and at the time of proposal.

The difficulty with requiring PWS compliance and State implementation by the same date is that States may not have enough lead time to adopt rules, train their own staff, and develop policies to implement and enforce new rules by the deadline for PWS compliance. In situations where the new rules are complex and compliance requires state review and ongoing interaction with PWSs, successful implementation can be very difficult, particularly for States with many small systems that have smaller staffs and fewer resources to anticipate the requirements of final rules. As noted above, Congress addressed this issue by extending the time for States to put their own rules in place from 18 months to two years after federal promulgation and, then, by generally providing for a one year interval before PWSs must comply (three years after promulgation). As a result, the 18 month interval contemplated by the 1994 proposals is no longer applicable, and the approach of setting the same date for PWS compliance and State rule implementation is no longer consistent with the phased approach laid out in the new SDWA amendments.

A final set of issues that must be addressed in connection with the Stage 1 DBPR proposal are compliance deadlines for ground water systems that currently disinfect. Reflecting the Negotiated Rulemaking Agreement, the 1994 proposal provided that ground water systems serving at least 10,000 that disinfect must comply three and one half years (42 months) after Stage 1 DBPR promulgation. Small ground water systems serving fewer than 10,000 that disinfect would be required to come into compliance five years (60 months) after Stage 1 DBPR promulgation. Again, the challenge here is to reconcile new statutory compliance provisions with the principles of simultaneous compliance, avoiding risk/risk tradeoffs, and deference to Congress' clear intent to preserve the ''delicate balance that was struck by the parties in structuring the negotiated rulemaking agreement''. (Joint Explanatory Statement of the Committee on Conference on S.1316, p2). An additional factor that must be considered in this context is that Congress affirmed the need for microbial ground water regulations but also clearly contemplated that such standards might not be promulgated until issuance of Stage 2 DBPR (no later than May, 2002).

Alternative Approaches

In light of the 1996 SDWA amendments and their conflicting implications for different elements of the compliance strategy agreed to by the Negotiating Committee and set forth in the 1994 IESWTR and Stage 1 DBPR proposals, EPA is today requesting comment on four alternative compliance approaches. The Agency also requests comment on any other compliance approaches or modifications to these options that commenters believe may be appropriate.

OPTION 1.—IMPLEMENT 1994 PROPOSAL SCHEDULE

Rule (promulgation)	Surface water PWS		Ground water PWS	
	≥10k	<10k	≥10k	<10k
DBP 1 (11/98)	5/00	5/02	5/02	11/03
IESWTR (11/98)	5/00	NA	NA	NA
LTESWTR (11/00)	[1] 5/02	5/02	NA	NA
GWDR (11/00)	NA	NA	([2])	([2])

[1] (If required).
[2] Not addressed.

Option 1 (schedule as proposed in 1994) simply continues the compliance strategy laid out in the 1994 Stage 1 DBPR and IESWTR proposals. This would provide that medium and large surface water PWSs (those serving at least 10,000 people) comply with the final Stage 1 DBPR and IESWTR within 18 months after promulgation, and that surface water systems serving fewer than 10,000 comply within 42 months of Stage 1 DBPR promulgation. This option also would provide that ground water systems serving at least 10,000 and that disinfect comply within 42 months, while ground water systems serving fewer than 10,000 comply within 60 months.

This approach was agreed to by EPA and other stakeholder members of the 1992 Negotiating Committee. However, it has been at least in part superseded by both the general 36 month PWS compliance period and the 24 month State adoption and implementation period provided under the 1996 SDWA amendments. If the proposed 1994 compliance schedule were to be retained, EPA would need to make a determination that the statutory compliance provision of 36 months was not necessary for large and medium surface systems because compliance within 18 months is ‘‘practicable’’. To maintain simultaneous compliance, the Agency would also have to make the same practicability determination for small surface water systems in complying with the LTESWTR and for ground water systems serving at least 10,000 in complying with the GWDR. In addition, the Agency would need to justify 42 months for small surface water systems and 60 months for small ground water systems with disinfection by making a national determination that the additional time was required due to the need for capital improvements at each of these small systems. EPA also would need to articulate a rationale for why States should not be provided the statutorily specified 24 months to implement new complex regulatory provisions before PWSs are required to comply. Finally, to implement this approach, the Agency would be required to modify the timing associated with the microbial backstop provision agreed to on July 15, 1997 by the M–DBP Advisory Committee (since a 18 month schedule would not allow time after promulgation for medium surface water systems (10,000–99,999) to collect HAA data prior to having to determine whether disinfection benchmarking is necessary).

EPA requests comment on the issues outlined above in connection with this option. In particular, the Agency requests comment and information to support a finding that compliance by specified systems in 18 months is practicable for some rules, and that extensions to 42 or 60 months for other systems are required to allow for capital improvements.

OPTION 2.—ADD 18 MONTHS TO 1994 PROPOSAL SCHEDULE

Rule (promulgation)	Surface water PWS		Ground water PWS	
	≥10k	<10k	≥10k	<10k
DBP 1 (11/98)	11/01	11/03	11/03	5/05
IESWTR (11/98)	11/01	NA	NA	NA
LTESWTR (11/00)	[1] 11/03	11/03	NA	NA
GWDR (11/00)	NA	NA	([2])	([2])

[1] (If required).
[2] Not addressed.

Option 2 (each date in proposed 1994 compliance strategy extended by 18 months) reflects the fact that the 1996 SDWA amendments generally extended the previous statutory deadlines by 18 months (to three years) and established an overall compliance period not to extend beyond 5 years. This second approach would result in simultaneous compliance for surface water systems. Large surface water systems (those serving at least 10,000) would have three years to comply in accordance with the baseline 3 year compliance period established under Section 1412(b)(10) of the 1996 Amendments.

Small surface water systems (under 10,000) would be required to comply with Stage 1 D/DBPR requirements within five years and applicable LTESWTR requirements within three years. Since the LTESWTR will be promulgated two years after Stage 1 DBPR (in accordance with the new SDWA M–DBP regulatory deadlines discussed above), the net result of this approach is that small surface water systems would be required to comply with both Stage 1 DBPR and IESWTR requirements by the same end date of November 2003, thus assuring simultaneous compliance. This meets the objective of both the reg-neg process and Congress to address risk-risk tradeoffs in implementing new M–DBP requirements.

USEPA believes that providing a five year compliance period for small surface water systems under the Stage 1 DBPR is appropriate and warranted under section 1412(b)(10), which expressly allows five years where necessary for capital improvements. Of necessity, capital improvements require preliminary planning and evaluation. Such planning requires, perhaps most importantly, identification of final compliance objectives. This then is followed by an evaluation of compliance alternatives, site assessments, consultation with appropriate state and local authorities, development of final engineering and construction designs, financing, and scheduling. In the case of the staggered M–DBP regulatory schedule established as part of the 1996 SDWA amendments, LTESWTR microbial requirements for small systems are required to be promulgated two years after the establishment of Stage 1 DBPR requirements. Under these circumstances, small systems will not even know what their final combined M–DBP compliance obligations are until **Federal Register** publication of the final LTESWTR. As a result, an additional two year period reflecting the two year Stage 1 DBPR/LTESWTR regulatory development interval established by Congress is required to allow for preliminary planning and evaluation which is an inherent component of any capital improvement process. EPA believes this approach is consistent with both the objective of assuring simultaneous compliance and not exceeding the overall statutory compliance period of five years. This same logic would also apply to ground water systems serving at least 10,000, since such systems would need the final GWDR to determine and implement a compliance strategy.

With regard to extended compliance schedules, EPA notes that the economic analysis developed as part of the M–DBP Advisory Committee indicates that there will be capital costs associated with implementation of both the IESWTR as well as the Stage I DBP rules. As outlined above, the 1996 SDWA amendments provide that a two year extension may be provided by EPA at the national level or by States on a case-by-case basis if either EPA or a State determines that additional time is necessary for capital improvements. EPA does not believe there is data presently in the record for either of these rulemakings to support a national determination by the Agency that a two-year extension is justified. EPA requests comment on this issue and, if a commenter believes such an extension is warranted, requests that the comments provide data to support such a position.

Adding 18 months to the 1994 proposed compliance strategy would result in 78 month (six and a half year) compliance period for small ground water systems. This is beyond the overall five year compliance period established by Congress under Section 1412(b)(10). EPA is not aware of a rationale to support this result that is consistent with both the objectives of the reg-neg process and the new SDWA amendments; however, the Agency requests comment on this issue. As discussed below, EPA believes there is a reasonable compliance strategy for addressing ground water systems that reflects the requirements of the SDWA amendments as well as the intent of the reg-neg process.

OPTION 3.—REQUIRE COMPLIANCE WITH ALL RULES WITHIN THREE YEARS OF PROMULGATION

Rule (promulgation)	Surface water PWS		Ground water PWS	
	≥10k	<10k	≥10k	<10k
DBP 1 (11/98)	11/01	11/01	11/01	11/01
IESWTR (11/98)	11/01	NA	NA	NA
LTESWTR (11/00)	[1] 11/03	11/03	NA	NA
GWDR (11/00)	NA	NA	11/03	11/03

[1] (If required).

Under this approach, all systems would be required to comply with Stage 1 DBPR, IESWTR, and LTESWTR within three years of final promulgation. This approach reflects the baseline three year compliance period included as part of the new SDWA compliance provisions. Unlike option 2 outlined above which simply adds an 18 month extension to the 1994 proposed compliance approach, this option is not tied to the 1994 proposal. Rather it applies the new baseline three year compliance period to the staggered M–DBP regulatory development schedule which was also established as part of the 1996 SDWA amendments.

This approach would result in simultaneous compliance for large surface water systems. However, it would eliminate the possibility of simultaneous compliance for small surface water systems and all ground water systems. Contrary to reg-neg objectives and Congressional intent, it would create an incentive for risk/risk tradeoffs on the part of small surface water systems who would be required to take steps to comply with Stage 1 DBPR provisions two years before coming into compliance with the LTESWTR, and for all ground water systems who would be required to take steps to comply with Stage 1 DBPR provisions two years before coming into compliance with the GWDR.

OPTION 4.—MERGE SDWA PROVISIONS WITH NEGOTIATED RULEMAKING OBJECTIVES

Rule (promulgation)	Surface water PWS		Ground water PWS	
	≥10k	<10k	≥10k	<10k
DBP 1 (11/98)	11/01	11/03	11/03	11/03
IESWTR (11/98)	11/01	NA	NA	NA
LTESWTR (11/00)	[1] 11/03	11/03	NA	NA
GWDR (11/00)	NA	NA	11/03	11/03

[1] (If required).

This option combines the principle of simultaneous compliance with the revised compliance provisions reflected in the 1996 SDWA amendments. Large surface water systems would be required to comply with Stage 1 DBPR and IESWTR within 3 years of promulgation, thus assuring simultaneous compliance and consistency with the baseline statutory compliance period of 3 years. Small surface water systems under 10,000 would comply with the provisions of the Stage 1 DBPR at the same time they are required to come into compliance with the analogous microbial provisions of the LTESWTR. This would result in small surface water systems simultaneously complying with both the LTESWTR and Stage 1 DBPR requirements. Under this approach, small systems would comply with LTESWTR requirements three years after promulgation and Stage 1 DBPR requirements five years after promulgation. For the reasons articulated under option two above, EPA believes providing a five year compliance period under Stage 1 DBPR is appropriate and necessary to provide for capital improvements.

For ground water systems, the 1994 proposed Stage 1 DBPR compliance schedules provided for only one half of the risk-risk tradeoff balance. They did not include a companion rule development and compliance schedules for the analogous microbial provisions of a Ground Water Disinfection Rule. The 1996 SDWA amendments provide an outside date for promulgation of ground water microbial requirements of ‘‘no later than’’ May 2002, but leave to EPA the decision of whether an earlier promulgation is more appropriate. In light of the reg-neg emphasis and Congressional affirmation of the principal of simultaneous compliance to assure no risk-risk tradeoffs, EPA has developed a ground water disinfection rule promulgation schedule that will result in a final GWDR by November 2000, the same date as the Congressional deadline for the LTESWTR. Ground water systems would be required to comply with the GWDR by November 2003, three years after promulgation, and to assure simultaneous compliance with DBP provisions, such systems would be required to comply with Stage 1 DBPR requirements by the same date. Again, for the reasons outlined under option 2, USEPA believes a five year compliance period for ground water systems is necessary and appropriate.

Option 4 assures that ground water systems will be required to comply with Stage 1 DBPR provisions at the same time that they comply with the microbial provisions of the Ground Water Disinfection Rule (GWDR). Successful implementation of this option requires that EPA develop and promulgate the GWDR by November 2000 as indicated above. The Agency recognizes that this is an ambitious schedule, but believes it is necessary to meet the twin objectives of simultaneous implementation and consistency with the new statutory compliance provisions of the 1996 SDWA. In evaluating this option, the Agency also considered the possibility of meeting these twin objectives in a somewhat different fashion by delaying final promulgation of the Stage I DBP rule as it applies ground water systems until the promulgation of the GWDR. This alternative possibility would assure simultaneous compliance and also provide a ‘‘safety net’’ in the event that the GWDR November 2000 promulgation schedule is delayed. EPA is concerned, however, that this approach may not meet or be consistent with new SDWA requirements which provide that the Stage I DBPR be promulgated by November 1998. The Agency requests comment on this issue.

Recommendation

EPA has evaluated each of the considerations identified in Options 1 through 4. On balance, the Agency believes that Option 4 is the preferred option. The primary reasons are (1) to allow States at least two years to adopt and implement M–DBP rules consistent with new two year time frame provided for under the 1996 SDWA amendments, (2) to match the compliance schedules for the LTESWTR and Stage 1 DBPR for small (<10,000 served) surface water systems to allow time for capital improvements and addressing risk-risk tradeoff issues, and (3) to assure that all ground water systems simultaneously comply with newly applicable microbial and Stage 1 DBPR requirements on the same compliance schedule provided for small surface water systems.

Request for Comments

EPA requests comment on both the compliance schedule options discussed above and on any other variations or combinations of these options. EPA also requests comment on its preferred option 4 and on the underlying rationale for allowing a five year compliance schedule for ground water and small surface water systems under the Stage 1 DBPR.

