EPA-815-Z-98-008

federal register

Wednesday
December 16, 1998

Part IV

Environmental Protection Agency

40 CFR Parts 9, 141, and 142
National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141, and 142

[WH-FRL-6199-8]

RIN 2040-AB82

National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this document, EPA is finalizing maximum residual disinfectant level goals (MRDLGs) for chlorine, chloramines, and chlorine dioxide; maximum contaminant level goals (MCLGs) for four trihalomethanes (chloroform, bromodichloromethane, dibromochloromethane, and bromoform), two haloacetic acids (dichloroacetic acid and trichloroacetic acid), bromate, and chlorite; and National Primary Drinking Water Regulations (NPDWRs) for three disinfectants (chlorine, chloramines, and chlorine dioxide), two groups of organic disinfection byproducts (total trihalomethanes (TTHMs)—a sum of the four listed above, and haloacetic acids (HAA5)—a sum of the two listed above plus monochloroacetic acid and mono- and dibromoacetic acids), and two inorganic disinfection byproducts (chlorite and bromate). The NPDWRs consist of maximum residual disinfectant levels (MRDLs) or maximum contaminant levels (MCLs) or treatment techniques for these disinfectants and their byproducts. The NPDWRs also include monitoring, reporting, and public notification requirements for these compounds. This document includes the best available technologies (BATs) upon which the MRDLs and MCLs are based. The set of regulations promulgated today is also know as the Stage 1 Disinfection Byproducts Rule (DBPR). EPA believes the implementation of the Stage 1 DBPR will reduce the levels of disinfectants and disinfection byproducts in drinking water supplies. The Agency believes the rule will provide public health protection for an additional 20 million households that were not previously covered by drinking water rules for disinfection byproducts. In addition, the rule will for the first time provide public health protection from exposure to haloacetic acids, chlorite (a major chlorine dioxide byproduct) and bromate (a major ozone byproduct).

The Stage 1 DBPR applies to public water systems that are community water systems (CWSs) and nontransient noncommunity water systems (NTNCWs) that treat their water with a chemical disinfectant for either primary or residual treatment. In addition, certain requirements for chlorine dioxide apply to transient noncommunity water systems (TNCWSs).

EFFECTIVE DATE: This regulation is effective February 16, 1999. Compliance dates for specific components of the rule are discussed in the Supplementary Information Section. The incorporation by reference of certain publications listed in today's rule is approved by the Director of the Federal Register as of February 16, 1999.

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

FOR FURTHER INFORMATION CONTACT: For general information contact, the Safe Drinking Water Hotline, Telephone (800) 426-4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9:00 am to 5:30 pm Eastern Time. For technical inquiries, contact Tom Grubbs, Office of Ground Water and Drinking Water (MC 4607), U.S. Environmental Protection Agency, 401 M Street SW, Washington, DC 20460; telephone (202) 260-7270. For Regional contacts see **SUPPLEMENTARY INFORMATION.**

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

Regulated entities. Entities regulated by the Stage 1 DBPR are community and nontransient noncommunity water systems that add a disinfectant during any part of the treatment process including a residual disinfectant. In addition, certain provisions apply to transient noncommunity systems that use chlorine dioxide. Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Community and nontransient noncommunity water systems that treat their water with a chemical disinfectant for either primary of residual treatment. In addition, certain requirements for chlorine dioxide apply to transient noncommunity water systems.
State, Local, Tribal, or Federal Governments.	Same as above.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in § 141.130 of this rule. If you have questions regarding the applicability of this action to a particular entity, contact one of the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section or the Regional contacts below.

Regional Contacts

I. Kevin Reilly, Water Supply Section, JFK Federal Bldg., Room 203, Boston, MA 02203, (617) 565-3616

II. Michael Lowy, Water Supply Section, 290 Broadway 24th Floor, New York, NY 10007-1866, (212) 637-3830

III. Jason Gambatese, Drinking Water Section (3WM41), 1650 Arch Street, Philadelphia, PA 19103-2029, (215) 814-5759

IV. David Parker, Water Supply Section, 345 Courtland Street, Atlanta, GA 30365, (404) 562–9460
V. Miguel Del Toral, Water Supply Section, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 886–5253
VI. Blake L. Atkins, Drinking Water Section, 1445 Ross Avenue, Dallas, TX 75202, (214) 665–2297
VII. Ralph Flournoy, Drinking Water/Ground Water Management Branch, 726 Minnesota Ave., Kansas City, KS 66101, (913) 551–7374
VIII. Bob Clement, Public Water Supply Section (8P2–W–MS), 999 18th Street, Suite 500, Denver, CO 80202–2466, (303) 312–6653
IX. Bruce Macler, Water Supply Section, 75 Hawthorne Street, San Francisco, CA 94105, (415) 744–1884
X. Wendy Marshall, Drinking Water Unit, 1200 Sixth Avenue (OW–136), Seattle, WA 98101, (206) 553–1890

Abbreviations Used in This Document

AWWA: American Water Works Association
AWWSCo: American Water Works Service Company
BAT: Best available technology
BDCM: Bromodichloromethane
CDC: Centers for Disease Control and Prevention
C.I.: Confidence Intervals
CMA: Chemicals Manufacturers Association
CPE: Comprehensive performance evaluation
CWS: Community water system
DBCM: Dibromochloromethane
DBP: Disinfection byproducts
D/DBP: Disinfectants and disinfection byproducts
DBPR: Disinfection Byproducts Rule
DBPRAM: Disinfection byproducts regulatory analysis model
DCA: Dichloroacetic acid
DOC: Dissolved organic carbon
DWSRF: Drinking Water State Revolving Fund
EC: Enhanced coagulation
EJ: Environmental justice
EPA: United States Environmental Protection Agency
ESWTR: Enhanced Surface Water Treatment Rule
FACA: Federal Advisory Committee Act
GAC10: Granular activated carbon with ten minute empty bed contact time and 180 day reactivation frequency
GAC20: Granular activated carbon with twenty minute empty bed contact time and 180 day reactivation frequency
GDP: Gross Domestic Product
GWR: Groundwater rule
HAA5: Haloacetic acids (five) (chloroacetic acid, dichloroacetic acid, trichloroacetic acid, bromoacetic acid, and dibromoacetic acid)
HAN: Haloacetonitriles
ICR: Information collection rule (issued under section 1412(b) of the SDWA)
ILSI: International Life Sciences Institute
IESTWR: Interim Enhanced Surface Water Treatment Rule
LOAEL: Lowest Observed Adverse Effect Level
LT1ESTWR: Long-Term 1Enhanced Surface Water Treatment Rule
MCL: Maximum contaminant level
MCLG: Maximum contaminant level goal
M–DBP: Microbial and Disinfectants/Disinfection Byproducts
mg/L: Milligrams per liter
MRDL: Maximum residual disinfectant level
MRDLG: Maximum residual disinfectant level goal
NDWAC: National Drinking Water Advisory Council
NIST: National Institute of Science and Technology
NOAEL: No Observed Adverse Effect Level
NODA: Notice of Data Availability
NOM: Natural organic matter
NPDWR: National Primary Drinking Water Regulation
NTNCWS: Nontransient noncommunity water system
NTP: National Toxicology Program
NTTAA: National Technology Transfer and Advancement Act
NTU: Nephelometric turbidity unit
OMB: Office of Management and Budget
PAR: Population attributable risk
PBMS: Performance based measurement system
PE: Performance evaluation
PODR: Point of diminishing return
PQL: Practical quantitation limit
PWS: Public water system
QC: Quality control
Reg. Neg.: Regulatory Negotiation
RFA: Regulatory Flexibility Act
RfD: Reference dose
RIA: Regulatory impact analysis
RSC: Relative source contribution
SAB: Science Advisory Board
SBREFA: Small Business Regulatory Enforcement Fairness Act
SDWIS: Safe Drinking Water Information System
SUVA: Specific ultraviolet absorbance
SDWA: Safe Drinking Water Act, or the "Act," as amended 1996
SWTR: Surface Water Treatment Rule
TC: Total coliforms
TCA: Trichloroacetic acid
TCR: Total Coliform Rule
TOC: Total organic carbon
TOX: Total organic halides
TTHM: Total trihalomethanes (chloroform, bromdichloromethane, dibromochloromethane, and bromoform)
TNCWS: Transient noncommunity water systems
TWG: Technical work group
UMRA: Unfunded mandates reform act
URTH: Unreasonable risk to health
WIDB: Water Industry Data Base

Table of Contents

I. Background
A. Statutory Requirements and Legal Authority
B. Regulatory History
1. Existing Regulations
2. Public Health Concerns To Be Addressed
3. Regulatory Negotiation Process
4. Federal Advisory Committee Process
5. 1997 and 1998 Notices of Data Availability (NODA)
II. Summary of Final Stage 1 Disinfection Byproduct Rule
A. Applicability
B. MRDLGs and MRDLs for Disinfectants
C. MCLGs and MCLs for TTHMs, HAA5, Chlorite, and Bromate
D. Treatment Technique for Disinfection Byproducts Precursors
E. BAT for Disinfectants, TTHMs, HAA5, Chlorite, and Bromate
F. Compliance Monitoring Requirements
G. Analytical Methods
H. Laboratory Certification Criteria
I. Variances and Exemptions
J. State Recordkeeping, Primacy, Reporting Requirements
K. System Reporting Requirements
L. Guidance Manuals
M. Regulation Review
III. Explanation of Final Rule
A. MCLGs/MRDLGs
1. MCLG for Chloroform
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
2. MCLG for Bromodichloromethane (BDCM)
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
3. MCLG for Dibromochloromethane (DBCM)
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
4. MCLG for Bromoform
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
5. MCLG for Dichloroacetic Acid (DCA)
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
6. MCLG for Trichloroacetic Acid (TCA)
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
7. MCLG for Chlorite and MRDLG for Chlorine Dioxide
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
8. MCLG for Bromate
a. Today's Rule
b. Background and Analysis
c. Summary of Comments

9. MCLG for Chloral Hydrate
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
10. MRDLG for Chlorine
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
11. MRDLG for Chloramine
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
B. Epidemiology
1. Cancer Epidemiology
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
2. Reproductive and Developmental Epidemiology
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
C. MCLs and BAT for TTHM, HAA5, Chlorite, and Bromate; MRDLs and BAT for Chlorine, Chloramines, and Chlorine Dioxide
1. MCLs for TTHMs and HAA5
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
2. MCL for Bromate
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
3. MCL for Chlorite
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
4. MRDL for Chlorine
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
5. MRDL for Chloramines
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
6. MRDL for Chlorine Dioxide
a. Today's Rule
b. Background Analysis
c. Summary of Comments
D. Treatment Technique Requirement
1. Today's Rule
2. Background and Analysis
3. Summary of Comments
E. Predisinfection Disinfection Credit
1. Today's Rule
2. Background and Analysis
3. Summary of Comments
F. Requirements for Systems to Use Qualified Operators
G. Analytical Methods
1. Today's Rule
2. Background and Analysis
3. Summary of Comments
4. Performance Based Measurement Systems
H. Monitoring Requirements
1. Today's Rule
2. Background and Analysis
3. Summary of Comments
I. Compliance Schedules
1. Today's Rule
2. Background and Analysis
3. Summary of Comments
J. Public Notice Requirements
1. Today's Rule
2. Background and Analysis
3. Summary of Comments
K. System Reporting and Record Keeping Requirements
1. Today's Rule
2. Summary of Comments
L. State Recordkeeping, Primacy, and Reporting Requirements
1. State Recordkeeping Requirements
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
2. Special Primacy Requirements
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
3. State Reporting Requirements
a. Today's Rule
b. Background and Analysis
c. Summary of Comments
M. Variances and Exemptions
1. Today's Rule
2. Background and Analysis
3. Summary of Comments
N. Laboratory Certification and Approval
1. Today's Rule
2. Background and Analysis
3. Summary of Comments
IV. Economic Analysis
A. Today's Rule
B. Background
1. Overview of RIA for the Proposed Rule
2. Factors Affecting Changes to the 1994 RIA
a. Changes in Rule Criteria
b. New Information Affecting DBP Occurrence and Compliance Forecast
c. New Epidemiology Information
C. Cost Analysis
1. Revised Compliance Forecast
2. System Level Unit Costs
3. National Costs
D. Benefits Analysis
1. Exposure Assessment
2. Baseline Risk Assessment Based on TTHM Toxicological Data
3. Baseline Analysis Based on Epidemiology Data
4. Exposure Reduction Analysis
5. Monetization of Health Endpoints
E. Net Benefits Analysis
F. Summary of Comments
V. Other Requirements
A. Regulatory Flexibility Analysis
1. Today's Rule
2. Background and Analysis
3. Summary of Comments
B. Paperwork Reduction Act
C. Unfunded Mandates Reform Act
1. Summary of UMRA Requirements
2. Written Statement for Rules with Federal Mandates of $100 million or More
a. Authorizing Legislation
b. Cost Benefit Analysis
c. Estimates of Future Compliance Costs and Disproportionate Budgetary Effects
d. Macro-economic Effects
e. Summary of State, Local, and Tribal Government and TheirConcerns
f. Regulatory Alternative Considered
3. Impacts on Small Governments
D. National Technology Transfer and Advancement Act
E. Executive Order 12866: Regulatory Planning and Review
F. Executive Order 12898: Environmental Justice
G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
H. Consultation with the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services
I. Executive Order 12875: Enhancing the Intergovernmental Partnership
J. Executive Order 13084: Consultation and Coordination with Indian Tribal Governments
K. Submission to Congress and the General Accounting Office
L. Likely Effect of Compliance with the Stage 1 DBPR on the Technical, Financial, and Managerial Capacity of Public Water Systems
VI. References

I. Background

A. Statutory Requirements and Legal Authority

The Safe Drinking Water Act (SDWA or the Act), as amended in 1986, requires USEPA to publish a "maximum contaminant level goal" (MCLG) for each contaminant which, in the judgement of the USEPA Administrator, "may have any adverse effect on the health of persons and which is known or anticipated to occur in public water systems" (Section 1412(b)(3)(A)). MCLGs are to be set at a level at which "no known or anticipated adverse effect on the health of persons occur and which allows an adequate margin of safety" (Section 1412(b)(4)).

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

The Act also requires that at the same time USEPA publishes an MCLG, which is a non-enforceable health goal, it also must publish a National Primary Drinking Water Regulation (NPDWR) that specifies either a maximum contaminant level (MCL) or treatment technique (Sections 1401(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"

As amended, EPA's general authority to set a maximum contaminant level goal (MCLG) and National Primary Drinking Water Regulation (NPDWR) applies to contaminants that may "have an adverse effect on the health of persons," that are "known to occur or there is a substantial likelihood that the contaminant will occur in public water

systems with a frequency and at levels of public health concern," and for which "in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems" (SDWA Section 1412(b)(1)(A)).

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

The amendments established a number of regulatory deadlines, including schedules for a Stage 1 Disinfection Byproduct Rule (DBPR), an Interim Enhanced Surface Water Treatment Rule (IESWTR), a Long-Term Final Enhanced Surface Water Treatment Rule (LTESWTR) affecting Public Water Systems (PWSs) that serve under 10,000 people, and a Stage 2 DBPR (Section 1412(b)(2)(C)). The Act as amended also requires EPA to promulgate regulations to address filter backwash (Section 1412(b)(14)). Finally, the Act requires EPA to promulgate regulations specifying criteria for requiring disinfection "as necessary" for ground water systems (Section 1412 (b)(8)).

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

B. Regulatory History

1. Existing Regulations

Surface Water Treatment Rule. Under the Surface Water Treatment Rule (SWTR) (54 FR 27486, June 29, 1989) (EPA,1989a), EPA set maximum contaminant level goals of zero for Giardia lamblia, viruses, and Legionella; and promulgated NPDWR for all PWSs using surface water sources or ground water sources under the direct influence of surface water. The SWTR includes treatment technique requirements for filtered and unfiltered systems that are intended to protect against the adverse health effects of exposure to Giardia lamblia, viruses, and Legionella, as well as many other pathogenic organisms. Briefly, those requirements include: (1) requirements for a maintenance of a disinfectant residual in the distribution system; (2) removal and/or inactivation of 3 logs (99.9%) for Giardia and 4 logs (99.99%) for viruses; (3) combined filter effluent performance of 5 nephelometric turbidity unit (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 (4) watershed protection and other requirements for unfiltered systems.

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

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

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

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

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

Information Collection Rule. The Information Collection Rule (ICR) is a monitoring and data reporting rule that was promulgated on May 14, 1996 (61 FR 24354) (EPA, 1996a). The purpose of the ICR is to collect occurrence and treatment information to help evaluate the need for possible changes to the current SWTR and existing microbial treatment practices, and to help evaluate the need for future regulation for disinfectants and disinfection byproducts (D/DBPs). The ICR will provide EPA with additional information on the national occurrence in drinking water of (1) chemical byproducts that form when disinfectants used for microbial control react with naturally occurring compounds already present in source water and (2) disease-causing microorganisms, including Cryptosporidium, Giardia, and viruses. The ICR will also provide engineering data on how PWSs currently control for such contaminants. This information is being collected because the 1992 Regulatory Negotiating Committee (henceforth referred to as the Reg. Neg. Committee) on microbial pathogens and disinfectants and DBPs concluded that additional information was needed to assess the potential health problem created by the presence of DBPs and pathogens in drinking water and to assess the extent and severity of risk in order to make sound regulatory and public health decisions. The ICR will also provide information to support regulatory impact analyses for various regulatory options, and to help develop monitoring strategies for cost-effectively implementing regulations.

The ICR pertains to large public water systems serving populations at least 100,000; a more limited set of ICR requirements pertain to ground water systems serving between 50,000 and 100,000 people. About 300 PWSs operating 500 treatment plants are involved with the extensive ICR data collection. Under the ICR, these PWSs monitor for water quality factors affecting DBP formation and DBPs

within the treatment plant and in the distribution system monthly for 18 months. In addition, PWSs must provide operating data and a description of their treatment plan design and surface water systems must monitor for bacteria, viruses, and protozoa. Finally, a subset of PWSs must perform treatment studies, using either granular activated carbon (GAC) or membrane processes, to evaluate DBP precursor removal and control of DBPs. Monitoring for treatment study applicability began in September 1996. The remaining occurrence monitoring began in July 1997.

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

2. Public Health Concerns to be Addressed

EPA's main mission is the protection of human health and the environment. When carrying out this mission, EPA must often make regulatory decisions with less than complete information and with uncertainties in the available information. EPA believes it is appropriate and prudent to err on the side of public health protection when there are indications that exposure to a contaminant may present risks to public health, rather than take no action until risks are unequivocally proven.

In regard to the Stage 1 DBPR, EPA recognizes that the assessment of public health risks from disinfection of drinking water currently relies on inherently difficult and preliminary empirical analysis. On one hand, epidemiologic studies of the populations in various geographic areas are hampered by difficulties of study design, scope, and sensitivity. On the other hand, uncertainty is involved in the interpretation of results using high dose animal toxicological studies of a few of the numerous byproducts that occur in disinfected drinking water to estimate the risk to humans from chronic exposure to low doses of these and other byproducts. Such studies of individual DBPs is insufficient to characterize risks from exposure to the entire mixture of DBPs in disinfected drinking water. While recognizing these uncertainties, EPA continues to believe that the Stage 1 DBPR is necessary for the protection of public health from exposure to potentially harmful DBPs.

A fundamental component in assessing the risk for a contaminant is the number of people that may be exposed to the parameter of concern. In this case, there is a very large population potentially exposed to DBPs through drinking water in the U.S. Over 200 million people are served by PWSs that apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants. While these disinfectants are effective in controlling many microorganisms, they react with natural organic and inorganic matter in the water to form DBPs, some of which may pose health risks. One of the most complex questions facing water supply professionals is how to minimize the risks from DBPs and still maintain adequate control over microbial contaminants. Because of the large number of people exposed to DBPs, there is a substantial concern for any risks associated with DBPs that may impact public health.

Since the discovery of chlorination byproducts in drinking water in 1974, numerous toxicological studies have been conducted. Results from these studies have shown several DBPs (e.g., bromodichloromethane, bromoform, chloroform, dichloroacetic acid, and bromate) to be carcinogenic in laboratory animals . Some DBPs (e.g., chlorite, BDCM, and certain haloacetic acids) have also been shown to cause adverse reproductive or developmental effects in laboratory animals. Although many of these studies have been conducted at high doses, EPA believes the studies provide evidence that DBPs present a potential public health risk that needs to be addressed.

In the area of epidemiology, a number of epidemiology studies have been conducted to investigate the relationship between exposure to chlorinated surface water and cancer. While EPA cannot conclude there is a causal link between exposure to chlorinated surface water and cancer, these studies have suggested an association, albeit small, between bladder, rectal, and colon cancer and exposure to chlorinated surface water. While there are fewer published epidemiology studies that have been conducted to evaluate the possible relationship between exposure to chlorinated surface water and reproductive and developmental effects, a recent study has suggested an association between early term miscarriage and exposure to drinking water with elevated trihalomethane levels. In addition to this study, another new study reported a small increased risk of neural tube defects associated with consumption of drinking water containing high levels of TTHMs. However, no significant associations were observed with individual THMs, HAAs, and haloacetonitriles (HANs) and adverse outcomes in this study. As with cancer, EPA cannot conclude at this time there is a causal link between exposure to DBPs and reproductive and developmental effects.

While EPA recognizes there are data deficiencies in the information on the health effects from the DBPs and the levels at which they occur, the Agency believes the weight-of-evidence presented by the available epidemiological studies on chlorinated drinking water and toxicological studies on individual DBPs support a potential hazard concern and warrant regulatory action at this time to reduce DBP levels in drinking water. Recognizing the deficiencies in the existing data, EPA believes the incremental two-stage approach for regulating DBPs, agreed upon by the regulatory negotiation process, is prudent and necessary to protect public health and meet the requirements of the SDWA.

In conclusion, because of the large number of people exposed to DBPs and the different potential health risks (e.g., cancer and adverse reproductive and developmental effects) that may result from exposure to DBPs, EPA believes the Stage 1 DBPR is needed to further prevent potential health effects from DBPs, beyond that controlled for by the 1979 total trihalomethane rule. Both the Reg. Neg. Committee for the 1994 proposed rule and the Microbial and Disinfectants/Disinfection Byproducts Advisory Committee (henceforth cited as the M-DBP Advisory Committee) formed in March 1997 under the Federal Advisory Committee Act (FACA), agreed with the need for the Stage 1 DBPR to reduce potential risks from DBPs in the near term, while acknowledging additional information is still needed for the Stage 2 DBPR (especially on health effects),

3. Regulatory Negotiation Process

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

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

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

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

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

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

4. Federal Advisory Committee Process

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

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

5. 1997 and 1998 Notices of Data Availability

In November 1997 EPA published a NODA (USEPA, 1997b) that summarized the 1994 proposal; described new data and information that the Agency has obtained and analyses that have been developed since the proposal; provided information concerning the July 1997 recommendations of the M–DBP Advisory Committee on key issues related to the proposal (described above); and requested comment on these recommendations, as well as on other regulatory implications that flow from the new data and information. The Agency solicited additional data and information that were relevant to the issues discussed in the DBP NODA. EPA also requested that any information the Agency should consider as part of the final rule development process regarding data or views submitted to the Agency since the close of the comment period on the 1994 proposal, be formally resubmitted during the 90-day

comment period unless already in the underlying record in the docket for the NODA.

In March 1998, EPA issued a second DBP NODA (EPA, 1998a) that summarized new health effects information received and analyzed since the November 1997 NODA and requested comments on several issues related to the simultaneous compliance with the Stage 1 DBPR and the Lead and Copper Rule. The 1998 NODA indicated EPA was considering increasing the MCLG for chloroform from zero to 0.3 mg/L and the proposed MCLG for chlorite from 0.08 mg/L to 0.8 mg/L. EPA also requested comment on increasing the Maximum Residual Disinfection Level Goal (MRDLG) for chlorine dioxide from 0.3 mg/L to 0.8 mg/L. Today's final rule was developed based on the outcome of the 1992 Reg. Neg., the 1994 proposed rule, the 1997 FACA process, and both the 1997 and 1998 DBP NODAs, as well as a wide range of technical comments from stakeholders and members of the public. A summary of today's rule follows.

II. Summary of Final Stage 1 Disinfection Byproduct Rule

A. Applicability

The final Stage 1 DBPR applies to community water systems (CWSs) and nontransient noncommunity water systems (NTNCWs) that treat their water with a chemical disinfectant for either primary or residual treatment. In addition, certain requirements for chlorine dioxide apply to transient noncommunity water systems (TNCWSs).

B. MRDLGs and MRDLs for Disinfectants

EPA is finalizing the following MRDLGs and maximum residual disinfectant levels (MRDLs) for chlorine, chloramines, and chlorine dioxide in Table II–1.

TABLE II–1.—MRDLGS AND MRDLS FOR DISINFECTANTS

Disinfectant residual	MRDLG (mg/L)	MRDL (mg/L)
Chlorine	4 (as Cl_2)	4.0 (as Cl_2)
Chloramine	4 (as Cl_2)	4.0 (as Cl_2)
Chlorine Dioxide	0.8 (as ClO_2)	0.8 (as ClO_2)

C. MCLGs and MCLs for TTHMs, HAA5, Chlorite, and Bromate

EPA is finalizing the MCLGs and MCLs in Table II–2.

TABLE II–2.—MCLGS AND MCLS FOR DISINFECTION BYPRODUCTS

Disinfection byproducts	MCLG (mg/L)	MCL (mg/L)
Total trihalomethanes (TTHM) [1]	N/A	0.080
—Chloroform	0	.....
—Bromodichloromethane	0	.....
—Dibromochloromethane	0.06	.....
—Bromoform	0	.....
Haloacetic acids (five) (HAA5) [2]	N/A	0.060
—Dichloroacetic acid	0	.....
—Trichloroacetic acid	0.3	.....
Chlorite	0.8	1.0
Bromate	0	0.010

N/A—Not applicable because there are no individual MCLGs for TTHMs or HAAs.
[1] Total trihalomethanes is the sum of the concentrations of chloroform, bromodichloromethane, dibromochloromethane, and bromoform.
[2] Haloacetic acids (five) is the sum of the concentrations of mono-, di-, and trichloroacetic acids and mono- and dibromoacetic acids.

D. Treatment Technique for Disinfection Byproduct Precursors

Water systems that use surface water or ground water under the direct influence of surface water and use conventional filtration treatment are required to remove specified percentages of organic materials (measured as total organic carbon) that may react with disinfectants to form DBPs as indicated in Table II–3. Removal will be achieved through a treatment technique (enhanced coagulation or enhanced softening) unless a system meets alternative criteria discussed in Section III.D.

TABLE II–3.—REQUIRED REMOVAL OF TOTAL ORGANIC CARBON BY ENHANCED COAGULATION AND ENHANCED SOFTENING FOR SUBPART H SYSTEMS USING CONVENTIONAL TREATMENT [a,b,c]

Source Water TOC (mg/L)	Source Water Alkalinity (mg/L as $CaCO_3$) (percent)		
	0–60	>60–120	>120
>2.0–4.0	35.0	25.0	15.0
>4.0–8.0	45.0	35.0	25.0

TABLE II–3.—REQUIRED REMOVAL OF TOTAL ORGANIC CARBON BY ENHANCED COAGULATION AND ENHANCED SOFTENING FOR SUBPART H SYSTEMS USING CONVENTIONAL TREATMENT [a,b,c]—Continued

Source Water TOC (mg/L)	Source Water Alkalinity (mg/L as $CaCO_3$) (percent)		
	0–60	>60–120	>120
>8.0	50.0	40.0	30.0

[a] Systems meeting at least one of the conditions in Section 141.135(a)(2) (i)–(vi) of the rule are not required to operate the removals in this table.
[b] Softening systems meeting one of the two alternative compliance criteria in Section 141.135(a)(3) of the rule are not required to meet the removals in this table.
[c] Systems practicing softening must meet the TOC removal requirements in the last column to the right.

E. BAT for Disinfectants, TTHMs, HAA5, Chlorite, and Bromate

Under the SDWA, EPA must specify the BAT for each MCL (or MRDL) that is set. PWS that are unable to achieve an MCL or MRDL may be granted a variance if they use the BAT and meet other requirements (see section III.M for a discussion of variances and exemptions). Table II.4 includes the BATs for each of the MCLs or MRDLs that EPA is promulgating in today's Stage 1 DBPR.

TABLE II–4.—BAT FOR DISINFECTANTS AND DISINFECTION BYPRODUCTS

Disinfectant/DBP	Best available technology
Disinfectants	
Chlorine residual	Control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.
Chloramine residual	Control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.
Chlorine dioxide residual	Control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.
Disinfection Byproducts	
Total trihalomethanes	Enhanced coagulation or enhanced softening or GAC10*, with chlorine as the primary and residual disinfectant.
Total haloacetic acids	Enhanced coagulation or enhanced softening or GAC10*, with chlorine as the primary and residual disinfectant.
Chlorite	Control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.
Bromate	Control of ozone treatment process to reduce production of bromate.

*GAC10 means granular activated carbon with an empty bed contact time of 10 minutes and reactivation frequency for GAC of no more than six months.

F. Compliance Monitoring Requirements

Compliance monitoring requirements are explained in Section III.H of today's rule. EPA has developed routine and reduced compliance monitoring schemes for disinfectants and DBPs to be protective from different types of health concerns, including acute and long-term effects.

G. Analytical Methods

EPA has approved five methods for measurement of free chlorine, four methods for combined chlorine, and six for total chlorine. EPA has also approved two methods for the measurement of chlorine dioxide residuals; three methods for the measurement of HAA5; three methods for the measurement of TTHMs; three methods for the measurement of TOC/Dissolved Organic Carbon (DOC); two methods for the monthly measurement of chlorite and one method for the daily monitoring of chlorite; two methods for bromide; one method for the measurement of bromate; and one method for the measurement of UV_{254}. Finally, EPA approved all methods allowed in § 141.89(a) for measuring alkalinity. These issues are discussed in more detail in section III.G.

H. Laboratory Certification Criteria

Consistent with other drinking water regulations, determinations of compliance with the MCLs may only be conducted by certified laboratories. EPA is requiring that analyses can be conducted by a party acceptable to EPA or the State in those situations where the parameter can adequately be measured by someone other than a certified laboratory and for which there is a good reason to allow analysis at other locations (e.g., for samples which normally deteriorate before reaching a certified laboratory, especially when taken at remote locations). For a detailed discussion of the lab certification requirements, see section III.N.

I. Variances and Exemptions

Variances and exemptions will be permitted in accordance with existing statutory and regulatory authority. For a detailed discussion see section III.M.

J. State Recordkeeping, Primacy, and Reporting Requirements

The Stage 1 DBPR requires States to adopt several regulatory requirements, including public notification requirements, MCLs for DBPs, MRDLs for disinfectants, and the requirements in Subpart L. In addition, States are required to adopt several special primacy requirements for the Stage 1 DPBR. States are also required to keep specific records in accordance with existing regulations and additional records specific to the Stage 1 DBPR. Finally, the rule does not require any

State additional reporting requirements beyond those required under existing regulations. These requirements are discussed in more detail in Section III.L.

K. System Reporting Requirements

System are required to report monitoring data to the State as discussed in Section III.K.

L. Guidance Manuals

EPA is developing guidance for both systems and States for the implementation of the Stage 1 DBPR and the IESWTR. The guidance manuals include: Guidance Manual for Enhanced Coagulation and Precipitative Softening; Disinfection Benchmark Guidance Manual; Turbidity Guidance Manual; Alternative Disinfectants and Oxidants Guidance Manual; M/DBP Simultaneous Compliance Manual; Sanitary Survey Guidance Manual; Unfiltered Systems Guidance Manual; and Uncovered Finished Water Reservoirs. Guidance manuals will be available after the publication of the Stage 1 DBPR.

M. Regulation Review

Under the provisions of the SDWA (Section 1412(b)(9)), the Agency is required to review NPDWRs at least once every six years. As mentioned previously, today's final rule revises, updates, and supersedes the regulations for total trihalomethanes, initially published in 1979. Since that time, there have been significant changes in technology, treatment techniques, and other regulatory controls that provide for greater protection of human health. As such, for today's rule, EPA has analyzed innovations and changes in technology and treatment techniques that have occurred since promulgation of the interim TTHM regulations. That analysis, contained primarily in the cost and technology document supporting this rule, supports the changes in the Stage 1 DBPR from the 1979 TTHM rule. EPA believes that the innovations and changes in technology and treatment techniques that result in changes to the 1979 TTHM regulations are feasible within the meaning of SDWA Section 1412(b).

III. Explanation of Final Rule

A. MCLGs/MRDLGs

MCLGs are set at levels at which no known or anticipated adverse health effects occur, allowing for an adequate margin of safety. Establishment of an MCLG for each specific contaminant is based on the available evidence of carcinogenicity or noncancer adverse health effects from drinking water exposure using EPA's guidelines for risk assessment (see the proposed rule at 59 FR 38677 for a detailed discussion of the process for establishing MCLGs).

The final Stage 1 DBPR contains MCLGs for: four THMs (chloroform, bromodichloromethane, dibromochloromethane, and bromoform); two haloacetic acids (dichloroacetic acid and trichloroacetic acid); bromate; and chlorite (see table II–2 for final MCLG levels). These MCLGs are the same as those proposed in 1994 with the exception of chlorite, which increased from 0.08 mg/L to 0.8 mg/L. The MCLG for chloral hydrate has been dropped since EPA has concluded that it will be controlled by the MCLs for TTHM and HAA5 and the enhanced coagulation treatment technique.

The final Stage 1 DBPR contains MRDLGs for chlorine, chloramines and chlorine dioxide (see table II–1 for final MRDLG levels). The MRDLGs are as the same as those proposed in 1994, with the exception of chlorine dioxide, which increased from 0.3 mg/L to 0.8 mg/L.

The MRDLG concept was introduced in the proposed rule for disinfectants to reflect the fact that these substances have beneficial disinfection properties. As with MCLGs, MRDLGs are established at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. MRDLGs are nonenforceable health goals based only on health effects and exposure information and do not reflect the benefit of the addition of the chemical for control for waterborne microbial contaminants. By using the term "residual disinfectant" in lieu of "contaminant", EPA intends to avoid situations in which treatment plant operators are reluctant to apply disinfectant dosages above the MRDLG during short periods of time to control for microbial risk.

EPA received numerous comments on the use of the term MRDLG. The majority of commenters agreed that the term MRDLG was appropriate to use in place of MCLG for disinfectants. Other commenters agreed, but felt that the language should more strongly reflect that disinfectants are necessary and that short-term exposure to elevated levels of the disinfectants is not a health concern. Some commenters suggested that MRDLGs be extended to ozone, potassium permanganate and iodine.

In response, EPA agrees with the majority of commenters that the use of the term MRDLG is appropriate and therefore the final rule retains this term. EPA believes the language on the importance of disinfectants is adequate in the rule and thus has not changed this language. EPA does not agree that the potential health effects from short-term exposure to elevated levels of disinfectants can be dismissed. Ozone does not require an MRDLG because it reacts so completely that it does not occur in water delivered to consumers. Finally, EPA believes the use of the MRDLGs for other disinfectants or oxidants would not be appropriate since MRDLGs are developed for regulated compounds controlled by MRDLs or treatment techniques and EPA does not allow these compounds to be used to demonstrate compliance with disinfection requirements.

The information EPA relied on to establish the MCLGs and MRDLGs was described in the 1994 proposal (EPA, 1994a), the 1997 DBP NODA (EPA, 1997b), and the 1998 NODA (EPA, 1998a). Criteria and assessment documents to support the MCLGs and MRDLGs are included in the docket (EPA, 1993a; EPA, 1994 d–h; EPA, 1997c; EPA, 1998 b–f; and EPA, 1998p). A summary of the occurrence and exposure information for this rule are detailed in "Occurrence Assessment for Disinfectants and Disinfection Byproducts in Public Drinking Water Supplies' (EPA, 1998u). The discussion of the data used to establish the MCLGs and MRDLGs and a summary of the major public comments for these chemicals are included below. A more detailed discussion is included below for chloroform, DCA, chlorite, chloride dioxide, and bromate than the other disinfectants and DBPs. This is the case because significant new data has become available since the 1994 proposal for these four DBPs and one disinfectant.

1. MCLG for Chloroform

a. Today's Rule. After careful consideration of all public comments, EPA has concluded at this time to promulgate an MCLG for chloroform of zero as proposed. This conclusion reflects an interim risk-management decision on the part of the Agency. The Agency recognizes the strength of the science in support of a non-linear approach for estimating carcinogenicity of chloroform. EPA received public comments that questioned the underlying basis and approach used to reach the science judgment that the mode of chloroform's carcinogenic action supports a nonlinear approach. Equally important are the policy and regulatory issues raised by stakeholders that touch on this issue. EPA believes that it is essential to pursue a further dialogue with stakeholders on the issues raised in the public comments before applying the substantial new data and science on the mode of carcinogenic

action discussed in the 1998 NODA to the important decision of moving to a non-linear cancer extrapolation approach for drinking water contaminants under the SDWA. Moreover, EPA will complete additional deliberations with the Agency's Science Advisory Board (SAB) (open to stakeholder presentations to the SAB) on the analytical approach used to evaluate and reach conclusions on mode of action data, and the science basis for the mode of carcinogenic action for chloroform.