B. Compliance Violations and State Primacy Obligations

A public water system that fails to comply with any applicable requirement of the SDWA (as defined in 1414 (I)) is subject to an enforcement action and a requirement for public notice under the provisions of section 1414. Applicable requirements include, but are not limited to, MCLs, treatment techniques, monitoring and reporting. These regulatory requirements are set out in 40 CFR l41.

The SDWA also requires States that would have primary enforcement responsibility for the drinking water regulations (‘‘primacy’’) to adopt regulations that are no less stringent than those promulgated by EPA. States must also adopt and implement adequate procedures for the enforcement of such regulations, and keep records and make reports with respect to these activities in accordance with EPA regulations. 5 U.S.C. 1413. EPA may promulgate regulations that require States to submit reports on how they intend to comply with certain requirements (e.g., how the State plans to schedule and conduct sanitary surveys required by the IESWTR), how the State plans to make certain decisions or approve PWS-planned actions (e.g., approve significant changes in disinfection under the IESWTR or approve Step 2 DBP precursor removals under the enhanced coagulation requirements of the Stage I DBPR), and how the State will enforce its authorities (e.g., correct deficiencies identified by the State during a sanitary survey within a specified time). The primacy regulations are set out in 40 CFR 142.

EPA drafted requirements for both the PWSs (part 141) and the primacy States (part 142) in the proposed rules. EPA is requesting comments on whether there are elements of the Advisory Committee’s recommendations in this Notice that should be treated as applicable requirements for the PWS and included in part l41 as enforceable requirements. Similarly, EPA requests comments on whether there are elements of the Advisory Committee’s recommendations in this Notice that should be treated as requirements for States and included in part 142 as primacy requirements.

C. Compliance With Current Regulations

EPA reaffirms its commitment to the current Safe Drinking Water Act regulations, including those related to microbial pathogen control and disinfection. Each public water system must continue to comply with the current rules while new microbial and disinfectants/disinfection byproducts rules are being developed.

M. Disinfection Studies

1. New *Giardia* Inactivation Studies at High pH Levels

The Surface Water Treatment Rule (SWTR) requires plants treating surface water to meet minimum inactivation/removal requirements for *Giardia* cysts and viruses. Under the SWTR, the concept of CT values (disinfectant residual concentration (C) multiplied by contact time (T)) is used for estimating inactivation efficiency of disinfection practices in plants. As a supplement to the rule, USEPA published a guidance manual document entitled ''Guidance Manual for Compliance with the Filtration and Disinfection Requirements for Public Water Systems Using Surface Water Sources'' (USEPA 1991a) [SWTR Guidance Manual]. In this manual, CT tables (Log inactivation versus CT values under different environmental conditions) are provided to utilities as a guidance in carrying out the disinfection requirements.

The SWTR Guidance Manual did not include CT values at pH values above 9 due to the limited research results available at the time of rule promulgation. pH values above 9 mainly exist in plants with lime softening processes. An approach for extending the existing CT tables in the SWTR Guidance Manual to the upper pH boundary (pH 11.5) that may occur in some plants is presented below. With this approach, the latest available data reported by Logsdon et al. (1994) was used as a basis for CT values at high pH values by applying a linear regression to Logsdon's experimental results in laboratory water and a safety factor to cover the variability in natural water.

Analysis of Logsdon's Data: Logsdon et al. (1994) performed *Giardia* inactivation experiments with free chlorine in both laboratory and natural waters at 5°C and at pH values of 9.5, 10.5, and 11.5. The analysis of MW-s's data is performed with the following assumptions:

1. Since the experimental data of MW-s et al. for CT values vs. log inactivation are relatively scattered, a sophisticated model will not improve the result of simulation. Rather, a linear regression was used to fit these data points, by assuming the dilution coefficient n=1 in the conventional Watson's Law (first-order kinetics).

2. Data points for inactivation greater than 3-logs in the Logsdon et al. report are not included in the linear regression because of their uncertainty.

3. Data points for natural water have a greater variability than those for laboratory water. Also, CT tables in the SWTR Guidance Manual were developed solely based on tests using laboratory water. To ensure consistency, therefore, data points for natural water from the Logsdon et al. study were not used. However, a safety factor was applied to the CT values estimated from laboratory data to reflect the variability of inactivation results in natural water.

4. To be consistent, the safety factor of CT values at pH > 9 is assumed to be the same as that for the existing CT values in the SWTR Guidance Manual at pH ≤ 9. To appropriately quantify a safety factor being applied to obtain those existing CT values in the SWTR Guidance Manual, the previous data base for pH ≤ 9 was reevaluated and interpreted in the same manner as that for pH > 9 (using a linear regression and a safety factor). Subsequently, the safety factor was set at a value such that, if multiplied by the CT values estimated by a linear regression, the resultant CT values would match the existing CT values in the SWTR Guidance Manual.

5. For determination of a safety factor, data from the following studies were considered: Jarroll et al. (1981), Rice et al. (1982), Hibler et al. (1987), and Rubin et al. (1989) [Those data were used as a basis for developing the existing CT values in the SWTR Guidance Manual.]. Only the data from Jarroll et al. (1981) were used in the linear regression because the protocols or conditions in other studies are not comparable to those used in the study by Logsdon et al. (1994), as noted below:

(1) The study by Hibler et al. (1987) was based on animal infectivity tests. Excystation was used in the study by Logsdon et al. (1994).

(2) The study by Rubin et al. (1989) was conducted only at 15°C while the study by Logsdon et al. (1994) was performed at 5°C.

(3) No data for control excystation was shown in the study by Rice et al. (1982) and therefore this data was not used in the regression analysis.

The data from Jarroll et al. (1981) for chlorine concentrations of 4 and 8 mg/L were not used in the regression analysis because the chlorine residual in the study by Logsdon et al. (1994) was no higher than 2.1 mg/L.

The Results of Data Analysis: The data from Jarroll et al. (1981) pertaining to log inactivation versus CT values are plotted in Figures 8—10 for pH values of 6, 7, and 8, respectively. Because Jarroll et al. found that essentially no inactivation at pH values of 6–8 was observed in control samples in which no disinfectant was added within 60 minutes (i.e., CT = 0, log inactivation = 0), the intercept of the linear regression line was zero.

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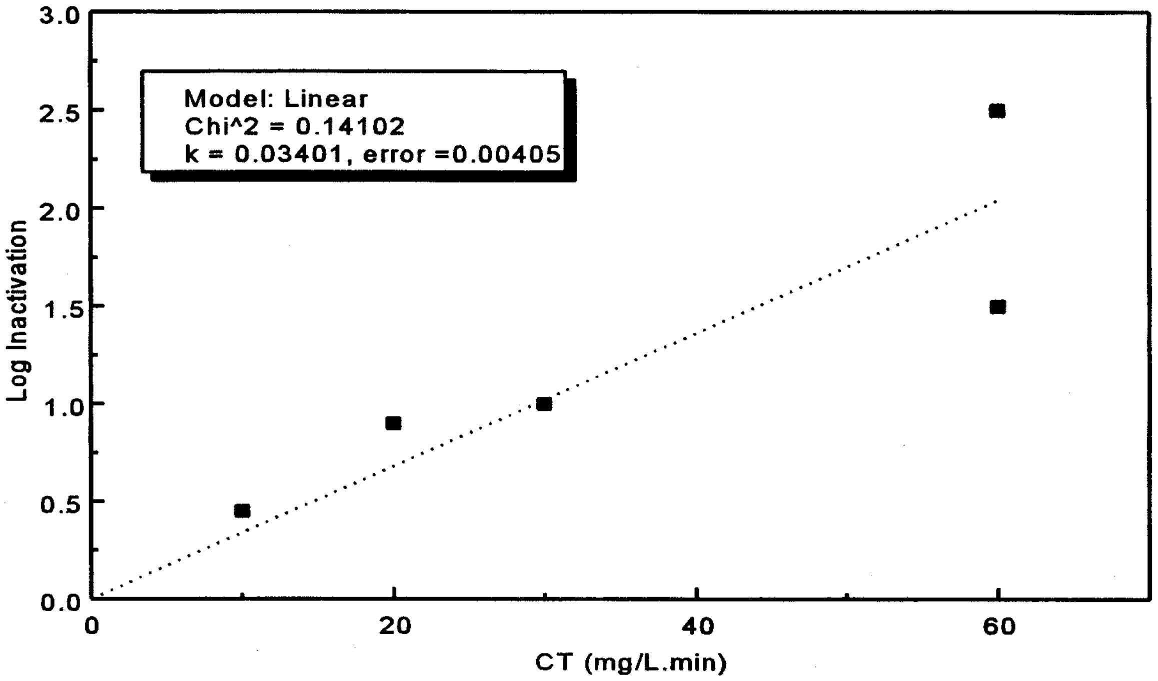

Figure 8: *Giardia* Inactivation with Free Chlorine @ pH 6 & 5 °C
(Data from Jarroll et al., 1981)

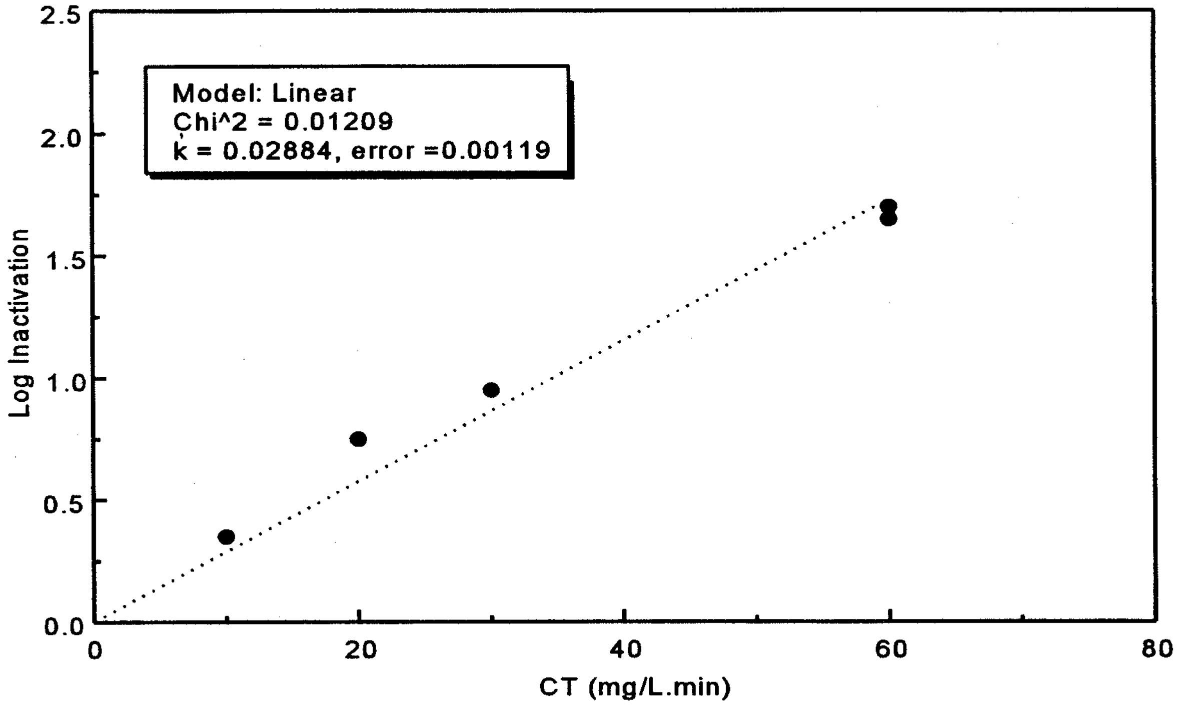

Figure 9: *Giardia* Inactivation with Free Chlorine @ pH 7 & 5 °C
(Data from Jarroll et al., 1981)

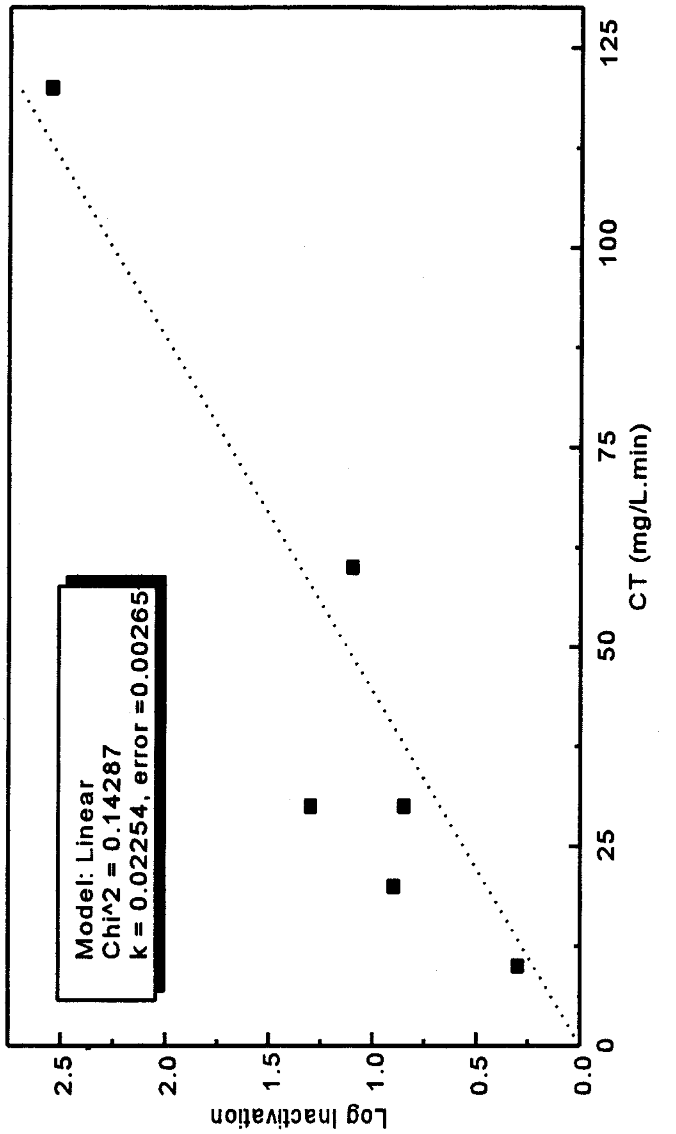

Figure 10: *Giardia* Inactivation with Free Chlorine @ pH 8 & 5 °C (Data from Jarroll et al., 1981)

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The regression results with the values of the Watson coefficient k are shown in each figure. Based on these results, CT values for a designated log inactivation at the three different pH values are estimated and shown in Table 6. By trials, it is found that if a safety factor of 1.5 is applied to those estimated CT values, the resulting CT values approximate the values in the SWTR Guidance Manual for chlorine concentration ≤ 2 mg/L: at pH 6, the safety-factored CT values are slightly higher than those in the SWTR Guidance Manual; at pH 7, the safety-factored CT values are about in the middle of the range of CT values in the SWTR Guidance Manual; at pH 8, the safety-factored CT values are in the low range of CT values in the SWTR Guidance Manual. Therefore, a safety factor of 1.5 appears appropriate for the development of CT tables at higher pHs.

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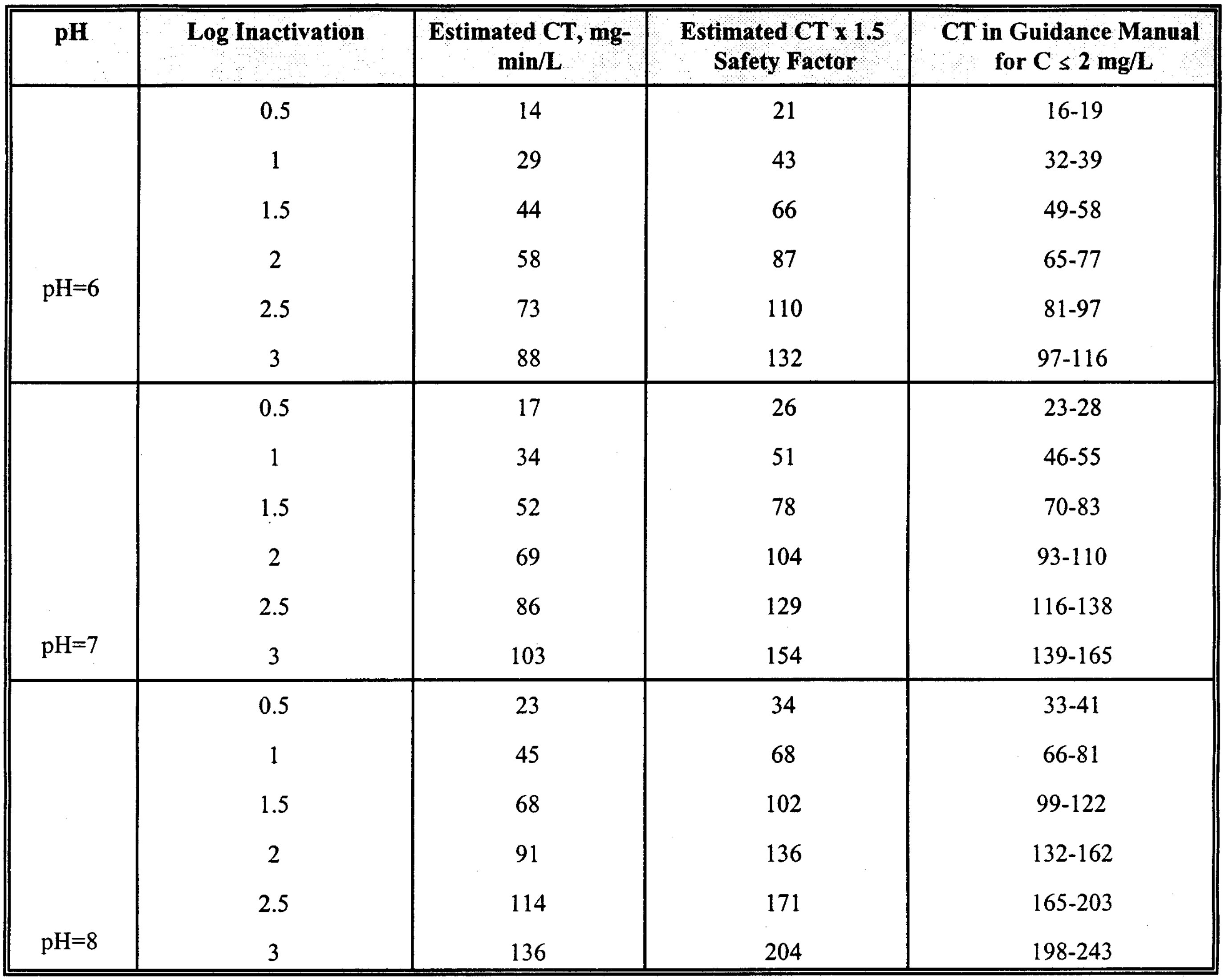
Table 6: Comparison of Estimated CT Values (Based on the Jarroll's Study) and Values in the Manual for C ≤ 2 mg/L for pH=6-8 at 5 °C



pH	Log Inactivation	Estimated CT, mg-min/L	Estimated CT x 1.5 Safety Factor	CT in Guidance Manual for C ≤ 2 mg/L
pH=6	0.5	14	21	16-19
	1	29	43	32-39
	1.5	44	66	49-58
	2	58	87	65-77
	2.5	73	110	81-97
	3	88	132	97-116
pH=7	0.5	17	26	23-28
	1	34	51	46-55
	1.5	52	78	70-83
	2	69	104	93-110
	2.5	86	129	116-138
	3	103	154	139-165
pH=8	0.5	23	34	33-41
	1	45	68	66-81
	1.5	68	102	99-122
	2	91	136	132-162
	2.5	114	171	165-203
	3	136	204	198-243

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The Logsdon data for *Giardia* inactivation with chlorine are shown in Figures 11–13 for pH values of 9.5, 10.5, and 11.5, respectively. Since Logsdon et al. (1994) also observed that little or no inactivation was caused by a high pH itself (i.e., non-disinfected lime softened water) in at least 6 hours, the intercept of the linear regression line should be zero. Based on the determinant k values indicated in each Figure, CT values required for inactivation in the range of 0.5–3 log at pH values of 9.5–11.5 and temperature of 5°C are estimated and tabulated in Table 7. To evaluate the adequacy of the safety factor value (1.5), the line of log inactivation versus the safety-factored CT values is also shown in each of Figures 11–13. It can be seen from Figures 11 and 12 that most data points for natural water are above the safety-factored line, and few points are near the line, indicating the safety factor of 1.5 is appropriate for the establishment of CT tables for pH > 9.

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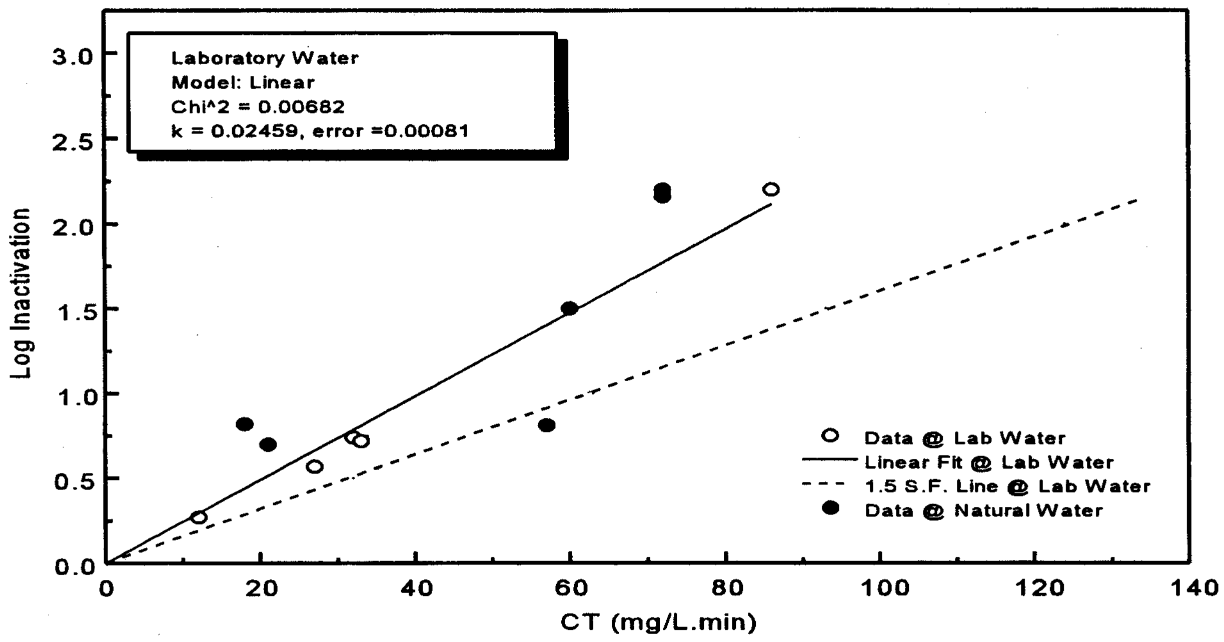

Figure 11: *Giardia* Inactivation with Free Chlorine @ pH 9.5 & 5 °C
(Data from Logsdon et al., 1994)

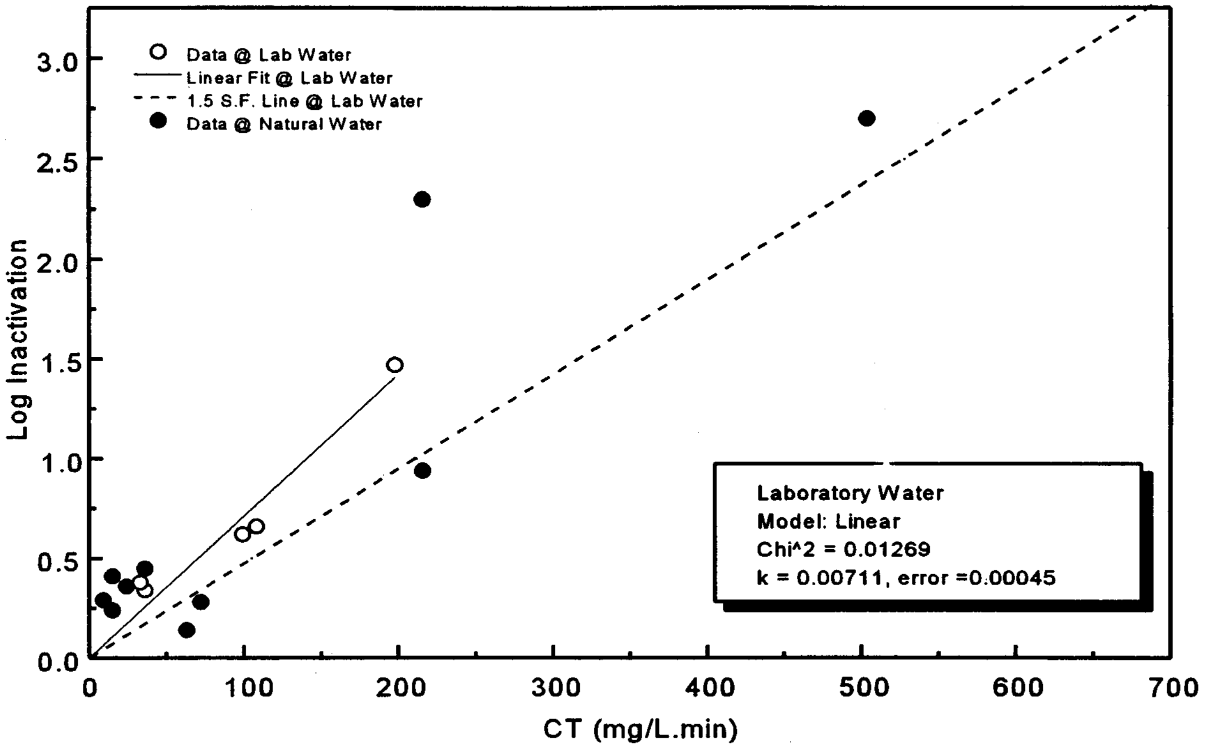

Figure 12: *Giardia* Inactivation with Free Chlorine @ pH 10.5 & 5 °C
(Data from Logsdon et al., 1994)

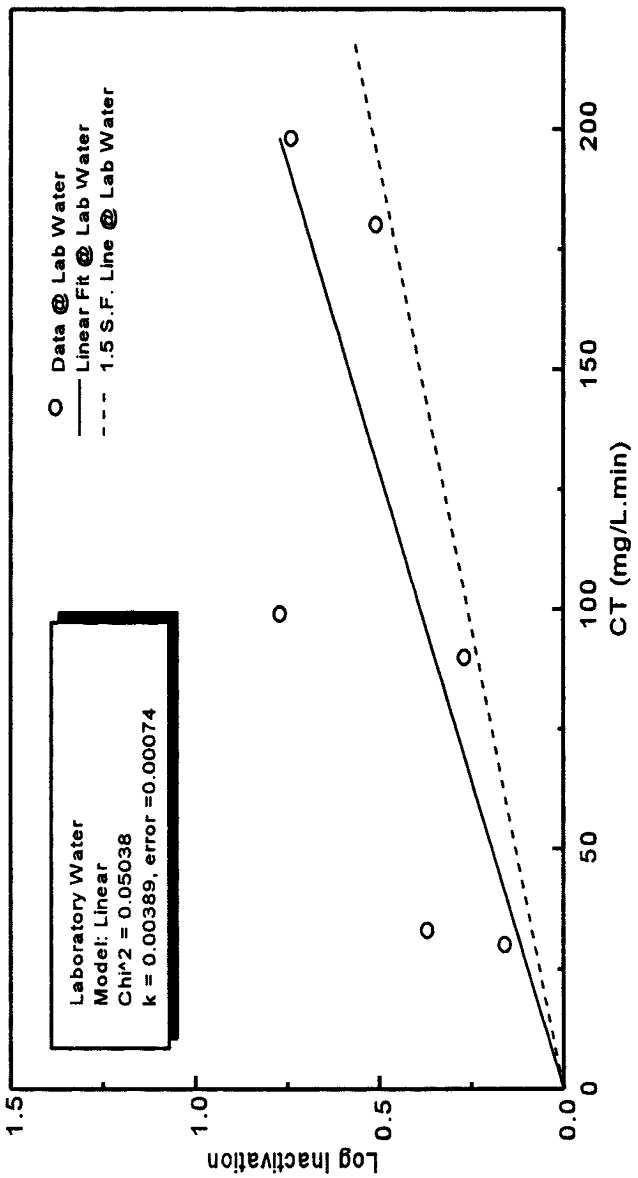

Figure 13: *Giardia* Inactivation with Free Chlorine @ pH 11.5 & 5 °C.
(Data from Logsdon et al., 1994)

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TABLE 7.—ESTIMATED CT VALUES FOR pH=9.5–11.5 AT C ≤ 2 mg/L AND AT 5°C—BASED ON THE LOGSDON'S STUDY FOR LABORATORY WATER

pH	Log inactivation	Estimated CT mg-min/L	Estimated CT × 1.5 S.F.
pH=9.5 ...	0.5	21	32
	1	42	63
	1.5	62	93
	2	83	124
	2.5	104	156
	3	125	188
pH=10.5	0.5	70	105
	1	141	212
	1.5	211	316
	2	282	423
	2.5	352	528
	3	422	633
pH=11.5	0.5	128	192
	1	256	384
	1.5	385	578
	2	513	770
	2.5	641	962
	3	769	1154

By comparing the data in Table 6 and 10, it is seen that estimated CT values at pH 9.5 are consistently lower than those at pH 8 in the SWTR Guidance Manual. To maintain the consistency of an increasing trend of CT values with an increasing pH and be conservative for compliance purposes, the mathematical model described in the SWTR Guidance Manual (equation 15 in Appendix F) by Clark and Regli (1993) is used to extend the existing CT tables in the SWTR Guidance Manual to pH=9.5, e.g., CT=60 mg/L for 0.5 log inactivation with 1 mg/L of chlorine at 5°C. As proposed in the SWTR Guidance Manual, the equation can be directly applied to estimate CT values for 0.5 and 5°C, and a twofold decrease in CT values for every 10°C increase in temperature can be assumed when it is higher than 5°C. Consequently, the CT values for *Giardia* inactivation with free chlorine at pH 9.5 are computed and shown in Table 8.