In evaluating how to proceed in the development of an MCLG for chloroform, the Agency believes two additional factors must be taken into consideration. First, as part of the 1996 SDWA amendments, Congress mandated that the Stage 1 DBPR rule be promulgated by November 1998. EPA has concluded that it would be impossible to complete the additional deliberations noted above in time to meet this statutory deadline. Second, as explained below, the Agency has also completed analysis indicating that regardless of whether the MCLG is based on a low-dose linear or non-linear extrapolation approach, the MCL enforceable standard for TTHMs of 0.08 mg/L will not be affected. In light of these issues, EPA believes it is appropriate and consistent with the public health goals of the SDWA to establish a zero MCLG for chloroform based on a linear default extrapolation approach until the Agency is able to complete additional deliberations with the Agency's SAB on the analytical approach used to evaluate and reach conclusions on mode of action data and the science basis for the mode of carcinogenic action for chloroform, and complete the process of further public dialogue on the important question of moving to a non-linear cancer extrapolation approach. EPA also notes that its approach is consistent with legislative history of the SDWA (see 56 FR 3533—EPA, 1991) and the 1996 SDWA Amendments.

b. Background and Analysis. As part of its 1994 Stage 1 DBP proposal (EPA, 1994a), EPA requested comment on a zero MCLG for chloroform. This was consistent with information provided to the 1992 Reg. Neg. Committee and was based on data from a drinking water study by Jorgensen et al. (1985) indicating an increase of kidney tumors in male rats in a dose-related manner. However, at the time of the proposal there was insufficient data to determine the mode of carcinogenic action for chloroform. Therefore, EPA based its 1994 proposal on a risk management decision that a presumptive or low-dose linear default (i.e, MCLG of zero) was appropriate until more research became available and there was an adequate opportunity to work with stakeholders and the scientific community to evaluate and assess the technical as well as policy and regulatory implications of such new information. The 1994 proposal also reflected the Agency's 1986 Guidelines for Carcinogen Risk Assessment (EPA, 1986) which recommended reliance on the default assumption of low-dose linearity in the absence of substantial information on the mechanism of carcinogenicity.

Since the 1994 proposal, over 30 toxicological studies have been published on chloroform. These studies were discussed in the November 1997 Stage 1 DBP NODA (EPA, 1997b). In addition, EPA published a second DBP NODA in March 1998 (EPA, 1998a) which discussed recommendations and findings from a 1997 International Life Sciences Institute project (ILSI, 1997), co-sponsored by EPA, on the cancer assessment for chloroform. The ILSI project included the analysis and conclusions from an expert panel which was convened and charged with reviewing the available database relevant to the carcinogenicity of chloroform, and considering how end points related to mode of action can be applied in hazard and dose-response assessment by using guidance provided by the EPA's 1996 Proposed Guidelines for Carcinogen Assessment (EPA, 1996b). The panel was made up of 10 internationally recognized scientists from academia, industry, government, and the private sector. Based on a consideration of the ILSI panel findings and an assessment of new data on chloroform since 1994, EPA requested comment in the 1998 NODA on the Agency's science conclusion that chloroform is a likely human carcinogen and that available scientific analysis supports a non-linear mode of action for estimating the carcinogenic risk associated with lifetime exposure from ingesting drinking water.

As part of the 1998 NODA, EPA also requested comment on a revised chloroform MCLG of 0.30 mg/L. The revised MCLG was premised on the substantial new science noted above that supports a non-linear mode of action. In calculating the specific MCLG, EPA relied upon data relating to hepatoxicity in dogs (EPA, 1994a). This hepatoxicity endpoint was deemed appropriate given that hepatic injury is the primary effect following chloroform exposure; and that an MCLG based on protection against liver toxicity should be protective against carcinogenicity given that the putative mode of action understanding for chloroform involves cytotoxicity as a key event preceding tumor development. The MCLG of 0.3 mg/L was calculated using a relative source contribution (RSC) of 80 percent. The RSC of 80 percent was based on the assumption that most exposure to chloroform is likely to come from ingestion of drinking water. The 80 percent assumption for the RSC was consistent with the calculations used to derive the MCLGs for D/DBPs in the 1994 proposal. Based on information received during the public comment period for the 1998 NODA, EPA is considering revising its estimate of the RSC for chloroform as discussed below.

Since the 1998 NODA, EPA has reevaluated elements of the analysis underlying a revised MCLG of 0.30 mg/L. Considering recent information not fully analyzed as part of the 1998 NODA, the Agency is considering revising the assumption of an 80% RSC from ingestion of drinking water in view of data which indicates that exposure to chloroform via inhalation and dermal exposure may potentially contribute a substantial percentage of the overall exposure to chloroform depending on the activity patterns of individuals. Also, EPA is in the process of developing a policy for incorporating inhalation and dermal exposure into the derivation of the RSC. Furthermore, there is considerable uncertainty regarding the potential exposure to chloroform via the dietary route and there is information which indicates individuals who are frequent swimmers may receive a large amount of chloroform during swimming. There are additional uncertainties regarding other possible highly exposed sub-populations, e.g., from use of humidifiers, hot-tubs, and outdoor misters. In conclusion, because there may be a potential for exposure to chloroform from other routes of exposure than ingestion of drinking water, EPA is considering using the 20 percent default floor to ensure adequate public health protection. The 20 percent has been used historically for drinking water contaminants other than D/DBPs when there is uncertainty in the available exposure data. The use of the 20 percent RSC for chloroform would produce a MCLG of 0.07 mg/L:

$$\text{MCLG for chloroform} = \frac{0.01\ \text{mg/kg/d} \times 70\ \text{kg} \times 0.2}{2\text{L/d}} = 0.07\ \text{mg/L}$$

In addition to its reassessment of technical assumptions underlying the revised MCLG, the Agency has also reviewed and carefully considered in detail a number of significant comments on the 1998 NODA. These comments reflect both substantial scientific support as well as significant concerns with a possible MCLG of 0.30 mg/L. As outlined in more detail below, a number of nationally recognized scientific experts strongly affirmed the data and technical rationale for relying upon a non-linear mode of action for chloroform. Other commenters, however, highlighted several scientific issues they felt were not adequately considered. These commenters also emphasized their concern that the policy, regulatory, and enforcement implications related to a revised MCLG were not raised by EPA in either the 1992 or the 1997 regulatory negotiation processes leading up to today's final rule. Thus, these commenters felt that a number of stakeholders who recommended support for components of the Stage 1 DBPR rule did so under one set of conditions and assumptions that the Agency subsequently changed without providing a sufficient opportunity for further debate and discussion.

EPA believes that an adequate opportunity for notice and comment was provided as a result of the 1997 and 1998 DBP NODAs on the underlying scientific data and technical issue of moving to a non-linear extrapolation approach based on an understanding of the mode of carcinogenic action for chloroform and recalculating the chloroform MCLG to a nonzero number. However, the Agency recognizes that reliance on a non-linear mode of action under the SDWA does represent a significant and precedential, albeit sound, application of new science to the policy development and risk management decision making process of establishing appropriately protective MCLGs. The Agency also recognizes that although, as discussed below, a revised MCLG for chloroform would not affect the TTHM MCL under today's rule, the precedential decision to utilize a non-linear cancer extrapolation approach clearly has important implications for the development of future MCLGs where there is also adequate scientific research and data to support such a non-linear analysis.

In reviewing the range of scientific, policy, and regulatory analyses and strongly held views associated with development of the chloroform MCLG, EPA notes that the one question not fundamentally at issue is the establishment of the 0.080 mg/L TTHM MCL. The majority of commenters who addressed the proposed TTHM MCL continue to support it. This is particularly important to EPA in light of congressional action with regard to the M–DBP process in the 1996 SDWA Amendments. In enacting the Amendments and particularly in expressing congressional intent in the conference Report, Congress was careful to emphasize "that the new provisions of this conference agreement not conflict with the parties' agreement nor disrupt the implementation of the regulatory actions," (such as the current agreement on an TTHM MCL of 0.080 mg/L). Both of these important elements of the Congressional intent were reflected in the statutory text. Section 1412(b)(2)(C) requires EPA to maintain the M–DBP rule staggered promulgation strategy agreed to by the negotiated rulemaking; and Section 1412(b)(6)(C) exempted the future M–DBP rules from the new cost-benefit standard-setting provision (1412(b)(6)(A)) but not from the new risk-risk provision (1412(b)(5)), because the latter was a part of the negotiated rulemaking agreement but the former was not.

The Agency, itself, also believes that the underlying logic, data, and rationale supporting establishment of a TTHM of 0.080 mg/L MCL is compelling, and this is a critical factor in the Agency's chloroform MCLG decision under today's rule. Under either a low-dose linear or non-linear extrapolation to derive the MCLG, the final TTHM MCL remains unaffected.

After thorough review of the data and comments, EPA believes the nonlinear cancer extrapolation approach is the most appropriate means to establish an MCLG for chloroform based on carcinogenic risk. However, in light of its own reconsideration of the appropriate RSC for chloroform under such an approach, considering the range of policy, regulatory, and enforcement issues raised as part of the public comment period, recognizing the importance of deliberations with SAB before proceeding further and, yet, recognizing that this cannot be accomplished within the constraints of meeting the statutory deadline for Stage 1 DBPR rule of November 1998, EPA has determined that on balance the more appropriate and prudent risk management decision at this time is to establish an MCLG for chloroform at the proposed presumptive default level of zero. As part of this decision, the Agency will complete additional deliberations with the Agency's SAB on the analytical approach used to evaluate and reach conclusions on mode of action data, and the science basis for the mode of carcinogenic action for chloroform. The SAB's review will be factored into the Agency's Stage 2 DBP rulemaking process. EPA will also include consideration of the regulatory, policy, and precedential issues involving chloroform in the Agency's Round 2 M–BP stakeholder process. EPA wishes to make clear that its interim decision in today's rule to set an MCLG of zero pending SAB review and further stakeholder involvement is not intended to prejudge the question of what the appropriate MCLG should be for purposes of regulatory decisions under the Stage 2 DBPR. EPA may decide to retain the zero MCLG for that rule, or to revise it, depending on the outcome of the SAB review, as well as any new scientific evidence that may become available. In regard to the appropriate RSC factor, in case a non-linear approach should ultimately be adopted, the Agency requests that stakeholders provide any data they man have bearing on this determination.

The fundamental objective of the SDWA is to establish protective public health goals (MCLGs) together with enforceable standards (MCLs or treatment techniques) to move the water treatment systems as close to the public health goal as is technologically and economically feasible. In the case of the chloroform and TTHMs, this objective is met with whichever extrapolation approach (low dose linear versus nonlinear) is relied upon.

c. Summary of Comments. EPA received numerous comments on both the 1994 proposed rule regarding the MCLG of zero for chloroform and the MCLG of 0.3 mg/L contained in the 1998 NODA. Some commenters were supportive of the MCLG of zero, while others were supportive of the 0.3 mg/L MCLG. The major reason raised by commenters for establishing a nonzero MCLG (e.g., 0.3 mg/L) was that there was convincing scientific evidence to conclude that a nonlinear margin of exposure approach for evaluating the carcinogenic risk from chloroform is warranted. Commenters who were

against establishing a nonzero MCLG for chloroform presented policy and scientific concerns. Scientific concerns raised by commenters opposed to the nonzero MCLG included their perceptions that: there is insufficient scientific evidence of a threshold for chloroform; the threshold assumption is also invalid because chloroform co-occurs with other mutagenic carcinogens; EPA ignored human data in establishing the MCLG for chloroform; the linkage between cytotoxicity and regenerative proliferation and kidney tumors is not supported by the data; and the evidence for genotoxicity is mixed and it would be difficult if not impossible to conclude that the evidence demonstrate chloroform has no direct effect on DNA. As detailed at greater length in the docket, EPA does not agree with these comments as a technical matter. The Agency does agree with the commenters view that further discussion of these issues with both the SAB and as part of additional public dialogue is appropriate.

The policy issues raised by commenters included their belief that: a zero MCLG is required to comply with provisions of the SDWA; EPA is required to use the 1986 Cancer Guidelines (EPA, 1986) until the 1996 Cancer Guidelines (EPA, 1996b) are formally finalized, and under the 1986 guidelines the MCLG for chloroform must be set at zero; EPA did not provide sufficient opportunity for the members of the FACA, established to assist in the development of the Stage 1 DBP rule, to properly consider the potential implications of a nonzero MCLG; and setting a MCLG for chloroform (0.3 mg/L) above the MCL for the TTHMs (0.08 mg/L) is illogical.

In response, EPA believes that the underlying science for using a nonlinear extrapolation approach to evaluate the carcinogenic risk from chloroform is well founded. As explained above, because of the issues raised during the public comment period, EPA believes additional review and dialogue with stakeholders is needed prior to departing from a long-held EPA policy of establishing zero MCLGs for known or probable carcinogens. EPA will also complete additional deliberations with the Agency's SAB on the analytical approach used to evaluate and reach conclusions on mode of action data, and the science basis for the mode of carcinogenic action for chloroform.

In response to the policy issues raised by commenters, EPA, historically, has established MCLGs of zero for known or probable human carcinogens based on the principle that any exposure to carcinogens might represent some finite level of risk and therefore an MCLG above zero did not meet the statutory requirement that the goal be set where no known anticipated adverse effects occur, allowing for an adequate margin of safety (56 FR 3533; EPA, 1991). However, if there is scientific evidence that indicates there is a "safe threshold" then a non-zero MCLG could be established with an adequate margin of safety (56 FR 3533; EPA, 1991)). Even though EPA, as an interim matter, is establishing an MCLG of zero for chloroform in today's rule, it believes it has the authority to establish nonzero MCLGs for carcinogens if the scientific evidence supports this finding.

In response to commenter's concerns with EPA using the proposed 1996 Guidelines for Carcinogen Risk Assessment (EPA, 1996b) instead of the Agency's 1986 guidelines, EPA believes it is important to point out that the 1986 guidelines provide for departures from default assumptions such as low dose linear assessment. For example, the 1986 EPA guidelines reflect the position of the OSTP (1985; Principle 26) "No single mathematical procedure is recognized as the most appropriate for low-dose extrapolation in carcinogenesis. When relevant biological evidence on mechanisms of action exists (e.g, pharmacokinetics, target organ dose), the models or procedure employed should be consistent with the evidence." The 1986 guideline goes on to further state "The Agency will review each assessment as to the evidence on carcinogenesis mechanisms and other biological or statistical evidence that indicates the suitability of a particular extrapolation model." The EPA's 1996 Proposed Guidelines for Carcinogen Risk Assessment allow EPA to use other default approaches to estimate cancer risk than the historic, linearized multistage default when there is an understanding of an agent's mode of carcinogenic action. EPA believes that reliance on the 1986 guidance allows EPA to reach the same conclusion on the carcinogenic risk from chloroform as if the 1996 guidelines were used. The use of the best available science is a core EPA principle and is statutorily mandated by the SDWA amendments of 1996. The 1996 Proposed Guidelines for Carcinogen Risk Assessment reflect new science and are consistent with the existing 1986 Guidelines for Carcinogen Risk Assessment. EPA considered the 1996 proposed guidelines in assessing the health effects data for chloroform and the other contaminants discussed in the 1998 March NODA.

EPA agrees with commenters that additional review by the FACA of the regulatory implications of a nonlinear approach is appropriate for policy reasons, and will initiate these discussions in the context of the Stage 2 DBPR FACA deliberations. In light of the November 1998 statutory deadline to promulgate the Stage 1 DBP rule and the steps necessary to complete a final rule, EPA has concluded that there is not enough time to meet with the SAB and FACA, provide ample opportunity for debate, resolve differing points of views, and complete additional analysis to meet stakeholders policy concerns in the context of the Stage 1 DBP rule. EPA notes, however, that regardless of the MCLG for chloroform, the MCL for the THMs remains at 0.08 mg/L. Since the MCL is the enforceable standard that water systems will be required to meet, a nonlinear or low dose linear extrapolation to derive the MCLG will not have a direct impact on the compliance obligations of public water systems or on the levels of chloroform allowed in public water systems, although it may be relevant to development of enforceable regulatory limits established under future rules.

2. MCLG for Bromodichloromethane (BDCM)

a. Today's Rule. The final MCLG for BDCM is zero. The zero MCLG is based on the classification of BDCM as a probable human carcinogen. The MCLG was determined in a weight-of-evidence evaluation which considered all relevant health data including carcinogenicity and reproductive and developmental toxicity animal data. EPA believes the data are insufficient at this time to determine the mode of carcinogenic action for BDCM, and therefore a low dose linear extrapolation approach is used to estimate lifetime cancer risk as a default.

b. Background and Analysis. In the 1994 Stage 1 DBPR proposal, the MCLG of zero for BDCM was based on large intestine and kidney tumor data from a National Toxicology Program (NTP) chronic animal study (NTP, 1987). Since the proposal, several new studies have been published on BDCM metabolism (EPA, 1997c). In addition, several new genotoxicity studies and short-term toxicity studies including reproductive evaluations were found for BDCM (EPA, 1997c). These new studies contribute to the weight-of-evidence conclusions reached in the 1994 proposal. Based on this evidence, the final MCLG for BDCM is zero based on sufficient evidence of carcinogenicity in animals.

c. Summary of Comments. Several commenters disagreed with the use of a

corn oil gavage animal cancer study to determine the MCLG for BDCM. Some commenters agreed with the EPA decision to use large intestine and kidney tumor data from the corn oil gavage study, but not liver tumor data in the quantitative estimation of carcinogenic risk. One commenter agreed that a low-dose linear extrapolation approach to dose-response assessment was appropriate at this time and consistent with EPA policy. However, this commenter suggested that EPA undertake chronic studies that include a drinking water study of BDCM and toxicokinetics. One commenter disagreed with the EPA conclusion that the evidence on the mutagenicity of BDCM is adequate.

In response, EPA agrees with commenters that a drinking water study is preferable to a corn oil gavage study to assess risk from DBPs in drinking water. However, the NTP corn oil gavage study is the best data available on BDCM for a quantitative risk estimation at this time. BDCM is currently being tested for toxicokinetics and cancer in a chronic BDCM drinking water rodent study by the NTP. When these data are available, EPA will reassess the cancer risk of BDCM. EPA believes that the animal data currently available on BDCM are consistent with EPA cancer guidelines on classifying BDCM as a probable human carcinogen given the evidence on mutagenicity and given there was an increased incidence of tumors at several sites in the animals. Additionally, tumors were found in both sexes of two rodent species. Finally, there have been several new studies on the genotoxicity of BDCM that have supported a mutagenic potential for BDCM (EPA, 1997c)

3. MCLG for Dibromochloromethane (DBCM)

a. Today's Rule. The final MCLG for DBCM is 0.06 mg/L. This MCLG is based on a weight of evidence evaluation of the cancer and noncancer data which resulted in the classification of DBCM as a possible human carcinogen.

b. Background and Analysis. In the 1994 proposal, the MCLG of 0.06 mg/L for DBCM was based on observed liver toxicity from a subchronic study and possible carcinogenicity (NTP, 1985). EPA is not aware of any new information that would change its evaluation of DBCM since the proposal. The final MCLG is therefore 0.06 mg/L.

c. Summary of Comments. Several commenters disagreed with the additional safety factor of 10 to account for possible carcinogenicity that was used in the MCLG calculation. One commenter agreed with EPA's decision to base the MCLG on noncarcinogenic endpoints. Several commenters disagreed with the use of a corn oil gavage study to determine the MCLG for DBCM.

In response, because the evidence of carcinogenicity was limited on DBCM (i.e., increased tumor response in only one of the two species tested), EPA classified DBCM as a possible human carcinogen. The additional factor of 10 to account for possible carcinogenicity follows EPA's science policy for establishing MCLGs (EPA, 1994a). EPA used liver effects from the NTP subchronic corn oil gavage study as the basis for the Reference Dose (RfD). EPA agrees with the comment that this is an appropriate basis for deriving the RfD for DBCM. EPA agrees with commenters that a drinking water study is preferable to a corn oil gavage study to assess risk from DBPs in drinking water. However, the NTP corn oil gavage study is the best data available on DBCM for derivation of the MCLG at this time. EPA does not plan to conduct additional chronic studies for DBCM but is conducting additional toxicokinetics and short term drinking water studies on DBCM to better understand the potential risk associated with exposure through drinking water.

4. MCLG for Bromoform

a. Today's Rule. The final MCLG for bromoform is zero. The zero MCLG is based on a weight-of-evidence classification that bromoform is a probable human carcinogen based on a consideration of all relevant health data including cancer and noncancer effects. EPA believes the data are insufficient at this time to determine the mode of carcinogenic action for bromoform, and therefore a low dose linear extrapolation approach is used to estimate lifetime cancer risk as a default.

b. Background and Analysis. The proposed MCLG for bromoform was zero. This MCLG was based on an NTP chronic animal carcinogenicity study (NTP, 1989). Since the proposal, new studies on the genotoxicity of bromoform were found. However, these new studies do not support changing the proposed MCLG of zero for bromoform. The final MCLG for bromoform is therefore zero.

c. Summary of Comments. Several commenters agreed with EPA's classification for bromoform as a probable carcinogen. Other commenters disagreed with this classification stating that there was insufficient evidence available because tumors were found in only one species and the increased number of tumors was small. These commenters generally felt that EPA should use an RfD approach in quantifying the risk for bromoform. Some commenters encouraged EPA to conduct more experiments on bromoform toxicity. Some commenters were concerned with the use of a corn oil gavage study to determine carcinogenic risk.

In response, although the increase in tumors was small, the increase was considered significant because large intestine tumors in both male and female rats are rare and thus provides sufficient evidence to classify bromoform as a probable human carcinogen. EPA does not plan on conducting additional chronic testing for bromoform at this time, but is conducting toxicokinetic studies and shorter term drinking water studies to better understand the potential risk associated with exposure to bromoform in drinking water. EPA agrees with commenters that drinking water studies are preferable to a corn oil gavage study to assess risk from DBPs in drinking water. However, the NTP corn oil gavage study is the best data available on bromoform for derivation of the MCLG.

5. MCLG for Dichloroacetic Acid (DCA)

a. Today's Rule. The final MCLG for DCA is zero. EPA has developed a weight-of-evidence characterization for DCA in which it evaluated all relevant health data (both cancer and noncancer effects). The MCLG of zero is based on sufficient evidence of carcinogenicity in animals which indicates that DCA is a probable human carcinogen (likely under proposed cancer guidelines). EPA believes the data are insufficient at this time to determine the mode of carcinogenic action for DCA and that the data is insufficient to quantify the potential cancer risk from DCA.

b. Background and Analysis. EPA proposed an MCLG of zero for DCA. This was based on classifying DCA as a probable human carcinogen in accordance with the 1986 EPA Guidelines for Carcinogen Risk Assessment (EPA, 1986). The DCA categorization was based primarily on findings of liver tumors in rats and mice, which was regarded as "sufficient" evidence in animals. No lifetime risk calculation was conducted at the time of the proposal because there was insufficient data to quantify the risk (EPA, 1994a).

As pointed out in the 1997 and 1998 DBP NODAs, several toxicological studies have been identified for DCA since the 1994 proposal (EPA, 1997c). In addition, EPA co-sponsored an ILSI project in which an expert panel was

convened to explore the application of the EPA's 1996 Proposed Guidelines for Carcinogen Risk Assessment (EPA, 1996b) to the available data on the potential carcinogenicity of chloroform and DCA. The panel considered data on DCA which included chronic rodent bioassay data and information on mutagenicity, tissue toxicity, toxicokinetics, and other mode of action information. The panel concluded that the potential human carcinogenicity of DCA "cannot be determined" primarily because of the lack of adequate rodent bioassay data (ILSI, 1997).

EPA prepared a new hazard characterization regarding the potential carcinogenicity of DCA in humans (EPA, 1998b). One objective of this report was to develop a weight-of-evidence characterization using the principles of the EPA's 1996 Proposed Guidelines for Carcinogen Risk Assessment (EPA, 1996b) which are consistent with the 1986 Guidelines. Another objective of the report was to consider new data since the 1994 proposal and to address the issues raised by the 1997 ILSI panel report.

EPA agreed with the ILSI panel report that the mode of action through which DCA induces liver tumors in both rats and mice cannot be reasonably determined at this time. EPA disagrees with the ILSI panel that the potential human carcinogenicity cannot be determined. Based on the hepatocarcinogenic effects of DCA in both rats and mice in multiple studies, as well as other date, for example, showing that DCA alters cell replication and gene expression, EPA concludes that DCA should be considered as a "likely" (probable) cancer hazard to humans (EPA, 1998b). Therefore, as in the 1994 proposed rule, EPA believes that the MCLG for DCA should remain zero to assure public health protection.

c. Summary of Comments. Some commenters agreed with the zero MCLG for DCA based on positive carcinogenic findings in two animal species. Several commenters stated that a zero MCLG was inappropriate due to evidence which indicates a nongenotoxic mode of action for DCA. The comment was raised that the animal evidence was insufficient to consider DCA a likely (probable) human carcinogen, and that DCA should be considered at most suggestive of carcinogenicity.

In response, EPA concludes that DCA should be considered as a probable (likely under the 1996 proposed guidelines) cancer hazard to humans (EPA, 1998b) based on the hepatocarcinogenic effects of DCA in both rats and mice in multiple studies, and mode of action related effects (e.g., mutational spectra in oncogenes, elevated serum glucocorticoid levels, alterations in cell replication and death). EPA considers the mode of action through which DCA induces liver tumors in both rats and mice to be unclear, and thus the likelihood of human hazard associated with low levels of DCA usually encountered in the environment or in drinking water is not sufficiently understood. EPA acknowledges that a mutagenic mechanism (i.e., direct DNA reactivity) may not be an important influence on the carcinogenic process at low doses. EPA believes that the lack of mutagenicity is not a sufficient basis to depart from a low dose linear default extrapolation approach for the cancer assessment. There must be other convincing evidence to explain how the tumors are caused by the chemical. The commenters have not presented such evidence. Although DCA tumor effects are associated with high doses used in the rodent bioassays, there is uncertainty regarding whether the mode of tumorgenesis is solely through mechanisms that are operative only at high doses. Therefore, as in the 1994 proposed rule, EPA believes that the MCLG for DCA should remain as zero to assure public health protection. NTP is implementing a new two year rodent bioassay that will include full histopathology at lower doses than those previously studied. Additionally, studies on the mode of carcinogenic action are being done by various investigators including the EPA health research laboratory.

6. MCLG for Trichloroacetic Acid (TCA)

a. Today's Rule. The final MCLG for TCA is 0.3 mg/L, as was proposed in 1994. This MCLG is based on developmental toxicity and limited evidence of carcinogenicity in animals.

b. Background and Analysis. The 1994 proposed rule included a MCLG of 0.3 mg/L for TCA based on developmental toxicity and possible carcinogenicity based on limited evidence in animal studies (i.e., hepatocarcinogenicity in mice). Since the proposal, a 2-year carcinogenicity study on TCA (DeAngelo et al., 1997) found that TCA was not carcinogenic in male rats. As was discussed in the 1997 DBP NODA (EPA, 1997b), there have also been several recent studies examining the mode of carcinogenic action for TCA. These new studies suggest that TCA does not operate via mutagenic mechanisms. For a more in depth discussion of this new data refer to the 1997 DBP NODA (EPA, 1997b) and related support documents (EPA, 1997c). This new information does not alter the original assessment of the health effects of TCA based on developmental toxicity and limited evidence of carcinogenicity. Therefore, the MCLG will remain 0.3 mg/L.

c. Summary of Comments. Several commenters agreed with the classification of TCA as a possible human carcinogen. One commenter felt that toxicity data on TCA indicated a threshold. Some commenters disagreed with the study selected for estimating the RfD (Smith et al. 1989). Some commenters stated the uncertainty factors used to establish the RfD were too high.

In response, EPA acknowledges that a DNA reactive mutagenic mechanism may not be involved in TCA's mode of carcinogenicity. Because an RfD was used in lieu of a quantitative cancer assessment for establishing the MCLG, however, there was no need to evaluate the mode of carcinogenic action for TCA at this time. EPA believes that the Smith et al. (1989) study is appropriate to use in quantifying risk from TCA since developmental toxicity was the most critical effect. EPA believes that an uncertainty factor of 3,000 is appropriate to account for inter and intraspecies differences (100), a lowest observed adverse effects level (LOAEL) (10), and lack of a two-generation reproductive study (3) (EPA, 1994a). These uncertainty factors are consistent with current Agency science policy on using uncertainty factors (EPA, 1994a).

7. MCLG for Chlorite and MRDLG for Chlorine Dioxide

a. Today's Rule. The final MCLG for chlorite is 0.8 mg/L and the final MRDLG for chlorine dioxide is 0.8 mg/L. The MCLG for chlorite was increased from the proposed value of 0.08 mg/L to 0.8 mg/L based on a weight-of-evidence evaluation of all health data on chlorite including a recent two-generation reproductive rat study sponsored by the Chemical Manufactures Association (CMA, 1996). The MRDLG for chlorine dioxide was increased from the proposed value of 0.3 mg/L to 0.8 mg/L based on a weight-of-evidence evaluation using all the health data on chlorine dioxide including the information on chlorite from the CMA study. EPA believes that data on chlorite are relevant to assessing the risks of chlorine dioxide because chlorine dioxide is rapidly reduced to chlorite. Therefore, the findings from the CMA study and previously described studies in the 1994 proposal were used to assess the risk for both chlorite and chlorine dioxide.

b. Background and Analysis. The 1994 proposal included an MCLG of

0.08 mg/L for chlorite. The proposed MCLG was based on an RfD of 3 mg/kg/d estimated from a lowest-observed-adverse-effect-level (LOAEL) for neurodevelopmental effects identified in a rat study by Mobley et al. (1990). This determination was based on a weight of evidence evaluation of all the available data at that time (EPA, 1994d). An uncertainty factor of 1000 was used to account for inter-and intra-species differences in response to toxicity (a factor of 100) and to account for use of a LOAEL (a factor of 10).

The 1994 proposal included an MRDLG of 0.3 mg/L for chlorine dioxide. The proposed MRDLG was based on a RfD of 3 mg/kg/d estimated from a no-observed-adverse-effect-level (NOAEL) for developmental neurotoxicity identified from a rat study (Orme et al., 1985; EPA, 1994d). This determination was based on a weight of evidence evaluation of all available health data at that time (EPA, 1994a). An uncertainty factor of 300 was applied that was composed of a factor of 100 to account for inter-and intra-species differences in response to toxicity and a factor of 3 for lack of a two-generation reproductive study necessary to evaluate potential toxicity associated with lifetime exposure. To fill this important data gap, the CMA sponsored a two-generation reproductive study in rats (CMA, 1996).

As described in more detail in the 1998 NODA (EPA, 1998a), EPA reviewed the CMA study and completed an external peer review of the study (EPA, 1997d). In addition, EPA reassessed the noncancer health risk for chlorite and chlorine dioxide considering the new CMA study (EPA, 1998d). This reassessment was also peer reviewed (EPA, 1998d). Based on this reassessment, EPA requested comment in the 1998 NODA (EPA, 1998a) on changing the proposed MCLG for chlorite from 0.08 mg/L to 0.8 mg/L based on the NOAEL identified from the new CMA study which reinforced the concern for neurodevelopmental effects associated with short-term exposures.

EPA determined that the NOAEL for chlorite should be 35 ppm (3 mg/kg/d chlorite ion, rounded) based on a weight-of-evidence approach. The data considered to support the NOAEL are summarized in EPA (1998d) and included the CMA study as well as previous reports on developmental neurotoxicity and other adverse health effects (EPA, 1998d). EPA continues to believe, as stated in the 1998 NODA (EPA, 1998a), that the RfD for chlorite should be 0.03 mg/kg/d (NOAEL of 3 mg/kg/d with an uncertainty factor of 100) and that a MCLG of 0.8 mg/L is appropriate. EPA has concluded that the RfD for chlorine dioxide should be 0.03 mg/L (NOAEL of 3 mg/kg/d with an uncertainty factor of 100) and that a MRDLG of 0.8 mg/L is appropriate.

c. Summary of Comments. EPA received numerous comments on the 1994 proposal (EPA, 1994a) and 1998 NODA (EPA, 1998a). The major comment from the 1994 proposal was that reliance on the Mobley et al. (1990) study for the MCLG for chlorite and the Orme et al. (1985) study for chlorine dioxide were inappropriate and that the results from the CMA study must be evaluated before any conclusions on the MCLG for chlorite or chlorine dioxide could be drawn. In relation to the 1998 NODA, several commenters supported changing the MCLG for chlorite and MRDLG for chlorine dioxide while others were concerned that the science did not warrant a change in these values. The major comments submitted against raising the MCLG and MRDLG focused on several issues. First, one commenter argued that the 1000-fold uncertainty factor used for chlorite in the proposal should remain in place because the CMA study used to reduce the uncertainty factor was flawed. Second, several commenters indicated that the LOAEL should be set at the lowest dose level (35 ppm) because certain effects at the lowest dose tested may have been missed. Finally, some commenters argued that an additional safety factor should be included to protect children and drinking water consumption relative to the body weight of children should be used instead of the default assumption of 2 L per day and 70 kg adult body weight.

EPA agrees with commenters on the 1994 proposal that the results from the CMA should be factored into any final decision on the MCLG for chlorite and chlorine dioxide. As explained in more detail in the 1998 DBP NODA (EPA, 1998a), EPA considered the findings from the CMA study along with other available data to reach its conclusions regarding the MCLG and MRDLG for chlorite and chlorine dioxide.

EPA disagrees with the commenter who suggested that the 1000-fold uncertainty factor for chlorite should remain because the CMA study was flawed. The study design for the neurodevelopmental component of the CMA study was in accordance with EPA's testing guidelines at the time the study was initiated. EPA had previously reviewed the study protocol for the CMA neurotoxicity component and had approved the approach. While EPA initially had some questions regarding the design of the neurodevelopmental component of the study (Moser, 1997), subsequent information submitted by the CMA provided clarification on certain aspects of the study design (CMA, 1998). EPA agrees that even with the clarifications that there are some limitations with the neurodevelopmental component of the CMA study. EPA believes that the neuropathology components of the CMA study were adequate. The functional operation battery had some shortcomings in that forelimb and hindlimb grip strength and foot splay were not evaluated. EPA believes the results from the motor activity component of the CMA study were difficult to interpret because of the high variability in controls. However, in its evaluation of the MCLG for chlorite and chlorine dioxide, EPA did not rely solely on the CMA study, but used a weight-of-evidence approach that included consideration of several studies. Thus, the shortcomings of one study are offset by the weight from other studies. EPA believes that the CMA study contributes to the weight-of the-evidence. The studies by Orme et al. (1985), Mobley et al. (1990), and CMA (1996) support a NOAEL of 3 mg/kg/d based on neurodevelopmental effects (e.g., decreased exploratory, locomotor behavior, decreased brain weight). Furthermore, the CMA study was reviewed by outside scientists as well as by EPA scientists. EPA's re-assessment for chlorite and chlorine dioxide presented in the 1998 March NODA was reviewed internally and externally in accordance with EPA peer-review policy. The three outside experts who reviewed the Agency's assessment agreed with the NOAEL of 3 mg/kg/day and the derived RfD.

Finally, EPA disagrees that an additional safety factor should be applied to provide additional protection for children or that drinking water consumption relative to the body weight of children should be used in developing the MCLG. The MCLG and MRDLG presented for chlorite and chlorine dioxide are considered to be protective of susceptible groups, including children, given that the RfD is based on a NOAEL derived from developmental testing, which includes a two-generation reproductive study. A two-generation reproductive study evaluates the effects of chemicals on the entire developmental and reproductive life of the organism. Additionally, current methods for developing RfDs are designed to be protective for sensitive populations. In the case of chlorite and chlorine dioxide a factor of 10 was used to account for variability between the average human response and the

response of more sensitive individuals. In addition, the important exposure is that of the pregnant and lactating female and the nursing pup. The 2 liter per day water consumption and the 70 kg body weight assumptions are viewed as adequately protective of all groups.

Based on a review of all the data and public comments, EPA believes that the MCLG for chlorite should be 0.8 mg/L and the MRDLG for chlorine dioxide should be 0.8 mg/L. EPA believes the MCLG and MRDLG are consistent with the discussions during the regulatory negotiations which recognized the need for an acceptable two-generation reproductive study prior to reducing the uncertainty factors for chlorite and chlorine dioxide. EPA believes the CMA provided an acceptable two-generation study with which to reduce the uncertainty factors. In addition, EPA believes potential health concerns in the proposal with having a MCLG for chlorite significantly below the MCL are no longer relevant because the MCL for chlorite in today's rule will remain at 1.0 mg/L while the MCLG has been revised to 0.8 mg/L. Given the margin of safety that is factored into the estimation of the MCLG of 0.8 mg/L, EPA believes that the MCL of 1.0 mg/L will be protective of public health of all groups, including fetuses and children.