The same temperature correction factor above is used to estimate CT values for pH values of 10.5 and 11.5 at temperature from 5 to 25°C, and 1.5 of temperature factor is applied to convert CT values at 5°C to those at 0.5°C. Subsequently, the safety-factored CT values for *Giardia* inactivation with free chlorine were estimated and summarized in Tables 11 and 13 for pH values of 10.5 and 11.5, respectively. It should be mentioned that although the level of chlorine residual (the C value) may affect CT values shown in Tables 12 and 13, it is recommended that those values are only applicable to a C value up to 3 mg/L, at least until more research data become available.

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Table 8: CT Values (mg-min/L) for Inactivation of Giardia by Free Chlorine at pH 9.5

C, mg/L	Log Inactivation at 0.5 °C						C, mg/L	Log Inactivation at 5 °C					
	0.5	1	1.5	2	2.5	3.0		0.5	1	1.5	2	2.5	3.0
0.4	74	149	223	297	371	446	0.4	53	105	158	210	263	315
0.6	79	158	237	316	395	474	0.6	56	112	168	224	279	335
0.8	82	165	247	330	412	494	0.8	58	117	175	233	292	350
1	85	170	256	341	426	511	1	60	121	181	241	302	362
1.2	88	175	263	350	438	525	1.2	62	124	186	248	310	372
1.4	90	179	269	358	448	538	1.4	63	127	190	254	317	381
1.6	91	183	274	366	457	549	1.6	65	129	194	259	324	388
1.8	93	186	279	372	465	558	1.8	66	132	198	264	329	395
2	95	189	284	378	473	567	2	67	134	201	268	335	402
2.2	96	192	288	384	480	575	2.2	68	136	204	272	339	407
2.4	97	194	292	389	486	583	2.4	69	138	206	275	344	413
2.6	98	197	295	393	492	590	2.6	70	139	209	278	348	418
2.8	99	199	298	398	497	597	2.8	70	141	211	282	352	422
3	100	201	301	402	502	603	3	71	142	213	285	356	427

Continued

C, mg/L	Log Inactivation at 10 °C						C, mg/L	Log Inactivation at 15 °C					
	0.5	1	1.5	2	2.5	3.0		0.5	1	1.5	2	2.5	3.0
0.4	35	70	105	140	175	210	0.4	26	53	79	105	131	158
0.6	37	75	112	149	186	224	0.6	28	56	84	112	140	168
0.8	39	78	117	156	194	233	0.8	29	58	88	117	146	175
1	40	80	121	161	201	241	1	30	60	90	121	151	181
1.2	41	83	124	165	207	248	1.2	31	62	93	124	155	186
1.4	42	85	127	169	211	254	1.4	32	63	95	127	159	190
1.6	43	86	129	173	216	259	1.6	32	65	97	129	162	194
1.8	44	88	132	176	220	264	1.8	33	66	99	132	165	198
2	45	89	134	178	223	268	2	33	67	100	134	167	201
2.2	45	91	136	181	226	272	2.2	34	68	102	136	170	204
2.4	46	92	138	183	229	275	2.4	34	69	103	138	172	206
2.6	46	93	139	186	232	278	2.6	35	70	104	139	174	209
2.8	47	94	141	188	235	282	2.8	35	70	106	141	176	211
3	47	95	142	190	237	285	3	36	71	107	142	178	213

Table 8: CT Values (mg-min/L) for Inactivation of *Giardia* by Free Chlorine at pH 9.5

Continued

C, mg/L	Log Inactivation at 20 °C						C, mg/L	Log Inactivation at 25 °C					
	0.5	1	1.5	2	2.5	3.0		0.5	1	1.5	2	2.5	3.0
0.4	21	42	63	84	105	126	0.4	18	35	53	70	88	105
0.6	22	45	67	89	112	134	0.6	19	37	56	75	93	112
0.8	23	47	70	93	117	140	0.8	19	39	58	78	97	117
1	24	48	72	97	121	145	1	20	40	60	80	101	121
1.2	25	50	74	99	124	149	1.2	21	41	62	83	103	124
1.4	25	51	76	102	127	152	1.4	21	42	63	85	106	127
1.6	26	52	78	104	129	155	1.6	22	43	65	86	108	129
1.8	26	53	79	105	132	158	1.8	22	44	66	88	110	132
2	27	54	80	107	134	161	2	22	45	67	89	112	134
2.2	27	54	81	109	136	163	2.2	23	45	68	91	113	136
2.4	28	55	83	110	138	165	2.4	23	46	69	92	115	138
2.6	28	56	84	111	139	167	2.6	23	46	70	93	116	139
2.8	28	56	84	113	141	169	2.8	23	47	70	94	117	141
3	28	57	85	114	142	171	3	24	47	71	95	119	142

Table 9: CT Values (mg-min/L) for Inactivation of *Giardia* by Free Chlorine at pH 10.5

Temp. °C	Log Inactivation @ pH=10.5					
	0.5	1	1.5	2	2.5	3.0
0.5	131	265	395	395	529	660
5	105	212	316	316	423	528
10	79	159	237	237	317	396
15	53	106	158	158	212	264
20	39	80	119	119	159	198
25	26	53	79	79	106	132

Table 10: CT Values (mg-min/L) for Inactivation of *Giardia* by Free Chlorine at pH 11.5

Temp. °C	Log Inactivation @ pH=11.5					
	0.5	1	1.5	2	2.5	3.0
0.5	240	480	723	963	1203	1443
5	192	384	578	770	962	1154
10	144	288	434	578	722	866
15	96	192	289	385	481	577
20	72	144	217	289	361	433
25	48	96	145	193	241	289

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In summary, the CT table for *Giardia* inactivation with free chlorine at pH 9.5 was developed by using the same approach in the SWTR Guidance Manual for the existing CT tables at lower pH values. For the development of CT tables at pH values of 10.5 and 11.5, the data reported by Logsdon et al. (1994) was used with a linear regression multiplied by a safety factor of 1.5. The new CT values are shown in Tables 11, 12, and 13 for pH values of 9.5, 10.5, and 11.5, respectively. USEPA solicits comment on the approach taken and whether the CT values shown in Tables 11, 12 and 13 are appropriate for revising existing guidance for estimating inactivation efficiencies for chlorine at pHs above 9. USEPA also solicits comment on other approaches for developing criteria by which systems could estimate inactivation efficiencies at pHs above 9.

2. Effectiveness of Different Disinfectants on *Cryptosporidium*

When the ESWTR was proposed in 1994, USEPA recognized that chlorine disinfectants were relatively ineffective in inactivating *Cryptosporidium*, but was not certain if alternative disinfectants might be more effective than chlorine. No public comment addressed this issue directly. Studies since the proposal have confirmed the ineffectiveness of chlorine species, such as free chlorine and monochloramine, for the practical inactivation of *Cryptosporidium*. However, new data suggest that sequential disinfection with free chlorine followed by monochloramine can achieve a greater degree of *Cryptosporidium* inactivation than by chlorine alone. Moreover, ozone and chlorine dioxide have been found to be much more effective than chlorine. Sequential disinfection such as ozone or chlorine dioxide followed by one of the chlorine species appears more powerful than either disinfectant alone in inactivating *Cryptosporidium*. The following data detail the inactivation of *Cryptosporidium* by individual disinfectants, as well as by sequential disinfectants.

The purpose of presenting this data in this section is to provide the public opportunity to comment on whether there is (a) sufficient information available for generating CT tables to estimate log inactivation of *Cryptosporidium*, comparable to what was done for *Giardia* under the SWTR, and (b) sufficient data to conclude that chlorination, at levels commonly practiced by utilities, is virtually ineffective for inactivating *Cryptosporidium*. Both of these issues relate to USEPA's rationale for using *Giardia* as the key target organism for defining the disinfection benchmark (see Section D).

Table 11a summarizes the data on disinfection of *Cryptosporidium* with chlorine species and ultraviolet radiation (UV). The results from studies with free chlorine indicate that some inactivation of *C. parvum* could be achieved at relatively high doses of chlorine (i.e., >1,000 mg/L of chlorine bleach and 80 mg/L of free chlorine) (Korich et al., 1990a; Ransome et al., 1993) and a high CT value (7,200 mg-min/L) (Korich et al., 1990a; Lykins et al., 1992). However, this common water disinfectant has been conclusively shown to be ineffective for inactivation of *C. parvum* oocysts at practical plant doses (<6 mg Cl_2/L) or CT values (Korich et al., 1990a; Ransome et al., 1993; Finch et al., 1997). The same is essentially true for monochloramine (Lykins et al., 1992; Finch et al., 1997) and the oxidant of permanganate (Finch et al., 1997). Therefore, it is unlikely that significant inactivation of *Cryptosporidium* will occur in water treatment plants with the single addition of these disinfectants at currently used levels.

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Table 11a: Summary of Literature Data on Inactivation of Waterborne *Cryptosporidium parvum* - with Free Chlorine, Chloramine, and Ultraviolet Radiation (UV)

Disinfectant	Test Condition	Analytical method	Inactivation	Reference
Free Chlorine	CT=1.44x10^6 (1000 mg/l, 24 hrs) @ pH 9.5, 10 °C	In vitro excystation	< one log	Ransome et al., 1993
	Practical plant doses (5 mg/L)	Viability in Neonatal BALB/c mice	Ineffective	Korich et al., 1990a
	CT=7,200 (80 mg/L, 90 min.)	Viability in Neonatal BALB/c mice	One log	Korich et al., 1990b
	CT=7,200 @ pH 7, 25 °C		2 log	Lykins et al., 1992
	CT=480 (2 mg/L, 240 min.) @ pH 6, 22 °C	Infectivity in Neonatal CD-1 mice	0.5 log	Finch et al., 1997
	CT=960 (4 mg/L, 240 min.) @ pH 8, & 22 °C	Infectivity in Neonatal CD-1 mice	Ineffective	
Chloramine	CT=7,200 @ pH 7, 25 °C		2 log	Lykins et al., 1992
	CT=4320 (3 mg/L, 24 hrs.) @ pH 7, 10 °C	In vitro Excystation	0.6 log	Ransome et al., 1993
	CT=960 (4 mg/L, 240 min.) @ pH 8, 22 °C	Infectivity in Neonatal CD-1 mice	Ineffective	Finch et al., 1997
UV	In a prolonged period (120 min)	Animal infectivity	Effective	Lorenzo-Lorenzo et al., 1993
	80 mW-s/cm^2 @ pH 7, 10 °C	In vitro excystation	1 log	Ransome et al., 1993
	8,748 mW-s/cm^2 on Oocysts captured on 2 µm filter	In vitro excystation	2 log	Campbell et al., 1995
	1,280 - 41,400 mW-s/cm^2 in a batch reactor	Infectivity in Neonatal CD-1 mice	Ineffective	Finch et al., 1997
	8,000 mW-s/cm^2 on Oocysts captured on 2 µm filter	Infectivity of BALB/c mice	> 3 log	Clancy et al., 1997

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As indicated in Table 11a, the literature data on *Cryptosporidium* inactivation with UV appear controversial because of different experimental protocols used by different investigators. Finch et al. (1997) found that UV was ineffective in inactivating *C. parvum* suspended in a batch reactor. However, significant inactivation was observed when the oocysts were captured in 2cm filters and exposed to a preset UV irradiation dose (Campbell et al., 1995; Clancy et al., 1997). More data are needed to evaluate the practical application of UV for inactivation of *Cryptosporidium* oocysts. Also, of interest are possible synergistic effects with UV application followed by residual disinfectants.

Table 11b summarizes the findings of inactivation of *Cryptosporidium* with ozone. The data obtained from bench-scale tests with oxidant-demand-free laboratory water indicate that for CT values between 1.2–23.0 mg-min/L, the range of inactivation was 0.5 to 5 log at temperatures of 5 to 25 °C and at pH values of 7 to 8 (Peeters et al., 1989; Korich et al., 1990a,b; Parker et al., 1993; Ransome et al., 1993; Finch et al., 1994 & 1997). The variability demonstrated in these results is influenced by the differences in test procedures used by different researchers, i.e., the different measures of *Cryptosporidium* inactivation (infectivity, excystation, etc.) and the different methods of CT calculations (initial ozone dose, average ozone concentration, and ozone residual).