The MCLG for chlorite is based on an RfD of 0.03 mg/kg/d using a NOAEL of 3 mg/kg/d and an uncertainty factor of 100 to account for inter- and intra-species differences. The MCLG for chlorite is calculated to be 0.8 mg/L by assuming an adult tap water consumption of 2 L per day for a 70 kg adult and using a relative source contribution of 80% (because most exposure to chlorite is likely to come from ingestion of drinking water—EPA,1998u). A more detailed discussion of this assessment is included in the public docket for this rule (EPA, 1998d).

$$\text{MCLG for chlorite} = \frac{0.03\ \text{mg/kg/d} \times 70\ \text{kg} \times 0.8}{2\text{L/day}} = 0.84\ \text{mg/L}$$

$$\text{MCLG for chlorite} = 0.8\ \text{mg/L (Rounded)}$$

For chlorine dioxide the MCLG is based on a NOAEL of 3 mg/kg/d and applying an uncertainty factor of 100 to account for inter-and intra-species differences in response to toxicity, the revised MRDLG for chlorine dioxide is calculated to be 0.8 mg/L. This MRDLG takes into account an adult tap water consumption of 2 L per day for a 70 kg adult and applies a relative source contribution of 80% (because most exposure to chlorine dioxide is likely to come from ingestion of drinking water—EPA, 1998u). A more detailed discussion of this assessment is included in the public docket for this rule (EPA, 1998d).

$$\text{MRDLG for chlorine dioxide} = \frac{0.03\ \text{mg/kg/d} \times 70\ \text{kg} \times 0.8}{2\text{L/day}} = 0.84\ \text{mg/L}$$

$$\text{MRDLG for chlorine dioxide} = 0.8\ \text{mg/L (Rounded)}$$

8. MCLG for Bromate

a. Today's Rule. The final MCLG for bromate is zero. The zero MCLG is based on a weight-of-evidence evaluation of both the cancer and noncancer effects which indicates there is sufficient laboratory animal data to conclude that bromate is a probable (likely under the 1996 proposed cancer guidelines) human carcinogen. EPA believes the data are insufficient at this time to determine the mode of carcinogenic action for bromate, and therefore a low dose linear extrapolation approach is used to estimate lifetime cancer risk as a default.

b. Background and Analysis. The 1994 proposed rule included a MCLG of zero for bromate based on a determination that bromate was a probable human carcinogen. This determination was based on results from a two species rodent bioassay by Kurokawa et al. (1986a and 1986b) that found kidney tumors in rats. Since the 1994 proposed rule, EPA has completed and analyzed a new chronic cancer study in male rats and mice for potassium bromate (DeAngelo et al., 1998). EPA reassessed the cancer risk associated with bromate exposure (EPA, 1998e), had this reassessment peer reviewed (EPA, 1998e), and presented its findings in the March 1998 NODA (EPA, 1998a). The new rodent cancer study by DeAngelo et al. (1998) contributes to the weight of the evidence for the potential human carcinogenicity of potassium bromate and confirms the study by Kurokawa et al. (1986 a,b).

c. Summary of Comments. Several commenters supported the zero MCLG for bromate. Others believed the MCLG of zero was not justified because there is evidence of a carcinogenic threshold. This evidence indicates that bromate causes DNA damage indirectly via lipid peroxidation, which generates oxygen radicals which in turn induce DNA damage. Other commenters argued that even if there is no carcinogenic threshold, EPA has overstated the potency of bromate by using the linearized multistage model and should instead use the Gaylor-Kodell model.

In response, EPA disagrees with commenters who believed that the zero MCLG was inappropriate. At this time, under the principles of both the 1986 EPA Guidelines for Carcinogen Risk Assessment (EPA, 1986) and the draft 1996 EPA Proposed Guidelines for Carcinogen Risk Assessment (EPA, 1996b) weight-of-evidence approach, bromate is considered to be a probable or likely human carcinogen. This weight of evidence conclusion of potential human carcinogenicity is based on sufficient experimental findings that include the following: tumors at multiple sites in rats; tumor responses in both sexes; and evidence for mutagenicity including point mutations and chromosomal aberrations in in vitro genotoxicity assays. Furthermore, EPA believes there is insufficient evidence at this time to draw conclusions regarding the mode of carcinogenic action for bromate. EPA acknowledges there are studies available showing that bromate may generate oxygen radicals which increase lipid peroxidation and damage DNA. However, no data are available that link this proposed mechanism to tumor induction. Thus, EPA believes that while there are studies which provide some evidence to support the commenters' claims, these studies are insufficient at this time to establish

lipid peroxidation and free radical production as key events responsible for the induction of the multiple tumor responses seen in the bromate rodent bioassays (EPA, 1998e). Given the uncertainty about the mode of carcinogenic action for bromate, EPA believes it is appropriate to use the default assumption of low dose linearity to estimate the cancer risk and establish the MCLG of zero for bromate. EPA is conducting additional studies investigating the mode of action for bromate.

EPA also disagrees with commenters who suggested that the Gaylor-Kodell model should be used for low-dose extrapolation of the bromate data. In the 1998 NODA, a low dose linear extrapolation of the DeAngelo et al. (1998) data was conducted using a one-stage Weibull time-to-tumor model. The Weibull model was considered to be the preferred approach to account for the reduction in animals at risk that may be due to the decreased survival observed in the high dose group toward the end of the study. The estimate of cancer risk from the DeAngelo et al. (1998) study is similar with the risk estimate derived from the Kurokawa et al. (1986a) study presented in the 1994 proposed rule.

Based on an evaluation of all the data and after review and consideration of the public comments, EPA believes the MCLG for bromate should be zero.

9. MCLG for Chloral Hydrate

a. Today's Rule. EPA has decided to not include an MCLG for chloral hydrate in the Stage 1 DBPR. This decision is based on an analysis of the technical comments and on the fact that chloral hydrate will be controlled by the MCLs for TTHM and HAAs and by the treatment technique of enhanced coagulation.

b. Background and Analysis. The 1994 proposed rule included an MCLG for chloral hydrate of 0.04 mg/L. This was based on a 90-day mice study by Sanders et al. (1982) which reported liver toxicity. A RfD of 0.0016 mg/kg/d was used (LOAEL of 16 mg/kg/d with an uncertainty factor of 10,000). In the 1997 DBP NODA (EPA,1997b) and supporting documents (EPA, 1997c), additional studies on chloral hydrate were discussed, however, these new studies did not indicate a change in the MCLG for chloral hydrate.

c. Summary of Comments. The majority of commenters disagreed with the MCLG of 0.04 mg/L for chloral hydrate. Several commenters questioned the need for an MCLG for chloral hydrate. These commenters mentioned its low toxic potential and the fact that safe concentrations of chloral hydrate are substantially greater than those present in drinking water. Commenters also questioned the need for an MCLG for chloral hydrate because the MCLs for THMs and HAAs and the treatment technique of enhanced coagulation will adequately control for chloral hydrate and because there were no monitoring provisions proposed. Other commenters argued that the use of a 10,000 uncertainty factor and the selection of the Sanders et al. (1982) study as a basis for setting the MCLG were inappropriate.

In response, EPA agrees with commenters that an MCLG for chloral hydrate is not needed. This is based on the fact that the TTHM and HAA MCLs and the treatment technique (i.e., enhanced coagulation/softening) will control for chloral hydrate, as well as other chlorination byproducts. In addition, chloral hydrate does not serve as an important indicator for other chlorination byproducts. The final rule, therefore, does not contain an MCLG for chloral hydrate. In light of this decision, EPA is not responding to comments on the uncertainty factor used as the basis for setting the MCLG.

10. MRDLG for Chlorine

a. Today's Rule. EPA is promulgating an MRDLG of 4 mg/L for chlorine based on a NOAEL from a chronic study in animals.

b. Background and Analysis. EPA proposed an MRDLG of 4 mg/L for chlorine. The MRDLG was based on a two-year rodent drinking water study in which chlorine was given to rats at doses ranging from 4 to 14 mg/kg/day and mice at doses ranging from 8 to 24 mg/kg/day (NTP, 1990). Neither systemic toxicity, nor effects on body weight and survival were found. Thus, the MRDLG was based on a NOAEL of 14 mg/kg/day and application of a 100 fold uncertainty factor to account for inter- and intra-species differences (EPA, 1994a). New information on chlorine has become available since the 1994 proposal and was discussed in the 1997 DBP NODA and is included in the public docket (EPA, 1997c). This new information did not contain data that would change the MRDLG. EPA has therefore decided to finalize the proposed MRDLG of 4 mg/L for chlorine.

c. Summary of Comments. Several commenters agreed with EPA's conclusion that there is no animal evidence of carcinogenicity for chlorine. Some commenters also agreed with EPA that 4 mg/L was the appropriate MCLG. Several commenters agreed with the proposed relative source contribution of 80 percent for chlorine. Some commenters agreed with the uncertainty factor of 100 while others felt that it was too high. Some commenters encouraged EPA to consider children in estimating risk from chlorine.

In response, EPA believes that an uncertainty factor of 100 is appropriate when a NOAEL from a chronic animal study is the basis for the RfD. Because current methods for developing RfDs are designed to be protective for sensitive subpopulations, the uncertainty factor of 100 is considered protective of children. Furthermore, animal studies indicate that chlorine is not a developmental toxicant.

11. MRDLG for Chloramine

a. Today's Rule. EPA is promulgating an MRDLG of 4 mg/L for chloramines based on a NOAEL from a chronic rodent study.

b. Background and Analysis. The 1994 proposed Stage I DBPR included an MRDLG for chloramines at 4 mg/L based on a NOAEL of 9.5 mg/kg/d for lack of toxicity in chronic rodent drinking water study and on application of an uncertainty factor of 100 to account of inter- and intra-species differences (EPA, 1994h). New information on chloramines has become available since the 1994 proposal and was included in the 1997 DBP NODA and is included in the public docket (EPA, 1997c). This new information did not contain data that would change the MRDLG. EPA has therefore decided to finalized the proposed MRDLG of 4 mg/L for chloramines.

c. Summary of Comments. Several commenters agreed with the MRDLG of 4 mg/L for chloramine (as chlorine). Some commenters felt that the MRDLG was too low due to conservative uncertainty factors. Many commenters agreed with EPA's conclusion that there is no animal evidence of carcinogenicity for chloramines. Many commenters agreed with the RSC of 80% for chloramine while other believed that the RSC should be higher.

In response, EPA believes that the uncertainty factor of 100 in the MRDLG calculation is appropriate to protect public health including that of children and sensitive subpopulations. EPA believes that the 80 percent is an appropriate ceiling for the RSC due to lack of exposure data on other sources of exposure.

B. Epidemiology

1. Cancer Epidemiology

a. Today's Rule. EPA has evaluated all of the cancer epidemiology data and the corresponding public comments received on the 1994 proposal (EPA,

1994a), 1997 NODA (EPA, 1997b), and 1998 NODA (EPA, 1998a). Based on this evaluation, EPA believes that the cancer epidemiology data provides important information that contributes to the weight-of-evidence evaluation on the potential health risks from exposure to chlorinated drinking water. At this time, however, the cancer epidemiology studies are insufficient to establish a causal relationship between exposure to chlorinated drinking water and cancer; and are thus considered limited for use in quantitative risk assessment. EPA's weight-of-evidence evaluation of the potential risk posed by chlorinated drinking water is further discussed in section IV of this preamble.

b. Background and Analysis. The preamble to the 1994 proposed rule discussed numerous cancer epidemiology studies that had been conducted over the past 20 years to examine the relationship between exposure to chlorinated water and cancer (EPA, 1994a). At the time of the regulatory negotiation, there was disagreement among the members of the Reg. Neg. Committee on the conclusions that could be drawn from these studies. Some members of the Committee felt that the cancer epidemiology data, taken in conjunction with the results from toxicological studies, provide ample and sufficient weight-of-evidence to conclude that exposure to DBPs in drinking water could result in increased cancer risk at levels encountered in some public water supplies. Other members of the Committee concluded that the cancer epidemiology studies on the consumption of chlorinated drinking water to date were insufficient to provide definitive information for the regulation.

In the 1998 DBP NODA (EPA, 1998a), EPA discussed several new epidemiology studies that had been published since the 1994 proposal. EPA concluded in the 1998 NODA, based on a review of all the cancer epidemiology studies (including the more recent studies), that a causal relationship between exposure to chlorinated surface water and cancer has not yet been demonstrated. However, several studies have suggested a weak association in various subgroups. Results from recent epidemiology studies continue to support the decision to pursue regulations to provide additional DBP control measures as discussed in section IV.D of this preamble.

c. Summary of Comments. Several commenters agreed with EPA's characterization that there was insufficient evidence to conclude that there was a causal relationship between exposure to chlorinated surface water and cancer. Other commenters disagreed with this characterization stating that they believed the evidence did indicate there was a strong association between exposure to chlorinated water and cancer. Other commenters stated that EPA had not clearly articulated the basis for its conclusions on the issue of causality.

In response, EPA continues to believe that there is insufficient evidence, based on the epidemiology data, to conclude there is a causal association between exposure to chlorinated waters and cancer. EPA agrees, however, that the basis for its conclusion on causality was not clearly articulated. This judgement of causality was based on evaluating the existing cancer epidemiologic database for the following criteria: strength of association, consistency of the findings, specificity of the association, as well as other information concerning the temporal sequence and presence of a dose-response relationship, and biological plausibility (Federal Focus, 1996; EPA, 1986; EPA 1996b).

EPA applied the criteria stated above to assess the possible causality of cancer using the best available cancer epidemiology studies (Cantor et al., 1985, McGeehin et al., 1993, King and Marrett, 1996, Cantor et al., 1998, Freedman et al., 1997, Hildesheim et al., 1998, Doyle et al., 1997). These studies found a weak association for bladder cancer, although the findings were not consistent within and among the studies. The specificity of the association, temporal association, and dose response relationship remain unknown. In addition, the biological mode of action has not been determined. Using the criteria for causality, the present epidemiologic data do not support a causal relationship between exposure to chlorinated drinking water and development of cancer at this time. This conclusion does not preclude the possibility that a causal link may be established at a later date by future epidemiology and toxicology studies.

Some commenters argued that the epidemiological evidence indicated an increased risk for cancer by exposure to chlorinated drinking water, while others argued that the epidemiological evidence does not support a health effects concern. As stated above, EPA believes that, at this time, a causal link between exposure to chlorinated drinking water and development of cancer cannot be determined. However, EPA believes that the epidemiological evidence suggests a potential increased risk for bladder cancer. It is therefore prudent public health policy to protect against this potential public health concern in light of the uncertainties and given the large population (over 200 million people) potentially exposed.

2. Reproductive and Developmental Epidemiology

a. Today's Rule. EPA has evaluated all of the reproductive and developmental epidemiology data and the public comments received on the 1994 proposal, 1997 NODA, and the 1998 NODA. Based on this evaluation, EPA believes that the reproductive and developmental epidemiology data provides important information that contributes to the weight-of-evidence evaluation on the potential risks from exposure to chlorinated drinking water. However, the reproductive epidemiology studies are insufficient to establish a causal relationship between exposure to chlorinated drinking water and reproductive and developmental effects and are limited for use in the quantification of risk.

b. Background and Analysis. In the preamble to the 1994 proposed DBPR, EPA discussed several reproductive epidemiology studies (EPA, 1994a). At the time of the proposal, EPA concluded that there was no compelling evidence to indicate a reproductive and developmental hazard due to exposure to chlorinated water because the epidemiologic evidence was inadequate and the toxicological data were limited. In 1993, an expert panel of scientists was convened by the International Life Sciences Institute to review the available human studies for developmental and reproductive outcomes and to provide research recommendations (EPA/ILSI, 1993). The expert panel concluded that the epidemiologic results should be considered preliminary given that the research was at a very early stage (EPA/ILSI, 1993; Reif et al., 1996). The 1997 NODA and the supporting documents (EPA, 1997c) presented several new studies (Savitz et al., 1995; Kanitz et al. 1996; and Bove et al., 1996) that had been published since the 1994 proposed rule and the 1993 ILSI panel review. Based on the new studies presented in the 1997 NODA, EPA stated that the results were inconclusive with regard to the association between exposure to chlorinated waters and adverse reproductive and developmental effects (EPA, 1997b).

In the 1998 DBP NODA (EPA, 1998a), EPA included the recommendations from an EPA convened expert panel in July 1997 to evaluate epidemiologic studies of adverse reproductive or developmental outcomes that may be associated with the consumption of disinfected drinking water published

since the 1993 ILSI panel review. A report was prepared entitled "EPA Panel Report and Recommendations for Conducting Epidemiological Research on Possible Reproductive and Developmental Effects of Exposure to Disinfected Drinking Water" (EPA, 1998f). The 1997 expert panel was also charged to develop an agenda for further epidemiological research. The 1997 panel concluded that the results of several studies suggest that an increased relative risk of certain adverse outcomes may be associated with the type of water source, disinfection practice, or THM levels. The panel emphasized, however, that most relative risks are moderate or small and were found in studies with limitations in design or conduct. The small magnitude of the relative risk found may be due to one or more sources of bias, as well as to residual confounding (factors not identified and controlled). Additional research is needed to assess whether the observed associations can be confirmed. In addition, the 1998 DBP NODA included a summary of a study by Waller et al. (1998) conducted in California and another study by Klotz and Pyrch (1998) conducted in New Jersey. EPA concluded that while the Waller et al. (1998) study does not prove that exposure to THMs in drinking water causes early term miscarriages, it does provide important new information that needs to be explored and that the study adds to the weight-of-evidence which suggests that exposure to DBPs may have an adverse health effect on humans. EPA indicated that the review of the Klotz and Pyrch study (1998) had not been completed in time for the 1998 NODA.

EPA has completed its review of the Klotz and Pyrch (1998) study and concluded that the results in the report provide limited evidence to substantiate the hypothesis that DBPs in drinking water cause adverse reproductive or developmental effects since the bulk of the findings are inconclusive. There is, however, a suggestion in the study that total THMs or some other component of surface water is associated with a small increased risk of neural tube defects; no significant associations, however, were observed with individual THMs, HAAs or other composite measures of exposure.

c. Summary of Comments. Several commenters agreed with EPA's conclusions on the significance of the reproductive and developmental effects from the various studies. Others believed EPA had not accurately characterized the potential adverse reproductive and developmental effects from exposure to DBPs in drinking water.

In response, EPA continues to believe that the available epidemiology data along with the toxicological findings suggest that exposure to DBPs may have adverse effects on humans. However, EPA believes the epidemiology evidence is insufficient at this time to conclude that there is a causal association between exposure to DBPs and adverse reproductive and developmental effects. As noted in the 1998 NODA, EPA has an epidemiology and toxicology research program that is examining the relationship between exposure to DBPs and adverse reproductive and developmental effects. In addition, EPA is pursuing appropriate follow-up studies to see if the observed association in the Waller et al. (1998) study can be replicated elsewhere. EPA will also be working with the California Department of Health Services to improve estimates of exposure to DBPs in the existing Waller et al. study population. EPA will collaborate with the Centers for Disease Control and Prevention (CDC) in a series of studies to evaluate if there is an association between exposure to DBPs in drinking water and birth defects. EPA is also involved in a collaborative testing program with the NTP under which several individual DBPs have been selected for reproductive and developmental laboratory animal studies. This information will be used in developing the Stage 2 DBPR.

C. MCLs and BAT for TTHM, HAA5, Chlorite, and Bromate; MRDLs and BAT for Chlorine, Chloramines, and Chlorine Dioxide

MCLs are enforceable standards which are established as close to the MCLG as feasible. Feasible means with the use of the best technology, treatment techniques, and other means which the Administrator finds available (taking costs into consideration) after examining for efficacy under field conditions and not solely under laboratory conditions.

EPA is promulgating MCLs for two groups of DBPs and two inorganic byproducts. EPA is also promulgating MRDLs for three disinfectants. EPA is promulgating these MCLs and MRDLs at the levels proposed in 1994. Systems will determine compliance with the MCLs and MRDLs in the same manner as was proposed in 1994, except for chlorite. EPA determined that additional monitoring requirements for chlorite were necessary based on the findings from the CMA two-generation reproductive and developmental study.

Along with introducing the concept of the MRDLG in the proposed rule, EPA also introduced the MRDL for the three disinfectants (chlorine, chloramines, and chlorine dioxide). The MRDLs are enforceable standards, analogous to MCLs, which recognize the benefits of adding a disinfectant to water on a continuous basis and to maintain a residual to control for pathogens in the distribution system. As with MCLs, EPA has set the MRDLs as close to the MRDLGs as feasible. The Agency has also identified the BAT which is feasible for meeting the MRDL for each disinfectant.

EPA received similar comments on the use of the term MRDL as with MRDLG. The majority of commenters agreed with the use of the term MRDL for the disinfectants and therefore EPA is using the term MRDL in the final rule.

1. MCLs for TTHMs and HAA5

a. Today's Rule. In today's rule, EPA is promulgating an MCL for TTHMs of 0.080 mg/L. TTHM is the sum of measured concentrations of chloroform, bromodichloromethane, dibromochloromethane, and bromoform. EPA is also promulgating an MCL for HAA5 of 0.060 mg/L. HAA5 is the sum of measured concentrations of mono-, di-, and trichloroacetic acids, and mono- and dibromoacetic acids. A system is in compliance with these MCLs when the running annual average of quarterly averages of all samples taken in the distribution system, computed quarterly, is less than or equal to the MCL. If the running annual average computed for any quarter exceeds the MCL, the system is out of compliance. EPA believes that by meeting MCLs for TTHMs and HAA5, water suppliers will also control the formation of other DBPs not currently regulated that may also adversely affect human health.

EPA has identified the best available (BAT) technology for achieving compliance with the MCLs for both TTHMs and HAA5 as enhanced coagulation or treatment with granular activated carbon with a ten minute empty bed contact time and 180 day reactivation frequency (GAC10), with chlorine as the primary and residual disinfectant, as was proposed in 1994.

b. Background and Analysis. The 1994 proposal for the Stage 1 DBPR included MCLs for TTHM and HAA5 at 0.080 and 0.060 mg/L, respectively (EPA, 1994a). In addition to the proposed MCLs, subpart H systems—utilities treating either surface water or groundwater under the direct influence of surface water—that use conventional treatment (i.e., coagulation, sedimentation, and filtration) or precipitative softening would be

required to remove DBP precursors by enhanced coagulation or enhanced softening. The removal of TOC would be used as a performance indicator for DBP precursor control.

As part of the proposed rule, EPA estimated that 17% of PWSs would need to change their treatment process to alternative disinfectants (ozone or chlorine dioxide) or advanced precursor removal (GAC or membranes) in order to comply with the Stage 1 requirements. This evaluation was important to assist in determining whether the proposed MCLs were achievable and at what cost. This evaluation required an understanding of the baseline occurrence for the DBPs and TOC being considered in the Stage 1 DBPR, an understanding of the baseline treatment in-place, and an estimation of what treatment technologies systems would use to comply with the Stage 1 DBPR requirements.

In 1997, at the direction of the M–DBP Advisory Committee, the TWG reviewed MCL compliance predictions developed for the 1994 proposal because of concern by several Committee members that modifications to the rule would result in more PWSs not being able to meet the new TTHM and HAA5 MCLs without installation of higher cost technologies such as ozone or GAC. Some members were concerned that allowing disinfection inactivation credit prior to precursor removal (by enhanced coagulation or enhanced softening) in order to prevent significant reductions in microbial protection would result in higher DBP formation and force systems to install alternative disinfectants or advanced precursor removal to meet the 1994 proposed TTHM and HAA5 MCLs. As discussed later in today's document in Section III.E (Preoxidation CT Credit), most PWSs can achieve significant reduction in DBP formation through the combination of enhanced coagulation (or enhanced softening) while maintaining predisinfection. The TWG's analysis indicated that there would be a decrease in the percentage of PWSs that would need to install higher cost technologies. This decrease was attributed to changes in the proposed IESWTR which altered the constraints by which systems could comply with the MCLs. The requirements of the IESWTR would also prevent significant reduction in microbial protection as described in the 1997 NODA (EPA, 1997a) and elsewhere in today's **Federal Register**. EPA has included a discussion of the prediction of technology choices in Section IV (Economic Analysis) of today's rule and a more detailed discussion in the RIA for this rule (EPA, 1998g). EPA continues to believe the proposed MCLs are achievable without large-scale technology shifts.

c. Summary of Comments. Several commenters questioned whether the TTHM MCL of 0.080 mg/L and the HAA5 MCL of 0.060 mg/L were set at a level that would preclude the use of chlorine as an effective disinfectant. EPA does not believe the MCLs will preclude the use of chlorine. While there are currently systems that are exceeding these MCLs, the Agency has concluded that most systems will be able to achieve compliance by relatively low cost alternatives such as: improved DBP precursor removal through enhanced coagulation or enhanced softening; moving the point of disinfection to reduce the reaction between chlorine and DBP precursors; the use of chloramines for residual disinfection instead of chlorine; or a combination of these alternatives.

Many commenters also questioned the need for a modified TTHM MCL and a new MCL for HAA5. As discussed in section I.B.2. of today's rule, EPA believes the potential public health risks do justify a reduction in exposure to DBPs and hence a modification in the MCL for TTHMs and a new MCL for HAA5. Also as discussed in section IV of this rule, EPA continues to believe that the potential risks associated with both TTHM and HAA5 and unregulated DBPs will be reduced by the combination of these MCLs and DBP precursor removal through enhanced coagulation and enhanced softening.

While most commenters agreed with EPA's definition of GAC10 and GAC20 (GAC with a 10 and a 20 minute empty bed contact time, respectively), several commenters thought that designating GAC as BAT meant that they would have to install GAC at their treatment plant. EPA is required to designate a BAT for any MCL that the Agency promulgates; however, a system may use any technology it wants to comply with the MCL. However, a system must install BAT prior to the State issuing a variance to one of these MCLs.

Commenters also questioned the use of group MCLs for TTHM and HAA5, instead of MCLs for the individual DBPs, since a group MCL does not take into account differing health effects and potencies of individual DBPs. EPA continues to believe that regulating TTHMs and HAAs as group MCLs is appropriate at this time for several reasons. First, EPA does not have adequate occurrence data for individual trihalomethanes and haloacetic acids to develop national occurrence estimates which are needed for estimating the potential costs and benefits of the rule (although the Agency has an adequate database of group occurrence). Second, there is not an adequate understanding of how water quality parameters (such as pH, temperature, bromide, and alkalinity) affect individual THM and HAA formation. Third, EPA does not have an adequate understanding of how treatment technologies control the formation of individual THMs and HAAs to enable specifying appropriate MCLs for individual TTHMs or HAAs at this time. Finally, there are inadequate health data to characterize the potential health risks for several of the HAAs and to then determine the potential benefits from reduction in exposures. In conclusion, EPA continues to believe the most appropriate approach for reducing the health risk from all DBPs is by the combination of TTHM and HAA5 MCLs and DBP precursor removal.

Some commenters stated that EPA may have underestimated HAA formation, especially in certain areas of the country. The Agency was aware that waters in particular regions of the country would be more difficult to treat in order to control for HAA5 than for TTHM. Based on additional data received since the proposal, EPA continues to believe that the HAA5 MCL can be met by most systems through the same general low-cost strategies as used for TTHM (e.g., improved DBP precursor removal, moving the point of disinfection, use of chloramines for residual disinfection) rather than higher cost alternatives (see section IV.C for cost estimates of technology treatment choices).

Many commenters also requested that States be granted sufficient flexibility in implementing this rule. While the State must adopt rules that are at least as stringent as those published in today's rule, EPA has given the States and systems much latitude in monitoring plans (frequency and location), allowable disinfectants, and other rule elements. Much of this flexibility carries over from the 1979 TTHM Rule (EPA, 1979).

Finally, some commenters stated that requirements in this rule are complicated. EPA acknowledges that this rule is complicated, but that this complexity is necessary in order to adequately and economically address the potential DBP risks. EPA was required to consider a host of complicating factors in developing regulatory requirements: different disinfectants, different health effects (acute and chronic), different DBP formation kinetics, different source water types and qualities, different treatment processes, and the need for

simultaneous compliance with other rules such as the Total Coliform Rule, Lead and Copper Rule, and Interim Enhanced Surface Water Treatment Rule. The Agency chose to evaluate all these factors by developing requirements that minimized impacts on various classes of systems while enabling States to implement the rule. In addition to the further description of the requirements in today's rule, EPA will publish a State implementation manual, a small system compliance manual, and a series of guidance manuals that will provide additional information to systems and States in implementing this rule.

EPA has reviewed all comments and determined that the requirements promulgated today are necessary to control the occurrence of TTHM and HAA5 and are feasible to achieve. These requirements take into account the difficulties in simultaneously controlling risks from DBPs and pathogens, while appropriately addressing implementation and compliance issues.

2. MCL for Bromate

a. Today's Rule. In today's rule, EPA is promulgating an MCL for bromate of 0.010 mg/L. Bromate is one of the principal byproducts of ozonation in bromide-containing source waters. The proposed MCL for bromate was 0.010 mg/l. A system is in compliance with the MCL when the running annual average of monthly samples, computed quarterly, is less than or equal to the MCL. If the running annual average computed for any quarter exceeds the MCL, the system is out of compliance. EPA has identified the BAT for achieving compliance with the MCL for bromate as control of ozone treatment process to reduce formation of bromate, as was proposed in 1994 (EPA, 1994a).

b. Background and Analysis. For systems using ozone, a separate MCL was proposed for the primary inorganic DBP associated with ozone usage: bromate. Although the theoretical 10^{-4} risk level for bromate is 0.005 mg/l, an MCL of 0.010 mg/L was proposed because available analytical detection methods for bromate were reliable only to the projected practical quantification limit (PQL) of 0.01 mg/L (EPA, 1994a).

In the preamble to the proposed rule, EPA requested comment on whether there were ways to set (or achieve) a lower MCL (i.e., 0.005 mg/L [5 µg/L]) and whether the PQL for bromate could be lowered to 5 µg/L in order to allow compliance determinations for a lower MCL in Stage 1 of the proposed rule. The proposed MCL of 0.010 mg/L for bromate was based on a projected PQL that would be achieved by improved methods. The PQL of the revised method is approximately 0.010 mg/L for bromate, as discussed in Section III.G (Analytical Methods). At the time of the November 1997 NODA, EPA was not aware of any new information that would lower the PQL for bromate and thus allow lowering the MCL. As a result, EPA concluded that the proposed bromate MCL was appropriate.

c. Summary of Comments. Several commenters were concerned that the bromate MCL may have been set at a level that would preclude the use of ozone. During the M–DBP Advisory Committee discussions, the TWG evaluated the feasibility of ozone for certain systems that were predicted to have problems in complying with the TTHM and HAA5 MCLs. While ozone was not feasible for all systems, it was feasible for many that did not have elevated source water bromide levels to react with ozone to form bromate. The TWG predicted that most of the systems not able to use ozone would be able to switch to chlorine dioxide for primary disinfection.

EPA has reviewed all comments and determined that the requirements promulgated today are necessary to control the occurrence of bromate and are feasible to achieve. For additional discussion on the treatment technologies for controlling bromate formation and their costs see the Cost and Technology Document for Controlling Disinfectants and Disinfection Byproducts (EPA, 1998k). These requirements take into account the difficulties in simultaneously controlling risks from DBPs and pathogens, while appropriately addressing compliance and implementation issues. In addition, the Reg. Neg. Committee and the M–DBP Advisory Committee supported these conclusions.

3. MCL for Chlorite

a. Today's Rule. In today's rule, EPA is promulgating an MCL for chlorite of 1.0 mg/L. EPA has modified the monitoring requirements from the proposed rule for the reasons discussed in section III.A.7. The issue of monitoring and MCL compliance determinations as they relate to the health effect of concern for chlorite were discussed in the proposed rule (EPA, 1994a). CWSs and NTNCWSs using chlorine dioxide for disinfection or oxidation are required to conduct sampling for chlorite both daily at the entrance to the distribution system and monthly (3 samples on the same day) within the distribution system. Additional distribution system monitoring is required when the chlorite concentration measured at the entrance to the distribution system exceeds a chlorite concentration of 1.0 mg/L. Distribution system monitoring may be reduced if certain conditions are met (described in section III.H of this rule).

b. Background and Analysis. For systems using chlorine dioxide, EPA proposed a separate MCL for chlorite associated with its usage in 1994. The proposed chlorite MCL of 1.0 mg/L was supported by the Reg. Neg. Committee because 1.0 mg/L was the lowest level considered practicably achievable by typical systems using chlorine dioxide, from both treatment and monitoring perspectives. The MCLG was 0.08 mg/L, due (in part) to data gaps that required higher uncertainty factors in the MCLG determination. The CMA agreed to fund new health effects research on chlorine dioxide and chlorite—with EPA approval of the experimental design—to resolve these data gaps. EPA completed its review of the study and published its findings in a NODA in March 1998. Those findings led to a chlorite MCLG of 0.8 mg/L and support for an MCL of 1.0 mg/L.

c. Summary of Comments. Many commenters requested that EPA not modify the MCL for chlorite prior to receipt and evaluation of the CMA study, since lowering the MCL could preclude the use of chlorine dioxide for drinking water disinfection. EPA has evaluated the CMA study and concluded that the MCLG for chlorite should be 0.8 mg/L. EPA believes the proposed MCL of 1.0 mg/L, based on a three sample average to determine compliance, is appropriate because this is the lowest level achievable by typical systems using chlorine dioxide. In addition, considering the margin of safety that is factored into the estimate of the MCLG, EPA believes the MCL will be protective of public health. Once the final MCLG was established, EPA decided that the chlorite MCL should be finalized at the level proposed which was as close as economically and technically feasible to the MCLG, and modified the proposed requirements for monitoirng and compliance in response to the health concerns associated with chlorite.

EPA has reviewed all comments and determined that the requirements promulgated today are necessary to control the occurrence of chlorite and are feasible to achieve. These requirements take into account the difficulties in simultaneously controlling risks from DBPs and pathogens, while appropriately addressing compliance and

implementation issues. In addition, the Reg. Neg. Committee and the M–DBP Advisory Committee supported these conclusions.

4. MRDL for Chlorine

a. Today's Rule. Chlorine is a widely used and highly effective water disinfectant. In today's rule, EPA is promulgating an MRDL for chlorine of 4.0 mg/L. As a minimum, CWSs and NTNCWSs must measure the residual disinfectant level at the same points in the distribution system and at the same time as total coliforms, as specified in § 141.21. Subpart H systems may use the results of residual disinfectant concentration sampling done under the SWTR (§ 141.74(b)(6) for unfiltered systems, § 141.74(c)(3) for systems that filter) in lieu of taking separate samples. Monitoring for chlorine may not be reduced.

A system is in compliance with the MRDL when the running annual average of monthly averages of all samples, computed quarterly, is less than or equal to the MRDL. Notwithstanding the MRDL, operators may increase residual chlorine levels in the distribution system to a level and for a time necessary to protect public health to address specific microbiological contamination problems (e.g., including distribution line breaks, storm runoff events, source water contamination, or cross-connections).

EPA has identified the best means available for achieving compliance with the MRDL for chlorine as control of treatment processes to reduce disinfectant demand, and control of disinfection treatment processes to reduce disinfectant levels.

b. Background and Analysis. The 1994 proposed Stage I DBPR included an MRDL for chlorine at 4.0 mg/L (EPA, 1994a). The MRDL for chlorine is equal to the MRDLG for chlorine. EPA requested comment on a number of issues relating to the calculation of the MRDLG for chlorine. New information on chlorine has become available since the 1994 proposal and was discussed in the 1997 NODA (EPA, 1997b). EPA believes that no new information has become available to warrant changing the proposed MRDL. EPA has therefore decided to promulgate the MRDL of 4.0 mg/L for chlorine.

c. Summary of Comments. Some commenters expressed concern that the MRDL for chlorine is too high. These commenters were concerned that 4 mg/L levels of chlorine would have a detrimental effect on piping materials and would cause taste and odor problems. One commenter supported the chlorine MRDL and the methods of calculating compliance with the MRDL. This commenter felt that 4.0 mg/L appropriately allows for disinfection under varying circumstances. One commenter requested that EPA increase the flexibility of utilities to meet the MRDL for chlorine during periods when chlorine levels in the distribution systems may need to be raised to protect public health.

EPA believes that the MRDL of 4.0 mg/L for chlorine is appropriate to control for potential health effects (MRDLG is 4.0 mg/L) from chlorine while high enough to allow for control of pathogens under a variety of conditions. EPA also believes that compliance based on a running annual average of monthly averages of all samples, computed quarterly is sufficient to allow systems to increase residual chlorine levels in the distribution system to a level and for a time necessary to protect public health to address specific microbiological contamination problems and still maintain compliance. If a system has taste and odor problems associated with excess chlorine levels it can lower its level of chlorine. Since there may not be any health effects associated with taste and odor problems, EPA does not have a statutory requirement to address this concern.

5. MRDL for Chloramines

a. Today's Rule. Chloramines are formed when ammonia is added during chlorination. In today's rule, EPA is promulgating an MRDL for chloramines of 4.0 mg/L (measured as combined total chlorine). As a minimum, CWSs and NTNCWSs must measure the residual disinfectant level at the same points in the distribution system and at the same time as total coliforms, as specified in § 141.21. Subpart H systems may use the results of residual disinfectant concentration sampling done under the SWTR (§ 141.74(b)(6) for unfiltered systems, § 141.74(c)(3) for systems that filter) in lieu of taking separate samples. Monitoring for chloramines may not be reduced.

A PWS is in compliance with the MRDL when the running annual average of monthly averages of all samples, computed quarterly, is less than or equal to the MRDL. Notwithstanding the MRDL, operators may increase residual chloramine levels in the distribution system to a level and for a time necessary to protect public health to address specific microbiological contamination problems (e.g., including distribution line breaks, storm runoff events, source water contamination, or cross-connections).

EPA has identified the best means available for achieving compliance with the MRDL for chloramines as control of treatment processes to reduce disinfectant demand, and control of disinfection treatment processes to reduce disinfectant levels.

b. Background and Analysis. The 1994 proposed Stage 1 DBPR included an MRDL for chloramines at 4.0 mg/L (EPA, 1994a). The MRDL for chloramines is equal to the MRDLG for chloramines. EPA requested comment on a number of issues relating to the calculation of the MRDLG for chloramines. New information on chloramines has become available since the 1994 proposal and was cited in the 1997 NODA and is included in the public docket for this rule (EPA, 1997b). This new information did not contain data that would warrant changing the MRDL. EPA has therefore decided to promulgate the proposed MRDL of 4.0 mg/L for chloramines.

c. Summary of Comments. Some commenters remarked that systems with high concentrations of ammonia would have difficulty meeting the MRDL for chloramine of 4.0 mg/L and still maintain adequate microbial protection. One commenter felt that there should not be a limit for chloramine residual due to variations in parameters such as distribution system configurations and temperature. One commenter felt that the MRDL for chloramines was too low and should not be set at the same level as the chlorine MRDL since chlorine is a stronger disinfectant than chloramines. This commenter felt that limiting the chloramine residual would reduce the capability to sustain high water quality in the distribution system. One commenter supported the chloramine MRDL and the methods of calculating compliance with the MRDL. This commenter felt that 4.0 mg/L adequately allows for disinfection under varying circumstances.

EPA believes that compliance based on a running annual average of monthly averages of all samples, computed quarterly, is sufficient to allow systems to increase residual chloramine levels in the distribution system to a level and for a time necessary to protect public health to address specific microbiological contamination problems and still maintain compliance. The MRDL for chloramine does not limit disinfectant dosage but rather disinfectant residual in the distribution system. EPA therefore, believes that systems with high levels of ammonia should be able to comply with the MRDL. Systems that have difficulty sustaining high water quality in the distribution system should consider modifying their

treatment or maintenance procedures to reduce demand. Although chlorine is a stronger disinfectant than chloramine, EPA believes that an MRDL of 4.0 mg/L is sufficient to provide adequate microbial protection.

6. MRDL for Chlorine Dioxide

a. Today's Rule. Chlorine dioxide is used primarily for the oxidation of taste and odor-causing organic compounds in water. It can also be used for the oxidation of reduced iron and manganese and color, and as a disinfectant and algicide. Chlorine dioxide reacts with impurities in water very rapidly, and is dissipated quickly. In today's rule, EPA is promulgating an MRDL of 0.8 mg/L for chlorine dioxide. Unlike chlorine and chloramines, the MRDL for chlorine dioxide may not be exceeded for short periods of time to address specific microbiological contamination problems because of potential health concerns with short-term exposure to chlorine dioxide above the MCL.

CWSs and noncommunity systems must monitor for chlorine dioxide only if chlorine dioxide is used by the system for disinfection or oxidation. Monitoring for chlorine dioxide may not be reduced. If monitoring is required, systems must take daily samples at the entrance to the distribution system. If any daily sample taken at the entrance to the distribution system exceeds the MRDL, the system is required to take three additional samples in the distribution system on the next day. Systems using chlorine as a residual disinfectant and operating booster chlorination stations after the first customer must take three samples in the distribution system: one as close as possible to the first customer, one in a location representative of average residence time, and one as close as possible to the end of the distribution system (reflecting maximum residence time in the distribution system). Systems using chlorine dioxide or chloramines as a residual disinfectant or chlorine as a residual disinfectant and not operating booster chlorination stations after the first customer must take three samples in the distribution system as close as possible to the first customer at intervals of not less than six hours.

If any daily sample taken at the entrance to the distribution system exceeds the MRDL and if, on the following day, any sample taken in the distribution system also exceeds the MRDL, the system will be in acute violation of the MRDL and must take immediate corrective action to lower the occurrence of chlorine dioxide below the MRDL and issue the required acute public notification. Failure to monitor in the distribution system on the day following an exceedance of the chlorine dioxide MRDL shall also be considered an acute MRDL violation.

If any two consecutive daily samples taken at the entrance to the distribution system exceed the MRDL, but none of the samples taken in the distribution system exceed the MRDL, the system will be in nonacute violation of the MRDL and must take immediate corrective action to lower the occurrence of chlorine dioxide below the MRDL. Failure to monitor at the entrance to the distribution system on the day following an exceedance of the chlorine dioxide MRDL shall also be considered a nonacute MRDL violation.

EPA has identified the best means available for achieving compliance with the MRDL for chlorine dioxide as control of treatment processes to reduce disinfectant demand, and control of disinfection treatment processes to reduce disinfectant levels.

b. Background and Analysis. EPA proposed an MRDL for chlorine dioxide of 0.8 mg/L in 1994. The MRDL was determined considering the tradeoffs between chemical toxicity and the beneficial use of chlorine dioxide as a disinfectant. The Reg. Neg. Committee agreed to this MRDL with the reservation that it would be revisited, if necessary, after completion of a two-generation reproductive study by CMA.

As discussed above for chlorite, a two-generation reproductive study on chlorite, which is relevant to health effects of chlorine dioxide, was completed by the CMA. EPA completed its review of this study and published its findings in a NODA in March 1998 (EPA, 1998a). Based on its assessment of the CMA study and a reassessment of the noncancer health risk for chlorite and chlorine dioxide, EPA concluded that the MRDLG for chlorine dioxide be changed from 0.3 mg/L to 0.8 mg/L. Since this new MRDLG was equal to the proposed MRDL for chlorine dioxide, the MRDL will remain 0.8 mg/L.

c. Summary of Comments. A number of commenters were concerned that the MRDL for chlorine dioxide not be lowered below the proposed level of 0.8 mg/L because this would preclude the use of chlorine dioxide as a water disinfectant. One commenter supported the MRDL for chlorine dioxide based on public health protection, adequate microbial protection, and technical feasibility. One commenter agreed that a running annual average of samples for compliance determination should not be allowed for chlorine dioxide. One commenter was concerned that the chlorine dioxide MRDL was too high and that EPA should consider children and vulnerable populations in establishing drinking water standards.

EPA has reassessed the health effects data on chlorine dioxide, including the new CMA two-generation study and determined that the MRDL should remain at 0.8 mg/L as proposed. EPA believes that this MRDL is set at a technically feasible level for the majority of chlorine dioxide plants. This is the case because EPA considered children and susceptible populations in its MRDLG determination (EPA, 1998h). The MRDL is set as close to this MRDLG as is technically and economically feasible.

D. Treatment Technique Requirement

1. Today's Rule

Today's rule establishes treatment technique requirements for removal of TOC to reduce the formation of DBPs by means of enhanced coagulation or enhanced softening. The treatment technique applies to Subpart H systems using conventional filtration treatment regardless of size. Subpart H systems are systems with conventional treatment trains that use surface water or ground water under the influence of surface water as their source. The treatment technique requirement has two steps of application. Step 1 specifies the percentage of influent TOC a plant must remove based on the raw water TOC and alkalinity levels. The matrix in Table III–1 specifies the removal percentages.

TABLE III–1.—REQUIRED REMOVAL OF TOTAL ORGANIC CARBON BY ENHANCED COAGULATION AND ENHANCED SOFTENING FOR SUBPART H SYSTEMS USING CONVENTIONAL TREATMENT [a,b]

Source water TOC (mg/L)	Source water alkalinity (mg/L as $CaCO_3$)		
	0–60 (percent)	>60–120 (percent)	>120[c] (percent)
>2.0–4.0	35.0	25.0	15.0

TABLE III–1.—REQUIRED REMOVAL OF TOTAL ORGANIC CARBON BY ENHANCED COAGULATION AND ENHANCED SOFTENING FOR SUBPART H SYSTEMS USING CONVENTIONAL TREATMENT [a,b]—Continued

Source water TOC (mg/L)	Source water alkalinity (mg/L as $CaCO_3$)		
	0–60 (percent)	>60–120 (percent)	>120[c] (percent)
>4.0–8.0	45.0	35.0	25.0
>8.0	50.0	40.0	30.0

[a] Systems meeting at least one of the conditions in Section 141.135(a)(2) (i)–(vi) of the rule are not required to meet the removals in this table.
[b] Softening systems meeting one of the two alternative compliance criteria in Section 141.135(a)(3) of the rule are not required to meet the removals in this table.
[c] Systems practicing softening must meet the TOC removal requirements in the last column to the right.

Step 2 provides alternate performance criteria when it is technically infeasible for systems to meet the Step 1 TOC removal requirements. For systems practicing enhanced coagulation, Step 2 of the treatment technique requirement is used to set an alternative TOC removal requirement (i.e. alternative percent removal of raw water TOC) for those systems unable to meet the TOC removal percentages specified in the matrix. The alternative TOC removal percentage is determined by performing jar tests on at least a quarterly basis for one year. During the jar tests, alum or an equivalent dose of ferric coagulant is added in 10 mg/L increments until the pH is lowered to the target pH value. The target pH is the value the sample must be at or below before the incremental addition of coagulant can be discontinued. For the alkalinity ranges 0–60, >60–120, >120–240, and >240 mg/L (as $CaCO_3$), the target pH values are 5.5, 6.3, 7.0, and 7.5, respectively. Once the Step 2 jar test is complete, the TOC removal (mg/L) is then plotted versus coagulant dose (mg/L). The alternative TOC removal percentage is set at the point of diminishing returns (PODR) identified on the plot.

Today's rule defines the PODR as the point on the TOC versus coagulant dose plot where the slope changes from greater than 0.3/10 to less than 0.3/10 and remains less than 0.3/10. After identifying the PODR, the alternative TOC removal percentage can be set. If the TOC removal versus coagulant dose plot does not meet the PODR definition, the water is considered not amenable to enhanced coagulation and TOC removal is not required if the PWS requests, and is granted, a waiver from the enhanced coagulation requirements by the State. Systems are required to meet the alternative TOC removal requirements during full-scale operation to maintain compliance with the treatment technique. For the technical reasons outlined in the 1997 DBP NODA (EPA 1997b), EPA has concluded that this definition of the PODR is a reliable indicator of the amount of TOC that is feasible to remove.

Systems practicing enhanced softening are not required to perform jar testing under today's treatment technique as part of a Step 2 procedure. Rather, they are required to meet one of three alternative performance criteria if they cannot meet the Step 1 TOC removal requirements. These criteria are: (1) Produce a finished water with a SUVA of less than or equal to 2.0 L/mg-m; (2) remove a minimum of 10 mg/L magnesium hardness (as $CaCO_3$); or (3) lower alkalinity to less then 60 mg/L (as $CaCO_3$). All three of these alternative performance criteria are measured monthly and can be calculated quarterly as a running annual average to demonstrate compliance. As discussed in the 1997 DBP NODA (EPA 1997b) EPA has not been able, from a technical and engineering standpoint, to identify a Step 2 testing procedure at this time that allows softening systems to set an alternative TOC removal amount. Enhanced softening systems unable to meet the Step 1 TOC removal requirements or any of the three alternative performance criteria may apply to the State for a waiver from the treatment technique requirements. EPA believes the three alternative performance criteria listed above provide assurance that softening systems have maximized TOC removal to the extent feasible.

Today's rule also provides alternative compliance criteria—which are separate and independent of the Step 2 enhanced coagulation procedure and the enhanced softening alternative performance criteria—from the treatment technique requirements provided certain conditions are met. These criteria are:

(1) the system's source water TOC is <2.0 mg/L;

(2) the system's treated water TOC is <2.0 mg/L;

(3) the system's source water TOC <4.0 mg/L, its source water alkalinity is >60 mg/L (as $CaCO_3$), and the system is achieving TTHM <40μg/L and HAA5 <30μg/L (or the system has made a clear and irrevocable financial commitment to technologies that will meet the TTHM and HAA level);

(4) the system's TTHM is <40μg/L, HAA5 is <30μg/L, and only chlorine is used for primary disinfection and maintenance of a distribution system residual;

(5) the system's source water SUVA prior to any treatment is ≤ 2.0 L/mg–m; and

(6) the system's treated water SUVA is ≤ 2.0 L/mg–m.

Alternative compliance criteria 1, 2, 5, and 6 are determined based on monthly monitoring calculated quarterly as a running annual average of all measurements. Alternative compliance criteria 3 is based on monthly monitoring for TOC and alkalinity or quarterly monitoring for TTHMs and HAA5, calculated quarterly as a running annual average of all measurements. Alternative criteria 4 is determined based on monitoring for TTHMs and HAA5, calculated quarterly as a running annual average of all measurements. SUVA, an indicator of DBP precursor removal treatability, is defined as the UV–254 (measured in m^{-1}) divided by the DOC concentration (measured as mg/L).

2. Background and Analysis

The general structure of the 1994 proposed rule and today's final rule are similar. The 1994 proposal included an enhanced coagulation and enhanced softening treatment technique requirement for Subpart H systems. The 1994 proposed rule included a TOC removal matrix for Step 1 TOC removal requirements and it also provided for a Step 2 jar test procedure for systems practicing enhanced coagulation. The PODR for the Step 2 procedure was defined as a slope of .3/10 on the TOC removal versus coagulant dose plot. The Step 2 procedure included a maximum pH value, now referred to as the "target pH" for conducting the jar tests and it also allowed systems to request a waiver from the State if the PODR was never

attained. The target pH values in the 1994 proposal were the same as those in today's final rule. A Step 2 procedure for enhanced softening systems was not specified in the proposal.

The proposed rule also provided for a number of exceptions to the enhanced coagulation and enhanced softening requirements, but it did not include use of SUVA as an alternative compliance criteria.

A major goal of the TOC removal treatment technique requirements was to minimize transactional costs to the States both in terms of limiting the number of systems seeking alternative performance criteria and in providing relatively simple methodologies for determining alternative performance criteria. In the 1997 DBP NODA (EPA 1997b), EPA presented new data and analysis and the basis for modifying the proposed criteria to those described in today's final rule. The 1997 NODA also solicited public comment on EPA's intended changes to the proposal and the recommendations of the M–DBP Advisory Committee to EPA. An overview of the key points in the 1997 NODA most pertinent to modifying the treatment technique requirements are presented below.

Data Supporting Changes in the TOC Removal Requirements. The proposed TOC removal percentages, which were set with the intent that 90% of affected systems would be able to achieve them, were developed with limited data. Since the proposal, several jar studies and analyses of full-scale plant TOC removal performance have been performed. They were analyzed by EPA as part of the M–DBP Advisory Committee process. This data will not be thoroughly reviewed here; instead, the major points salient to development of the final regulation will be summarized. See the 1997 DBP NODA (EPA 1997b) to review EPA's detailed analysis of the new data.

As discussed in greater detail in the 1997 DBP NODA, research by Singer et al. (1995) indicated that a significant number of waters, especially low-TOC, high-alkalinity waters in the first row of the proposed TOC removal matrix, would probably not be able to meet the TOC removal percentages and would therefore need to use the Step 2 protocol to establish alternative performance criteria. The Singer et al. (1995) study raised concern regarding the number of systems that might need to use the Step 2 procedure to set alternative performance criteria. A study by Malcolm Pirnie, Inc. and Colorado University addressed this issue by developing a nationally representative database of 127 source waters and used this data to develop a model to predict enhanced coagulation's ability to remove TOC from different source waters (Edwards, 1997; Tseng & Edwards, 1997; Chowdhury, 1997). The model was subsequently used to analyze the level or percentage of TOC removal that is operationally feasible to achieve for the boxes in the proposed TOC removal matrix. Nine predictive equations for TOC removal were developed, one for each box of the TOC removal matrix, to select TOC removal percentages that could be "reasonably" met by 90 percent of the systems implementing enhanced coagulation. The equations indicated that many systems having source waters within the low TOC boxes of the matrix (i.e. 2.0–4.0 mg/L, the first row of the matrix) would meet the Step 2 slope criterion before meeting the required TOC removal percentages. In other words, less than 90 percent of the systems in this row could achieve the proposed TOC removal with reasonable coagulant doses. The equations indicated that the TOC removal percentages in the medium and high TOC boxes (the bottom two rows of the matrix) could be met by approximately 90 percent of the systems in these boxes. The research team also examined 90th-percentile SUVA curves, in conjunction with the nine TOC removal curves, to predict what TOC removal percentage is appropriate for each of the nine boxes of the matrix.

An analysis of full-scale TOC removal has also been performed since 1994. Data was obtained from 76 treatment plants of the American Water Works Service Company (AWWSCo) system, plants studied by Randtke et al. (1994), and plants studied by Singer et al. (1995). These data represent a one-time sampling at each plant under current operating conditions when enhanced coagulation was not being practiced. This sampling is different from the proposed compliance requirements which would be based on an annual average of monthly samples. Based on current treatment at the plants in the study, 83 percent of the systems treating moderate-TOC, low-alkalinity water removed an amount of TOC greater than that required by the TOC removal matrix, whereas only 14 percent of the systems treating water with low TOC and high alkalinity met the proposed TOC removal requirements. The results of the survey, coupled with the information discussed in the preceding paragraph, indicate that the proposed TOC removal percentages in the top row of the matrix might be too high for 90 percent of plants to avoid the Step 2 procedure, while the removal percentages in the bottom two rows may be reasonable and allow 90 percent of plants to avoid the Step 2 procedure. Therefore, the TOC removal percentages in the first row have been lowered 5.0 percentage points to enable 90 percent of plants to comply without unreasonable coagulant dosage or resorting to the Step 2 procedure.

Data Supporting the Use of SUVA as an Exemption from Treatment Technique Requirements. At the time of the proposal, insufficient data on SUVA was available to define precise criteria for when enhanced coagulation would not be effective for removing DBP precursors. The M–DBP Advisory Committee examined the role of SUVA as an indicator of the amount of DBP precursor material enhanced coagulation is capable of removing. It has been well established that coagulation primarily removes the humic fraction of the natural organic matter (NOM) in water (Owen et al., 1993). Furthermore, Edzwald and Van Benschoten (1990) have found SUVA to be a good indicator of a water's humic content. The humic fraction of a water's organic content significantly affects DBP formation upon chlorination.

A study by White et al. (1997) showed that waters with high initial SUVA values exhibited significant reductions in SUVA as a result of coagulation, demonstrating a substantial removal of the humic (and other UV-absorbing) components of the organic matter, whereas waters with low initial SUVA values exhibited relatively low reductions in SUVA. For all of the waters examined, the SUVA tended to plateau at high alum doses, reflecting that the residual organic matter was primarily non-humic and therefore unamenable to removal by enhanced coagulation. SUVA's ability to indicate the amount of humic matter present, and enhanced coagulation's ability to preferentially remove humic matter, logically establishes SUVA as an indicator of enhanced coagulation's ability to remove humic substances from a given water. The M–DBP Advisory Committee therefore recommended that a SUVA value ≤ 2.0 L/mg–m be an exemption from the treatment technique requirement and that this SUVA value also be added as a Step 2 procedure.

Effect of Coagulant Dose on TOC Removal for Enhanced Softening. At the time of proposal, limited data was available on the effectiveness of TOC removal by enhanced coagulation and enhanced softening and on conditions that define feasibility. Several studies examined the relationship between increased coagulant dose and TOC removal (Shorney et al., 1996; Clark et

al. 1994). These studies indicate some improvement in TOC removal with small doses of iron salts (5 mg/L ferric sulfate), but no additional TOC removal during softening occurred with increased coagulant addition (up to 25 mg/L dose). Pilot testing by the City of Austin's softening plant confirmed the study's jar test results by showing that increasing ferric sulfate doses beyond the level required for turbidity removal provided no additional TOC removal.

Multiple jar tests on various waters performed by Singer et al. (1996) examined the relationship between use of lime and soda ash and TOC removal. Only lime and soda ash (no coagulants) were used in the tests. The study showed the removal of 10 mg/L of magnesium hardness would probably have less of an impact on plant residual generation than using a lime soda-ash process. However, the amount of residual material generated under both scenarios could be substantial.

Step 2 Requirements for Softening Systems. As stated above, the proposed rule did not include a Step 2 procedure for softening plants because of a lack of data. The M-DBP Advisory Committee examined new data that had been collected since the proposal to determine if a Step 2 procedure for softening plants could be identified. Data included the current TOC removals being achieved by softening plants covered by the ICR (49 plants). The data were analyzed to find the appropriate TOC removal levels for softening plants. The results of plotting the average TOC percent removals on a percentile basis indicated that the relative impact of meeting the TOC removal requirement in the proposed rule would be greatest in the low TOC group (>2–4 mg/L). However, forcing a plant to increase pH may require it to add soda ash (due to the decrease in alkalinity caused by high lime dose necessary to raise the pH). This would be a significant treatment change due to the additional solids generation and because significant amounts of magnesium hydroxide may precipitate at the higher pH. Most softening plants are normally operated without soda ash addition because of the high cost of soda ash, the additional sludge production, the increased chemical addition to stabilize the water, and the increased sodium levels in the finished water (Randtke et al., 1994 and Shorney et al., 1996). Due to these difficulties, EPA does not currently believe that a lime and soda-ash softening process would be a viable Step 2 procedure for softening systems. The final rule instead specifies two alternative compliance criteria, mentioned earlier in this section, as a Step 2 procedure for softening systems.

3. Summary of Comments

A large number of comments on the 1994 proposal questioned whether the required TOC removal percentages could be obtained by 90 percent of affected systems. In response, since the time of proposal, a large body of additional data and analysis has been developed to help address this question. The analyses discussed above showed that the top row of the TOC removal matrix needed to be lowered by 5.0 percentage points to enable 90 percent of systems within the row to achieve the required TOC removal without unreasonable coagulant doses. Analysis also showed the TOC removal percentages contained in the two lower rows of the TOC removal matrix accurately reflected the TOC removal 90 percent of these systems could remove. EPA believes the final TOC removal matrix, which includes the adjustments to the top row mentioned above, accurately reflects the TOC removal that 90 percent of the systems affected by the rule could practically achieve.

Commenters questioned why systems that meet the DBP Stage 1 MCLs for TTHM and HAA5 must still practice enhanced coagulation. The enhanced coagulation treatment technique is designed to remove DBP precursor material to help reduce the risks posed by DBPs. Also, EPA believes that enhanced coagulation would reduce the number of systems switching to alternative disinfectants, which was a goal of the Reg. Neg. Committee. EPA believes that even if systems are meeting the MCLs, an additional risk reduction benefit can be achieved through removal of DBP precursor material at a relatively low cost to the system. Therefore, systems that meet the MCLs must still practice enhanced coagulation to decrease the risks posed by DBPs in general.

The Agency received numerous comments on the 1994 proposal that expressed doubt regarding the definition of the PODR. Specifically, the commenters stated that the accuracy of the slope criterion (0.3 mg/L TOC removed per 10 mg/L coagulant added) for determining the PODR was not supported with adequate data. The data developed since the proposal and the corresponding analysis demonstrate that the slope criterion accurately predicts the PODR. The analyses discussed above showed that there is a particular relationship between SUVA and the slope criterion, namely, that they both predict the PODR at the same point of the TOC removal versus coagulant dose curve. Since SUVA is a very good predictor of the humic fraction of TOC, which is the fraction preferentially removed by enhanced coagulation, and the PODR predicted by SUVA and the slope criterion agree, EPA believes the slope criterion of 0.3 mg/L TOC removal per 10 mg/L of coagulant addition accurately predicts the PODR.

The majority of commenters did not support requiring the use of bench-scale filtration as part of the Step 2 enhanced coagulation procedure. The commenters generally believed that using filtration at bench scale is of limited value because the great majority of TOC is removed via sedimentation, not through filtration. Additionally, some commentors felt that attempting to replicate full-scale filtration at bench scale can contain inherent inaccuracy. EPA generally agrees that a Step 2 filtration procedure should not be required. The Agency believes that most of the TOC removed by conventional treatment plants is removed in the sedimentation basin rather than in the filters. Therefore, requiring a bench-scale filtration procedure as part of Step 2 testing will not increase the accuracy of the procedure or its value to the treatment technique implementation. Accordingly, today's final rule does not require the use of a bench scale filtration procedure during Step 2 enhanced coagulation testing. Detailed guidance on conducting the Step 2 testing will be provided in the Guidance Manual for Enhanced Coagulation and Enhanced Precipatative Softening.

Commenters expressed varied opinions regarding the frequency of Step 2 testing. Several commenters stated that the rule should not set a minimum testing frequency, but that it should be left to State discretion based on source water characteristics. Other commenters believed a minimum of quarterly monitoring should be required with a provision for more frequent testing to address source water quality events. EPA believes that Step 2 testing frequency should be related to seasonal and other variations in source water quality as these variations may influence the amount of TOC removal the treatment plant can achieve. Accordingly, EPA recommends that systems utilizing the Step 2 procedure for compliance perform Step 2 testing quarterly for one year after the effective data of the rule. The system may then apply to the State to reduce testing to a minimum of once per year. If the State does not approve the request for reduced testing frequency, the system must continue to test quarterly.

E. Predisinfection Disinfection Credit

1. Today's Rule

Today's rule does not impose any constraints on the ability of systems to practice predisinfection and take microbial inactivation credit for predisinfection to meet the disinfection requirements of the SWTR. Utilities are free to take disinfection credit for predisinfection, regardless of the disinfectant used, for disinfection that occurs after the last point the source water is subject to surface water run-off and prior to the first customer.

2. Background and Analysis

The 1994 proposed Stage 1 DBPR (EPA,1994a) discouraged the use of disinfectants prior to precursor (measured as TOC) removal by not allowing compliance credit for the SWTR's disinfection requirements to be taken prior to removal of a specified percentage of TOC. The proposed IESWTR options were intended to include microbial treatment requirements to prevent increases in microbial risk due to the loss of predisinfection credit. These options were to be implemented simultaneously with the Stage 1 DBPR. The purpose of not allowing predisinfection credit was to maximize removal of organic precursors (measured as TOC) prior to the addition of a disinfectant, thus lowering the formation of DBPs.

Many drinking water systems use preoxidation to control a variety of water quality problems such as iron and manganese, sulfides, zebra mussels, Asiatic clams, and taste and odor. The 1994 proposed rule did not preclude the continuous addition of oxidants to control these problems. However, the proposed regulation, except under a few specific conditions, did not allow credit for compliance with disinfection requirements prior to TOC removal. Analysis supporting the proposed rule concluded that many plants would be able to comply with the Stage 1 MCLs for THMs and HAA5 of 0.080 mg/L and 0.060 mg/L, respectively, by reductions in DBP levels as a result of reduced disinfection practice in the early stages of treatment. Also, enhanced coagulation and enhanced softening were thought to lower the formation of other unidentified DBPs as well. The 1994 proposal assumed that addition of disinfectant prior to TOC removal would initiate DBP formation through contact of the chlorine with the TOC, effectively eliminating the value of enhanced coagulation for DBP reduction. Finally, the analysis underlying the 1994 proposed elimination of the preoxidation credit assumed that the addition of disinfectant was essentially "mutually exclusive" to the goal of reducing DBP formation by the removal of TOC. As discussed below, new data developed since 1994 suggest this may not be the case.

Reasons for Disinfectant Use. In order to obtain information on the impact that disallowing predisinfection would have on utilities' disinfection practices, a survey was sent out to ICR utilities to obtain information on their current predisinfection practices. The results of the survey of 329 surface water treatment plants indicated that 80 percent (263) of these plants use predisinfection for one or more reasons. The survey indicated that the majority of the plants using predisinfection were doing so for multiple reasons. However, the main reason reported for predisinfection was microbial inactivation. Algae control, taste and odor control, and inorganic oxidation, in that order, were the next most frequently cited reasons for practicing predisinfection. Seventy-seven percent of plants that predisinfected reported that their current levels of *Giardia lamblia* inactivation would be lowered if predisinfection was discontinued and no subsequent additional disinfection was added to compensate for change in practice. Eighty-one percent of plants that predisinfected would have to make major capital investments to make up for the lost logs of *Giardia lamblia* inactivation. For example, to maintain the same level of microbial protection currently afforded, construction to provide for additional contact time or use of a different disinfectant might be needed if predisinfection credit was eliminated.

In addition to the ICR mail survey, results from EPA's Comprehensive Performance Evaluations (CPE) from 307 PWSs (4 to 750 mgd) reported that 71% of the total number of plants used predisinfection and 93% of those that predisinfected used two or three disinfectant application points during treatment.

Based on the above information, EPA believes that predisinfection is used by a majority of PWSs for microbial inactivation, as well as other drinking water treatment objectives. Therefore, disallowing predisinfection credit could influence systems to make changes in treatment to comply with the disinfection requirements of the SWTR or to maintain current levels of microbial inactivation.

Impact of Point of Chlorination on DBP Formation. The results of a study by Summers et al. (1997) indicate that practicing enhanced coagulation, while simultaneously maintaining prechlorination, can still result in decreased DBP formation (especially for TOX and TTHM). Greater benefits are realized by moving the point of chlorination to post-rapid mixing or further downstream for HAA5 control, and to mid-flocculation or post-sedimentation for TOX and TTHM control. These data show that the assumption made in the 1994 proposal, namely that application of any disinfectant prior to TOC removal would critically effect DBP formation, was not accurate. The data indicate that simultaneous employment of enhanced coagulation and predisinfection does not necessarily mean that DBP formation cannot be substantially controlled (see EPA 1997b for detailed analysis).

Impact on Softening Plants. In order to obtain additional information on the current TOC removals being achieved by softening plants, a survey was sent to all the ICR softening utilities (49 plants) requesting that they fill out a single page of information with yearly average, maximum and minimum values for multiple operating parameters for each softening plant. The survey showed that in spite of the fact that 78 percent of softening plants are using free chlorine for at least a portion of their disinfection, 90 percent of plants are currently meeting an 80 µg/L MCL level for TTHMS. All the softening plants reported average HAA5 levels below 60 µg/L. Without predisinfection credit, these plants may have to provide disinfection contact time after sedimentation, which could mean significantly increasing the free chlorine contact time to make up for a shortened detention time.

3. Summary of Comments

Most commenters stated that the proposed elimination of predisinfection would result in many plants not being able to maintain existing levels of disinfection or comply with the SWTR disinfection requirements without making significant compensatory changes in their disinfection practice. Commenters were concerned that without predisinfection the level of microbial risk their customers were exposed to could significantly increase, and that eliminating microbial inactivation credit for predisinfection to comply with the SWTR might influence utilities to abandon predisinfection to more easily comply with the TTHM and HAA5 MCLs. EPA agrees with this concern and therefore the final rule has been modified from the proposal to allow predisinfection credit.

F. Requirements for Systems to Use Qualified Operators

EPA believes that systems that must make treatment changes to comply with requirements to reduce the microbiological risks and risks from disinfectants and disinfection byproducts should be operated by personnel who are qualified to recognize and react to problems. Therefore, in today's rule, the Agency is requiring that all systems regulated under this rule be operated by an individual who meets State specified qualifications, which may differ based on size and type of the system. Subpart H systems already are required to be operated by qualified operators under the provisions of the SWTR (40 CFR 141.70(c)). Current qualification or certification programs developed by the States should, in many cases, be adequate to meet this requirement for Subpart H systems. Also, States must maintain a register of qualified operators.

EPA encourages States which do not already have operator certification programs in effect to develop such programs. The Reg. Neg. Committee and TWG believed that properly trained personnel are essential to ensure safer drinking water. States with existing operator certification programs may wish to update their programs for qualifying operators under the SWTR. In these cases, States may wish to indicate that their operator certification programs are being developed in accordance with EPA's new guidelines.

G. Analytical Methods

1. Today's Rule

Chlorine (Free, Combined, and Total). Today's rule approves four methods for measuring free, combined, and total chlorine to determine compliance with the chlorine MRDL (using either free or total chlorine) and chloramines MRDL (using either combined or total chlorine): ASTM Method D1253–86 (ASTM, 1996), Standard Methods 4500–Cl D (APHA, 1995), 4500–Cl F (APHA, 1995), and 4500–Cl G (APHA, 1995). Additionally, this rule approves two methods for measuring total chlorine to determine compliance with the chlorine MRDL and chloramines MRDL: Standard Methods 4500–Cl E (APHA, 1995) and 4500–Cl I (APHA, 1995). The rule also contains an additional method for measuring free chlorine to determine compliance with the chlorine MRDL: Standard Method 4500–Cl H (APHA, 1995).

Chlorine Dioxide. Today's rule approves two methods for determining compliance with the chlorine dioxide MRDL: Standard Methods 4500–ClO_2 D (APHA, 1995) and 4500–ClO_2 E (APHA 1995). EPA did not approve Standard Method 4500–ClO_2 C (APHA, 1995), which was included in the 1994 proposed rule. The Agency determined, in concurrence with the majority of commenters on this issue, that Standard Method 4500–ClO_2 C is outdated and inaccurate in comparison to chlorine dioxide methods approved in today's rule and is inadequate for compliance monitoring.

TTHM. Today's rule approves three methods for determining compliance with the TTHM MCL: EPA Methods 502.2 (EPA, 1995), 524.2 (EPA, 1995), and 551.1 (EPA, 1995).

HAA5. Today's rule approves three methods for determining compliance with the HAA5 MCL: EPA Methods 552.1 (EPA, 1992) and 552.2 (EPA, 1995) and Standard Method 6251B (APHA, 1995).

Bromate. Today's rule approves a method for determining compliance with the bromate MCL: EPA Method 300.1 (EPA, 1997e). EPA has demonstrated this method to be capable of quantifying bromate at the MCL of 10 µg/L under a wide range of solution conditions. EPA did not approve EPA Method 300.0 (EPA, 1993b) for bromate analysis, although this method was included for analysis of bromate in the 1994 proposed rule. As stated in the proposed rule, EPA Method 300.0 is not sensitive enough to measure bromate at the MCL established in today's rule. EPA Method 300.1 was developed subsequent to the proposed rule in order to provide a method with adequate sensitivity to assess bromate compliance.

Chlorite. Today's rule approves two methods for determining compliance with the chlorite MCL: EPA Methods 300.0 (EPA, 1993b) and 300.1 (EPA, 1997e). As described elsewhere in today's rule, chlorite compliance analyses are made on samples taken in the distribution system during monthly monitoring, or during additional distribution system monitoring as required. Today's rule establishes the following method for daily monitoring of chlorite: Standard Method 4500-ClO_2 E (APHA, 1995), amperometric titration. As stated elsewhere in today's rule, daily monitoring of chlorite is conducted on samples taken at the entrance to the distribution system. Commenters supported the use of amperometric titration as a feasible method for daily monitoring of chlorite.

TOC. Today's Rule approves three methods for TOC analysis: Standard Methods 5310 B, 5310 C, and 5310 D, as published in the Standard Methods 19th Edition Supplement (APHA, 1996). EPA believes that all of these methods can achieve the precision and detection level necessary for compliance determinations required in today's rule when the quality control (QC) procedures contained in the method descriptions and this rule are followed. However, while any of these methods may be used, EPA advises that a consistent method be employed for all measurements in order to reduce the impact of possible instrument bias.

In accordance with the concerns of commenters, today's rule requires certain QC procedures for TOC analyses in addition to those contained in the method descriptions. These additional QC steps are designed to increase the integrity of the analysis and have been found to be effective in data collection under the ICR. Filtration of samples prior to TOC analysis is not permitted, as this could result in removal of organic carbon. Where turbidity interferes with TOC analysis, samples should be homogenized and, if necessary, diluted with organic-free reagent water. TOC samples must either be analyzed or must be acidified to achieve pH less than 2.0 by minimal addition of phosphoric or sulfuric acid as soon as practical after sampling, not to exceed 24 hours. Samples must be analyzed within 28 days.

SUVA (Specific Ultraviolet Absorbance). Today's rule establishes SUVA as an alternative criterion for demonstrating compliance with TOC removal requirements contained in today's rule. SUVA is a calculated parameter defined as the UV absorption at 254 nm (UV_{254}) (measured as m^{-1}) divided by the DOC concentration (measured as mg/L). If the UV absorption is first determined in units of cm^{-1}, the SUVA equation is multiplied by 100 to convert to m^{-1}, as shown below:

$$SUVA = 100\ (cm/m)\ [UV_{254}\ (cm^{-1})/DOC\ (mg/L)]$$

Two separate analytical methods are necessary to make this measurement: UV_{254} and DOC. Today's rule approves three methods for DOC analysis: Standard Methods 5310 B, 5310 C, and 5310 D, as published in the Standard Methods 19th Edition Supplement (APHA, 1996); and approves Standard Method 5910 B (APHA, 1995) for UV_{254} analysis.

The final rule contains QC steps for the SUVA analyses that are required in addition to those mandated in the method descriptions. These requirements were developed in response to comments solicited by EPA in the 1997 DBP NODA (EPA, 1997b) and are as follows:

—sample acquisition (DOC and UV_{254} samples used to determine a SUVA value must be taken at the same time and at the same location. SUVA must be determined on water prior to the addition of disinfectants/oxidants.)
—sample preservation (DOC samples must either be analyzed or must be acidified to achieve pH less than 2.0 by minimal addition of phosphoric or sulfuric acid as soon as practical after sampling, not to exceed 48 hours. The pH of UV_{254} samples may not be adjusted.)
—holding times (DOC samples must be analyzed within 28 days of sampling. UV_{254} samples must be analyzed as soon as practical after sampling, not to exceed 48 hours.)
—filtration (Prior to analysis, UV_{254} and DOC samples must be filtered through a 0.45 µm pore-diameter filter. DOC samples must be filtered prior to acidification.)
—background concentrations in the filtered blanks (Water passed through the filter prior to filtration of the sample must serve as the filtered blank. This filtered blank must be analyzed using procedures identical to those used for analysis of the samples and must meet the following criteria: TOC <0.5 mg/L.)