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Table 11b: Summary of Literature Data on Inactivation of Waterborne *Cryptosporidium* Oocysts - with Ozone*

Water Type	Test Condition	Analytical method	Inactivation	Reference
Laboratory Water (Bench-Scale)	CT= 4.1-4.6 @ room temp.	Viability in Neonatal Swiss OF1	2 log	Peeters et al., 1989
	CT=5 (constant residual of 1.0 mg/L, 5 min) @ pH=7, 25 °C.	Viability in Neonatal BALB/c mice	2 log	Korich et al., 1990a,b
	CT=10 (residual 1.0 mg/L) @ 22 °C	DAPI/PI	0.5 log	Parker et al., 1993
	CT=5-19 (residual 0.3-1.3) @ pH 7, 10 °C	In vitro excystation	1-1.5 log	Ransome et al., 1993
	CT=2.5-23 (ave. Residual 0.38-2.3 mg/L) @ pH 7, 22 °C	Infectivity in Neonatal CD-1 mice	0.6-4.7 log	Finch et al., 1997
	CT=2.8 (0.75 mg/L, 3.7 min.) @ pH=6, 22 °C	Same above	1.5 log	
	CT=1.2 (0.5 mg/L, 2.4 min.) @ pH=8, 22 °C	Same above	0.5 log	
Natural Water (Pilot-Scale)	CT=10-15 @ pH 7, 15 °C, 0.3 NTU, Alk=10 mg $CaCO_3$/L, TOC=1.5 mg/L		3 log	Danial et al., 1993
	CT=6, @ pH 8, 24 °C, 0.5 NTU, Alk=59 mg $CaCO_3$/L, TOC=1.7 mg/L	Infectivity in Neonatal BALB/c mice	2 log	Miltner et al., 1997

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Therefore, caution should be used when comparing the results from one study to another. For instance, a CT value of 10 mg-min/L for 0.5-log inactivation was obtained from the study conducted by Parker et al. (1993), who used vital dyes to evaluate the viability of *Cryptosporidium*. This result is incomparable to the data shown in Table 11b. Subsequently, Korich et al. (1993) found that vital stains are of questionable value for determining oocyst viability.

In another example, in a series of experiments at pH 7 and at temperatures of 5–22 °C, Finch et al. (1997) found a 45–92% reduction in ozone concentration at initial residuals of 0.6–2.2 mg/L and contact times of 5–15 minutes. Parker et al. (1993) reported that the *Cryptosporidium* inactivation level was greater when the ozone concentration was maintained at a constant level (i.e., through a batch mode reactor), compared to when the same initial ozone dose was allowed to decay during the same contact time. Both Finch et al. (1994) and Parker et al. (1993) found that an increase in temperature caused a higher inactivation at the same ozone residual and the same contact time. It appears that an increase of 15 °C decreases by half the CT values needed for a 2-log inactivation.

Owens et al. (1994) observed that *C. muris* is slightly more resistant to ozone than *C. parvum*, and proposed that *C. muris* be used as a surrogate model for *C. parvum*. However, the data that support this hypothesis are very limited.

Two pilot-scale studies with natural waters have been performed (Danial et al., 1993; Miltner et al., 1997). The CT values of ozone required to achieve 2- and 3-logs inactivation of *Cryptosporidium* were 6.0 mg-min/L (pH 8, 24 °C) (Miltner et al., 1997) and 10–15 mg-min/L (pH 7, 15 °C) (Danial et al., 1993). It appears that higher CT values are required in natural water for inactivation of *Cryptosporidium* than in laboratory water; this may be attributed to the existing oxidant demands in natural water or other factors. Danial et al. (1993) indicated that the ozone residual for a given dose rapidly decomposed as the pH was increased from 7 to 9 during lime addition. This finding implies that if ozonation is practiced in lime-softening water plants, it will be necessary to adjust the pH downstream.

When inactivation of *Cryptosporidium* oocysts is compared with that of *Giardia* cysts with similar test protocols, *C. parvum* is approximately 10 times more resistant to ozone than *G. lamblia* in laboratory water (Finch et al., 1994) and *G. muris* in natural water (Owens et al., 1994; Miltner et al., 1997). These findings imply that the use of ozone cannot be expected to significantly inactivate *Cryptosporidium* at the concentration and contact times employed in inactivating *Giardia* in water treatment practices.

Table 11c summarizes the findings of *Cryptosporidium* inactivation with chlorine dioxide. For CT values between 23–213 mg-min/L, the range of inactivation is 0.5–3.2 log or higher at temperatures of 10–25 °C and at pH values of 7–8 in laboratory water (Peeters et al., 1989; Korich et al., 1990b; Ransome et al., 1993; Finch et al., 1995 & 1997). Similar to ozone, chlorine dioxide is also unstable in the water. In 0.05 M phosphate buffer water at pH 8 and 22 °C, Finch et al. (1997) found that a 49–99% reduction in chlorine dioxide concentrations occurs after 15–120 minutes at initial residuals of 0.36–3.3 mg/L. LeChevallier et al. (1997b) recently performed a pilot-scale study in a natural water by evaluating viability of oocysts with both an in-vitro excystation assay and a tissue culture infectivity. While the difference in results with the two methods was not shown, the study reported that a CT value of 40 mg-min/L results in 1-log inactivation of oocysts at pH 8.0 and 20°C, and a 0.5-log inactivation at pH 6.0. The study also revealed that a temperature reduction from 20 to 10 °C decreases the effectiveness of chlorine dioxide by 40%.

The existing data show chlorine dioxide as an effective disinfectant for *Cryptosporidium* inactivation. However, CT values required for *Cryptosporidium* inactivation appear much higher than those for same log inactivation of *Giardia* under comparable water conditions (Lisle and Rose, 1995). Since the 1994 D/DBP proposed rule has set the maximum contaminant levels for chlorine dioxide and chlorite (by-product of chlorine dioxide), at 0.8 mg/L and 1 mg/L, respectively, the use of chlorine dioxide may be limited for the inactivation of *Cryptosporidium*.

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Table 11c: Summary of Literature Data on Inactivation of Waterborne *Cryptosporidium parvum* - with Chlorine Dioxide

Water Type	Test Condition	Analytical method	Inactivation	Reference
Laboratory Water (Bench-Scale)	CT=6.6 (residual=0.22 mg/L, 30 min.) @ room temp.	Viability in Neonatal Swiss OF1	1.2 log	Peeters et al., 1989
	CT=60-80 @ pH 7, 25 °C,	Viability of Neonatal BALB/c mice	1-1.4 log	Korich et al., 1990b
	CT=75 (residual 5 mg/L, 15 min) @ pH 7, 10 °C	In vitro excystation	>1 log	Ransome et al., 1993
	CT= 27-30, 40, & 70 @ pH 7, 22 °C	Infectivity in Neonatal CD-1 mice	1, 2, & 3 log	Finch et al., 1995
	CT=168 (1.4 mg/L, 120 min.) @ pH=8, 22 °C	Infectivity in Neonatal CD-1 mice	1.7 log	Finch et al., 1997
Natural Water (Pilot-Scale)	CT=40 @ Pilot scale, TOC=2-4 mg/L, 20 °C	In vitro excystation and tissue culture infectivity	1 log @ pH 8 0.18 log @ pH 6	LeChevallier et al., 1997b

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Table 12 summarizes the results from Finch et al. (1997). Finch et al. found that sequential disinfection of *C. parvum* oocysts by different disinfectants is more effective than that indicated by the effectiveness of each disinfectant from independent studies, i.e., the effect is synergistic. According to their current report, greater than 2.9-log inactivation of oocysts can be achieved when *C. parvum* is exposed to 0.75 mg/L initial ozone residual for 3.7 minutes and then 2.0 mg/L free chlorine residual for 265 minutes (pH 6). Based on the additive effects of ozone and free chlorine alone under similar conditions, a 2.0-logs inactivation is expected. Similarly, the inactivation by monochloramine following ozonation is increased by 1.5 log-units when compared with either ozone or monochloramine alone.

Additional 1.2-log inactivation due to the synergism of chlorine dioxide and free chlorine has also been obtained at pH 8. Furthermore, sequential exposure of *C. parvum* oocysts to free chlorine followed by a monochloramine (pH 8.0) reduces infectivity by 0.6 log. Since the expected inactivation by either chlorine species at pH 8 is virtually zero, there is a synergism between free chlorine and monochloramine. It should be noted that combinations of chlorine species with other disinfectants may stimulate the formation of chlorate (Siddiqui et al., 1996) or other toxic disinfectant byproducts. Also, the synergistic effect with sequential disinfectants has only been observed in bench-scale studies in a single laboratory. Nevertheless, such findings suggest new strategies for the effective inactivation of *Cryptosporidium*. For a practical application, further investigations are being conducted at a wider range of water quality conditions (pH, temperature, and disinfectant demand) (USEPA, 1995b).

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Table 12: Summary of Literature Data on Inactivation of Waterborne *Cryptosporidium parvum* - with Sequential Disinfectants

Sequential Disinfectants	Test Condition	Analytical method	Inactivation	Reference
Ozone & Free Chlorine	O_3=0.75 mg/L for 3.7 min, Cl_2=2.0 mg/L for 265 min, @ pH 6, 22 °C	Infectivity in Neonatal CD-1 mice	2.9 log	Finch et al., 1997
Ozone & Monochloramine	O_3=0.5 mg/L for 2.4 min, NH_2Cl=2.0 mg/L for 240 min, @ pH 8, 22 °C	Same above	1.9 log	
Chlorine Dioxide & Free Chlorine	ClO_2=1.3 mg/L for 120 min, Cl_2=1.3 mg/L for 120 min, @ pH 8, 22 °C	Same above	2.9 log	
Free Chlorine & Monochloramine	Cl_2=4.0 mg/L for 15 min, NH_2Cl=4.0 mg/L for 240 min, @ pH 8, 22 °C	Same above	0.6 log	
Ozone, Hydrogen Peroxide & UV_{254}	O_3=0.5 mg/L & H_2O_2=1.5 mg/L for 3.4 min, UV=131 W.s/cm, pH 8, 22 °C	Same above	1.1 log	

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Analytical Method—Four analytical methods are currently being used to evaluate inactivation of *Cryptosporidium* oocysts: in vitro excystation, vital dyes (DAPI/PI staining), animal infectivity, and tissue culture infectivity. It has been shown that excystation and DAPI/PI staining consistently underestimate inactivation when compared with animal infectivity, which is more expensive (Finch et al., 1994; Black et al., 1996). The use of different animal models also leads to inconsistent results for *Cryptosporidium* infectivity. Although the tissue culture technique may provide a convenient, low-cost alternative to animal infectivity, only limited data exist with this method (LeChevallier et al., 1997b).

Cryptosporidium Inactivation Map—In conjunction with development of the long-term ESWTR, USEPA is developing a graph of CT values versus log inactivation under various water quality conditions. The Agency is also exploring other means that utilities can use to estimate *Cryptosporidium* inactivation with different single or sequential disinfectants. Additional data, especially under natural water/field conditions, is necessary to develop this graph. Finch et al. (1994) attempted to establish CT tables for *Cryptosporidium* inactivation with ozone by analyzing numerous sets of experimental data by using both the Chick-Watson model and the Hom model. It was found that the inactivation kinetics of *C. parvum* by ozone deviated from the simple first-order Chick-Watson model and was better described by a nonlinear Hom model. A further analysis, however, hasn't been performed on a broader data basis to evaluate such a finding. Moreover, a much better understanding of *Cryptosporidium* inactivation with sequential disinfectants is needed.

3. New Virus Inactivation Studies

One of the treatment options that USEPA proposed as part of the ESWTR was to include a 4-logs minimal inactivation requirement for viruses, in addition to any physical removal of viruses that might be achieved. USEPA intends to consider this option when additional data become available. However, significant data are available regarding disinfection conditions necessary to achieve different inactivation levels of viruses. The availability of such data is discussed below.

USEPA's guidance manual to the SWTR (USEPA, 1991a), assumes that CT values for chlorine necessary to achieve a 0.5-log inactivation of *Giardia* cysts will result in greater than a 4-log inactivation of viruses. This assumption is based on the comparison between the effects of free chlorine on *Giardia lamblia* and hepatitis A virus (HAV). In the proposed ESWTR, USEPA noted that some viruses are more resistant to chlorine than is HAV, and the use of disinfectants other than free chlorine to achieve 0.5-log inactivation of *Giardia* may not yield a 4-log inactivation of viruses. Achieving adequate inactivation of viruses may be of greater concern when disinfectants other than chlorine (e.g., chlorine dioxide and ozone) are used to inactivate *Cryptosporidium* oocysts.

CT tables in the SWTR for estimating viral inactivation efficiency with chlorine dioxide and ozone were based on laboratory studies using HAV and poliovirus 1, respectively. Very few studies have since been conducted to investigate viral inactivation with chlorine dioxide. Huang et al. (1997) evaluated the disinfection effects of chlorine dioxide on six viruses, including poliovirus type 1, coxsackievirus type B_3, echovirus 11, adenovirus type 7, herpes simplex virus 1, and mumps virus. All viruses were completely inactivated at CT=90 mg-min/L (3 mg/L of initial dose and 30 minutes of contact time) at pH values of 3, 5, and 7, but not 9. Complete inactivation of all six viruses was also found at CT=30 mg-min/L (1 mg/L of initial dose and 30 minutes of contact time) at pH 7.0. At 7.0 mg/L of initial dose, greater than 10 minutes of contact time were required for complete inactivation at the same pH.

More studies have been performed to evaluate viral inactivation efficiencies by ozone than by chlorine dioxide. The results from these studies are summarized in Table 13.

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Table 13: Literature Data on Inactivation of Viruses with Ozone*

Virus	Ozone Dose & Contact Time	pH	Temp °C	Inactivation	Reference
Hepatitis A virus (HAV)	Residual=0.27 mg/L & <48 sec.	7.0	10	4-6 log	Herbold et al., 1989
	Initial 1 mg/L & 24 sec.	6-7	4	4 log	Vaughn et al., 1990
	Residual 0-1.4 mg/L (Initial 0.3-1.7 mg/L) & 5 sec.	6-10	3-10	>4 to > 6 log	Hall & Sobsey, 1993
MS2 Coliphage	Initial 0.6-1.8 mg/L & 60-240 sec. (Paired study w/PV3)	7	22	2.7-7 log	Finch et al., 1992
	Residual 0.04 mg/L & 20 sec.	7	22	4 log	
	Residual-not detected & <60 sec. (Natural water w/TOC 1.3 -6.7 mg/L)	7-8	4-22	~ 100%	
	Residual 0-1.4 mg/L (Initial 0.3-1.7 mg/L) & 5 sec.	6-10	3-10	>4 to > 5 log	Hall & Sobsey, 1993
Poliovirus 1 (PV1)	Residual 0.08 mg/L & <6 sec.	7	10	4-6 log	Herbold et al., 1989
	Initial 1 mg/L & 5 min.	6.4	17	4 log	Kaneko, 1989
	CT=0.15 mg-min/L	8	24	2 log	Miltner et al., 1997
Poliovirus 3 (PV3)	Initial 0.6-1.8 mg/L & 60-240 sec. (Paired study w/MS2)	7	22	1.6-3.6 log or high	Finch et al., 1992
T2 Phage	Residual 0.6 mg/L & 4 min.	7	17	3 log	Kaneko, 1989

* Bench studies except one conducted by Miltner et al., 1997 who performed a pilot study with natural water at 0.5 NTU and 59 mg $CaCO_3$/L.