Bromide. Today's rule approves the following two methods for monitoring bromide: EPA Methods 300.0 (EPA, 1993b) and 300.1 (EPA, 1997e).

Alkalinity. Today's rule approves three methods for measuring alkalinity: ASTM Method D1067–92B (ASTM, 1994), Standard Method 2320 B (APHA, 1995), and Method I–1030–85 (USGS, 1989).

pH. Today's rule requires the use of methods that have been previously approved in § 141.23(k) for measurement of pH.

Approved analytical methods are summarized in Table III–2.

TABLE III–2.—APPROVED ANALYTICAL METHODS

Analyte	EPA method	Standard method	Other
Chlorine (free, combined, total)		4500–Cl D	ASTM D1253–8.
		4500–Cl F	
		4500–Cl G	
(Total)		4500–Cl E	
		4500–Cl I	
(Free)		4500–Cl H	
Chlorine Dioxide		4500–ClO_2 D	
		4500–ClO_2 E	
TTHM	502.2		
	524.2		
	551.1		
HAA5	552.1	6251 B	
	552.2		
Bromate	300.1		
Chlorite (monthly)	300.0		
	300.1		
(Daily)		4500–ClO_2 E	
TOC/DOC		5310 B	
		5310 C	
		5310 D	
UV_{254}		5910 B	
Bromide	300.0		
	300.1		
Alkalinity		2320 B	ASTM D1067–92B.
			USGS I–1030–85.
pH	150.1	4500–H+B	ASTM D1293–84.
	150.2		

2. Background and Analysis

Chlorine (Free, Combined, and Total). In the 1994 proposed rule, EPA included all Standard Methods for analysis of free, combined, and total chlorine that were approved in today's rule.

Chlorine Dioxide. The 1994 proposed rule included the same three methods for analyzing chlorine dioxide (ClO_2) that are approved under the SWTR and ICR regulations. Two of these methods, Standard Methods 4500.ClO_2 C (APHA, 1992) and 4500.ClO_2 E (APHA, 1992), are amperometric methods. The third proposed method was Standard Method 4500.ClO_2 D (APHA, 1992), a colorimetric test using the color indicator N,N-diethyl-*p*-phenylenediamine (DPD).

TTHM. The 1994 proposed rule included three methods for the analysis of TTHMs. They were EPA Methods 502.2, 524.2, and 551. In 1995, EPA Method 551 was revised to EPA Method 551.1, rev. 1.0 (EPA, 1995), which was approved for ICR monitoring under 40 CFR 141.142.

EPA Method 551.1 has several improvements upon EPA Method 551. The use of sodium sulfate is strongly recommended over sodium chloride for the MTBE extraction of DBPs. This change was in response to a report indicating elevated recoveries of some brominated DBPs due to bromide impurities in the sodium chloride (Xie, 1995). Other changes to EPA Method 551.1 include a buffer addition to stabilize chloral hydrate, elimination of the preservative ascorbic acid, and modification of the extraction procedure to minimize the loss of volatile analytes. The revised method requires the use of surrogate and other quality control standards to improve the precision and accuracy of the method.

HAA5. The 1994 proposed rule included two methods for the analysis of five haloacetic acids—EPA Method 552.1 (EPA, 1992) and Standard Method 6233B (APHA, 1992). Both methods use capillary column gas chromatographs equipped with electron capture

detectors. The two methods differ in the sample preparation steps. EPA Method 552.1 uses solid phase extraction disks followed by an acidic methanol derivitization. Standard Method 6233B is a small volume liquid-liquid (micro) extraction with methyl-t-butyl ether, followed by a diazomethane derivitization. Following the proposed rule, Standard Method 6233B was revised and renumbered 6251B (APHA, 1995) to include bromochloroacetic acid, for which a standard was not commercially available in 1994. Recognizing these improvements, EPA approved Standard Method 6251B for analysis under the ICR (40 CFR Part 141 or EPA, 1996a). Several commenters requested that the revised and renumbered method, Standard Method 6251B, also be approved for the analysis of haloacetic acids under the Stage 1 DBPR.

In 1995 EPA published a third method for HAAs, EPA Method 552.2 (EPA, 1995), and subsequently approved it for HAA analysis under the 1996 ICR (40 CFR Part 141 or EPA, 1996a). EPA Method 552.2 is an improved method, combining the micro extraction procedure of Standard Method 6233B with the acidic methanol derivitization procedure of EPA Method 552.1. It is capable of analyzing nine HAAs.

Bromate. The 1994 proposed rule required systems that use ozone to monitor for bromate ion. EPA proposed EPA Method 300.0 (EPA, 1993b) for the analysis of bromate and chlorite ions. However, at the time of the proposal, EPA was aware that EPA Method 300.0 was not sensitive enough to measure bromate ion concentration at the proposed MCL of 10 µg/L. EPA recognized that modifications to the method would be necessary to increase the method sensitivity. Studies at that time indicated that changes to the injection volume and the eluent chemistry would decrease the detection limit below the MCL. Many commenters to the 1994 proposal agreed that EPA Method 300.0 was not sensitive enough to determine compliance with a MCL of 10 µg/L bromate ion, given that MCLs are typically set at 5 times the minimum detection levels (MDLs).

Following the proposal, EPA improved EPA Method 300.0 and renumbered it as EPA Method 300.1 (EPA, 1997b). EPA Method 300.1 specifies a new, high capacity ion chromatography (IC) column that is used for the analysis of all anions listed in the method, instead of requiring two different columns as specified in EPA Method 300.0. The new column has a higher ion exchange capacity that improves chromatographic resolution and minimizes the potential for chromatographic interferences from common anions at concentrations 10,000 times greater than bromate ion. For example, quantification of 5.0 µg/L bromate is feasible in a matrix containing 50 mg/L chloride. Minimizing the interferences permits the introduction of a larger sample volume to yield method detection limits in the range of 1–2 µg/L.

In the 1997 DBPR NODA (EPA, 1997b), EPA discussed EPA Method 300.1 and projected that by using it laboratories would be able to quantify bromate with the accuracy and precision necessary for compliance determination with an MCL of 10 µg/L. Although there would be a limited number of laboratories that would be qualified to do such analyses, EPA determined that there should be adequate laboratory capacity for bromate ion compliance monitoring by the time the rule becomes effective.

Chlorite. The proposed rule required systems using chlorine dioxide for disinfection or oxidation to perform monthly monitoring for chlorite ion in the distribution system. EPA designated EPA Method 300.0 (ion chromatography) for chlorite analysis. EPA considered other methods using amperometric and potentiometric techniques but decided that only the ion chromatography method (EPA Method 300.0) would produce results with the accuracy and precision needed for determining compliance. Subsequent to the proposed rule, EPA Method 300.0 was improved in order to achieve lower detection limits for bromate ion and renumbered as EPA Method 300.1.

TOC. To satisfy requirements of the Stage 1 DBPR, the 1994 proposed rule directed that a TOC analytical method should have a detection limit of at least 0.5 mg/L and a reproducibility of ± 0.1 mg/L over a range of 2 to 5 mg/L TOC. The proposed rule included two methods for analyzing TOC: Standard Methods 5310 C, which is the persulfate-ultraviolet oxidation method, and 5310 D, the wet-oxidation method (APHA, 1992). These methods were selected because, according to data published in Standard Methods (APHA 1992), they could achieve the necessary precision and detection limit. Standard Method 5310 B, the high-temperature combustion method, was considered but not proposed because it was described in Standard Methods (1992, APHA) as having a detection limit of 1 mg/L. The proposal stated that if planned improvements to the instrumentation used in Standard Method 5310 B were successful, the next version would be considered for promulgation. Revisions of Standard Methods 5310 B, C, and D were published in Standard Methods 19th Edition Supplement (APHA, 1996). The revised version of Standard Method 5310 B recognized the capacity of certain high temperature instruments to achieve detection limits below 1 mg/L using this method.

SUVA (Specific Ultraviolet Absorbance). SUVA analytical methods were not addressed in the 1994 proposed rule because SUVA had not been developed and proposed as a compliance parameter for TOC removal requirements at that time. The analytical methods and associated QC procedures for DOC and UV_{254} approved in today's rule are those on which the Agency solicited comment in the 1997 DBPR NODA (EPA, 1997b).

Bromide. The 1994 proposed rule included EPA Method 300.0 for analysis of bromide. EPA believed that the working range of this method adequately covered the requirements proposed for bromide monitoring. As described above, EPA developed Method 300.1 for improved bromate analysis subsequent to the proposed rule. EPA Method 300.1 can also effectively measure bromide at the concentration of 50 µg/L, required in today's rule for reduced monitoring of bromate.

Alkalinity. The proposed rule included all methods approved by EPA for measuring alkalinity. These methods have all been approved in today's rule.

3. Summary of Comments

Following is a discussion of major comments on the analytical methods requirements of the Stage 1 DBPR.

Chlorine. A commenter to the 1994 proposal recommended approval of ASTM method D1253–86. EPA determined that this method is equivalent to Standard Method 4500–Cl D, and has approved this method in today's rule.

Chlorine Dioxide. EPA received comments on the proposed rule detailing weaknesses of the methods selected to calculate ClO_2. Commenters pointed out that other halogenated species, such as free chlorine, chloramines, and chlorite, as well as common metal ions (e.g. copper, manganese, chromate) will interfere with these methods. Additionally, where these methods determine concentrations by difference, they are potentially inaccurate and subject to propagation of errors. Commenters specifically criticized Standard Method 4500–ClO_2 C (APHA 1995), amperometric method I, which was characterized as outdated and inaccurate, and stated that Standard

Method 4500-ClO_2 E (APHA 1995), amperometric method II, is a substantially better method. Consequently, in the 1997 DBP NODA, EPA requested comment on removing Standard Method 4500-ClO_2 C from the list of approved methods for the analysis of chlorine dioxide for compliance with the MRDL.

Comments on the 1997 DBPR NODA favored eliminating Standard Method 4500.ClO_2 C as an approved method for ClO_2 compliance analysis. EPA does not approve this method in today's rule. EPA recognizes that the two methods approved for ClO_2 monitoring under today's rule are subject to interferences. However, EPA believes that these methods can be used effectively to indicate compliance with the ClO_2 MRDL when the quality control procedures contained in the method descriptions are followed. Several commenters also encouraged EPA to approve a more sensitive and specific method for ClO_2 analysis, and suggested alternative methods including Acid Chrome Violet K, Lissamine Green B, and Chlorophenol Red. While EPA supports the development of improved analytical methods for chlorine dioxide, the Agency believes that at this time the methods suggested by commenters have not gone through the necessary performance validation processes to warrant their approval for compliance monitoring.

Bromate. In the 1994 proposed rule, EPA discussed the fact that the current version of EPA Method 300.0 was not sensitive enough to measure bromate ion concentrations at the proposed MCL and requested comment on modifications to EPA Method 300.0 to improve its sensitivity. In the 1997 NODA, EPA presented EPA Method 300.1 and requested comment on replacing EPA Method 300.0 with EPA Method 300.1 for the analysis of bromate.

Commenters agreed that EPA Method 300.1 is a more sensitive method than EPA Method 300.0 for low level bromate analysis and the majority suggested that EPA Method 300.1 be the approved method for bromate analysis. One commenter requested that interlaboratory round-robin testing be conducted before EPA Method 300.1 is accepted for Stage 1 DBPR compliance monitoring. EPA considers interlaboratory round-robin testing of EPA Method 300.1 to be unnecessary because this method is essentially an improvement of EPA Method 300.0 which is already approved. EPA Method 300.1 primarily makes use of a superior analytical column to achieve increased sensitivity for bromate analysis. Moreover, the efficacy of EPA Method 300.1 in a wide range of sample matrices is demonstrated by the performance validation data contained in the published method description. Based on a review of all the public comments, EPA is approving EPA Method 300.1 for bromate analysis in today's rule.

Chlorite. EPA solicited comment in the 1997 DBPR NODA on approving EPA Method 300.1, in addition to EPA Method 300.0, for compliance analysis of chlorite. The majority of commenters on this issue favored approval of both methods and today's rule establishes both for determining compliance with the chlorite MCL.

In the 1994 proposed rule, EPA requested comment on changing monitoring requirements for chlorite to reflect concern about potential acute health effects. Several commenters stated that daily monitoring of chlorite would be feasible if an amperometric analytical method could be used. Commenters suggested that daily amperometric analyses for chlorite be conducted on samples taken from the entrance to the distribution system, and that weekly or monthly analyses using ion chromatography still be required as a check, because ion chromatography is a more accurate analytical method. Commenters noted that daily monitoring for chlorite would provide improved operational control of plants and reduce the likelihood of systems incurring compliance violations.

Today's rule establishes amperometric titration (Standard Method 4500-ClO_2 E) for daily analyses of chlorite samples taken at the entrance to the distribution system, along with monthly (or quarterly if reduced, or additional as required), analyses by ion chromatography (EPA Methods 300.0 and 300.1) of chlorite samples taken from within the distribution system. EPA believes that the ion chromatography method, rather than the amperometric method, should be used for making chlorite compliance determinations in the distribution system due to its greater accuracy. However, the amperometric method is sufficient for the purposes of daily monitoring at the entrance to the distribution system, which are to significantly aid in proper operational control of a treatment plant and to indicate when distribution system testing is appropriate. For this reason, only the ion chromatographic methods (EPA Method 300.0 and 300.1), and not the amperometric titration methods, are approved in today's rule for determining compliance with the chlorite MCL.

A minority of commenters on this issue suggested that the DPD method (Standard Method 4500-ClO_2 D (APHA 1995)) be approved for daily monitoring of chlorite ion levels. EPA has determined that the accuracy and precision of the DPD method (Standard Method 4500-ClO_2 D) in the measurement of chlorite are substantially worse than with Standard Method 4500-ClO_2 E, and are insufficient for this method to be used for daily monitoring of chlorite. As a consequence, EPA has not approved the DPD method for chlorite monitoring in today's rule.

TOC. EPA received several comments on the 1994 proposal requesting approval of Standard Method 5310 B for TOC compliance analysis. Commenters stated that newer instrumentation could achieve a detection limit of 0.5 mg/L TOC using this method. Following the publication of a revised version of Method 5310 B in Standard Methods 19th Edition Supplement (APHA 1996) which recognized the capacity of some combustion based TOC analyzers to achieve detection limits below 1 mg/L, EPA requested comment on approving Standard Method 5310 B, along with Standard Methods 5310 C and 5310 D, for the analysis of TOC in the 1997 DBPR NODA.

The majority of commenters on TOC analysis urged EPA to approve all three methods. Commenters were concerned, though, that because these three methods employ different processes to oxidize organic carbon to carbon dioxide, results from different TOC analyzers could vary to a degree that is of regulatory significance. Specifically, the efficiency of oxidation of large organic particles or very large organic molecules such as tannins, lignins, and humic acids may be lower with persulfate based instruments (APHA 1996). Although available data comparing different TOC methods is limited, one study observed a persulfate catalytic oxidation technique to underestimate the TOC concentration measured by a high temperature catalytic oxidation technique by 3-6% on stream water and soil water samples (Kaplan, 1992). Standard Methods recommends checking the oxidation efficiency of the instrument with model compounds representative of the sample matrix, because many factors can influence conversion of organic carbon to carbon dioxide (APHA 1996).

EPA believes that the potential regulatory impact of small disparities in oxidation efficiencies between different TOC analyzers is minor. Studies using PE samples indicate that for instruments calibrated in accordance with the

procedures specified in *Standard Methods* (APHA, 1996), the magnitude of measurement error due to analytical discrepancies between instruments will typically be less than the measurement uncertainty attributed to a particular instrument (EPA, 1994c). In addition, EPA anticipates that most systems will use a consistent method for TOC analyses and that this will assist in minimizing the importance of instrument bias. This practice was suggested by several commenters.

Commenters also suggested that EPA implement a formal certification process for laboratories measuring TOC. Some commenters recommended that EPA require a laboratory approval process for TOC measurements under the Stage 1 DBPR that is similar to what is required under the ICR. EPA requires that TOC analyses be conducted by a party approved by EPA or the State but not that TOC measurements be subject to the same laboratory certification procedures required for the analysis of DBPs. However, today's rule contains QC requirements for TOC analyses which are in addition to those in *Standard Methods*. These additional QC procedures pertain to sample preservation and holding time, and have been found to be effective for TOC analyses under the ICR.

SUVA. In the 1997 DBPR NODA, EPA solicited comment on a range of issues dealing with the determination of SUVA including: analytical methods, sampling, sample preparation, filter types, pH, interferences to UV, high turbidity waters, quality control, and other issues that should be addressed. The Agency requested comment on approving Standard Method 5910 B for measuring UV_{254} and Standard Methods 5310 B, C, and D, for measuring DOC. In requesting comment on filtration, EPA noted that filtration is necessary prior to both UV_{254} and DOC analyses in order to eliminate particulate matter and separate the operationally defined dissolved organic matter (based on a 0.45 µm-pore-diameter cut-off). However, filtration can also corrupt samples through adsorption of carbonaceous material onto the filter or its desorption from it (APHA 1996). In addition, EPA requested comment on requiring that UV_{254} and DOC analyses be measured from the same sample filtrate.

The majority of commenters on SUVA analytical methods recommended that EPA approve Standard Methods 5310 B, C, and D, for DOC analysis and Standard Method 5910 B for UV_{254} analysis. EPA has approved these methods in today's rule. In addition, commenters stressed the importance of sample preparation, especially filtration, in the measurement of DOC and observed that sufficient washing of filters prior to filtration of samples is critical to preventing contamination of the samples by organic carbon from the filters. Several comments on the 1997 DBPR NODA expressed opposition to a requirement that UV_{254} and DOC analyses be made on the same sample filtrate. Commenters stated that this is impractical because UV analyses are often conducted at the treatment plant while DOC analyses are typically run off-site. Commenters also noted that DOC samples should be acid preserved whereas pH adjustment of samples for UV_{254} analysis is improper.

Today's rule establishes that samples for DOC and UV_{254} analyses must be filtered through a 0.45 µm-pore-diameter filter. EPA does not have specific requirements on the type of filter that is used, provided it has a 0.45 µm pore-diameter, but will provide guidance on this issue in the *Guidance Manual for Enhanced Coagulation*. This manual will be available for public review after promulgation of the Stage 1 DBPR. Today's rule addresses filter washing prior to analysis by requiring that water passed through the filter prior to filtration of the sample serve as the filtered blank. The filtered blank must be analyzed using procedures identical to those used for analysis of the samples and must meet the following criteria: TOC < 0.5 mg/L. These criteria are the maximum allowable background concentrations specified for these analyses under the ICR. In the *Guidance Manual for Enhanced Coagulation*, EPA will furnish instructions on sample handling and filter washing to assist systems in achieving acceptable field reagent blanks.

Filtration of samples for DOC analysis must be done prior to acid preservation, as stipulated in today's rule. This is necessary because acidification of the sample to pH < 2 can cause substantial precipitation of dissolved organic species. Because biological activity will rapidly alter the DOC of a sample that has not been preserved, EPA requires that DOC samples be acidified to pH < 2.0 within 48 hours of sampling. Consequently, filtration of DOC samples must be done within 48 hours in order to allow acid preservation within this time period. The pH of UV_{254} samples may not be adjusted. Today's rule places a maximum holding time from sampling to analysis of 2 days for UV_{254} samples and 28 days for DOC samples. These holding times are the same as those approved for ICR data collection.

Because the filtration procedures for UV_{254} and DOC samples are largely identical, EPA anticipates that most systems will find it economical when determining SUVA to filter one sample. The filtrate would then be split into two portions, one of which would be used for UV analysis while the other would be acid preserved and used for DOC analysis. However, EPA has not included a requirement that the DOC and UV_{254} analyses used in the SUVA determination be made on the same sample filtrate. Instead, EPA requires that DOC and UV_{254} samples used to determine a SUVA value must be taken at the same time and at the same location.

In the 1997 DBPR NODA, EPA also observed that because disinfectants/oxidants (chlorine, ozone, chlorine dioxide, potassium permanganate) typically reduce UV_{254} without substantially impacting DOC, raw water SUVA should be determined on water prior to the application of disinfectants/oxidants. If disinfectants/oxidants are applied in raw-water transmission lines upstream of the plant, then raw water SUVA should be based on a sample collected upstream of the point of disinfectant/oxidant addition. For determining settled-water SUVA, if the plant applies disinfectants/oxidants prior to the settled water sample tap, then settled-water SUVA should be determined in jar testing. No commenters were opposed to these provisions and today's rule requires that samples used for SUVA determinations be taken from water prior to the addition of any oxidants/disinfectants.

A few commenters stated that SUVA should not be subject to rigorous analytical procedures because the application of SUVA in this rule is based on a relationship which is largely empirical (i.e. correlations between SUVA and TOC removal by coagulation). EPA recognizes the empirical nature of this relationship and the variance it has displayed in studies. Regulations, however, must address specific SUVA values if SUVA is to serve as an alternative compliance parameter. For compliance with these regulations to be meaningful, SUVA must be determined accurately. Consequently, today's rule requires certain QC procedures in the DOC and UV_{254} analyses that are used to calculate SUVA.

Today's rule establishes the removal of 10 mg/L magnesium hardness (as CaCO3) as an alternative performance criterion that systems practicing enhanced softening can use to demonstrate compliance with the treatment technique requirement for TOC removal. However, EPA did not propose methods for the analysis of

magnesium in drinking water and therefore the final rule does not contain any approved methods for magnesium. EPA expects to propose magnesium analytical methods to be used for compliance monitoring under the Stage 1 DBPR by the end of 1998.

4. Performance Based Measurement Systems

On October 6, 1997, EPA published a Document of the Agency's intent to implement a Performance Based Measurement System (PBMS) in all of its programs to the extent feasible (EPA, 1997f). The Agency is currently determining the specifics steps necessary to implement PBMS in its programs and preparing an implementation plan. Final decisions have not yet been made concerning the implementation of PBMS in drinking water programs. However, EPA is currently evaluating what relevant performance characteristics should be specified for monitoring methods used in the drinking water programs under a PBMS approach to ensure adequate data quality. EPA would then specify performance requirements in its regulations to ensure that any method used for determination of a regulated analyte is at least equivalent to the performance achieved by other currently approved methods. EPA expects to publish its PBMS implementation strategy for water programs in the **Federal Register** by the end of calendar year 1998.

Once EPA has made its final determinations regarding implementation of PBMS in programs under the Safe Drinking Water Act, EPA would incorporate specific provisions of PBMS into its regulations, which may include specification of the performance characteristics for measurement of regulated contaminants in the drinking water program regulations.

H. Monitoring Requirements

1. Today's Rule

Today's rule establishes monitoring requirements to support implementation of the enhanced coagulation and enhanced softening treatment technique, implementation of new MCLs for TTHM, HAA5, bromate, and chlorite, and implementation of MRDLs for chlorine, chloramines, and chlorine dioxide. Monitoring for DBPs, disinfectant residuals, and TOC must be conducted during normal operating conditions. Failure to monitor in accordance with the monitoring plan is a monitoring violation. Where compliance is based on a running annual average of monthly or quarterly samples or averages and the system's failure to monitor makes it impossible to determine compliance with MCLs or MRDLs, this failure to monitor will be treated as a violation.

Tables III–3 and III–4 below summarize routine and reduced monitoring requirements of today's rule.

TABLE III–3.—ROUTINE MONITORING REQUIREMENTS [1]

Requirement (reference)	Location for sampling	Large surface systems [2]	Small surface systems [2]	Large ground water systems [3]	Small ground water systems [3]
TOC and Alkalinity (141.132(d)(1)).	Source Water [4] ..... Only required for plants with conventional filtration treatment.	1sample/month/plant [3]	1 sample/month/ plant[3].	NA	NA.
TTHMs and HAA5 (141.132(b)(1)(i)).	25% in dist sys at max res time, 75% at dist sys representative locations.	4/plant/quarter	1/plant/quarter[5] ..... at maximum residence time. if pop.<500, then 1/plant/yr [8]. during warmest month.	1/plant/quarter [6] ..... at maximum residence time.	1/plant/year [5,6] at maximum residence time. during warmest month.
Bromate [7] (141.132(b)(3)(i)).	Dist sys entrance point.	1/month/trt plant using O_3.	1/month/trt plant using O_3.	1/month/trt plant using O_3.	1/month/trt plant using O_3.
Chlorite[8] (daily) (141.132(b)(2)(i)(A)).	Dist sys entrance point.	Daily/trt plant using ClO_2.	Daily/trt plant using ClO_2.	Daily/trt/plant using ClO_2.	
Chlorite[8] (monthly) 141.132(b)(2)(i)(B)).	Dist sys: 1 near first cust, 1 in dist sys middle, 1 at max res time.	3 sample set/month ..	3 sample set/month ..	3 sample set/month ..	3 sample set/month.
Chlorine and chloramines (141.132(c)(1)(i)).	Same points as total coliform in TCR.	Same times as total coliform in TCR.	Same times as total coliform in TCR.	Same times as total coliform in TCR.	Same times as total coliform in TCR.
Chlorine dioxide[8] (141.132(c)(2)(i)).	Dist sys entrance point.	Daily/trt plant using ClO_2.	Daily/trt plant using ClO_2.	Daily/trt plant using ClO_2.	Daily/trt plant using ClO.

[1] Samples must be taken during representative operating conditions. Provisions for reduced monitoring shown elsewhere.

[2] Large surface (subpart H) systems serve 10,000 or more persons. Small surface (subpart H) systems serve fewer than 10,000 persons.

[3] Large systems using ground water not under the direct influence of surface water serve 10,000 or more persons. Small systems using ground water not under the direct influence of surface water serve fewer than 10,000 persons.

[4] Subpart H systems which use conventional filtration treatment (defined in section 141.2) must monitor 1) source water TOC prior to any treatment and 2) treated TOC at the same time; these two samples are called paired samples. Systems must take a source water alkalinity sample at the same time.

[5] If the annual monitoring result exceeds the MCL, the system must increase monitoring frequency to 1/plant/quarter. Compliance determinations will be based on the running annual average of quarterly monitoring results.

[6] Multiple wells drawing water from a single aquifer may, with State approval, be considered one treatment plant for determining the minimum number of samples.
[7] Only required for systems using ozone for oxidation or disinfection.
[8] Only required for systems using chlorine dioxide for oxidation or disinfection. Additional chlorite monitoring required if daily sample exceeds MCL. Additional chlorine dioxide monitoring requirements apply if any chlorine dioxide sample exceeds the MRDL.

TABLE III–4.—REDUCED MONITORING REQUIREMENTS [1]

Requirement (reference)	Location for reduced sampling	Reduced monitoring frequency and prerequisites [2]
TOC and Alkalinity (141.132(d)(2)).	Paired samples [3]	Subpart H systems-reduced to 1 paired sample/plant/quarter if 1) avg TOC < 2.0 mg/l for 2 years or 2) avg TOC < 1.0 mg/l for 1 year.
TTHMs and HAA5s (141.132(b)(1)(ii)).	In dist sys at point with max res time.	Monitoring cannot be reduced if subpart H system source water TOC > 4.0 mg/l. Subpart H systems serving 10,000 or more-reduced to 1/plant/qtr if 1) system has completed at least 1 yr of routine monitoring and 2) *both* TTHM and HAA5 running annual averages are no more than 40 µg/l and 30 µg/l, respectively. Subpart H systems serving <10,000 and ground water systems [4] serving 10,000 or more-reduced to 1/plant/yr if 1) system has completed at least 1 yr of routine monitoring and 2) *both* TTHM and HAA5 running annual averages are no more than 40 µg/l and 30 µg/l, respectively. Samples must be taken during month of warmest water temperature. Subpart H systems serving <500 may not reduce monitoring to less than 1/plant/yr. Groundwater systems [6] serving<10,000-reduced to 1/plant/3yr if 1) system has completed at least 2 yr of routine monitoring and *both* TTHM and HAA5 running annual averages are no more than 40 µg/l and 30 µg/l, respectively or 2) system has completed at least 1 yr of routine monitoring and *both* TTHM and HAA5 annual samples are no more than 20 µg/l and 15 µg/l, respectively. Samples must be taken during month of warmest water temperature.
Bromate [5] (141.132(b)(3)(ii)).	Dist sys entrance point	1/qtr/trt plant using O_3, if system demonstrates 1) avg raw water bromide <0.05 mg/l (based on annual avg of monthly samples).
Chlorite [6] (141.132(b)(2)(iii)).	Dist sys: 1 near first cust, 1 in dist sys middle, 1 at max res time.	Systems may reduce routine distribution system monitoring from monthly to quarterly if the chlorite concentration in all samples taken in the distribution system is below 1.0 mg/L for a period of one year; 3 samples per quarter.
Chlorine, chlorine dioxide [6], chloramines (141.132(c)(2)(ii) and (c)(2)(iii).	NA	Monitoring may not be reduced.

[1] Samples must be taken during representative operating conditions. Provisions for routine monitoring shown elsewhere.
[2] Requirements for cancellation of reduced monitoring are found in the regulation.
[3] Subpart H systems which use conventional filtration treatment (defined in Section 141.2) must monitor 1) source water TOC prior to any treatment and 2) treated TOC before continuous disinfection (except that systems using ozone followed by biological filtration may sample after biological filtration) at the same time; these two samples are called paired samples.
[4] Multiple wells drawing water from a single aquifer may, with State approval, be considered one treatment plant for determining the minimum number of samples.
[5] Only required for systems using ozone for oxidation or disinfection.
[6] Only required for systems using chlorine dioxide for oxidation or disinfection.

The formation rate of DBPs is affected by type and amount of disinfectant used, water temperature, pH, amount and type of precursor material in the water, and the length of time that water remains in the treatment and distribution systems. For this reason, today's rule specifies the points in the distribution system (and, in some cases, the time) where samples must be taken. For purposes of this regulation, multiple wells drawing raw water from a single aquifer may, with State approval, be considered one plant for determining the minimum number of samples.

TTHM and HAA5. Any system may take samples in excess of the required frequency. In such cases, at least 25 percent of all samples collected each quarter must be taken at locations within the distribution system that represent the maximum residence time of the water in the system. The remaining samples must be taken at locations representative of at least average residence time in the distribution system.

Subpart H Systems Serving 10,000 or More People. Routine Monitoring: CWSs and NTNCWSs using surface water (or ground water under direct influence of surface water) (Subpart H systems) that treat their water with a chemical disinfectant and serve 10,000 or more people must routinely take four water samples each quarter for both TTHMs and HAA5 for each treatment plant in the system. At least 25 percent of the samples must be taken at the point of maximum residence time in the distribution system. The remaining samples must be taken at representative points in the distribution system. This monitoring frequency is the same as the frequency required under the current TTHM rule (§ 141.30).

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure III–1). Systems eligible for reduced monitoring may reduce the monitoring frequency for TTHMs and HAA5 to one sample per treatment plant per quarter. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year is no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5. Systems that do not meet these levels must revert to routine monitoring in the quarter immediately following the quarter in which the system exceeded 0.060 mg/L for TTHM or 0.045 mg/L for HAA5. Additionally, the State may return a system to routine monitoring at the State's discretion.

FIGURE III–1.—ELIGIBILITY FOR REDUCED TTHM AND HAA5 MONITORING: GROUND WATER SYSTEMS SERVING 10,000 OR MORE PEOPLE AND SUBPART H SYSTEMS SERVING 500 OR MORE PEOPLE

Ground water systems serving 10,000 or more people, and Subpart H systems serving 500 or more people, may reduce monitoring of TTHMs and HAA5 if they meet all of the following conditions:
—The annual average for TTHMs is no more than 0.040 mg/L.
—The annual average for HAA5 is no more than 0.030 mg/L.
—At least one year of routine monitoring has been completed.
—Annual average source water TOC level is no more than 4.0 mg/L prior to treatment (applies to Subpart H systems only).

Compliance Determination: A public water system (PWS) is in compliance with the MCL when the running annual arithmetic average of quarterly averages of all samples, computed quarterly, is less than or equal to the MCL. If the running annual average computed for any quarter exceeds the MCL, the system is out of compliance.

Subpart H Systems Serving 500 to 9,999 People. Routine Monitoring: Systems are required to take one water sample each quarter for each treatment plant in the system. Samples must be taken at the point of maximum residence time in the distribution system.

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure III–1). Systems eligible for reduced monitoring may reduce the monitoring frequency for TTHMs and HAA5 to one sample per treatment plant per year. Sample must be taken at a distribution system location reflecting maximum residence time and during the month of warmest water temperature. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year is no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5. Systems that do not meet these levels must revert to routine monitoring in the quarter immediately following the quarter in which the system exceeded 0.060 mg/L for TTHM or 0.045 mg/L for HAA5. Additionally, the State may return a system to routine monitoring at the State's discretion.

Compliance Determination: A PWS is in compliance with the MCL for TTHM and HAA5 when the annual average of all samples, taken that year, is less than or equal to the MCL. If the average for these samples exceeds the MCL, the system is out of compliance.

Subpart H Systems Serving Fewer than 500 People. Routine Monitoring: Subpart H systems serving fewer than 500 people are required to take one sample per year for each treatment plant in the system. The sample must be taken at the point of maximum residence time in the distribution system during the month of warmest water temperature. If the annual sample exceeds the MCL, the system must increase monitoring to one sample per treatment plant per quarter, taken at the point of maximum residence time in the distribution system.

Reduced Monitoring: These systems may not reduce monitoring. Systems on increased monitoring may return to routine monitoring if the annual average of quarterly samples is no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5.

Compliance Determination: A PWS is in compliance when the annual sample (or average of annual samples, if additional sampling is conducted) is less than or equal to the MCL. If the annual sample exceeds the MCL, the system must increase monitoring to one sample per treatment plant per quarter. If the running annual average of the quarterly samples then exceeds the MCL, the system is out of compliance.

Ground Water Systems Serving 10,000 or More People. Routine Monitoring: CWSs and NTNCWSs using only ground water sources not under the direct influence of surface water that treat their water with a chemical disinfectant and serve 10,000 or more people are required to take one water sample each quarter for each treatment plant in the system. Samples must be taken at points that represent the maximum residence time in the distribution system.

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure III–1). Systems eligible for reduced monitoring may reduce the monitoring frequency to one sample per treatment plant per year. Sample must be taken at a distribution system location reflecting maximum residence time and during the month of warmest water temperature. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year is no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5. Systems that do not meet these levels must revert to routine monitoring in the quarter immediately following the quarter in which the system exceeded 0.060 mg/L for TTHM or 0.045 mg/L for HAA5. Additionally, the State may return a system to routine monitoring at the State's discretion.

Compliance Determination: A PWS is in compliance with the MCL when the running arithmetic annual average of quarterly averages of all samples, computed quarterly, is less than or equal to the MCL. If the running annual average for any quarter exceeds the MCL, the system is out of compliance.

Ground Water Systems Serving Fewer than 10,000 People Routine Monitoring: CWSs and NTNCWSs using only ground water sources not under the direct influence of surface water that treat their water with a chemical disinfectant and serve fewer than 10,000 people are required to sample once per year for each treatment plant in the system. The sample must be taken at the point of maximum residence time in the distribution system during the month of warmest water temperature. If the sample (or the average of annual samples if more than one sample is taken) exceeds the MCL, the system must increase monitoring to one sample per treatment plant per quarter.

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure III–2). Systems eligible for reduced monitoring may reduce the monitoring frequency for TTHMs and HAA5 to one sample per three-year monitoring cycle. Sample must be taken at a distribution system location reflecting maximum residence time and during the month of warmest water temperature. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year is no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5. Systems that do not meet these levels must resume routine monitoring. Systems on increased monitoring may return to routine monitoring if the annual average of quarterly samples is no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5.

Compliance Determination: A PWS is in compliance when the annual sample (or average of annual samples) is less than or equal to the MCL.

FIGURE III–2.—ELIGIBILITY FOR REDUCED TTHM AND HAA5 MONITORING: GROUND WATER SYSTEMS SERVING FEWER THAN 10,000 PEOPLE

Systems using ground water not under the direct influence of surface water that serve fewer than 10,000 people may reduce monitoring for TTHMs and HAA5 if they meet either of the following conditions:

1. The average of two consecutive annual samples for TTHMs is no more than 0.040 mg/L, the average of two consecutive annual samples for HAA5 is no more than 0.030 mg/L, and at least two years of routine monitoring has been completed.
2. The annual sample for TTHMs is no more than 0.020 mg/L, the annual sample for HAA5 is no more than 0.015 mg/L, and at least one year of routine monitoring has been completed.

Chlorite. Routine Monitoring: CWSs and NTNCWSs using chlorine dioxide for disinfection or oxidation are required to conduct sampling for chlorite both daily at the entrance to the distribution system and monthly within the distribution system. Additional distribution system monitoring may be required, and distribution system monitoring may be reduced if certain conditions are met. This monitoring is described below.

Routine Monthly Monitoring—Systems are required to take a three sample set each month in the distribution system. One sample must be taken at each of the following locations: (1) as close as possible to the first customer, (2) in a location representative of average residence time, and (3) as close as possible to the end of the distribution system (reflecting maximum residence time in the distribution system). As described elsewhere in this document, all samples taken in the distribution system must be analyzed by ion chromatography (Methods 300.0 and 300.1).

Routine Daily Monitoring—Systems must take one sample each day at the entrance to the distribution system. As described elsewhere in this document (section III.G), samples taken at the distribution system entrance may be analyzed by amperometric titration (Method 4500–ClO_2 E). If the chlorite MCL is exceeded at the entrance to the distribution system, the system is not out of compliance. However, the system must carry out addition monitoring as described in the following paragraph.

Additional Monitoring: On any day when the chlorite concentration measured at the entrance to the distribution system exceeds the chlorite MCL (1.0 mg/L), the system is required to take a three sample set in the distribution system on the following day, at the locations specified for routine monthly monitoring. If the system is required to conduct distribution system monitoring as a result of having exceeded the chlorite MCL at the entrance to the distribution system, and the average of the three samples taken in the distribution system is below 1.0 mg/L, the system will have satisfied its routine monthly monitoring requirement for that month. Further distribution system monitoring will not be required in that month unless the chlorite concentration at the entrance to the distribution system again exceeds 1.0 mg/L.

Reduced Monitoring: Systems may reduce routine distribution system monitoring for chlorite from monthly to quarterly if the chlorite concentration in all samples taken in the distribution system is below 1.0 mg/L for a period of one year and the system has not been required to conduct any additional monitoring. Systems that qualify for reduced monitoring must continue to conduct daily monitoring at the entrance to the distribution system. If the chlorite concentration at the entrance to the distribution system exceeds 1.0 mg/L, the system must resume routine monthly monitoring.

Compliance Determination: A PWS is out of compliance with the chlorite MCL when the arithmetic average concentration of any three sample set taken in the distribution system is greater than 1.0 mg/L.

Bromate. Routine Monitoring: CWSs and NTNCWSs using ozone for disinfection or oxidation are required to take at least one sample per month for each treatment plant in the system using ozone. The sample must be taken at the entrance to the distribution system when the ozonation system is operating under normal conditions.

Reduced Monitoring: Systems may reduce monitoring from monthly to once per quarter if the system demonstrates that the annual average raw water bromide concentration is less than 0.05 mg/L, based upon monthly measurements for one year.

Compliance Determination: A PWS is in compliance if the running annual arithmetic average of samples, computed quarterly, is less than or equal to the MCL.

Chlorine. Routine Monitoring: As a minimum, CWSs and NTNCWSs must measure the residual disinfectant level (as either free chlorine or total chlorine) at the same points in the distribution system and at the same time as total coliforms, as specified in § 141.21. Subpart H systems may use the results of residual disinfectant concentration sampling done under the SWTR (§ 141.74(b)(6)(i) for unfiltered systems, § 141.74(c)(3)(i) for systems that filter) in lieu of taking separate samples.

Reduced Monitoring: Monitoring for chlorine may not be reduced.

Compliance Determination: A PWS is in compliance with the MRDL when the running annual arithmetic average of monthly averages of all samples, computed quarterly, is less than or equal to the MRDL. Notwithstanding the MRDL, operators may increase residual chlorine levels in the distribution system to a level and for a time necessary to protect public health to address specific microbiological contamination problems (e.g., including distribution line breaks, storm runoff events, source water contamination, or cross-connections).

Chloramines. Routine Monitoring: As a minimum, CWSs and NTNCWSs must, measure the residual disinfectant level (as either total chlorine or combined chlorine) at the same points in the distribution system and at the same time as total coliforms, as specified in § 141.21. Subpart H systems may use the results of residual disinfectant concentration sampling done under the SWTR (§ 141.74(b)(6) for unfiltered systems, § 141.74(c)(3) for systems that filter) in lieu of taking separate samples.

Reduced Monitoring: Monitoring for chloramines may not be reduced.

Compliance Determination: A PWS is in compliance with the MRDL when the running annual arithmetic average of monthly averages of all samples, computed quarterly, is less than or equal to the MRDL. Notwithstanding the MRDL, operators may increase residual chloramine levels in the distribution system to a level and for a time necessary to protect public health to address specific microbiological contamination problems (e.g., including distribution line breaks, storm runoff events, source water contamination, or cross-connections).

Chlorine Dioxide Routine Monitoring: CWSs, NTNCWSs, and TNCWSs must monitor for chlorine dioxide only if chlorine dioxide is used by the system for disinfection or oxidation. If monitoring is required, systems must take daily samples at the entrance to the

distribution system. If the MRDL (0.8 mg/L) is exceeded, the system must conduct additional monitoring.

Additional Monitoring: If any daily sample taken at the entrance to the distribution system exceeds the MRDL, the system is required to take three additional samples in the distribution system on the next day. Samples must be taken at the following locations.

Systems using chlorine as a residual disinfectant and operating booster chlorination stations after the first customer—These systems must take three samples in the distribution system: one as close as possible to the first customer, one in a location representative of average residence time, and one as close as possible to the end of the distribution system (reflecting maximum residence time in the distribution system).

Systems using chlorine dioxide or chloramines as a residual disinfectant or chlorine as a residual disinfectant and not operating booster chlorination stations after the first customer—These systems must take three samples in the distribution system as close as possible to the first customer at intervals of not less than six hours.

Reduced Monitoring: Monitoring for chlorine dioxide may not be reduced.

Compliance Determination: Acute violations—If any daily sample taken at the entrance to the distribution system exceeds the MRDL and if, on the following day, one or more of the three samples taken in the distribution system exceeds the MRDL, the system will be in acute violation of the MRDL and must issue the required acute public notification. Failure to monitor in the distribution system on the day following an exceedance of the chlorine dioxide MRDL shall also be considered an acute MRDL violation.

Nonacute violations—If any two consecutive daily samples taken at the entrance to the distribution system exceed the MRDL, but none of the samples taken in the distribution system exceed the MRDL, the system will be in nonacute violation of the MRDL. Failure to monitor at the entrance to the distribution system on the day following an exceedance of the chlorine dioxide MRDL shall also be considered a nonacute MRDL violation.

Important Note: Unlike chlorine and chloramines, the MRDL for chlorine dioxide may not be exceeded for short periods of time to address specific microbiological contamination problems.

TOC. Routine Monitoring: CWSs and NTNCWSs which use conventional filtration treatment must monitor each treatment plant water source for TOC on a monthly basis, with samples taken in both the source water prior to any treatment and in the treated water no later than the point of combined filter effluent turbidity monitoring. At the same time, systems must monitor for source water alkalinity.

Reduced Monitoring: Subpart H systems with an average treated water TOC of less than 2.0 mg/L for two consecutive years, or less than 1.0 mg/L for one year, may reduce monitoring for both TOC and alkalinity to one paired sample per plant per quarter.

Compliance Determination: Compliance criteria for TOC are dependent upon a variety of factors and is discussed elsewhere in this rule.

2. Background and Analysis

The monitoring requirements in today's rule are the same as those in the 1994 proposed rule, with the exception of requirements for bromide monitoring and chlorite.

Bromide Monitoring for Reduced Bromate Monitoring. The 1994 proposal included a provision for reduced bromate monitoring for utilities with source water bromide concentrations less than 0.05 mg/L. EPA believes there is a very small likelihood that systems using ozone will exceed the bromate MCL if source water bromide concentrations are below this level. The provision did not specify a bromide monitoring frequency, however. Today's rule allows utilities to reduce bromate monitoring from monthly to once per quarter if the system demonstrates, based on representative monthly samples over the course of a year, that the average raw water bromide concentration is less than 0.05 mg/L.

Chlorite Monitoring. The proposed rule required treatment plants using chlorine dioxide to monitor for chlorite ion by taking a three sample set in the distribution system, once per month, and to analyze these samples using ion chromatography. However, the proposal states that after the Negotiating Committee had agreed to the above monitoring scheme for chlorite at its last meeting in June, 1993, EPA's Reference Dose Committee met and determined a different toxicological endpoint for chlorite, based on the identification of neurobehavioral effects. In light of this finding, EPA asserted that it did not believe the proposed monthly monitoring requirement for chlorite was sufficiently protective of public health. Following the proposed rule, EPA acquired additional information on chlorite toxicity, including the results of a two-generation study sponsored by the CMA. This additional information, discussed elsewhere in this document (III.A.7), supported EPA's finding of neurobehavioral health effects resulting from chlorite, along with the rationale for daily monitoring at the entrance to the distribution system as a trigger for further compliance monitoring in the distribution system.

3. Summary of Comments

TOC. Many commenters expressed confusion regarding the raw and finished water TOC monitoring scheme and their relationship to compliance calculations. Commenters noted, correctly, that changes in alkalinity and TOC level can move the utility to a different box of the TOC removal matrix, and questioned whether this would affect requisite monitoring. As in the proposal, moving to a different box of the matrix will not affect monitoring requirements. Utilities are required to take a minimum of one paired (raw and finished water) TOC sample per month. Commenters were also concerned that the TOC monitoring provisions would limit their ability to take additional TOC samples for operational control. This concern is unfounded; EPA recommends in the Enhanced Coagulation and Enhanced Precipitative Softening Guidance Manual that utilities take as many TOC samples as necessary to maintain proper operational control. EPA also recommends that TOC compliance samples, as opposed to operational samples, be taken on a constant schedule or be identified one month prior to the samples being taken. This will allow utilities to take numerous operational samples and still provide for unbiased compliance sampling. Systems may use their sampling plans for this purpose.

Chlorite. In the proposal, EPA solicited comment on changing the frequency and location of chlorite monitoring in consideration of potential acute health effects. Commenters stated that daily monitoring of chlorite would be feasible if amperometric titration were allowed as an analytical method. Commenters recommended that daily amperometric analyses for chlorite be conducted on samples taken from the entrance to the distribution system, and that weekly or monthly analyses using ion chromatography still be required as a check since ion chromatography is a more accurate analytical method. Several comments stated that daily monitoring for chlorite would improve operational control of plants and decrease the probability of a PWS exceeding the chlorite MCL in the distribution system. However, commenters requested that if daily monitoring for chlorite were to be

required, a provision for reduced chlorite monitoring be included as well.

In response to these comments, today's rule requires treatment plants using chlorine dioxide to conduct daily monitoring for chlorite by taking one sample at the entrance to the distribution system. This sample may be measured using amperometric titration (Standard Method 4500-ClO_2 E). Treatment plants are also required to take a three sample set from the distribution system once per month, as was proposed in 1994. In addition, today's rule requires that on any day that the concentration of chlorite measured at the distribution system entrance exceeds the MCL, the treatment plant must take a three sample set in the distribution system on the following day. All samples taken in the distribution system must be analyzed by ion chromatography (Method 300.0 or 300.1).

EPA recommends that treatment plants keep chlorite levels below 1.0 mg/L and believes that if treatment plants exceed the MCL in finished water, immediate distribution system testing is warranted to ensure that chlorite levels are below 1.0 mg/L. EPA has not, however, changed the compliance determination for chlorite from the 1994 proposed rule. Compliance is still based on the average of three sample sets taken in the distribution system. The results of daily monitoring do not serve as a compliance violation; rather, they can only trigger immediate distribution system monitoring. Moreover, if the treatment plant is required to take distribution system samples by the results of daily monitoring and the average chlorite concentration in the three distribution system samples is below the MCL, then that sampling will meet the treatment plant's requirement for routine monthly monitoring in the distribution system for that month. Today's rule also includes a provision for reduced chlorite monitoring. Treatment plants may reduce routine distribution system monitoring for chlorite from monthly to quarterly if the chlorite concentration in all samples both at the entrance to the distribution system and within the distribution system are below 1.0 mg/L for a period of one year.

In summary, after review of all public comments and associated data, EPA believes that these provisions for chlorite monitoring will be both feasible for treatment plants and provide a level of protection to public health commensurate with the toxic effects associated with chlorite.

I. Compliance Schedules

1. Today's Rule

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

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

Subpart H water systems covered by today's rule that serve a population of 10,000 or more generally have three years from promulgation to comply with all requirements of this rule. In cases where capital improvements are needed to comply with the rule, States may grant such systems up to an additional two years to comply. These deadlines were consistent with those for the IESWTR.

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

2. Background and Analysis

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

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

A complicating factor that EPA took into account in developing today's deadlines is that the SDWA 1996 Amendments changed two statutory provisions that elements of the 1992

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

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

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

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

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

Under today's Stage 1 DBPR, EPA has already provided small subpart H systems and ground water systems the two-year extension for capital improvements since these systems will not know with certainty until November 2000 if capital improvements will be needed for simultaneous compliance with the Stage 1 DBPR and LT1/GWR. States considering whether to grant a two-year capital improvement extension for compliance with the GWR or LT1 will also need to consider the impact of such extensions on compliance with today's rule, given that a similar extension for capital improvement has already been provided in the initial compliance schedule for the Stage 1 DBPR. EPA believes, however, that these systems will generally not require extensive capital improvements that take longer than three years to install to meet Stage 1 DBPR, GWR, and LT1 requirements, or will require no capital improvements at all. However if needed, EPA will work with States and utilities to address systems that require time beyond November 2003 to comply. This strategy may include exemptions.

In addition, EPA will provide guidance and technical assistance to States and systems to facilitate timely compliance with both DBP and microbial requirements. EPA will request comment on how best to do this when the Agency proposes the LTESWTR and GWR.

3. Summary of Comments

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

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

In conclusion EPA believes that the compliance deadlines outlined above for systems covered by this rule are appropriate and consistent with the requirements of the 1996 SDWA amendments. The Agency notes, however, that some elements of Option 4 outlined in the 1997 NODA apply to systems that may be covered by future Long Term Enhanced and Ground Water rules. EPA intends to follow the deadline strategy outlined in Option 4 for these future rules. However, as today's action only relates to the Stage 1 DBPR, the Agency will defer final action on deadlines associated with future rules until those rules, themselves, are finalized.

J. Public Notice Requirements

1. Today's Rule

Today's action addresses public notification by promulgating public notification language for the regulated compounds in 40 CFR Section 141.32 (e). EPA takes this opportunity to note that the 1996 amendments to the SDWA require the Agency to make certain changes to the public notice regulations. EPA intends to propose changes to the public notice requirements in the **Federal Register** shortly after promulgation of the Stage 1 DBPR. Applicable changes in the public notice requirements, when they become effective, will supersede today's provisions. In general, the public notification for the Stage 1 DBPR is not substantially changed from that included in the 1994 Proposed Stage 1 DBPR (EPA, 1994a).

2. Background and Analysis

Under Section 1414(c)(1) of the Act, each owner or operator of a public water system must give notice to the persons served by the system of (1) any violation of any MCL, treatment technique requirement, or testing provision prescribed by an NPDWR; (2) failure to comply with any monitoring requirement under section 1445(a) of the Act; (3) existence of a variance or exemption; (4) failure to comply with the requirements of a schedule prescribed pursuant to a variance or exemption; and (5) notice of the concentration level of any unregulated contaminant for which the Administrator has required public notice.

EPA promulgated the current regulations for public notification on October 28, 1987 (52 FR 41534—EPA, 1987). These regulations specify general notification requirements, including frequency, manner, and content of notices, and require the inclusion of EPA-specified health effects information in each public notice. The public notification requirements divide violations into two categories (Tier 1 and Tier 2) based on the seriousness of the violations, with each tier having different public notification requirements. Tier 1 violations include violations of an MCL, treatment technique, or a variance or exemption schedule. Tier 1 violations contain health effects language specified by EPA which concisely and in non-technical terms conveys to the public the adverse health effects that may occur as a result of the violation. States and water utilities remain free to add additional information to each notice, as deemed appropriate for specific situations. Tier 2 violations include monitoring violations, failure to comply with an analytical requirement specified by an NPDWR, and operating under a variance or exemption.

Today's final rule contains specific health effects language for the contaminants which are in today's rulemaking. EPA believes that the mandatory health effects language is the most appropriate way to inform the affected public of the potential health implications of violating a particular EPA standard.

3. Summary of Comments

EPA received comments on the topic of the public notification language for TTHM, HAA5, chlorine, chloramines, chlorine dioxide, and enhanced coagulation. Some commenters noted that the language in 141.32(e)(79) is satisfactory. One commenter requested that the language for DBPs be modified to recognize that disinfectants react with naturally occurring organic and inorganic matter to form DBPs. Some commenters did not support the use of the same public notification language for both DBP MCL and enhanced coagulation treatment technique violations. Several commenters suggested that the content of the notices for chlorine, chloramine, and chlorine dioxide should reflect that disinfection is an essential step in surface water treatment. One commenter suggested that the language for chlorine dioxide acute effects should be deleted. Other commenters felt that the notice to consumers of chlorine dioxide violations at the treatment facility which do not result in violations in the distribution system (nonacute violations) should not require public notification.

In response, EPA has modified the public notification language for DBPs to indicate that disinfectants react with naturally occurring organic and inorganic matter to form DBPs. EPA believes it is appropriate to use the same public notification language for the enhanced coagulation treatment technique violation as for violations for the TTHM and HAA5 MCLs, since enhanced coagulation is meant to limit exposure to DBPs. EPA believes the current language in the public notification language is appropriate to reflect that disinfection is an essential step in water treatment. EPA believes that since the potential health effects from chlorine dioxide are short-term that it is appropriate to maintain the acute effects language to protect the fetus, infants, and children. In general, the public notification requirements for the Stage 1 DBPR will not substantially change from that included in the 1994 Proposed Stage 1 DBPR (EPA, 1994a).

K. System Reporting and Record Keeping Requirements

1. Today's Rule

The Stage 1 DBPR, consistent with the current system reporting regulations under 40 CFR 141.31, requires PWSs to report monitoring data to States within ten days after the end of the compliance period. In addition, systems are required to submit the data required in § 141.134. These data are required to be submitted quarterly for any monitoring conducted quarterly or more frequently, and within 10 days of the end of the monitoring period for less frequent monitoring. Systems that are required to do extra monitoring because of the disinfectant used have additional reporting requirements specified. This applies to systems that use chlorine dioxide (must report chlorine dioxide and chlorite results) and ozone (must report bromate results).

Subpart H systems that use conventional treatment are required to report either compliance/noncompliance with DBP precursor (TOC) removal requirements or report which of the enhanced coagulation/enhanced softening exemptions they are meeting. There are additional requirements for systems that cannot meet the required TOC removals and must apply for an alternate enhanced coagulant level. These requirements are included in § 141.134(b).

Calculation of compliance with the TOC removal requirements is based on normalizing the percent removals over the most recent four quarters, since compliance is based on that period. Normalization, which would prescribe equal weight to the data collected each month, is necessary since source water quality changes may change the percent TOC removal requirements from one month to another. EPA has developed a sample reporting and compliance calculation sheet that will be available in the enhanced coagulation guidance manual to assist utilities in making these calculations.

2. Summary of Comments

There were no significant comments on the system reporting and recordkeeping requirements and therefore EPA is finalizing the requirements as proposed.

L. State Recordkeeping, Primacy, and Reporting Requirements

The SDWA provides that States and eligible Indian Tribes may assume primary enforcement responsibilities.

Fifty-four out of fifty-six State and territorial jurisdictions have applied for and received primary enforcement responsibility (primacy) under the Act. No Tribes have received primacy. To obtain primacy for the federal drinking water regulations, States must adopt their own regulations which are at least as stringent as the federal regulations. This section describes the regulations and other procedures and policies that States must adopt to implement the final Stage 1 DBPR.

To implement the final rule, States are required to adopt the following regulatory requirements:

—Section 141.32, Public Notification;
—Section 141.64, MCLs for Disinfection Byproducts;
—Section 141.65, MRDLs for Disinfectants;
—Subpart L, Disinfectant Residuals, Disinfectant Byproducts, and Disinfection Byproduct Precursors.

In addition to adopting regulations no less stringent than the federal regulations, States must adopt certain requirements related to this regulation in order to have their program revision applications approved by EPA. This rule also requires States to keep specific records and submit specific reports to EPA.

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

As a result, States that have primacy for every existing NPDWR already in effect may obtain interim primacy for this rule, beginning on the date that the State submits its complete and final primacy application for this rule to EPA, or the effective date of its revised regulations, whichever is later. In addition, a State which wishes to obtain interim primacy for future NPDWRs must obtain primacy for this rule.

1. State Recordkeeping Requirements

a. Today's Rule. The current regulations in § 142.14 require States with primacy to keep various records, including analytical results to determine compliance with MCLs, MRDLs, and treatment technique requirements; system inventories; State approvals; enforcement actions; and the issuance of variances and exemptions. The Stage 1 DBPR requires States to keep additional records of the following, including all supporting information and an explanation of the technical basis for each decision:

(1) Records of determinations made by the State when the State has allowed systems additional time to install GAC or membrane filtration. These records must include the date by which the system is required to have completed installation;

(2) Records of systems that are required to meet alternative minimum TOC removal requirements or for whom the State has determined that the source water is not amendable to enhanced coagulation. These records must include the results of testing to determine alternative limits and the rationale for establishing the alternative limits;

(3) Records of subpart H systems using conventional treatment meeting any of the enhanced coagulation or enhanced softening exemption criteria;

(4) Register of qualified operators;

(5) Records of systems with multiple wells considered to be one treatment plant for purposes of determining monitoring frequency;

(6) Records of the sampling plans for subpart H systems serving more than 3,300 persons must be keep on file at the State after submission by the system;

(7) A list of laboratories that have completed performance sample analyses and achieved the quantitative results for TOC, TTHMs, HAA5, bromate, and chlorite; and

(8) A list of all systems required to monitor for disinfectants and DBPs under subpart L.

b. Background and Analysis. In addition to requesting comments on the requirements (1) through (5), and (7) and (8) listed above, EPA also requested comments on whether States should be required to keep the monitoring plan submitted by systems serving more than 3,300 people on file at the State after submission to make it available for public review.

c. Summary of Comments. There were several commenters who suggested that EPA should keep in mind State budget constraints when requiring specific additional recordkeeping requirements. Other commenters stated that they believed the requirements were necessary. EPA understands commenters concerns with requiring recordkeeping requirements that are unnecessary, but believes this information is important to conduct effective State program oversight, including the review of State decisions and their basis. After further review, EPA has decided to eliminate the requirement in the proposal that States must keep records of systems that apply for alternative TOC performance criteria. EPA is more concerned with the systems that are required to meet alternative TOC performance criteria, not the systems that have applied for the alternative performance criteria. In addition, EPA has added three recordkeeping requirements, two of which were originally in the reporting requirements section and one for which EPA requested comment.

The first additional requirement will require States to keep lists of all systems required to monitor for various disinfectants and DBPs (#8 above). The second additional requirement will require States to maintain a list of laboratories that have completed performance sample analyses and achieved the quantitative results for TOC, TTHMs, HAA5, bromate, and chlorite (#6 above). EPA believes both of these recordkeeping requirements are necessary to ensure adequate EPA program oversight. As discussed below, these two requirements are no longer in the State reporting requirements as EPA has decided that the requirements in the proposal on State reporting requirements are not needed on a regular basis, but are needed for program oversight. The third additional requirement pertains to the request for comment in the proposal on maintaining the monitoring plans submitted by systems (#6 above). Several commenters supported this additional requirement stating that it was a necessary element for implementing the final rule. Others believed it was not necessary to keep this on file because the public could request this information from the system or the State as normal public records. EPA believes that it is important for States to review, and keep on file the systems monitoring plan to ensure that the PWS is monitoring and calculating compliance in accordance with the plan. This will also enable the public to view the plan. Thus, EPA is adding this requirement to the final recordkeeping requirements. In conclusion, based on a review of all public comments the final

rule contains eight State recordkeeping requirements in addition to those required under current regulations in § 142.14.

2. Special Primacy Requirements

a. Today's Rule. To ensure that a State program includes all the elements necessary for an effective and enforceable program under today's rule, a State application for program revision approval must include a description of how the State will:

(1) Determine the interim treatment requirements for systems granted additional time to install GAC and membrane filtration under 141.64(b)(2).

(2) Qualify operators of community and nontransient noncommunity water systems subject to this regulation under 141.130(c). Qualification requirements established for operators of systems subject to 40 CFR Part 141 Subpart H (Filtration and Disinfection) may be used in whole or in part to establish operator qualification requirements for meeting subpart L requirements if the State determines that the subpart H requirements are appropriate and applicable for meeting subpart L requirements.

(3) Approve DPD colorimetric tests kits for free and total chlorine measurements under 141.131(c)(2). State approval granted under subpart H (§ 141.74(a)(2)) for the use of DPD colorimetric test kits for free chlorine testing would be considered acceptable approval for the use of DPD test kits in measuring free chlorine residuals as required in subpart L.

(4) Approve parties to conduct analyses of water quality parameters under 141.132(a)(2) (pH, alkalinity, bromide, and residual disinfectant concentration measurements). The State's process for approving parties performing water quality measurements for systems subject to subpart H requirements may be used for approving parties measuring water quality parameters for systems subject to subpart L requirements, if the State determines the process is appropriate and applicable.

(5) Define criteria to use in determining if multiple wells are being drawn from a single aquifer and therefore can be considered as a single source under 141.132(a)(2). Such criteria will be used in determining the monitoring frequency for systems using only ground water not under the direct influence of surface water.

(6) Approve alternative TOC removal levels as allowed under 141.135(b).

b. Background and Analysis. As discussed above, EPA included several special primacy requirements to ensure that State programs contain all the essential elements for an effective program. Specifically, EPA believes the special requirements are important to ensure that the process or approach used by the State for evaluating whether the interim treatment in place for systems granted additional time to install GAC or membranes or alternative enhanced coagulation levels will be protective of public health. The requirement to have qualified operators is important because the treatment technologies used to comply with the Stage 1 DBPR and the IESWTR simultaneously are complex and will require a certain level of expertise. The requirement to approve parties for conducting analyses of specific water quality parameters is important because each of the parameters required to be tested is critical to a specific component of the final rule (e.g., bromide ion is important because for bromate it is possible to reduce monitoring from monthly to once per quarter, if a system demonstrates that the average raw water bromide concentration is less than 0.05 mg/L based upon representative monthly measurements for one year). Finally, it is important to define the criteria used to determine if multiple wells are to be considered a single source as this could have significant implications for monitoring.

c. Summary of Comments. There were no significant comments on the primacy requirements. The only change from the proposal was to delete the requirement that States must have approved parties to perform temperature evaluations. This requirement was included in the proposed rule because of the need to have accurate measurements as a part of the process for not allowing predisinfection credit. Since the final rule allows credit for compliance with applicable disinfection requirements consistent with the SWTR, the temperature requirement was removed.

3. State Reporting Requirements

a. Today's Rule. EPA currently requires in § 142.15 that States report to EPA information such as violations, variance and exemption status, and enforcement actions. The Stage 1 DBPR does not add any additional reporting requirements.

b. Background and Analysis. The preamble to the proposed rule included six State reporting requirements. These included:

(1) A list of all systems required to monitor for various disinfectants and disinfection byproducts;

(2) A list of all systems for which the State has granted additional time for installing GAC or membrane technology and the basis for the additional time;

(3) A list of laboratories that have completed performance sample analyses and achieved the quantitative results for TOC, TTHMs, HAA5, bromate, and chlorite;

(4) A list of all systems using multiple ground water wells which draw from the same aquifer and are considered a single source for monitoring purposes;

(5) A list of all Subpart H systems using conventional treatment which are not required to operate with enhanced coagulation, and the reason why enhanced coagulation is not required for each system; and

(6) A list of all systems with State-approved alternate performance standards (alternate enhanced coagulation levels).

c. Summary of Comments. Several commenters stated that the reporting requirements were not necessary to operate an oversight program and that these reports could be made available for EPA review during annual audits. EPA agrees with commenters that the reports are not necessary to operate an oversight program, and that if needed EPA could request this information from the States. However, EPA does believe it is important that States maintain this information in their records. In conclusion, based on commenters concerns and for the reasons cited above, the final rule contains no additional State reporting requirements other than those required by 142.15.

M. Variances and Exemptions

1. Today's Rule

Variances may be granted in accordance with section 1415(a)(1)(A) of the SDWA and in accordance with 1415(e) and EPA's regulations. Exemptions may be granted in accordance with section 1416(a) of the SDWA and EPA's regulations.

2. Background and Analysis

Variances. The SDWA provides for two types of variances—general variances and small system variances. Under section 1415(a)(1)(A) of the SDWA, a State which has primary enforcement responsibility (primacy), or EPA as the primacy agency, may grant variances from MCLs to those public water systems of any size that cannot comply with the MCLs because of characteristics of the water sources. The primacy agency may grant general variances to a system on condition that the system install the best available technology, treatment techniques, or other means, and provided that alternative sources of water are not

reasonably available to the system. At the time this type of variance is granted, the State must prescribe a compliance schedule and may require the system to implement additional control measures. Furthermore, before EPA or the State may grant a general variance, it must find that the variance will not result in an unreasonable risk to health (URTH) to the public served by the public water system.

Under section 1413(a)(4), States that choose to issue general variances must do so under conditions, and in a manner, that are no less stringent than section 1415. Of course, a State may adopt standards that are more stringent than the EPA standards. EPA specifies BATs for general variance purposes. EPA may identify as BAT different treatments under section 1415 for variances other than the BAT under section 1412 for MCLs. EPA's section 1415 BAT findings may vary depending on a number of factors, including the number of persons served by the public water system, physical conditions related to engineering feasibility, and the costs of compliance with MCLs. In this final rule, EPA is not specifying different BAT for variances under section 1415(a). Section 1415(e) authorizes the primacy Agency (EPA or the State) to issue variances to small public water systems (those serving less than 10,000 persons) where the system cannot afford to comply with an MCL and where the primacy agency determines that the terms of the variances ensure adequate protection of public health (63 FR 1943–57; EPA, 1998j). These variances also may only be granted where EPA has identified a variance technology under Section 1412(b)(15) for the contaminant, system size and source water quality in question.

Prior to the 1996 SDWA amendments, EPA was required to set the MCL for a contaminant as close to the MCLG as is feasible. Section 1412(b)(4)(D) of the SDWA states that "the term "feasible" means with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)."

The cost assessment for the feasibility determinations have historically been based upon impacts to regional and large metropolitan water systems serving populations greater than 50,000 people. Since large systems served as the basis for the feasibility determinations, the technical and/or cost considerations associated with these technologies often were not applicable to small water systems. While EPA will continue to use feasibility for large systems in setting NPDWRs, the 1996 amendments to the SDWA specifically require EPA to make small system technology assessments for both existing and future regulations.

The 1996 amendments to the SDWA identifies three categories of small public water systems that need to be addressed: (1) those serving a population between 3301 to 10,000; (2) those serving a population of 501—3300; and (3) those serving a population of 26—500. The SDWA requires EPA to make determinations of available compliance technologies and, if needed, variance technologies for each size category. A compliance technology is a technology that is affordable and that achieves compliance with the MCL and/or treatment technique. Compliance technologies can include point-of-entry or point-of-use treatment units. Variance technologies are only specified for those system size/source water quality combinations for which there are no listed compliance technologies.

EPA has completed an analysis of the affordability of DBP control technologies for each of the three size categories included above. Based on this analysis, multiple affordable compliance technologies were found for each of the three system sizes (EPA, 1998q and EPA, 1998r) and therefore variance technologies were not identified for any of the three size categories. The analysis was consistent with the methodology used in the document "National-Level Affordability Criteria Under the 1996 Amendments to the Safe Drinking Water Act" (EPA, 1998s) and the "Variance Technology Findings for Contaminants Regulated Before 1996" (EPA, 1998t).

Exemptions. Under section 1416(a), EPA or a State may exempt a public water system from any requirements related to an MCL or treatment technique of an NPDWR, if it finds that (1) due to compelling factors (which may include economic factors such as qualification of the PWS as serving a disadvantaged community), the PWS is unable to comply with the requirement or implement measure to develop an alternative source of water supply; (2) the exemption will not result in an unreasonable risk to health; and; (3) the PWS was in operation on the effective date of the NPWDR, or for a system that was not in operation by that date, only if no reasonable alternative source of drinking water is available to the new system; and (4) management or restructuring changes (or both) cannot reasonably result in compliance with the Act or improve the quality of drinking water.

If EPA or the State grants an exemption to a public water system, it must at the same time prescribe a schedule for compliance (including increments of progress or measures to develop an alternative source of water supply) and implementation of appropriate control measures that the State requires the system to meet while the exemption is in effect. Under section 1416(b)(2)(A), the schedule prescribed shall require compliance as expeditiously as practicable (to be determined by the State), but no later than 3 years after the effective date for the regulations established pursuant to section 1412(b)(10). For public water systems which do not serve more than a population of 3,300 and which need financial assistance for the necessary improvements, EPA or the State may renew an exemption for one or more additional two-year periods, but not to exceed a total of 6 years, if the system establishes that it is taking all practicable steps to meet the requirements above.

A public water system shall not be granted an exemption unless it can establish that either: (1) the system cannot meet the standard without capital improvements that cannot be completed prior to the date established pursuant to section 1412(b)(10); (2) in the case of a system that needs financial assistance for the necessary implementation, the system has entered into an agreement to obtain financial assistance pursuant to section 1452 or any other Federal or state program; or (3) the system has entered into an enforceable agreement to become part of a regional public water system.

3. Summary of Comments on Variance and Exemptions

In the 1994 proposal, EPA requested comment on whether exemptions to the rule should be granted if a system could demonstrate to the State that due to unique water quality characteristics it could not avoid, through the use of BAT, the possibility of increasing total health risk to its consumers by complying with the Stage 1 regulations. The Agency requested information under which such a scenario may unfold. Several commenters supported granting exemptions provided a system could demonstrate that installation of BAT will increase the total health risk.

After additional consideration, EPA believes it is not appropriate, for several reasons, to grant exemptions based on a demonstration that the use of BAT could increase the total health risk by complying with the Stage 1 DBPR. First,

EPA does not believe the analytical tools and methodologies are currently available that would allow a determination of whether the total health risk from the installation of BAT would increase. Second, at the time of proposal there was concern that in waters with high bromide concentrations it may be possible to increase the concentrations of certain brominated DBPs when using precursor removal processes even though the concentrations of the TTHMs and HAA5 may decrease. Also, at the time of proposal, the health risks associated with many of the brominated DBPs was unknown, and it was unclear whether the benefits of lowering the concentrations of chlorinated DBPs outweigh the possible downside risks of increasing certain brominated DBPs. Since the proposal, some additional health effects research has been completed evaluating the toxicity of brominated DBPs. However, this research is still preliminary and no conclusions can be drawn on the potential for increased risks from the brominated DBPs. In addition, it is unclear to what extent the use of precursor removal processes will change the concentrations of certain brominated DBPs. The ICR data should provide some additional information that may be helpful in this area along with additional ongoing research. This information will be available for consideration in the Stage 2 rule deliberations. Based on the reasons stated above, EPA does not believe it is appropriate to allow exemptions to the rule based on a finding that the installation of BAT would increase the total risk from DBPs.

N. Laboratory Certification and Approval

1. Today's Rule

EPA recognizes that the effectiveness of today's regulations depends on the ability of laboratories to reliably analyze the regulated disinfectants and DBPs at the MRDL or MCL, respectively. Laboratories must also be able to measure the trihalomethanes and haloacetic acids at the reduced monitoring trigger levels, which are between 25 and 50 percent of the MCLs for these compound classes. EPA has established State primacy requirements for a drinking water laboratory certification program for the analysis of DBPs. States must adopt a laboratory certification program as part of primacy. [40 CFR 142.10(b)]. EPA has also specified laboratory requirements for analyses of DBP precursors and disinfectant residuals which must be conducted by approved parties. [40 CFR 141.89 and 141.74]. EPA's "Manual for the Certification of Laboratories Analyzing Drinking Water", EPA 815-B-97-001—(EPA, 1997g), specifies the criteria for implementation of the drinking water laboratory certification program.

In today's rule, EPA is promulgating MCLs for TTHMs, HAA5, bromate, and chlorite. Today's rule requires that only certified laboratories be allowed to analyze samples for compliance with the proposed MCLs. For the disinfectants and certain other parameters in today's rule, which have MRDLs or monitoring requirements, EPA is requiring that analyses be conducted by a party acceptable to the State.

Performance evaluation (PE) samples, which are an important tool in the SDWA laboratory certification program (laboratories seeking certification) may be obtained from a PE provider approved by the National Institute of Science and Technology (NIST). To receive and maintain certification, a laboratory must use a promulgated method and, at least once per year, successfully analyze an appropriate PE sample. In the drinking water PE studies, NIST-approved providers will provide samples for bromate, chlorite, five haloacetic acids, four trihalomethanes, free chlorine, and alkalinity. The NIST-approved PE providers will provide total chlorine and TOC samples in the wastewater PE studies and have the potential to provide these samples for drinking water studies. Due to the lability of chlorine dioxide, EPA does not expect a suitable PE sample can be designed for chlorine dioxide measurements.

PE Sample Acceptance Limits for Laboratory Certification. Historically, EPA has set minimum PE acceptance limits based on one of two criteria: statistically derived estimates or fixed acceptance limits. Statistical estimates are based on laboratory performance in the PE study. Fixed acceptance limits are ranges around the true concentration of the analyte in the PE sample. Today's rule combines the advantages of these approaches by specifying statistically-derived acceptance limits around the study mean, within specified minimum and maximum fixed criteria.