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In general, the tested viruses, including HAV, MS2 coliphage, poliovirus 1 (PV1), poliovirus 3 (PV3), and T2 phage, are relatively sensitive to ozone, and more than 4-logs inactivation of these viruses can be achieved with less than 2 mg/L of ozone and 5 minutes of contact time in a wide range of pH values and temperatures (Herbold et al., 1989; Kaneko, 1989; Vaughn et al., 1990; Finch et al., 1992; Hall and Sobsey, 1993; Miltner et al., 1997). Finch et al. (1992) reported that MS2 coliphage was extremely sensitive to ozone in both laboratory water and natural water, and that complete viral inactivation could occur during the process of satisfying ozone demand in natural water. In paired experiments, they also found that there was significantly less inactivation of PV3 than MS2 coliphage under the same ozonation conditions. In contrast, Hall and Sobsey (1993) demonstrated that MS2 coliphage was at least as resistant to ozone as HAV in a pH range of 6–10, suggesting that MS2 coliphage might be a good model for predicting HAV inactivation by ozone. In a continuous-flow system with a constant flow of ozone and viral suspensions, Herbold et al. (1993) found that HAV required approximately three times the ozone that PV1 required for the same inactivation. In a similar system, Botzenhart et al. (1993) showed that MS2 coliphage was more resistant to ozone than PhiX 174 coliphage.

Some researchers have pointed out that viral disinfection with ozone is difficult to evaluate, not only due to the relatively short inactivation times, but also because the concentration of ozone significantly decreases during the contact time. Finch et al. (1992) found ozone dose and the interaction between ozone dose and dissolved organic carbon (DOC) were the most important factors affecting ozone inactivation of MS2 coliphage in surface waters. Inactivation of MS2 coliphage was significantly reduced when the natural DOC in the water increased during spring runoff, presumably because the ozone concentration was rapidly depleted by the DOC. This effect, however, was not observed when an ozone residual of 0.1 mg/L at the end of 30 seconds was detected, resulting in greater than 4-logs inactivation of MS2 coliphage under all water quality conditions.

Finch et al. (1992) found that the effects of temperature and turbidity on inactivation rates were indistinguishable from experimental error. This contrasts with other studies that reported that viral inactivation with ozone was more efficient at lower temperatures (Botzenhart et al., 1993; Herbold et al., 1993), and the presence of kaolin particles at 1 mg/L or higher resulted in a greater level of ozone residual required for the same level of viral inactivation (Kaneko, 1989). Vaughn et al. (1990) observed that the pH-related effects on ozonation of viruses was not significant in a pH range of 6–8. Kaneko (1989) reported that the presence of ammonium decreased the ozone concentration and thus decreased the inactivation efficiency of ozone.

Kaneko (1989) also revealed that ozonation of viruses could be divided into three phases: an initial large reduction of viruses; a subsequent logarithmic reduction of viruses; and finally, a slow reduction in response to decreasing ozone concentrations. Thus, it is not surprising that the viral inactivation rate beginning 5 minutes after adding the disinfectant was greater with chlorine than with ozone, even though the inactivation rates within 5 minutes of the addition of ozone were 10 to 1,000 higher than the initial rates of inactivation with chlorine (Kaneko and Igarashi, 1983; Kaneko, 1989).

Finch et al. (1992) have concluded that, when comparing the ozone inactivation data for MS2 coliphage, PV3, and *Giardia muris,* the conditions for inactivating *G. muris* cysts are the most rigorous and it is likely that enteric viruses will be inactivated by greater than 4 logs when *Giardia* is inactivated by 3 logs. Such a comparison is also needed for chlorine dioxide. Although the tested enteric viruses appear to be more susceptible to ozone than *Giardia,* no data are yet available on the effectiveness of ozone in inactivating Norwalk virus and other pathogenic human viruses, especially when they are clumped and adsorbed to organic matter as they usually are in natural water. The varying results on viral inactivation with ozone suggest that ozone inactivation studies need to measure and report ozone concentrations over time.

III. Economic Analysis of the M–DBP Advisory Committee Recommendations

A. Overview of RIA for Proposed Rule

The Regulatory Impact Analysis (RIA) for the proposed IESWTR (59 FR 38832, July 29, 1994), estimated national capital and annualized costs (amortized capital and annual operating costs) for surface water systems serving at least 10,000 people at $3.6 billion and $391 million respectively. These costs were based on the assumption that systems would also be required to provide enough treatment to achieve less than a 10^{-4} risk level from giardiasis while meeting the Stage 1 DBPR. 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.

The Regulatory Impact Analysis for the Interim Enhanced Surface Water Treatment Rule (USEPA, 1994d) predicted that ESWTR compliance would result in no more than a few hundred infections caused by waterborne *Giardia* per year per 100 million people. This is hundreds of thousands of cases fewer than predicted in the absence of an ESWTR. USEPA estimated that the benefit per *Giardia* infection avoided would be $3000 per case. Using this estimate, the 400,000 to 500,000 *Giardia* infections per year that could be avoided would have an economic value of $1.2 to $1.5 billion per year. This suggests that the benefit nationwide of avoiding *Giardia* infections is as much as three or four times greater than the estimated $391 million national annual cost of providing additional contact time.

Table 14 shows this $391 million estimated cost as described in the proposal (using 1992 $s and a discount rate of 10 percent). The table also converts this cost to 1997$s (with a 10 percent discount rate) to provide for comparison with costs based on provisions included in this notice.

For a more detailed discussion of the cost and benefit analysis of the 1994 proposal refer to The Regulatory Impact Analysis for the Interim Enhanced Surface Water Treatment Rule (USEPA, 1994d).

B. What's Changed Since the Proposed Rule

The cost estimates in the proposed rule reflect cost estimates for one of several regulatory alternatives included in the proposal. At the time of proposal USEPA assumed that additional data would be collected under the ICR to more accurately estimate costs and benefits of the *Giardia* based rule option as well as alternative regulatory options. National source water occurrence data for *Giardia* and *Cryptosporidium* are being collected as part of the ICR to help this effort. Due to the delays discussed earlier in this Notice and the new expedited rule deadlines, ICR data will not be available for the IESWTR impact analysis. From February 1997, however, the Agency has worked with stakeholders to identify additional data available since 1994 to be used in developing components of the expedited rules. 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. The Committee met five times from March to July, 1997 to discuss issues related to the IESWTR and Stage I D/DBPR.

USEPA has also evaluated comments received on the proposal in its consideration of elements to be included in a regulatory option independent of ICR source water occurrence data. These comments suggested (1) sufficient degrees of effectiveness of current treatment, including filtration, in preventing waterborne transmission of *Cryptosporidium* and (2) a revised approach focussing on optimizing treatment processes. In response to these comments, new information received and the Advisory Committee's recommendations, USEPA has developed the Economic Analysis described in summary below. Details of the analysis used to derive the costs and benefits described below are available in the draft document Economic Analysis of M/DBP Advisory Committee Recommendations for the Interim Enhanced Surface Water Treatment Rule (USEPA, 1997a). The economic analyses are based on the Committee's recommendations to USEPA on issues including turbidity control, removal of *Cryptosporidium*, disinfection benchmarking and sanitary surveys.

C. Summary of Cost Analysis

1. Total National Costs

USEPA is considering several approaches, based on the recommendations of the Advisory Committee. The two most substantial approaches, from the perspective of costs and benefits, govern turbidity performance and turbidity monitoring. The Microbial and Disinfectants/Disinfection Byproducts Committee made a number of recommendations that are indicated in this Notice for comment, including new turbidity provisions with associated monitoring requirements, disinfection benchmarking practices to help ensure there are no significant increases in microbial risk while systems comply with the Stage 1 DBPR and a sanitary survey provision of relatively minimal costs. USEPA estimates that the national capital and annualized costs (amortized capital and annual operating costs) of these provisions (based on a 10 percent interest rate) would be $730 million and $312 million, respectively [Table 14] (USEPA, 1997a). These figures include costs associated with improved treatment, turbidity monitoring, a disinfection benchmark and sanitary surveys. This represents a reduction of over $3.4 billion (in 1997 $s) from the capital costs estimated for the proposed rule. This is accounted for primarily by the recommendations for changes in the level of disinfection required and restoration of disinfection credit prior to precursor removal. This would result in fewer systems needing to install additional disinfectant contact basins, relative to the costs in the 1994 proposal.

A discount rate of 10 percent was used to calculate the unit costs for the national cost model. This discount rate provides both a link to the 1994 IESWTR cost analyses and is a reasonable estimation of the cost to utilities to finance capital purchases assumed to be necessary due to the proposal.

In order to demonstrate the sensitivity of the national cost model to different discount rates, the national costs at 10 percent are compared to national costs calculated using a 7% discount rate. This rate represents the standard social discount rate preferred by the Office of Management and Budget for benefit-cost analyses of government programs and regulations. Tables of unit cost estimates at the 7 percent rate are included in the appendix to the draft Economic Analysis and displayed for comparative purposes (USEPA, 1997a). Costs presented in the Economic Analysis are expressed in June 1997 constant dollars.

The water flow rates that were used in calculating the costs of the 1994 proposal (in 1992 $s and 1997 $s) were also used in calculating the national costs of the recommended provisions discussed in this Notice. Additional analyses gauged the sensitivity of the cost model to a different input value for maximum flow rates for the largest system category (systems serving >1 million people). With this adjusted flow rate (using a 10 percent discount rate) total annualized national costs would be $314 million, compared to $312 million based on flow rates used in the 1994 proposal.

USEPA requests comment on how the new data have been used and any additional data that would improve the assessment of costs and benefits.

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Table 14: Costs of the Interim Enhanced Surface Water Treatment Rule ($000)

	Advisory Committee Recommendations (1997 $s)			1994 Proposal	
	10 Percent discount rate	7 Percent discount rate	10 Percent w/adjusted flow rates)	1997 $s (10 percent discount rate)	1992 $s (7 percent discount rate)
Utility Costs					
Total Utility Treatment Capital	730,802			4,139,555	3,665,568
Annual Utility Costs					
Annualized Capital	*101,834*				
Annual O & M	*101,102*				
Total Treatment	202,936	191,251	205,124	442,231	391,702
Turbidity Monitoring	95,982	95,982	95,982		
Total Annual Utility Costs	298,918	287,233	301,106	442,231	391,702
One-Time Utility Costs					
Turbidity Monitoring Start-up	4,291	4,291	4,291		
Disinfection Benchmarking	2,691	2,691	2,691		
State Costs					
Annual State Costs					
Turbidity Monitoring	5,257	5,257	5,257		
IFAs and CPEs	547	547	547		
Sanitary Survey	6,781	6,781	6,781	979	867
One-Time State Costs					
Start-up/Implementation	407	407	407	3,057	2,708
Disinfection Benchmarking	3,112	3,112	3,112		
Summary of Total Costs					
Utility Costs					
Total Annual	298,918	287,233	301,106	442,231	391,702
One-Time	6,983	6,983	6,983		
State Costs					
Total Annual	12,585	12,585	12,585	979	867
One-Time	3,519	3,519	3,519	3,057	
Total One-Time Costs	**10,501**	**10,501**	**10,501**	**3,057**	**2,708**
Total Annual Costs	**311,503**	**299,818**	**313,691**	**443,210**	**392,569**

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2. Household Costs

Household costs are a way to represent water system treatment costs as a costs to the system customer. Figure 14 displays results of the household cost analyses for a 0.3 NTU, 1 maximum CFE NTU turbidity treatment approach discussed in this Notice. As can be seen from the graph, a small percentage of the systems might, using this methodology, incur a maximum cost per household of approximately $110 per year. The highest household costs are incurred in households served by small systems that need to implement all of the activities to comply.

It must be borne in mind that the upper bound of the graph displays an extrapolated curve, and does not represent actual data points. The assumptions and structure of this analysis, in describing the curve, tend to overestimate the highest costs. To find itself on the upper bound of the curve, a system would have to implement all, or almost all, of the treatment activities. These systems, conversely, might seek less costly alternatives, such as connecting into a larger regional water system. In the judgment of the Advisory Committee's Technical Work Group, this extreme situation and the resulting high values may occur only for a small number of households.

Based on this analysis, over 97 percent of the households are estimated to incur annual costs of less than $20 per household per year and over 50 percent are estimated to incur costs of less than $2 per household per year.

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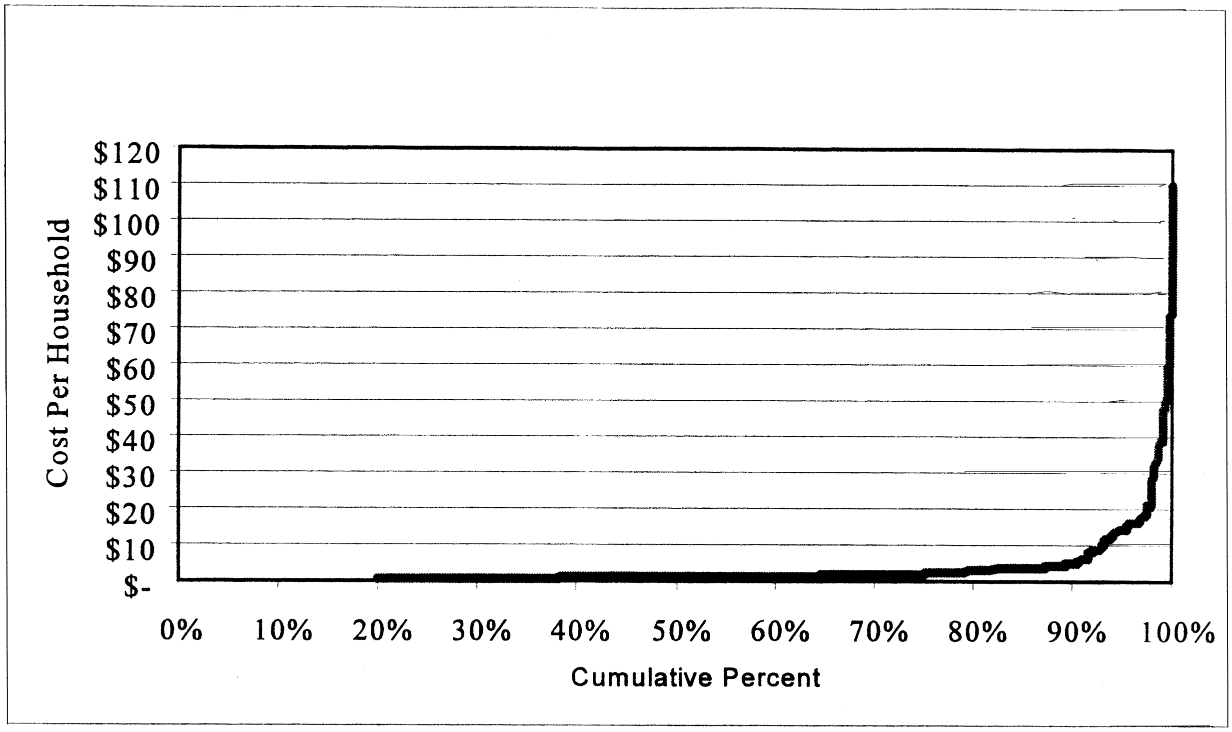
Figure 14: Cumulative Percentage of Household Costs



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D. Cost of Turbidity Performance Criteria and Associated Monitoring

1. System Level Impact Analysis

The TWG developed a list of treatment activities that systems would be expected to employ in order to implement Advisory Committee recommendations. These activities were grouped into 10 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 described in the draft document Technologies and Costs for the Interim Enhanced Surface Water Treatment Rule (USEPA, 1997b).

2. National Impact Analyses

a. Decision Tree. The decision tree is a table of treatment activities that taken either singly or in combination will help utilities evaluate what is potentially involved in meeting the turbidity limits recommended by the Advisory Committee, i.e., the requirement that utilities serving more than 10,000 people be required to achieve a 95 percentile turbidity limit of 0.3 NTU and at no time exceed a turbidity value of 1 NTU (Appendix A, USEPA, 1997a). Percentages in a decision tree represent the projected percentage of public water systems using that activity to meet the turbidity limits recommended by the Advisory Committee. These percentages were factors in the national cost model and generally 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 draft Economic Analysis of M/DBP Advisory Committee Recommendations for the Interim Enhanced Surface Water Treatment Rule (Economic Analysis) (USEPA, 1997a).

b. Utility Costs. Turbidity Treatment. The number of systems, the associated total capital costs, and the associated total annualized costs were estimated for seven system size categories. Total annual costs were calculated for each possible treatment activity and for each system size category. Unit costs were converted to annualized cost totals (in thousands of dollars) using the methodology described in the draft Economic Analysis.

As indicated in Table 14, the estimate of national annualized turbidity treatment costs are $203 million based on the Advisory Committee's recommended 0.3 NTU 95th percentile CFE standard while meeting a 1 NTU maximum combined filter effluent level (calculated with a 10% interest rate in 1997$s).

Turbidity Monitoring. A generalized turbidity monitoring model was developed to provide a framework for estimating costs associated with individual filter monitoring. The model assumes turbidimeters for each filter and an on-line Supervisory Control And Data Acquisition (SCADA) system. Filter readings would be taken at least once every 15 minutes and tabulated. The model assumes that once each work shift (8 hours) the turbidity data would be converted to a reviewable form, and would then be reviewed by a system manager. In cases where the monitoring recorded exceedances as described below, a report would be made to the State and, if warranted, an individual filter review or system assessment might occur. Annual utility monitoring costs are estimated at $96 million as shown in Table 14 above.

Under the approach recommended by the Advisory Committee, exception reporting to the State is warranted if:

—An individual filter has a turbidity level greater than 1.0 NTU for 2 consecutive measurements 15 minutes apart.

—An individual filter has a turbidity level greater than 0.5 NTU at the end of the first 4 hours of filter operation for 2 consecutive measurements 15 minutes apart.

—If a plant reports exceedances of 1.0 NTU at one filter for 3 consecutive months, an individual filter assessment (IFA) is required to be performed by the utility.

—If a plant records exceedances of 2.0 NTU at one filter in 2 consecutive months, a comprehensive performance evaluation (CPE) is required and must be performed by a third party.

c. State Costs. Annual Review Costs. Under the recommended provisions, it would be the State's responsibility to review system data to ensure that all systems in the State are in compliance with the provisions. State activities include compliance tracking, review of Statewide utility data, record keeping, and compliance determinations. Annual State costs for review (nationwide) are estimated to be $5.3 million (USEPA, 1997a).

Implementation and Start-Up Costs Related to Turbidity Monitoring. One-time State implementation activities include the adoption of the rule and State regulation development. As shown in Table 14, the rule would collectively cost States a total of $407,000 to implement turbidity monitoring provisions.

Exception Costs (Exception Reports, IFAs and CPEs). Under the approach recommended by the Advisory Committee, a monthly exception report would be filed by each utility at which a plant exceeds individual filter effluent (IFE) turbidities of either 1.0 NTU for 2 consecutive measurements 15 minutes apart, or 0.5 NTU at the end of the first 4 hours of a filter run.

In addition to the monthly exception report of individual filter effluent exceedances, additional steps are triggered when exceedances persist. If an individual filter has turbidity levels greater than 1.0 NTU based on 2 consecutive measurements fifteen minutes apart at any time in each of 3 consecutive months, the system conducts a self assessment of the filter utilizing as guidance relevant portions of guidance issued by the Environmental Protection Agency for Comprehensive Performance Evaluation (CPE). If an individual filter has turbidity levels greater than 2.0 NTU based on 2 consecutive measurements fifteen minutes apart at any time in each of two consecutive months, the system will arrange for the conduct of a CPE by the State or a third party approved by the State.

The following assumptions were made by the Technical Working Group of the Advisory Committee regarding the percentage of systems per year that would trigger an interaction with the State based on the recommended provisions.

—10 percent of systems per year are assumed to file monthly reports to the State based on individual filter effluent provisions

—2 percent of systems per year are assumed to trigger Individual Filter Assessment (IFA) provisions

—1 percent of systems per year are assumed to trigger Comprehensive Performance Evaluation (CPE) provisions.

Based on these assumptions, approximately 28 IFAs and 14 CPEs will be conducted each year at an estimated cost of $5,000 and $25,000 each, respectively. States are expected, therefore, to incur annual costs (nationally) of $64,000 to review the exception reports, $138,000 and $345,300 in annual costs for IFAs and CPEs, respectively. The combined total annual State cost for these items is $572,000 (Table 14, above).

E. Disinfection Benchmark

1. Decision Tree

The Advisory Committee recommended that a utility prepare a disinfection profile if they:

—measure TTHM levels of at least 80 percent of the MCL (0.064 mg/l) as an annual average for the most recent 12-month period for which compliance data are available.

—measure HAA% level of at least 80 percent of the MCL (0.048 mg/l) as an annual average for the most recent 12-month compliance period for which compliance data are available.

HAA and TTHM figures from the 1996 Water Industry Data Base (WIDB) were used to estimate the percentage of systems that would be required to prepare a disinfection profile.

2. Utility Costs

Utility costs associated with profiling were divided into four activity areas; cost per system, cost per plant using paper data (i.e., for those plants that currently use paper to document their plant profile data), cost per plant using mainframe data, and cost per plant using PC data. Plants with paper data were assumed to represent half of the number of plants needing profiling, while plants with mainframe data and plants with PC data each represent 25 percent of all plants. The TWG assumed that all plants currently collect this data in either an electronic or paper format, and, therefore, would not incur additional data collection expenses due to microbial profiling. Data reporting costs per plant that are associated with microbial profiling include; data entry and spreadsheet development, data manipulation and analysis, and data review. Costs per system include those to; read and understand the rule, mobilization and planning, generation of reports to State and for in-house review, and meet and review profile with the State. The national costs associated with microbial profiling for utilities was estimated at $2.7 million [Table 14].

3. State Costs

States will review profiles as part of its sanitary survey process. Utilities required to develop a disinfection profile that subsequently decide to make a significant change in disinfection practice must consult with the state prior to making such a change. Table 14 details the total national State costs of profiling (one-time) at $3.1 million.

F. Sanitary Surveys

States are expected to conduct sanitary surveys on a rotating basis, in general no less frequently than once every 3 years for community water systems (CWSs) and no less frequently than every 5 years for noncommunity water systems (NCWSs). For this analysis, 80 percent of Systems are assumed to have already conducted a sanitary survey. The remaining 20 percent of systems are considered to require new surveys in order to comply with the requirements in the IESWTR. The total national cost estimate for sanitary surveys, as shown in Table 14, is estimated at $6.7 million.

G. Summary of Benefits Analysis

The economic benefits of the provisions recommended by the Advisory Committee 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 in drinking water supplies through improvements in filtration at water systems. 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 benefits analysis quantitatively examines health damages avoided based on the provisions recommended by the Advisory Committee. The assessment also discusses, but does not quantify, other economic benefits that may result from the provisions, including reduced risk of outbreaks, avoided costs of averting behavior such as boiling water.

The assessment of net benefits is always somewhat problematic due to the relative ease of quantifying compliance treatment costs versus the difficulty of assigning monetary values to the avoidance of health damages and other benefits arising from a regulation. The challenge of assessing net benefits for the recommended provisions is compounded by the fact that there are large areas of scientific uncertainty regarding the exposure to and the risk assessment for *Cryptosporidium*. Areas where important sources of uncertainty enter the benefits assessment include the following.

- Occurrence of *Cryptosporidium* oocysts in source waters.
- Occurrence of *Cryptosporidium* oocysts in finished waters.
- Reduction of *Cryptosporidium* oocysts due to treatment, including filtration and disinfection.
- Viability of *Cryptosporidium* oocysts after treatment.
- Infectivity of *Cryptosporidium*.
- Incidence of infections and associated symptomatic response (including impact of under reporting).
- Characterization of the risk.
- Willingness to pay to reduce risk and avoid costs.

The cumulative impact of these uncertainties on the outcome of the exposure and risk assessment is impossible to measure. The benefit analysis attempts to take into account some of these uncertainties 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 following two assumptions were made about the performance of current treatment in removing or inactivating oocysts to estimate finished water *Cryptosporidium* concentrations. The standard assumption is that current treatment results in a mean physical removal and inactivation of oocysts of 2.5 logs and a standard deviation ±0.63 logs). Because the finished water concentrations of oocysts represent the baseline against which improved removal from the recommended provisions 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 ±0.63 logs) was also used to calculate finished water concentrations of *Cryptosporidium*.

USEPA made three assumptions about the improved log removal of oocysts that would result from the turbidity provisions recommended by the Advisory Committee. These were based on studies of treatment removal efficiencies discussed earlier in this Notice (Table 1: *Cryptosporidium* and *Giardia lamblia* removal efficiencies by rapid granular filtration). A range of 2–6 logs removal of *Cryptosporidium* oocysts were observed in these studies. 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.

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, as described above, i.e., that sites currently achieving the highest filtered water turbidity performance 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 15 contains the assumptions used to generate the new treatment distribution.

TABLE 15.—IMPROVED REMOVAL ASSUMPTIONS

Additional log removal with committee recommendations			
	Low	Mid	High
Plants now meeting 0.2 NTU limit	None	None	None
Plants operating between 0.2–0.3 NTU	0.15	0.25	0.3
Plants now meeting 0.4 NTU limit	0.35	0.5	0.6

TABLE 15.—IMPROVED REMOVAL ASSUMPTIONS—Continued

Additional log removal with committee recommendations			
	Low	Mid	High
Plants now failing to meet 0.4 NTU limit	0.5	0.75	0.9

The TWG working group assumed that for plants to achieve a 0.3 NTU 95th percentile standard they would operate their plants to achieve a 0.2 NTU limit. Therefore, systems meeting a 95th percentile limit of 0.2 NTU were assumed to make no further treatment changes to meet a 0.3 NTU standard, and therefore show no incremental increase in log removal.

Given the uncertainties described above, assumptions were made in developing the risk characterization. In summary, USEPA assumed:

—an exponential dose/response function for estimating infection rates (Haas et al., 1996)

—2 liters per person daily water consumption with a log normal distribution (Haas and Rose, 1995)

—a national surface water distribution of oocysts based on Monte Carlo analysis of data collected by LeChevallier and Norton (USEPA, 1996a)

—A uniform distribution of percentage of oocysts that would be infectious with a mean value of 10 percent

—An estimated 0.39 mean ratio (triangular distribution) of people that are infected to people that become ill (Haas, et al., 1996).

—The cost of an avoided case of cryptosporidiosis was estimated to be approximately $1800 per case. This was extrapolated from the estimate of $3,000 for giardiasis used in the RIA for the proposal, and based on the relatively shorter average length of illness.

Risk characterization uses these assumptions to calculate the number of illnesses avoided in Table 16. Using this number of illnesses avoided, the cost of illnesses avoided is calculated under each current log treatment assumption (i.e., 2.5 and 3.0 logs) for each of the improved removal assumptions. Table 16 summarizes the mean expected value of potential benefits expected to accrue to the recommended provisions under the six different scenarios, as well as the range.

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Table 16: Summary of Potential Benefits

	Current Treatment Assumption	
	2.5 Logs	**3.0 Logs**
Cost of Illness Avoided Annually		
LOW (improved removal assumption)		
Number of Illnesses Avoided (Expected Value)	**319,000**	**136,000**
Cost of Illness Avoided	**$574.2 million**	**$244.8 million**
MID (improved removal assumption)		
Number of Illnesses Avoided (Expected Value)	**437,000**	**165,000**
Cost of Illness Avoided	**$786.6 million**	**$297.0 million**
HIGH (improved removal assumption)		
Number of Illnesses Avoided (Expected Value)	**469,000**	**177,000**
Cost of Illness Avoided	**$844.2 million**	**$318.6 million**
Mortalities Prevented Annually		
Low (Expected Value)	**48**	**19**
Mid (Expected Value)	**63**	**23**
High (Expected Value)	**67**	**24**
Value of Lives Saved	**Benefits not quantified, but could be substantial (estimated at $300 million annually at 2.5 logs or $100 million at 3.0 logs).**	
Reduced Risk of Outbreaks		
Cost of Illness Avoided	**Benefits not quantified, but could be substantial for large outbreak ($720 million cost of illness avoided for Milwaukee).**	
Emergency Expenditures		
Liability Costs		
Averting Behavior	**Benefits not quantified, but could be substantial for large outbreak ($19.5 million to $61.9 million for Milwaukee).**	

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IV. National Technology Transfer and Advancement Act

Under section 12(d) of the National Technology Transfer and Advancement Act (''NTTAA''), 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.