EPA believes that specifying statistically-derived PE acceptance limits with upper and lower bounds on acceptable performance provides the flexibility necessary to reflect improvement in laboratory performance and analytical technologies. The acceptance criteria maintain minimum data quality standards (the upper bound) without artificially imposing unnecessarily strict criteria (the lower bound). Therefore, EPA is establishing the following acceptance limits for measurement of bromate, chlorite, each haloacetic acid, and each trihalomethane in a PE sample.

EPA is defining acceptable performance for each chemical measured in a PE sample from estimates derived at a 95% confidence interval from the data generated by a statistically significant number of laboratories participating in the PE study. However, EPA requires that these acceptance criteria not exceed ±50% nor be less than ±15% of the study mean. If insufficient PE study data are available to derive the estimates required for any of these compounds, the acceptance limit for that compound will be set at ±50% of the study true value. The true value is the concentration of the chemical that EPA has determined was in the PE sample.

EPA recognizes that when using multianalyte methods, the data generated by laboratories that are performing well will occasionally exceed the acceptance limits. Therefore, to be certified to perform compliance monitoring using a multianalyte method, laboratories are required to generate acceptable data for at least 80% of the regulated chemicals in the PE sample that are analyzed with the method. If fewer than five compounds are included in the PE sample, data for each of the analytes in that sample must meet the minimum acceptance criteria in order for the laboratory to be certified.

Approval Criteria for Disinfectants and Other Parameters. Today's rule establishes MRDLs for the three disinfectants—chlorine, chloramines, and chlorine dioxide. In addition, EPA has established monitoring requirements for TOC, alkalinity, and bromide; there are no MCLs for these parameters. In previous rules [40 CFR 141.28, .74, and .89], EPA has required that measurements of alkalinity, disinfectant residuals, pH, temperature, and turbidity be made with an approved method and conducted by a party approved (not certified) by the State. In today's rule, EPA requires that samples collected for compliance with today's requirements for alkalinity, bromide, residual disinfectant, and TOC be conducted with approved methods and by a party approved by the State.

Other Laboratory Performance Criteria. For all contaminants and parameters required to be monitored in today's rule, the States may impose other requirements for a laboratory to be

certified or a party to be approved to conduct compliance analyses.

2. Background and Analysis

The laboratory certification and approval requirements that today's rule establishes are unchanged from those proposed by EPA in 1994.

3. Summary of Comments

EPA received few comments on laboratory certification and approval. Commenters requested clarification of the use of the ±50% upper bound and ±15% lower bound, along with the use of statistically derived limits. EPA believes that statistically derived limits provide flexibility to allow laboratory certification standards to reflect improvement in laboratory performance and analytical technologies. As laboratories become more proficient in conducting these analyses, statistically derived acceptance limits may drop. However, to prevent the exclusion of laboratories capable of producing data of sufficient quality for compliance purposes, EPA has established a lower bound for acceptance limits of ±15%. EPA is imposing an upper bound on acceptable performance to establish minimum data quality standards. Results outside of this range have unacceptable accuracy for compliance determinations. These upper and lower bounds were not determined statistically; they are the data quality objectives the Agency has determined as acceptable.

IV. Economic Analysis

Under Executive Order 12866, Regulatory Planning and Review, EPA must estimate the costs and benefits of the Stage 1 DBPR in a Regulatory Impact Analysis (RIA) and submit the analysis to Office of Management and Budget (OMB) in conjunction with publishing the final rule. EPA has prepared an RIA to comply with the requirements of this Order. This section provides a summary of the information from the RIA for the Stage 1 DBPR (USEPA 1998g).

A. Today's Rule

EPA has estimated that the total annualized cost, for implementing the Stage 1 DBPR is $701 million in 1998 dollars (assuming a 7 percent cost of capital). This estimate includes annualized treatment costs to utilities ($593 million), start-up and annualized monitoring costs to utilities ($91.7 million), and startup and annualized monitoring costs to states ($17.3 million). Annualized treatment costs to utilities includes annual operation and maintenance costs ($362 million) and annualized capital costs assuming 7 percent cost of capital ($230 million). The basis for these estimates, and alternate cost estimates using different cost of capital assumptions are described later in this section. While the benefits of this rule are difficult to quantify because of the uncertainty associated with risks from exposure to DBPs (and the resultant reductions in risk due to the decreased exposure from DBPs), EPA believes that there is a reasonable likelihood that the benefits will exceed the costs. Various approaches for assessing the benefits are considered and described in the benefits and net benefits sections of this preamble.

B. Background

1. Overview of RIA for the Proposed Rule

In the RIA for the 1994 proposed Stage 1 DBPR (EPA, 1994i) EPA estimated the national capital and annualized utility costs (sum of amortized capital and annual operating costs, assuming 10% cost of capital) for all systems at $4.4 billion and $1.04 billion, respectively. The cost and reduction in DBP exposure estimates of the 1994 RIA were derived using a Disinfection Byproduct Regulatory Analysis Model (DBPRAM). The DBPRAM consisted of a collection of analytical models which used Monte Carlo simulation techniques to produce national forecasts of compliance and exposure reductions for different regulatory scenarios. The TWG, representing members of the Reg. Neg. Committee, used the best available information at the time as inputs to the DBPRAM, and for making further adjustments to the model predictions. The Stage 1 DBPR compliance and exposure forecasts were affected by constraints imposed by the 1994 proposed IESWTR option which would have required systems to provide enough disinfection, while not allowing for disinfection credit prior to TOC removal by enhanced coagulation, to achieve a 10_{-4} annual risk of infection from Giardia (EPA, 1994a). The compliance forecast assumed that a substantial number of systems would need to install advanced technologies to meet the Stage 1 DBPR because of needing to achieve the 10_{-4} annual risk level from Giardia while no longer being allowed disinfection credit prior to TOC removal.

Predicted benefits for the proposed Stage 1 DBPR were derived assuming a baseline risk ranging from 1 to 10,000 cancer cases per year (based on analysis of available toxicological and epidemiological data) and assuming reductions in the cancer risks were proportional to reductions in TTHM, HAA5, or TOC levels (predicted from compliance forecasts). Negotiators agreed that the range of possible risks attributed to chlorinated water should consider both toxicological data and epidemiological data, including the Morris et al. (1992) estimates. No consensus, however, could be reached on a single likely risk estimate. Therefore, the predicted benefits for the proposal ranged from one to several thousands cases of cancer being avoided per year after implementation of the Stage 1 DBPR. Despite, the uncertainty in quantifying the benefits from the Stage 1 DBPR, the Reg. Neg. Committee recognized that risks from chlorinated water could be large, and therefore should be reduced. The Reg. Neg. Committee also recommended that the proposed Stage 1 DBPR provided the best means for reducing risks from DBPs until better information become available.

For a more detailed discussion of the cost and benefit analysis of the 1994 proposed DBPR refer to the preamble of the proposed rule (EPA, 1994a) and the RIA for the proposed rule (EPA, 1994i).

2. Factors Affecting Changes to the 1994 RIA

a. Changes in Rule Criteria. Based on the new data reflecting the feasibility of enhanced coagulation, as discussed previously, the enhanced coagulation requirements were modified by decreasing the percent TOC removal requirements by 5 percent for systems with low TOC level waters (i.e., 2–4 mg/L TOC). These new percent TOC removal requirements were used with new source and finished water TOC occurrence data to revise the estimates for the number of systems requiring enhanced coagulation.

The IESWTR was revised from the proposal to allow inactivation credit for disinfection prior to and during stages of treatment for precursor removal. Also, the proposed IESWTR was revised to include disinfection benchmark criteria, in lieu of requiring treatment to an acceptable risk level, to prevent increases in microbial risk while systems complied with the Stage 1 DBPR. These two rule changes were considered in revising the forecasts of compliance and changes in exposure resulting from the Stage 1 DBPR.

b. New Information Affecting DBP Occurrence and Compliance Forecasts. Since the rule was proposed, new sources of data have become available that were used to update the 1994 RIA. The new data includes:

• Updated costs for different treatment technologies (e.g., membranes) used in the DBP Cost and Technology Document, (EPA, 1998k);

• 1996 data from the AWWA Water Industry Data Base on TOC, TTHM and HAA5 occurrence, and disinfection practices;

• Plant schematics of treatment processes for ICR utilities;

• Research data from numerous sources regarding the efficacy of enhanced coagulation for precursor removal and resultant DBP formation (Krasner, 1997; and EPA, 1997b);

• New research results produced in jar tests by TWG members documenting the effect of moving the point of predisinfection under varying conditions (Krasner, 1997 and EPA, 1997b).

This new information has been described in the 1997 DBP NODA (EPA, 1997b). Public comments received in 1997, supported using the above information in revising the decision tree analysis. Discussion on the decision tree changes are in section IV.C of this preamble.

c. New Epidemiology Information. Since the proposal, EPA has completed an reassessment of the Morris et al. (1992) meta-analysis (Poole, 1997). Review of the meta-analysis indicated that the estimate of cancer cases had limited utility for risk assessment purposes for methodological reasons (EPA, 1998l and EPA, 1998m). EPA has decided not to use the Morris et al. (1992) meta-analysis to estimate the potential benefits from the Stage 1 DBPR. EPA has considered new epidemiology studies conducted since the time of proposal and completed an assessment of the potential number of bladder cancer cases that could be attributed to exposure from chlorinated surface waters. Based on this assessment of epidemiological studies, EPA estimates that between 1100–9300 bladder cancer cases per year could be attributed to exposure to chlorinated surface waters (EPA, 1998c). Due to the wide uncertainty in these estimates, the true number of attributable cases could also be zero. The basis for these bladder cancer case estimates and potential reductions in risk resulting from the Stage 1 DBPR is discussed further in the benefits and net benefits sections that follow.

C. Cost Analysis

National cost estimates of compliance with the Stage 1 DBPR were derived from estimates of utility treatment costs, monitoring and reporting costs, and start-up costs. Utility treatment costs were derived using compliance forecasts of technologies to be used and unit costs for the different technologies.

1. Revised Compliance Forecast

The TWG, supporting the M–DBP Advisory Committee, used the 1996 AWWA Water Industry Data Base (WIDB) to reevaluate the compliance decision tree used in the RIA for the 1994 proposal. The WIDB provided occurrence data on TOC level in raw water and finished water, TTHM and HAA5 levels within distribution systems, and information on predisinfection practices.

The above information was used to predict treatment compliance choices that plants would likely make under the Stage 1 DBPR. Table IV–1 illustrates how the compliance forecast changed for large systems using surface water since the time of proposal.

TABLE IV–1.—COMPARISONS OF COMPLIANCE FORECASTS FOR SURFACE WATER SYSTEMS SERVING ≥10,000 POPULATION FROM THE 1994 PROPOSAL AND FINAL RULE

Treatment	1994		1998	
	# systems	% systems	# systems	% systems
(A) No Further Treatment	386	27.7	544	39.0
(B) Chlorine/Chloramines	41	2.9	231	16.6
(C) Enhanced Coagulation + Chloramines	136	9.7	265	19.0
(D) Enhanced Coagulation + Chlorine	600	43.0	265	19.0
(E) Ozone, Chlorine Dioxide, Granular Activated Carbon, Membranes	232	16.6	90	6.5
Total *	1,395	100	1,395	100

* May not add to total due to independent rounding.

Notable is that the percentage of systems predicted to use advanced technologies (ozone, chlorine dioxide, GAC, or membrane) dropped from 17 percent to 6.5 percent since proposal, and the percentage of systems not affected by the rule increased from 28 percent to 39 percent. This shift in predicted compliance choices is mainly attributed to less stringent disinfection requirements under the IESWTR which would reduce the formation of DBPs and reduce the number of systems requiring treatment to meet the Stage 1 DBPR. It also appears that a substantial number of systems may have already made treatment changes to comply with the 1994 proposed rule.

Table IV–2 illustrates how the compliance forecast changed for small systems using surface water since the time of proposal. As for large systems, the percentage of systems predicted to use advanced technologies dropped substantially, from 17 percent to 6.5 percent. This drop in use of advanced technology (i.e., ozone/chloramines and membrane technologies) is attributed to the change in the IESWTR (as described above) from the time of proposal. However, unlike for large systems, the overall percentage of systems predicted to require treatment modifications did not change. A higher percentage of small systems (70 percent) are predicted to be affected than large systems (61 percent) because previously smaller systems did not have to comply with a TTHM standard.

TABLE IV–2.—COMPARISON OF COMPLIANCE DECISION TREE FOR SURFACE WATER SYSTEMS SERVING <10,000 POPULATION FROM THE 1994 PROPOSAL AND FINAL RULE

	1994		1998	
	# systems	% systems	# systems	% systems
No Further Treatment	1,549	30	1,549	30
Number of Affected Systems	3,615	70	3,615	70
Treatment:				
Chlorine/Chloramine	155	3.0	826	16.0
Enhanced Coagulation	2,169	42.0	1,983	38.4
Enhanced Coagulation/Chloramine	465	9.0	465	9.0
Ozone/Chloramine	258	5.0	184	3.6
Enhanced Coagulation+Ozone, Chloramine	258	5.0	0	0
Membranes	310	6.0	157	3.0

Table IV–3 illustrates the compliance forecast for ground water systems. This forecast did not change from the time of proposal. A smaller percentage of small ground water systems are anticipated to need treatment changes (12 percent) than large ground water systems (15 percent) because the use of disinfectants is more prevalent in large versus small ground water systems.

TABLE IV–3.—COMPLIANCE DECISION TREE FOR ALL GROUND WATER SYSTEMS

	Systems <10,000		Systems ≥10,000	
	# systems	% systems	# systems	% systems
No Further Treatment	59,847	88	1,122	85
Percentage of Affected Systems	8,324	12	198	15
Treatment:				
Chlorine/Chloramine	5,403	8	119	9
Ozone/Chloramine	0	0	26	2
Membranes	2,921	4	53	4

2. System Level Unit Costs

Tables IV–4 and IV–5 present the unit cost estimates in 1998 dollars that were utilized for each of the different treatment technologies in each system size category. Unit costs are presented in $ per 1000 gallons which includes operation and maintenance costs and amortized capital costs (using a 7% discount rate and a 20 year amortization period). One dollar per thousand gallons equates to approximately $100 per household per year as an average for communities in the U.S. More detailed information on these unit costs is available from the EPA's Cost and Technology Document (EPA, 1998k).

TABLE IV–4.—SURFACE WATER SYSTEMS COSTS FOR DBP CONTROL TECHNOLOGIES ($/KGAL) AT 7% COST OF CAPITAL

	Population size category											
	25–100	100–500	500–1K	1–3.3K	3.3–10K	10–25K	25–50K	50–75K	75–100K	100K–500K	500K–1M	>1M
Chlorine/Chloramine	0.71	0.19	0.06	0.03	0.03	0.02	0.01	0.01	0.01	0.01	0.01	0.01
Enhanced Coagulation (EC)	0.15	0.13	0.12	0.11	0.09	0.08	0.07	0.07	0.07	0,07	0.06	0.06
EC/Chloramine	0.87	0.32	0.18	0.14	0.12	0.09	0.08	0.08	0.08	0.07	0.07	0.07
Ozone/Chloramine	12.67	3.21	1.05	0.52	0.38	0.23	0.13	0.10	0.08	0.06	0.04	0.04
EC+Ozone, Chloramine	12.82	3.34	1.17	0.63	0.47	0.30	0.20	0.17	0.15	0.13	0.11	0.10
EC+GAC10	6.24	2.43	1.21	0.81	0.59	0.46	0.37	0.35	0.29	0.24	0.19	0.16
EC+GAC20	14.11	5.87	3.45	2.45	1.87	1.48	1.05	1.00	0.90	0.64	0.48	0.41
Chlorine Dioxide	24.33	5.73	1.65	0.64	0.24	0.11	0.07	0.07	0.06	0.05	0.04	0.04
Membranes	3.40	3.47	3.39	2.65	1.72	0.96	0.96	0.87	0.87	0.87	0.87	0.87

TABLE IV–5.—GROUND WATER SYSTEMS COSTS FOR DBP CONTROL TECHNOLOGIES ($/KGAL) AT 7% COST OF CAPITAL

	Population size category											
	25–100	100–500	500–1K	1–3.3K	3.3–10K	10–25K	25–50K	50–75K	75–100K	100K–500K	500K–1M	>1M
Chlorine/Chloramine	0.72	0.19	0.06	0.03	0.03	0.02	0.01	0.01	0.01	0.01	0.01	0.01
Ozone/Chloramine	12.67	3.21	1.05	0.52	0.38	0.23	0.13	0.10	0.08	0.06	0.04	0.04
Membranes	3.41	3.47	3.39	2.65	1.72	0.96	0.96	0.87	0.87	0.87	0.87	0.87

3. National Costs

Table IV–6 provides a detailed summary of national costs in 1998 dollars under the Stage 1 DBPR for different cost of capital assumptions under a 20 year amortization period. A cost of capital rate of 7 percent was used to calculate the unit costs for the national compliance cost model. This rate represents the standard discount rate preferred by OMB for benefit-cost analyses of government programs and regulations. The 3 percent and 10 percent rates are provided as a sensitivity analysis to show different assumptions about the cost of capital that would affect estimated

costs. The 10 percent rate also provides a link to the 1994 Stage 1 DBPR cost analysis which was based on a 10 percent rate. EPA believes that the cost estimates presented in Table IV–6 are probably within +/−30 percent. Uncertainty around the cost estimates pertain to compliance forecast estimates, unit cost estimates for the different technologies as they may pertain to individual sites, and estimated costs associated with monitoring.

TABLE IV–6.—SUMMARY OF COSTS UNDER THE STAGE 1 DBPR ($000)

Utilities Costs	Surface water systems			Ground water systems			All systems
	Small	Large	Total	Small	Large	Total	
Summary of Costs at 3 Percent Cost of Capital							
Treatment Costs							
Total Capital Costs	242,652	554,564	797,216	997,537	528,539	1,526,076	2,323,292
Annual O&M	23,068	201,308	224,376	83,910	54,243	137,153	362,530
Annualized Capital Costs	16,326	37,161	53,487	67,287	35,618	102,905	156,392
Annual Utility Treatment Costs	39,394	238,469	277,863	151,197	89,861	240,058	518,922
Monitoring and Reporting Cost:							
Start-Up Costs	59	28	87	674	26	700	787
Annual Monitoring	10,867	14,619	25,486	38,803	26,326	65,129	90,615
State Costs:							
Start-Up Costs	.....	.....	.....	.....	.....	.....	2,919
Annual Monitoring	.....	.....	.....	.....	.....	.....	13,243
Total Annual Costs at 3 Percent Cost of Capital	.....	.....	.....	.....	.....	.....	626,486
Summary of Costs at 7 Percent Cost of Capital							
Total Capital Costs	242,652	554,564	797,216	997,537	528,539	1,526,076	2,323,292
Annual O&M	23,068	201,308	224,376	83,910	54,243	137,153	362,530
Annualized Capital Costs	22,786	62,355	85,141	94,403	50,046	144,499	229,590
Annual Utility Treatment Costs	45,855	263,663	309,518	178,313	104,289	282,602	592,120
Monitoring and Reporting Cost:							
Start-Up Costs	82	39	121	946	36	982	1,103
Annual Monitoring	10,867	14,619	25,486	38,803	26,326	65,129	90,615
State Costs:							
Start-Up Costs	.....	.....	.....	.....	.....	.....	4,099
Annual Monitoring	.....	.....	.....	.....	.....	.....	13,243
Total Annual Costs at 7 Percent Cost of Capital	.....	.....	.....	.....	.....	.....	701,180
Summary of Costs at 10 Percent Cost of Capital							
Total Capital costs	242,652	554,564	797,216	997,537	528,539	1,526,076	2,323,292
Annual O&M	23,068	201,308	224,376	83,910	54,243	137,153	362,530
Annualized Capital Costs	28,423	74,639	103,062	117,328	62,522	179,850	282,912
Annual Utility Treatment Costs	51,491	275,947	327,438	201,238	116,765	317,003	645,442
Monitoring and Reporting Cost:							
Start-Up Costs	102	48	150	1,177	45	1,222	1,372
Annual Monitoring	10,867	14,619	25,486	38,803	26,326	65,129	90,615
State Costs:							
Start-Up Costs	.....	.....	.....	.....	.....	.....	5,100
Annual Monitoring	.....	.....	.....	.....	.....	.....	13,243
Total Annual Costs at 10 Percent Cost of Capital	.....	.....	.....	.....	.....	.....	755,772

The total national costs of the final Stage 1 DBPR are less than estimated in the RIA for the proposed rule in 1994. The estimated capital costs of the 1994 proposal in 1998 dollars is $4.97 billion and the total annual cost (assuming a 10 percent cost of capital as was assumed in 1994) is $1.3 billion. The drop in national costs from the 1994 proposal is mainly attributed to the lowering of the number of surface water systems anticipated to need advanced technologies and lower membrane technology costs as described above.

D. Benefits Analysis

1. Exposure Assessment

A large portion of the U.S. population is exposed to DBPs via drinking water. Over 200 million people in the U.S. are served by PWSs which apply a disinfectant (e.g., chlorine) to water in order to provide protection against microbial contaminants. Because of the large number of people potentially exposed to DBPs, there is a substantial concern for any health risks which may be associated with exposure to DBPs.

Several factors are necessary to assess the exposure to DBPs: the size of the population potentially at risk; the method and rate of ingestion; and the concentration of DBPs in drinking

water. Because DBPs are formed in drinking water by the reaction of disinfectants with natural organic and inorganic matter, the population at risk is identified as the population served by drinking water systems that disinfect. The population served by each of four system categories, taken from recent Safe Drinking Water Act Information System data (SDWIS) is estimated in Table IV–7. Based on recent information from SDWIS, it was assumed that all surface water systems disinfect and a portion of ground water systems disinfect (95 percent by population among large systems and 83 percent by population among small systems). Approximately 239 million persons are estimated to be served by water systems that disinfect and are potentially exposed to DBPs. This widespread exposure represents over 88 percent of the total U.S. population (270 million). The route of exposure is through drinking disinfected tap water.

TABLE IV–7.—POPULATION POTENTIALLY EXPOSED TO DBPS

	Population served	% of population receiving disinfected water	Population served by systems that disinfect
Large Surface Water: >10,000 persons	141,297,000	100	141,297,000
Small Surface Water: <10,000 persons	17,232,000	100	17,232,000
Large Ground Water: >10,000 persons	56,074,000	95	53,270,300
Small Ground Water: < 10,000 persons	32,937,000	83	27,337,710
Total			239,137,010

In general, little data are available on the occurrence of DBPs on a national basis. Although there is sufficient occurrence data available for THMs in large water systems to develop a national occurrence distribution for that subset of systems, data are limited for small water systems. Similarly, some occurrence data for HAA5 are available for large surface water systems, but not small surface water and groundwater systems.

2. Baseline Risk Assessment Based on TTHM Toxicological Data

EPA performed a quantitative risk assessment using the dose-response information on THMs. This assessment, however, captures only a portion of the potential risk associated with DBPs in drinking water. It is not possible, given existing toxicological and exposure data, to gauge how much of the total cancer risk associated with the consumption of chlorinated drinking water is posed by TTHMs alone. An assessment of THMs, however, provides some estimation of the potential human risk, albeit limited.

Performing the risk assessment based on TTHM toxicological data requires making several assumptions and extrapolations (from a nonhuman species to humans, from high doses in the laboratory study to lower environmental exposures, and from a nondrinking water route to the relevant route of human exposure). Assumptions are also made about the occurrence of TTHMs and the individual DBPs. EPA estimated the pre-Stage 1 DBPR TTHM concentration levels by calculating a weighted average (based on populations receiving disinfected waters) of TTHM levels among the different system type categories described in Table IV–7. TTHM levels among systems serving greater than 10,000 people were estimated based on average concentrations among systems in AWWA's WIDB. TTHM levels in systems serving less than 10,000 people were estimated through modeling. Modeling consisted of applying TTHM predictive equations to estimates of DBP precursor levels and treatment conditions. The mean weighted average baseline TTHM concentrations among all the system type categories was 44 µg/L.

Occurrence data from an EPA DBP field study indicate that chloroform is the most common THM (in general, about 70 percent of total THMs), with bromoform being the least common (1 percent). Bromodichloromethane has an occurrence of approximately 20 percent of the total THMs, with dibromochloromethane comprising the final 8 percent of the total THMs. In the absence of more detailed occurrence data, these proportions are used to divide the average TTHM concentration into the concentration for the four individual compounds.

Two estimates of risk factors were used to estimate the cancer incidence. The first set of lifetime unit risk factors represent the upper 95 percent confidence limit of the dose-response function. The second estimate of lifetime unit risk is the maximum likelihood estimate used in the 1994 analysis that represents the central tendency of the dose-response function (Bull, 1991). The annual unit risk is calculated by dividing the lifetime risk by a standard assumption of 70 years per lifetime. To calculate the annual incidence of cancer due to consumption of TTHMs in drinking water, the annual drinking water unit risk is multiplied by the number of units, in this case the concentration of TTHMs in µg/L, broken out into individual THMs based on the proportions presented above. Based on these cancer risk estimates derived from laboratory animal studies, the annual 95th percentile upper bound number of cancer cases attributable to TTHMs is approximately 100. This means that there is a 95 percent chance that the annual number of cases are less than or equal to 100. Using the maximum likelihood or "best" estimates, the annual number of cancer cases is about 2.

3. Baseline Analysis Based on Epidemiology Data

Epidemiological studies can be used to assess the overall population risk associated with a particular exposure. Since the late 1970s, epidemiological investigations have attempted to assess whether chlorinated drinking water contributes to the incidence of bladder, colon, rectal, and other cancers. Several studies have reported a weak association between bladder cancer and exposure to chlorinated drinking water, but a causal relationship has not been confirmed (Freedman, et al., 1997).

Several cancer epidemiological studies examining the association between exposure to chlorinated surface water and cancer were published subsequent to the 1994 proposed rule and the 1992 meta-analysis. In general, these new studies are better designed than the studies published prior to the 1994 proposal. The new studies include incidence of disease, interviews with the study subjects, and better exposure assessments. More evidence is available

on bladder cancer for a possible association to exposure to chlorinated surface water than other cancer sites. Because of the limited data available for other cancer sites such as colon and rectal cancer, the RIA focuses on bladder cancer.

Based on the best studies, a range of potential risks was developed through the use of the population attributable risk (PAR) concept. Epidemiologists use PAR to quantify the fraction of disease burden in a population (e.g., bladder cancer) that could be eliminated if the exposure (e.g., chlorinated drinking water) was absent. PAR (also referred to as attributable risk, attributable portion, or etiologic fraction) provides a perspective on the potential magnitude of risks associated with various exposures under the assumption of causality. For example, the National Cancer Institute estimates that there will be 54,500 new cases of bladder cancer in 1997. If data from an epidemiological study analyzing the impact of consuming chlorinated drinking water reports a PAR of 1 percent, it can be estimated that 545 (54,500 × .01) bladder cancer cases in 1997 may be attributable to chlorinated drinking water.

Under the Executive Order #12866 that requires EPA to conduct a RIA, EPA has chosen to estimate an upper bound bladder cancer risk range for chlorinated drinking water using the PAR. EPA suggested this approach in the 1998 NODA (EPA, 1998a). While EPA recognizes the limitations of the current epidemiologic data base for making these estimates, the Agency considers the data base reasonable for use in developing an upper bound estimate of bladder cancer risk for use in the RIA. In light of the toxicological evidence, EPA recognizes that the risks from chlorinated drinking water may be considerably lower than those derived from the currently available epidemiological studies. EPA selected studies for inclusion in the quantitative analysis if they contained the pertinent data to perform a PAR calculation and met all three of the following criteria:

1. The study was a population-based, case-control, or cohort study conducted to evaluate the relationship between exposure to chlorinated drinking water and incidence of cancer cases, based on personal interviews; (all finally selected studies were population-based, case-control studies)

2. The study was of high quality and well designed (e.g., adequate sample size, high response rate, adjusted for known confounding factors); and,

3. The study had adequate exposure assessments (e.g., residential histories, actual THM data).

Using the above criteria, five bladder cancer studies were selected for estimating the range of PARs.

- Cantor, et al., 1985;
- McGeehin, et al., 1993;
- King and Marrett, 1996;
- Freedman, et al., 1997; and
- Cantor, et al., 1998.

The PARs from the five bladder cancer studies ranged from 2 percent to 17 percent. These values were derived from measured risks (Odds Ratio and Relative Risk) based on the number of years exposed to chlorinated surface water. Because of the uncertainty in these estimates, it is possible that the PAR could also be zero. The uncertainties associated with these PAR estimates are large due to the common prevalence of both the disease (bladder cancer) and exposure (chlorinated drinking water).

In order to apply these PAR estimates to the U.S. population to estimate the number of bladder cancer cases attributable to DBPs in drinking water, a number of assumptions must be made. These include: (1) that the study populations selected for each of the cancer epidemiology studies are reflective of the entire population that develops bladder cancer; (2) that the percentage of those cancer cases in the studies exposed to chlorinated drinking water are reflective of the bladder cancer cases in the U.S.; (3) that DBPs were the only carcinogens in these chlorinated surface waters; and (4) that the relationship between DBPs in chlorinated drinking water exposure and bladder cancer is causal.

The last of these assumptions is perhaps the most open to question. As noted in the March 1998 NODA, the results of the studies are inconsistent. In light of these concerns, the Agency agrees that causality between exposure to chlorinated water and bladder cancer has not been established and that the number of cases attributable to such exposures could be zero.

Based on the estimate of 54,500 new bladder cancer cases per year nationally, as projected by the National Cancer Institute for 1997, the numbers of possible bladder cancer cases per year potentially associated with exposures to DBPs in chlorinated drinking water estimated from the five studies range from 1,100 (0.02 × 54,500) to 9,300 (.17 × 54,500) cases. As noted above, due to the uncertainty in these estimates, the number of cases could also be zero. In making these estimates it is necessary to assume that these bladder cancer cases are attributed to DBPs in chlorinated surface water, even though the studies examined the relationship between chlorinated surface water and bladder cancer. This derived range is not accompanied by confidence intervals (C.Is), but the C.Is. are likely to be very wide. EPA believes that the mean risk estimates from each of the five studies provides a reasonable estimate of the potential range of risk suggested by the different epidemiological studies. Table IV–8 contains a summary of the risk estimates from the 1994 draft RIA and the estimates derived from the more recent analysis.

A related analysis based on odds ratios was conducted to derive a range of plausible estimates for cancer epidemiologic studies (EPA, 1998n). This analysis was also based on bladder cancer studies (the five studies cited above in addition to Doyle *et al.* 1997). For the purpose of this exercise, the annual U.S. expected number of 47,000 bladder cancers cited by Morris et al.(1992) was used to calculate estimates of the cancers prevented. The number of cancers attributable to DBP exposure was estimated not to exceed 2,200–9,900 per year and could include zero. As would be expected from related analysis performed in the same data, this range is similar to the 1,100–9300 PAR range. EPA has used the 1100–9300 PAR range for the RIA.

TABLE IV–8.—NUMBER OF CANCER CASES ATTRIBUTABLE TO DBPS: COMPARISON OF ESTIMATES IN 1994 AND 1998

	1994 estimates	1998 estimates
Number of New Bladder Cancer Cases/Year	Approx. 50,000	54,500.
Number of Estimated Deaths Due to Bladder Cancer/Year	Did not state	12,500.
Attributable to DBPs in Drinking Water		
Data Source	>15 studies	5 studies that meet specific criteria.
Causality	No	No.
Percent Attributable to DBPs	Did not state	2% to 17%.

TABLE IV–8.—NUMBER OF CANCER CASES ATTRIBUTABLE TO DBPS: COMPARISON OF ESTIMATES IN 1994 AND 1998—Continued

	1994 estimates	1998 estimates
Number of Cancer Cases Attributable to DBPs:		
Estimated Using Toxicological Data	Less than 1*	Zero to 100.**
Estimated Using Epidemiological Data	Over 10,000***	Zero to 9,300.****

*Based on maximum likelihood estimates of risk from THMs.
**Based on IRIS 95th percent C.I. estimates of risk from THMs.
***Indicates rectal and bladder cancer cases.
****Indicates only bladder cancer cases.

The current benefits analysis is structured in roughly the same manner as that presented in the 1994 RIA. The baseline cancer risks could lie anywhere from zero to 100 cases per year based on toxicological data; and zero to 9,300 cases per year based on epidemiological data. Consequently, the task is to assess the economic benefit of the final Stage 1 DBPR in the face of this broad range of possible risk.

4. Exposure Reduction Analysis

EPA predicted exposure reductions due to the current Stage 1 DBPR relative to the present baseline. EPA used the concentration of TTHMs as a marker to measure the exposure to the range of DBPs because data are available on the baseline occurrence and formation of TTHMs. There are limited data on the total mix of byproducts in drinking water. Therefore, the reduction in TTHMs is assumed to reflect the reduction in exposure to all DBPs. To determine the change in exposure, it is necessary to estimate the pre-Stage 1 baseline average TTHM concentration and the post Stage 1 average TTHM concentration. The difference in the pre- and post-Stage 1 TTHM concentrations reflect the potential reduction in TTHMs and thus in DBPs.

As described previously, the estimated pre-Stage 1 TTHM weighted average concentration is 44 μg/L for all system sizes and types of systems. The post Stage 1 TTHM concentrations for each system category were estimated based on the technology compliance forecasts previously discussed and estimated reductions in TTHM levels depending upon technology. The post-Stage 1 TTHM weighted average concentration is estimated at 33 μg/L. This represents a 24 percent reduction in TTHM levels resulting from the Stage 1 DBPR. Further details of the above analysis is described in the RIA for the Stage 1 DBPR (USEPA, 1998g).

5. Monetization of Health Endpoints

The range of potential benefits from the Stage 1 DBPR can be estimated by applying the monetary values for fatal and nonfatal bladder cancer cases with the estimate of the number of bladder cancer cases reduced by the rule. The following assumptions are used to estimate the range of potential benefits:

- An estimate of the number of bladder cancer cases attributable to DPBs in drinking water ranging from 0 to 9,300 annually.
- A 24 percent reduction in exposure to TTHMs due to the Stage 1 DBPR (75 percent CI of 19 to 30 percent) will result in an equivalent reduction in bladder cancer cases
- A value per statistical life saved for fatal bladder cancers represented by a distribution with a mean of $5.6 million
- A willingness to pay to avoid a nonfatal case of bladder cancer represented by a distribution with a mean of $587,500

Using the low end of the risk range of 0 bladder cancer cases attributable to DBPs results in a benefits estimate of $0. To calculate the high end of the range, the 9,300 estimate of attributable cases is multiplied by the percent reduction in exposure to derive the number of bladder cancer cases reduced (9,300 × .24 = 2,232 bladder cancer cases reduced). This assumes a linear relationship between reduction in TTHMs concentrations and reduction in cancer risk (e.g., 24 percent reduction in TTHMs concentration is associated with a 24 percent reduction in cancer risk). Assuming 23 percent of the bladder cancer cases end in fatality and 77 percent are nonfatal, the number of fatal bladder cancer cases reduced is 513 (2,232 × .23) and the number of nonfatal bladder cancer cases is 1,719 (2,232 × .77). Based on the valuation distributions described above, the estimate of benefits at the mean associated with reducing these bladder cancer cases is approximately $4 billion. It should be noted that these estimates do not include potential benefits from reducing other health effects (e.g, colon/rectal cancer and reproductive endpoints) that cannot be quantified at this time. As a result, EPA believes that the potential benefits discussed in today's rule may be a substantial underestimate of potential benefits that will be realized as a consequence of today's action. While the low end of the range cannot extend below $0, it is possible that the high end of the range could extend beyond $4 billion if the other reductions in risk could be quantified and monetized. No discount factor has been applied to these valuations, although there is likely to be a time lag between compliance with the rule and the realization of benefits.

Given this wide range of potential benefits and the uncertainty involved in estimating the risk attributable to DBPs, EPA undertook five different approaches to assessing the net benefits of the Stage 1 DBPR. These approaches are described in the net benefits section and should be considered both individually and in the aggregate.

E. Net Benefits Analysis

The potential economic benefits of the Stage 1 DBPR derive from the increased level of public health protection and associated decreased level of risk. The quantification of the benefits resulting from DBP control is complicated by the uncertainty in the understanding of the health risks. Epidemiological studies, referred to previously, suggest an association between bladder cancer and exposure to chlorinated surface water; however, these risks are uncertain. The lowest estimate in the selected epidemiological studies of the number of new bladder cancer cases per year attributable to chlorinated surface water is 1,100 cases, while the highest is 9,300 cases. EPA recognizes that while these risks may be real, they also could be zero. Assessment of risks based only on toxicological data for THMs, indicate a much lower risk (2 cancer cases per year at the most likely estimate, to about 100 cases per year using the 95 percent confidence level upper bound), but THMs represent only a few of the many DBPs in drinking water.

EPA explored several alternative approaches for assessing the benefits of the Stage 1 DBPR: Overlap of Benefit and Cost Estimates; Minimizing Total Social Losses; Breakeven Analysis;

Household Costs; and Decision-Analytic Model. A summary of the analysis of each approach is presented below. More detailed descriptions are described in the RIA (USEPA, 1998g).