The Agency does not believe that this Notice addresses any technical standards subject to the NTTAA. A commenter who disagrees with this conclusion should indicate how the Notice is subject to the Act and identify any potentially applicable voluntary consensus standards.

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Dated: October 22, 1997.

Robert Perciasepe,

Assistant Administrator.

Appendix A—U.S. Environmental Protection Agency, Microbial/Disinfection by-Products (M/DBP), Federal Advisory Committee

Agreement in Principle

1.0 Introduction

Pursuant to requirements under the Safe Drinking Water Act (SDWA), the Environmental Protection Agency (EPA) is developing interrelated regulations to control microbial pathogens and disinfectants/disinfection byproducts (D/DBPs) in drinking water. These rules are collectively known as the microbial/disinfection byproducts (M/DBP) rules.

The regulations are intended to address complex risk trade-offs between the two different types of contaminants. In keeping with the agreement reached during the 1992–93 negotiated rulemaking on these matters, EPA issued a Notice of Proposed Rulemaking for Disinfection By-Products Stage I on July 29, 1994. EPA also issued a Notice of Proposed Rulemaking for an Interim Enhanced Surface Water Treatment Rule (IESWTR) on July 29, 1994. Finally, in May 1996, EPA promulgated a final Information Collection Rule (ICR), to obtain data on source water quality, byproduct formation and drinking water treatment plant design and operations.

As part of recent amendments to the SDWA, Congress has established deadlines for all the M/DBP rules, beginning with a November 1998 deadline for promulgation of both the IESWTR and the Stage I D/DBP Rule. To meet this new deadline, EPA initiated an expedited schedule for development of these two rules. Building on the 1994 proposals, EPA intends to issue a Notice of Data Availability (NODA) in November 1997 for public comment. EPA also decided to establish a committee under the Federal Advisory Committee Act (FACA) for development of the rules.

The M/DBP Advisory Committee is made up of organizational members (parties) named by EPA (see Attachment A). The immediate task of the Committee has been to discuss, evaluate and provide advice on data, analysis and approaches to be included in the NODA to be published in November 1997. This Committee met four times from March through June 1997, with the initial objective to reach consensus, where possible, on the elements to be contained in the D/DBP Stage I and IESWTR NODA. Where consensus was not reached, the Committee sought to develop options and/or to clarify key issues and areas of agreement and disagreement. This document is the Committee's statement on the points of agreement reached.

2.0 Agreement in Principle

The Microbial and Disinfection By-Products Federal Advisory Committee considered the technical and policy issues involved in developing a DBP Stage I rule and an IESWTR under the Safe Drinking Water Act and recommends that the Environmental Protection Agency base the applicable sections of its anticipated M/DBP Notice of Data Availability (NODA) on the elements of agreement described below.

This agreement in principle represents the consensus of the parties on the best conceptual principles that the Committee was able to generate within the allocated time and resources available.

The USEPA, a party to the negotiations, agrees that:

1. The person signing this agreement is authorized to commit this party to its terms.

2. EPA agrees to hold a meeting in July 1997 following circulation of a second draft of the NODA to obtain comments from the parties and the public on the extent to which the applicable sections of the draft NODA are consistent with the agreements below.

3. Each party and individual signatory that submits comments on the NODA agrees to support those components of the NODA that reflect the agreements set forth below. Each party and individual signatory reserves the right to comment, as individuals or on behalf of the organization he or she represents, on any other aspect of the Notice of Data Availability.

4. EPA will consider all relevant comments submitted concerning the Notice(s) of Proposed Rulemaking and in response to such comments will make such modifications in the proposed rule(s) and preamble(s) as EPA determines are appropriate when issuing a final rule.

5. Recognizing that under the Appointments Clause of the Constitution governmental authority may be exercised only by officers of the United States and recognizing that it is EPA's responsibility to issue final rules, EPA intends to issue final rules that are based on the provisions of the Safe Drinking Water Act, pertinent facts, and comments received from the public.

6. Each party agrees not to take any action to inhibit the adoption of final rule(s) to the extent it and corresponding preamble(s) have the same substance and effect as the elements of this agreement in principle.

2.1 MCLs

MCLs should remain at the levels proposed: 0.080 mg/l for TTHMs, 0.060 mg/l for HAA5, and 0.010 mg/l for bromate.

2.2 Enhanced Coagulation

The proposed enhanced coagulation provisions should be revised as follows:

a. The top row of the TOC removal table (3x3 matrix) should be modified for systems that practice enhanced coagulation by lowering the TOC removal percentages by 5% across the top row, while leaving the other rows the same.

b. SUVA (specific UV absorbance) should be used for determining whether systems would be required to use enhanced coagulation. The use of a raw water SUVA < 2.0 liter/mg-m as a criterion for not requiring a system to practice enhanced coagulation should be added to those proposed in § 141.135(a)(1)(i)–(iv).

c. For a system required to practice enhanced coagulation or enhanced softening, the use of a finished water SUVA < 2.0 liter/mg-m should be added as a Step 2 procedure. Such a criterion would be in addition to the proposed Step 2 procedure, not in lieu of it.

d. The proposed TOC removals for softening systems should be modified by lowering the value for TOC removal in the matrix at alkalinity >120 mg/l and TOC between 2–4 mg/l by 5% (which would make it equal to the value for non-softening systems) and leaving the remaining values as proposed.

e. If a system is required to practice enhanced softening, lime softening plants would not be required to perform lime soda softening or to lower alkalinity below 40–60 mg/l as part of any Step 2 procedure.

f. There is no need to separately address softening systems in the 3x3 matrix or the Step 1 regulatory language, which was identical to enhanced coagulation regulatory language in the proposed D/DBPR. The revised matrix should appear as follows:

TOC (mg/l)	Alkalinity (mg/l)		
	0 – < 60	60 – < 120	≥ 120
2–4	35	25	15
4–8	45	35	25
>8	50	40	30

2.3 Microbial Benchmarking/Profiling

A microbial benchmark 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 should be established as follows:

A. *Applicability.* The following PWSs to which the IESWTR applies must prepare a disinfection profile:

(1) PWSs with measured TTHM levels of at least 80% of the MCL (0.064 mg/l) as an annual average for the most recent 12 month compliance period for which compliance data are available prior to November 1998 (or some other period designated by the State),

(2) PWSs with measured HAA5 levels of at least 80% of the MCL (0.048 mg/l) as an annual average for the most recent 12 month period for which data are available (or some other period designated by the State)—In connection with HAA5 monitoring, the following provisions apply:

(a) PWSs that have collected HAA5 data under the Information Collection Rule must use those data to determine the HAA5 level, unless the State determines that there is a more representative annual data set.

(b) For those PWSs that do not have four quarters of HAA5 data 90 days following the IESWTR promulgation date, HAA5 monitoring must be conducted for four quarters.

B. *Disinfection profile.* A disinfection profile consists of a compilation of daily *Giardia lamblia* log inactivations (or virus inactivations under conditions to be specified), 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(s)). The PWS will then determine the lowest average month (critical period) for each 12 month period and average critical periods to create a ‘‘benchmark’’ reflecting the lower bound of a PWS’s current disinfection practice. Those PWSs that have all necessary data to determine profiles, using operational data collected prior to promulgation of the IESWTR, may use up to three years of operational data in developing those profiles. Those PWSs that do not have three years of operational data to develop profiles must conduct the necessary monitoring to develop the profile for one year beginning no later than 15 months after promulgation, and use up to two years of existing operational data to develop profiles.

C. *State review.* The State will review disinfection profiles as part of its sanitary survey. Those PWSs required to develop a disinfection profile that subsequently decide to make a significant change in disinfection practice (i.e., move point of disinfection, change the type of disinfectant, change the disinfection process, or any other change designated as significant by the State) must consult with the State prior to implementing such a change. Supporting materials for such consultation must include a description of the proposed change, the disinfection profile, and an analysis of how the proposed change will affect the current disinfection.

D. *Guidance.* EPA, in consultation with interested stakeholders, will develop detailed guidance for States and PWSs on how to develop and evaluate disinfection profiles, identify and evaluate significant changes in disinfection practices, and guidance on moving the point of disinfection from prior to the point of coagulant addition to after the point of coagulant addition.

2.4 Disinfection Credit

Consistent with the existing provisions of the 1989 Surface Water Treatment Rule, credit for compliance with applicable disinfection requirements should continue to be allowed for disinfection applied at any point prior to the first customer.

EPA will develop guidance on the use and costs of oxidants that control water quality problems (e.g., zebra mussels, Asiatic clams, iron, manganese, algae) and whose use will reduce or eliminate the formation of DBPs of public health concern.

2.5 Turbidity

Turbidity Performance Requirements. For all surface water systems that use conventional treatment or direct filtration, serve more than 10,000 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 shall be determined based on measurements of the combined filter effluent at four-hour intervals.

Individual Filter Requirements. All surface water systems that use rapid granular filtration, serve more than 10,000 people, and are required to filter shall conduct continuous monitoring of turbidity for each individual filter and shall provide an exceptions report to the State on a monthly basis. Exceptions reporting shall include the following: (1) any individual filter with a turbidity level greater than 1.0 NTU based on 2 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 2 consecutive measurements fifteen minutes apart. A filter profile will be produced 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 2 consecutive measurements fifteen minutes apart at any time in each of 3 consecutive months, the system shall conduct a self-assessment of the filter utilizing as guidance relevant portions of guidance issued by the Environmental Protection Agency for Comprehensive Performance Evaluation (CPE). If an individual filter has turbidity levels greater than 2.0 NTU based on 2 consecutive measurements fifteen minutes apart at any time in each of two consecutive months, the system will arrange for the conduct of a 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.

2.6 *Cryptosporidium* MCLG

EPA should establish an MCLG to protect public health. The Agency should describe existing and ongoing research and areas of scientific uncertainty on the question of which species of *Cryptosporidium* represents a concern for public health (e.g. *parvum, muris, serpententious*) and request further comment on whether to establish an MCLG on the genus or species level.

In the event the Agency establishes an MCLG on the genus level, EPA should make clear that the objective of this MCLG is to protect public health and explain the nature of scientific uncertainty on the issue of taxonomy and cross reactivity between strains. The Agency should indicate that the scope of MCLG may change as scientific data on specific strains of particular concern to human health become available.

2.7 Removal of *Cryptosporidium*

All surface water systems that serve more than l 0,000 people and are required to filter must achieve at least a 2 log removal of *Cryptosporidium*. Systems which use rapid granular filtration (direct filtration or conventional filtration treatment—as currently defined in the SWTR), and meet the turbidity requirements described in Section 2.5 are assumed to achieve at least a 2 log removal of *Cryptosporidium*. Systems which use slow sand filtration and diatomaceous earth filtration and meet existing turbidity performance requirements (less than 1 NTU for the 95th percentile or alternative criteria as approved by the State) are assumed to achieve at least a 2 log removal of *Cryptosporidium*.

Systems may demonstrate that they achieve higher levels of physical removal.

2.8 Multiple Barrier Concept

EPA should issue a risk-based proposal of the Final Enhanced Surface Water Treatment Rule for *Cryptosporidium* embodying the multiple barrier approach (e.g. source water protection, physical removal, inactivation, etc.), including, where risks suggest appropriate, inactivation requirements. In establishing the Final Enhanced Surface Water Treatment Rule, the following issues will be evaluated:

- Data and research needs and limitations (e.g. occurrence, treatment, viability, active disease surveillance, etc.);
- Technology and methods capabilities and limitations;
- Removal and inactivation effectiveness;
- Risk tradeoffs including risks of significant shifts in disinfection practices;
- Cost considerations consistent with the SDWA;
- Reliability and redundancy of systems;
- Consistency with the requirements of the Act.

2.9 Sanitary Surveys

Sanitary surveys operate as an important preventive tool to identify water system deficiencies that could pose a risk to public health. EPA and ASDWA have issued a joint guidance dated 12/21/95 on the key components of an effective sanitary survey. The following provisions concerning sanitary surveys should be included.

I. Definition

(A) A sanitary survey is 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.

(B) 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.

(C) A sanitary survey must address each of the eight elements outlined in the December 1995 EPA/STATE Guidance on Sanitary Surveys.

II. Frequency

(A) Conduct sanitary surveys for all surface water systems (including groundwater under the influence) no less frequently than every three years for community systems except as provided below and no less frequently than every five years for noncommunity systems.

—May ‘‘grandfather’’sanitary surveys conducted after December 1995, if they address the eight sanitary survey components outlined above.

(B) For community systems determined by the State to have outstanding performance based on prior sanitary surveys, successive sanitary surveys may be conducted no less than every five years.

III. Follow Up

(A) Systems must respond to 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.

(B) States must 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.

Agreed to by:

Name, Organization

Date

Signed By:

Peter L. Cook, National Association of Water Companies
Michael A. Dimitriou, International Ozone Association
Cynthia C. Dougherty, US Environmental Protection Agency
Mary J.R. Gilchrist, American Public Health Association
Jeffrey K. Griffiths, National Association of People with AIDS
Barker Hamill, Association of State Drinking Water Administrators
Robert H. Harris, Environmental Defense Fund
Edward G. Means III, American Water Works Association
Rosemary Menard, Large Unfiltered Systems
Erik D. Olson, Natural Resources Defense Council
Brian L. Ramaley, Association of Metropolitan Water Agencies
Charles R. Reading Jr., Water and Wastewater Equipment Manufacturers Association
Suzanne Rude, National Association of Regulatory Utility Commissioners
Ralph Runge, Chlorine Chemistry Council
Coretta Simmons, National Association of State Utility Consumer Advocates
Bruce Tobey, National League of Cities
Chris J. Wiant, National Association of City and County Health Officials; National Environmental Health Association

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