Overlap of Benefit and Cost Estimates. One method to characterize net benefits is to compare the relative ranges of benefits and costs. Conceptually, an overlap analysis tests whether there is enough of an overlap between the range of benefits and the range of costs for there to be a reasonable likelihood that benefits will exceed costs. In a theoretical case where the high end of the range of benefits estimates does not overlap the low end of the range of cost estimates, a rule would be difficult to justify based on traditional benefit-cost rationale.

For the Stage 1 DBPR, the overlap analysis (Figures IV–1a and IV–1b) show that there is substantial overlap in the estimates of benefits and costs. The range of quantified benefits extends from zero to over $4 billion. The zero end of the range of estimated benefits represents the possibility that there is essentially no health benefit from reducing exposure to DBPs. The other end of the range assumes there are 9,300 bladder cancer cases per year attributable to DBPs and there is a 24 percent annual reduction in exposure with the promulgation of the rule, resulting in avoidance of 2,232 cases. Assuming that number of avoided cases, approximately 513 would have been fatalities and would result in a cost savings of approximately $3 billion (each avoided fatality results in a cost savings of $5.6 million). Additionally, 1,719 non-fatal cases avoided would result in a cost savings of approximately $1 billion (each avoided non-fatal case results in a cost savings of $0.6 million). The sum of the cost savings is approximately $4 billion. The high end of the benefits range could potentially be higher if other health damages are avoided. The range of cost estimates is significantly smaller, ranging from $500 million to $900 million annually. Although these cost estimates have uncertainty, the degree of uncertainty is of little consequence to the decisions being made given the scale of the uncertainty for the benefits.

Figure IV–1b, on the other hand, indicates that while the quantified benefits could exceed the costs, there is the possibility that there could be negative net benefits if there were no health benefits.

BILLING CODE 6560–50–U

Figure IV–1a Overlap of Estimated Benefits and Costs of the Stage 1 DBPR

Figure IV–1b Overlap of the Ranges of the Estimated Benefits and Costs of the Stage 1 DBPR

Figure IV-1a Overlap of Estimated Benefits and Costs of the Stage 1 DBPR

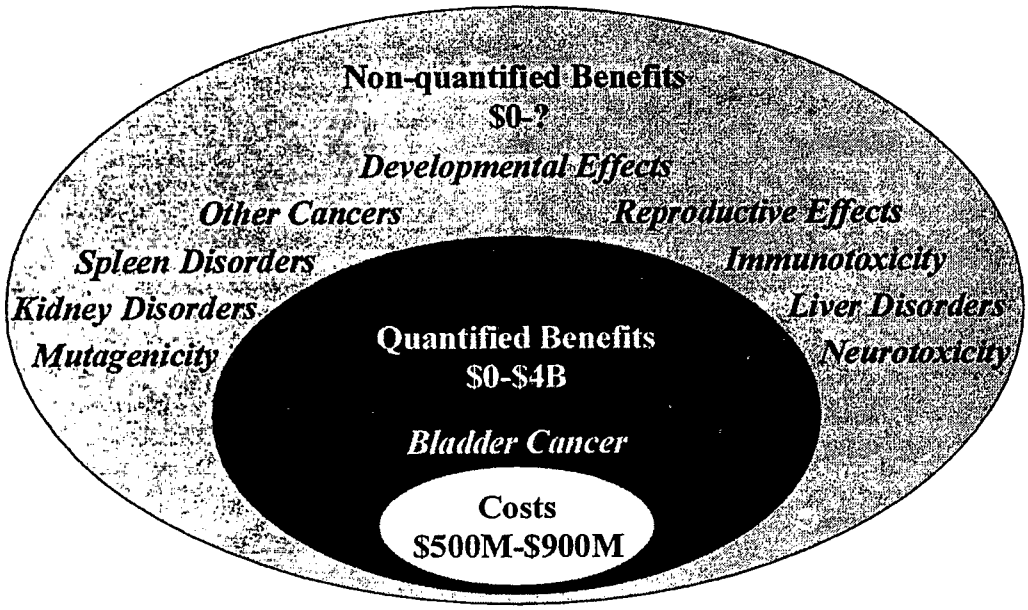
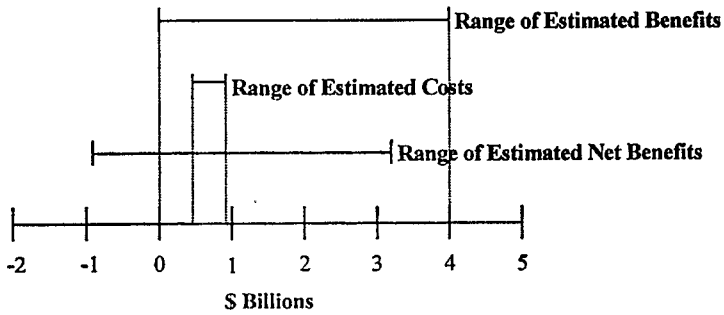


Figure IV-1b Overlap of the Ranges of the Estimated Benefits and Costs of the Stage 1 DBPR



BILLING CODE 6560–50–C

Minimizing Total Social Losses Analysis. Minimizing Total Social Losses analysis, sometimes called "minimizing regrets" analysis, is a decision-aiding tool that is suited for use in situations where it is impossible to pin down the exact nature and extent of a risk. The basic premise of Minimizing Total Social Losses analysis is to estimate total social costs for policy alternatives over a range of plausible risk scenarios. The actual, or "true" risk is unknowable, so instead this analysis asks what range and level of risks could be true, and then evaluates the total costs to society if particular risk levels within that range turned out to be the "true" value. Total social costs include both the cost to implement the policy option, plus costs related to residual (i.e., remaining) health damages at each risk level after implementation of the policy option.

Under this analysis the "total social costs" (water treatment costs plus costs of health damages still remaining after treatment) are calculated for three regulatory alternatives (No Action, Stage 1, and Strong Intervention—otherwise known as the proposed Stage 2 requirements of the 1994 proposal) across a range of risk scenarios (< 1; 100; 1,000; 2,500; 5,000; 7,500; and 10,000 attributable bladder cancer cases annually). Total social costs for each regulatory alternative for different risk assumptions are presented in Table IV–9. The results indicate that the Stage 1 DBPR has the least social cost among the three alternatives analyzed across the range of risks from 2,500 through 7,500 attributable bladder cancer cases annually.

Total "social loss" for each risk scenario are also indicated in Table IV–9. The "social loss" is the cost to society of making a wrong choice among the regulatory alternatives. It is computed as the difference between the total social cost (water treatment cost plus remaining health damages) of an alternative at a given risk scenario and the total social cost of the best alternative (least total social cost alternative for that risk scenario). The regulatory alternatives across the different risk levels can also be compared to see which alternative minimizes the maximum potential loss. The best alternative, by this "mini-max" criteria, would be the one in which the upper bound of potential losses is smallest.

BILLING CODE 6560–50–U

TABLE IV-9

Stage 1 DBPR Minimizing Maximum Loss Analysis (Billions of Dollars; 1998 Dollars)

	Risk Scenarios						
	<1 Cancer Case	100 Cancer Cases	1,000 Cancer Cases	2,500 Cancer Cases	5,000 Cancer Cases	7,500 Cancer Cases	10,000 Cancer Cases
No Action							
Cost of DBP Rule Option	$0	$0	$0	$0	$0	$0	$0
Residual Health Costs [1]	$0	$0.176	$1.755	$4.388	$8.776	$13.164	$17.552
Total Excess Social Losses	$0	$0.176	$1.755	$4.388	$8.776	$13.164	$17.552
Excess Social Losses	***$0***	***$0***	***$0***	***$0.352***	***$1.405***	***$2.458***	***$4.129***
Stage 1							
Cost of DBP Rule Option	$0.701	$0.701	$0.701	$0.701	$0.701	$0.702	$0.701
Residual Health Cost [1,2]	$0	$0.131	$1.335	$3.335	$6.670	$10.005	$13.340
Total Social Costs	$0.701	$0.832	$2.036	$4.036	$7.371	$10.706	$14.041
Excess Social Losses	***$0.701***	***$0.656***	***$0.281***	***$0***	***$0***	***$0***	***$0.617***
Strong Intervention (RegNeg Stage II Placeholder)							
Cost of DBP Rule Option	$2.892	$2.892	$2.892	$2.892	$2.892	$2.892	$2.892
Residual Health Cost [1,3]	$0	$0.106	$1.053	$2.633	$5.266	$7.899	$10.531
Total Social Costs	$2.892	$2.998	$3.945	$5.525	$8.158	$10.791	$13.423
Excess Social Losses	***$2.892***	***$2.823***	***$2.190***	***$1.489***	***$0.787***	***$0.085***	***$0***

1 Mean values from Crystal Ball Simulation **2** Assumes 24 percent reduction in exposure **3** Assumes 40 percent reduction in exposure

Gray shading represents maximum excess social loss for each alternative action (row).

BILLING CODE 6560–50–C

Under the Stage 1 DBPR alternative, the worst loss that could happen would occur if the lowest end of the risk range is true. This would result in total social losses of $0.7 billion per year. It is concluded that the maximum potential loss of the Stage 1 alternative is smaller than that of No Action ($4.1 billion) by a factor of 6 and smaller than that of Strong Intervention ($2.9 billion) by a factor of 4. Thus, the Stage 1 DBPR is the best of the 3 alternatives at minimizing the maximum social loss.

The 1994 Reg. Neg. and 1997 M–DBP Advisory Committees implicitly applied this type of "minimizing maximum loss" framework when developing and evaluating the DBP regulatory options. In the face of large uncertainty regarding risk from DBPs, they decided that a moderate response, relying on the more cost-effective of the available treatment methods was appropriate as an interim step until more information on risk becomes available.

Break Even Analysis. Breakeven analysis represents another approach to assessing the benefits of the Stage 1 DBPR given the scientific uncertainties. Breakeven is a standard benchmark of cost effectiveness and economic efficiency, and is essentially the point where the benefits of the Stage 1 DBPR are equal to the costs. Normally, the benefits and costs of an option are calculated separately and then compared to assess whether and by what amount benefits exceed costs. In the case of the Stage 1 DBPR, independently estimating benefits is difficult, if not impossible, because of the 10,000-fold uncertainty surrounding the risk. Instead, the breakeven analysis works backwards from those variables that are less uncertain. In this case, implementation costs for the rule and the monetary value associated with the health endpoints are used to calculate what baseline risk and risk reduction estimates are needed in order for the benefits, as measured in avoided health damages associated with bladder cancer, to equal the costs.

Two important concepts for this analysis are the cost of illness measure and the willingness-to-pay measure. The cost of illness measure includes medical costs and lost wages associated with being unable to work as a result of illness. In comparison, willingness-to-pay measures how much one would pay to reduce the risk of having all the discomfort and costs associated with nonfatal cancer if such an option existed. The main difference between these two methods is that willingness-to-pay incorporates pain and suffering, as well as changes in behavior into the valuation, while cost of illness does not. EPA has estimated the cost of a non-fatal case of bladder cancer at $121,000 using the cost of illness method, and at $587,500 using the willingness-to-pay approach.

Assuming an annual cost of $701 million and assumptions about the monetary value of preventing both fatal and nonfatal bladder cancer cases, the Stage 1 DBPR would need to reduce 438 bladder cancer cases per year using the willingness-to-pay measure for nonfatal cancers or 574 cases per year using the cost of illness measure. If exposure is reduced by 24 percent, the baseline number of bladder cancer cases attributable to DBPs in chlorinated drinking water required to break even would need to range from 1,820 to 2,390 new cases annually. Although these values are well above the range indicated by existing toxicological data for THMs alone, they fall within the attributable risk range suggested by the epidemiological studies.

Household Cost Analysis. A fourth approach for assessing the net benefits of the Stage 1 DBPR is to calculate the costs per household for the rule. Household costs provide a common sense test of benefit/cost relationships and are another useful benchmark for comparing the willingness-to-pay to reduce the possible risk posed by DBPs in drinking water. It is essentially a household level breakeven analysis. It works backwards from the cost to ask whether the implied amount of benefits (willingness-to-pay) needed to cover costs is a plausible amount.

About 115 million households are located in service areas of systems affected by the Stage 1 DBPR. Of these households, 71 million (62 percent) are served by large surface water systems. Approximately 4.2 million (4 percent) are served by small surface water systems. Large ground water systems served 24 million households (21 percent) and small ground water systems serve 15.7 million households (14 percent).

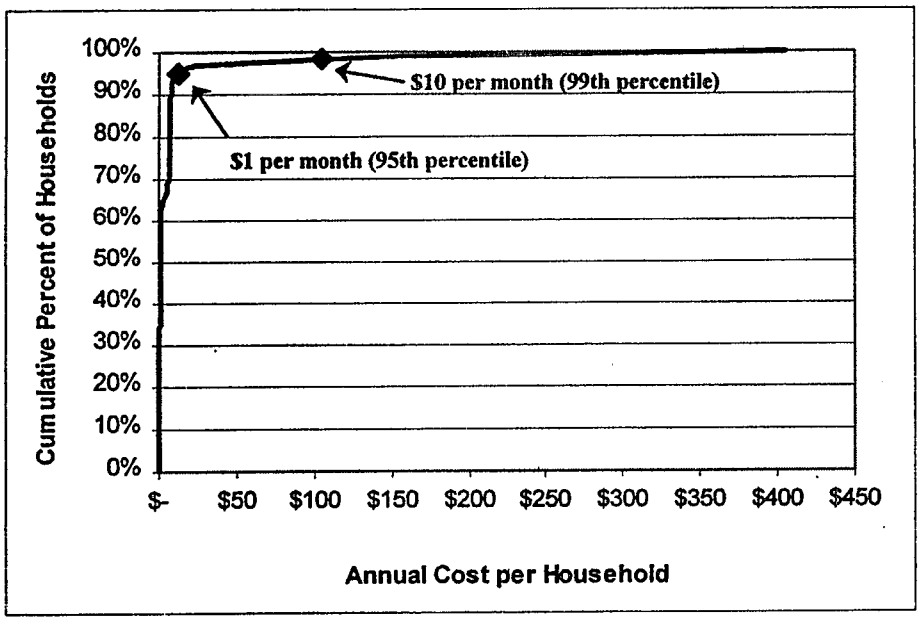
All of the households served by systems affected by the Stage 1 DBPR will incur some additional costs (e.g., monitoring costs), even if the system does not have to change treatment to comply with the proposed rule. The costs calculated below include both monitoring and treatment costs.

The cumulative distribution of household costs for all systems and by each system type is displayed in Figures IV–2a, IV–2b, IV–2c. The distributions show that the large percentage of households will incur small additional costs, with a small portion of systems facing higher costs. At the highest end of the distribution, approximately 1,400 households served by surface water systems in the 25–100 size range switching to membrane technology will face an average annual cost increase of $400 per year ($33 per month).

BILLING CODE 6560.50-U

Figure IV-2a

Cumulative Distribution of Annual Household Costs under the Stage 1 DBPR



BILLING CODE 6560-50-C

The households have been sorted into three cost categories for the ease of comparison (Table IV–10). The first category includes households with a cost increase of less than $12 per year, less than $1 per month. The second category contains households with costs greater than $12 per year, but less than $120 per year ($10 per month). The third category includes households with cost increases greater than $120 per year to $400 per year ($33 per month).

Across all system categories (see Figure IV–2a), 95 percent of the households (110.1 million) fall within the first category and will incur less than $1 per month additional costs due to the Stage 1 DBPR. An additional 4 percent (4.4 million) are in the second category at between $1 and $10 per month cost increase and 1 percent (1.0 million) are in the highest category ($10–$33.40 per month).

For households served by large surface water systems (Figure IV–2b), 98 percent will incur less than $1 per month, 2 percent will incur between $1 and $10 per month, and 0.03 percent will incur greater than $10 per month. The highest cost ($125 annually, $10.40 monthly) is faced by households served by systems in the 10,000 to 25,000 size range implementing membrane technology.

For households served by small surface water systems (Figure IV–2c), 71 percent will incur less than $1 per month, 28 percent will incur between $1 and $10 per month, and 1 percent will incur greater than $10 per month. The highest cost ($400 annually, $33 monthly) is faced by households served by systems in the 25–100 size range implementing membrane technology.

For households served by large ground water systems (Figure IV–2b), 95 percent will incur less than $1 per month, 4 percent will incur between $1 and $10 per month, and 1 percent will incur greater than $10 per month. The highest cost ($125 annually, $10.40 monthly) is faced by households served by systems in the 10,000 to 25,000 size range implementing membrane technology.

For households served by small ground water systems (Figure IV–2c), 91 percent will incur less than $1 per month, 5 percent will incur between $1 and $10 per month, and 4 percent will incur greater than $10 per month. The highest cost ($357 annually, $29.75 monthly) is faced by households served by systems in the 25–100 size range implementing membrane technology.

BILLING CODE 6560–50–U

Table IV-10

Summary of the Number of Households and Percentage of Total Households in Each Cost Category

	All Systems		$0 - $12 per Year Cost/Household		$12.01 - $120 per Year Cost/Household		$120.01 - $400 per Year Cost/Household	
	# Households	% Total	# Households	% Total	# Households	% Total	# Households	% Total
Total	115,490,000	100%	110,093,000	95%	4,387,000	4%	1,011,000	1%
Large Surface Water	71,378,000	61.8%	69,870,000	60%	1,489,000	1%	20,000	0.02%
Small Surface Water	4,267,000	3.7%	3,009,000	3%	1,204,000	1%	54,000	0.05%
Large Ground Water	24,174,000	20.9%	22,969,000	20%	939,000	0.8%	266,000	0.2%
Small Ground Water	15,671,000	13.6%	14,245,000	12%	755,000	0.7%	671,000	1%

Summary of the Number of Households and Percentage of Households in Each Cost Category by System Type

	All Systems		$0 - $12 per Year Cost/Household		$12.01 - $120 per Year Cost/Household		$120.01 - $400 per Year Cost/Household	
	# Households	% System Category	# Households	% System Category	# Households	% System Category	# Households	% System Category
Total	115,490,000	100%	110,093,000	95%	4,387,000	4%	1,011,000	1%
Large Surface Water	71,378,000	100%	69,870,000	98%	1,489,000	2%	20,000	0.03%
Small Surface Water	4,267,000	100%	3,009,000	71%	1,204,000	28%	54,000	1%
Large Ground Water	24,174,000	100%	22,969,000	95%	939,000	4%	266,000	1%
Small Ground Water	15,671,000	100%	14,245,000	91%	755,000	5%	671,000	4%

Figure IV-2b: Cumulative Distribution of Annual Costs per Household for Large Surface and Ground Water Systems

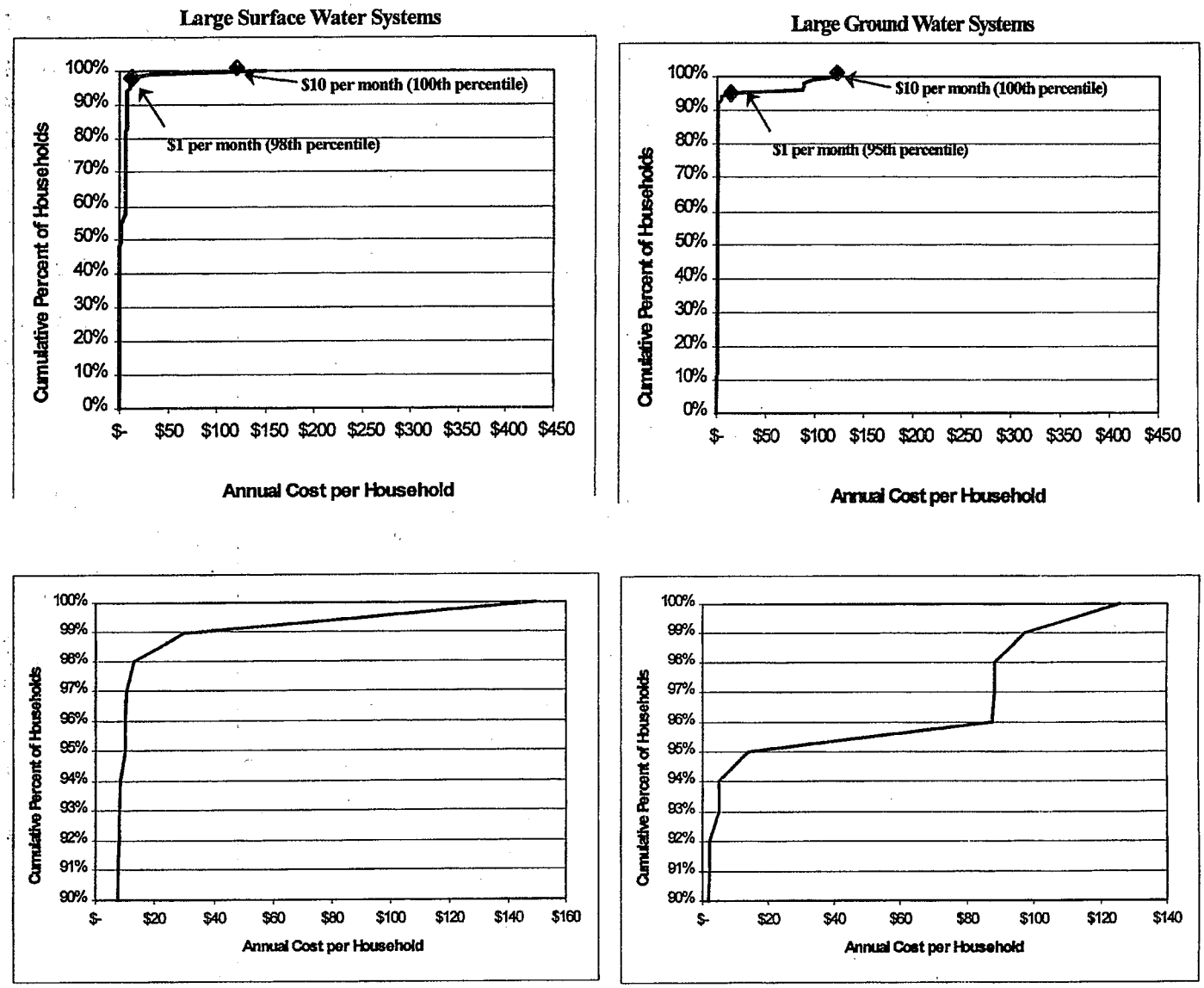
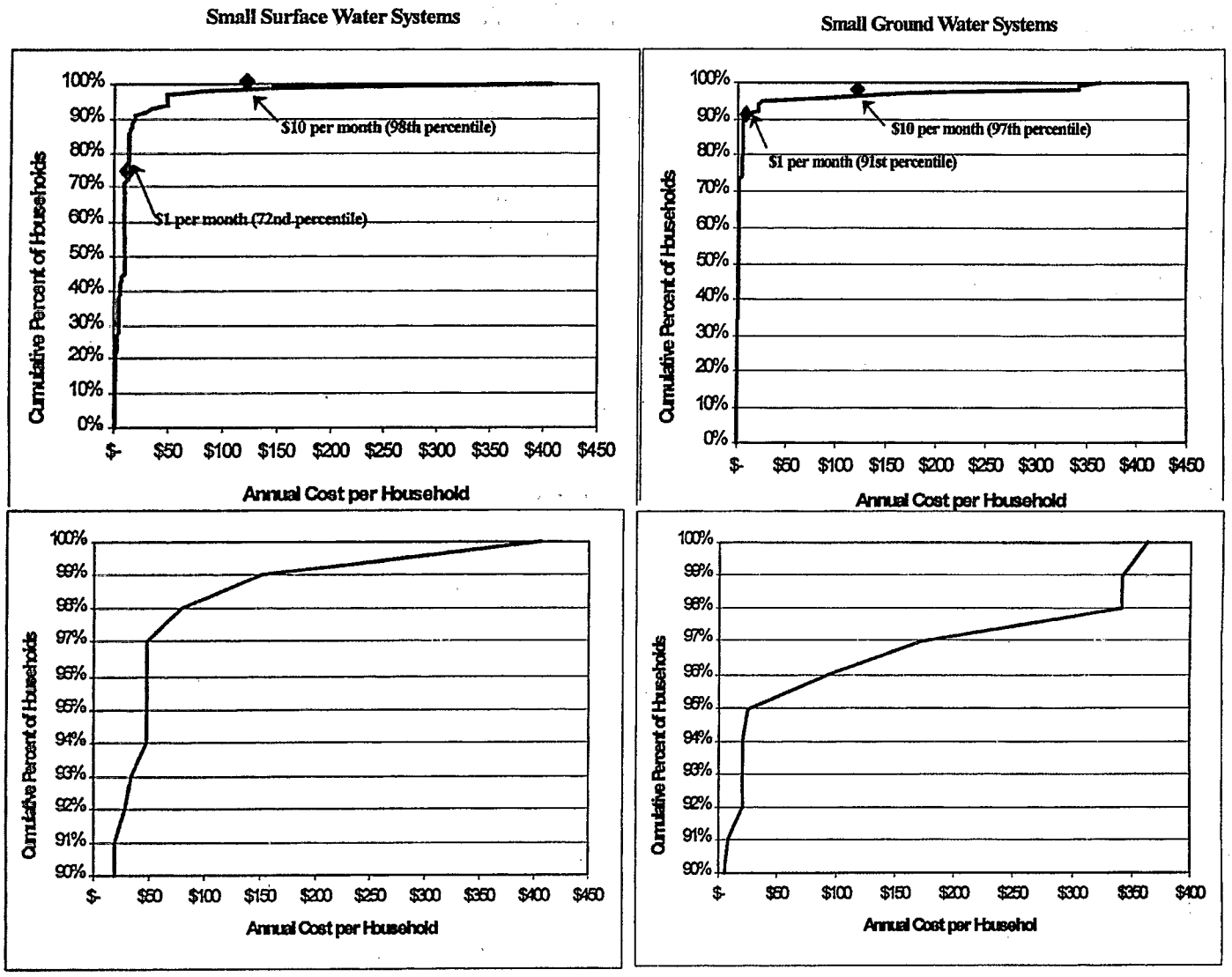


Figure IV-2c Cumulative Distribution of Annual Costs per Household for Small Surface and Ground Water Systems



BILLING CODE 6560-50-C

In the small proportion of systems where household costs are shown to be much greater—up to several hundreds of dollars per year—these results are driven by the assumption that membrane technologies will be the selected treatment, as noted above. Additionally, two points must be made: (1) a number of these systems may find less expensive means of compliance (e.g., selection of alternative source water, purchased water, or consolidation with other systems); and (2) if these systems do install membranes, they may receive additional water quality and/or compliance benefits beyond those associated with DBPs. For example, because membranes are so effective, systems that install membranes are likely to incur lower compliance costs for future rulemakings.

Given the uncertain nature of the risks associated with DBPs, household costs provide a common sense estimate of willingness-to-pay to reduce the risks: Would the average household (95 percent of households) be willing to pay less than $1 per month ($12 per year) to reduce the potential risks posed by DBPs?

Willingness to pay studies are not available to directly answer this question. Taking the $1 per month figure as a measure of implied public health benefit at the household level, it is useful to ask what benefits can be identified that could balance a $1 per month expenditure. First, it is entirely possible that there is much more than a dollar-a-month's worth of tangible health benefit based on reduced risk of bladder cancer alone. Second, the broad exposure to DBPs and the possible health effects involved offer the possibility that there are significant additional health benefits of a tangible nature. However, the agency recognizes that in the small percentage of situations where the costs per household is between $120 to $400 per year, this may indeed be a difficult financial burden to meet (e.g., may exceed household willingness-to-pay).

Finally, the preventive weighing and balancing of public health protection also provides a margin of safety—a hedge against uncertainties. Recent survey research conducted in the drinking water field provides compelling empirical evidence that the number one priority of water system customers is the safety of their water. Although definitive economic research has not been performed to investigate the extent of household willingness-to-pay for such a margin of safety, there is strong evidence from conventional customer survey research implying a demand for this benefit.

Decision Analytical model. The RIA also discusses a fifth type of analysis in which probability functions are used to model the uncertainty surrounding three variables (rule cost, exposure reduction, and attributable bladder cancer risk) in order to derive a probability distribution function for annual net benefit of the Stage I rule. Because there is little actual data on these probability functions, this approach should be considered illustrative only. It is not discussed further here, but is discussed in Chapter 6 of the RIA for the Stage 1 DBPR (EPA, 1998g).

While any one of the above analytical approaches by itself may not make a definitive case for the benefit-cost effectiveness for the Stage 1 DBPR, taken collectively EPA believes they indicate that the Stage 1 DBPR benefits to society will exceed the costs. The monetized benefits in the five alternatives represent only a portion of total potential benefits. Benefits associated with other cancer sites (rectal and colon) and other health endpoints (such as developmental and reproductive effects) could not be quantified at this time, and while they could be nil, they also could be quite large. Based on a careful weighing of the projected costs against the potential quantified and non-quantified benefits, EPA has determined that the benefits of the rule justify its costs.

F. Summary of Comments

Many commenters expressed concern about the wide range of benefits given the high national cost of the rule. EPA has revised the benefits analysis; and while the associated uncertainties remain large, EPA believes the benefits of the Stage 1 DBPR justify its costs.

Other commenters expressed concern with using the data from Morris *et al.* (1992) for quantifying benefits. They believed that the studies used in the meta-analysis were different in design and thus not appropriate to use in meta-analysis. In addition the commenters believed that potential confounding factors or bias may not have been adequately controlled in the selected studies. Others believed there was utility in using the meta-analysis to provide a perspective on the potential cancer risks. Several commenters were supportive of the Poole (1997) evaluation of the Morris *et al.* (1992) meta-analysis stating that they concurred that the Morris analysis should not be used for estimating benefits for the Stage 1 DBPR. Other commenters suggested a better use of the resources used to complete the Poole report would have been to complete a new meta-analysis using the more recent studies that have come out since the Morris *et al.* (1992) meta-analysis and that the Poole evaluation did not advance the science in this area. Several commenters were critical of the PAR analysis (described in EPA, 1998a) used to characterize the potential baseline bladder cancer cases per year that could be attributable to exposure to chlorinated drinking water. They present several arguments including: questioning whether such an analysis is warranted given the inconsistencies in the studies used to complete the analysis; stating that the use of the term upper bound of any suggested risk of cancer is inappropriate because this does not include the potential risks from other cancer sites such as colon and rectal; using the assumption of causality is not warranted given the inconsistencies in the studies used to complete the PAR analysis; and the PAR analysis should include a lower bound estimate of zero.

EPA agrees that the use of the Morris *et al.* (1992) meta-analysis for estimating benefits is not appropriate for the reasons cited by commenters (e.g., studies of different designs and discussed in more detail in the 1998 DBP NODA). EPA is currently considering whether a new meta-analysis that uses the most recent epidemiology studies would be useful for the Stage 2 rulemaking. The Poole (1997) report considered a meta analysis of the available data. Poole used several techniques to evaluate the data and included several new studies that were available at the time of his analysis. Poole concluded that the cancer epidemiology data considered in his evaluation should not be combined into a single summary estimated and that the data had limited utility for risk assessment purposes. More recent studies by Cantor *et al.* (1998), Doyle *et al.* (1997) and Freedman *et al.* (1997) were not available at the time of his evaluation.

EPA understands commenters concerns with the PAR analysis, especially concerns with assuming "causality" in the PAR evaluation when it is stated in other sections of the preamble that EPA does not believe causality has been established. Even though causality has not been established, EPA is required to estimate the potential impacts of major regulations such as the DBP Stage 1 rule. The Agency believes it is appropriate to conduct the PAR analysis as described in the 1998 DBP NODA (EPA, 1998a), to provide estimates of the

potential risk that may need to be reduced. EPA agrees that the use of the term "upper bound of any suggested risk" is not appropriate because there are other potential risks that have not been quantified that may contribute to the overall risk estimates. In addition, EPA agrees that the estimates of the potential cancer cases should include zero as this is a possibility given the uncertainties in the data. EPA agrees that several assumptions are made in the analysis regarding the national extrapolation of the results and that there is insufficient information at this time to validate these assumptions. However, given the need to develop national estimates of risk, EPA believes it is appropriate to make these assumptions in order to provide a perspective on the potential risks from exposure to chlorinated surface waters.

Commenters expressed concerns with the high costs associated with systems that must adopt alternative advanced technologies, especially for small systems. Since the 1994 proposal, the projected national costs for the Stage 1 DBPR have dropped significantly (as discussed above). This is mainly due to the revised compliance forecast and lower membrane technology costs. In the revised compliance forecast, fewer systems using surface water will need advanced technologies to comply. This shift to lesser use of advanced technologies to comply with the Stage 1 DBPR also pertains to small systems (those serving less than 10,000 people).

Commenters expressed concern for the high costs associated with the Stage 2 DBPR and whether EPA would obtain enough information to adequately understand the risks that might be avoided to justify such a rule. EPA agrees that additional health effects information is needed before reproposing the Stage 2 DBPR and will address this issue in the next round of FACA deliberations. Based on new data generated through research, EPA will reevaluate the Stage 2 regulations and re-propose, as appropriate.

V. Other Requirements

A. Regulatory Flexibility Act

1. Today's Rule

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

Throughout the 1992–93 negotiated rulemaking process for the Stage 1 DBPR and IESWTR and in the July 1994 proposals for these rules, a small PWS was defined as a system serving fewer than 10,000 persons. This definition reflects the fact that the original 1979 standard for total trihalomethanes applied only to systems serving at least 10,000 people. The definition thus recognizes that baseline conditions from which systems serving fewer than 10,000 people will approach disinfection byproduct control and simultaneous control of microbial pathogens is different than that for systems serving 10,000 or more persons. EPA again discussed this approach to the definition of a small system for these rules in the 1998 DBP NODA (EPA, 1998a). EPA is continuing to define "small system" for purposes of this rule and the IESWTR as a system which serves fewer than 10,000 people.

The Agency has since proposed and taken comment on its intent to define "small entity" as a public water system that serves 10,000 or fewer persons for purposes of its regulatory flexibility assessments under the RFA for all future drinking water regulations. (See Consumer Confidence Reports Rule, 63 FR 7620, Feb. 13, 1998.) In that proposal, the Agency discussed the basis for its decision to use this definition and to use a single definition of small public water system whether the system was a "small business", "small nonprofit organization", or "small governmental jurisdiction." EPA also consulted with the Small Business Administration on the use of this definition as it relates to small businesses. Subsequently, the Agency has used this definition in developing its regulations under the Safe Drinking Water Act. This approach is virtually identical to the approach used in the Stage 1 DBPR and IESWTR. Since, EPA is not able to certify that the final Stage 1 DBPR will not have a significant economic impact on a substantial number of small entities, EPA has completed a final RFA and will publish a small entity compliance guidance to help small entities comply with this regulation.

2. Background and Analysis

The Regulatory Flexibility Act requires EPA to address the following when completing a final RFA: (1) state succinctly the objectives of, and legal basis for, the final rule; (2) summarize public comments on the initial RFA, the Agency's assessment of those comments, and any changes to the rule in response to the comments; (3) describe, and where feasible, estimate the number of small entities to which the final rule will apply; (4) describe the projected reporting, record keeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirements and the type of professional skills necessary for preparation of reports or records; and (5) describe the steps the Agency has taken to minimize the impact on small entities, including a statement of the reasons for selecting the chosen option and for rejecting other options which would alter the impact on small entities. EPA has considered and addressed all the above requirements in the Regulatory Impact Analysis (RIA) for the Stage 1 DBPR (EPA 1998g). The following is a summary of the RFA.

The first requirement is discussed in section I of today's rule. The second, third and fifth requirements are summarized below. The fourth requirement is discussed in V.B (Paperwork Reduction Act) and the Information Collection Requirement.

Number of Small Entities Affected. EPA estimates that 69,491 groundwater systems will be affected by the Stage 1 DBPR, with 68,171 (98%) of these systems serving less than 10,000 persons. Of the 68,171 small systems affected, EPA estimates that 8,323 (12%) will have to modify treatment to comply with the Stage 1 DBPR. Of these, 5,403 systems (8%) will use chloramines to comply and 2,921 systems (4.3%) will use membranes to comply. Use of these technologies by small groundwater systems will result in total capital costs of $998 million and an annualized treatment cost of $180 million.

EPA estimates that 6,560 surface water systems will be affected by the Stage 1 DBPR, with 5,165 (79%) of these systems serving less than 10,000 persons. It is estimated that 3,616 (70%) of these small systems will have to modify treatment to comply with the Stage 1 DBPR and 3,459 (67%) of these systems will use a combination of enhanced coagulation, chloramines, and ozone, while another 157 systems (3%) will use membranes. Use of these technologies by small surface water systems will result in total capital costs of $243 million and an annualized treatment cost of $46 million.

EPA has included several provisions which will reduce the economic burden of compliance for these small systems. These requirements, discussed in greater detail in the RIA (EPA, 1998g), include:

—Less routine monitoring. Small systems are required to monitor less frequently for such contaminants as TTHMs and HAA5. Also, ground water systems (the large majority of small systems) are required to monitor less frequently than Subpart H systems (surface water systems and groundwater under the direct influence of surface water) of the same size.

—Extended compliance dates. Systems that use only ground water not under the direct influence of surface water serving fewer than 10,000 people have 60 months from promulgation of this rule to comply. This is in contrast to large Subpart H systems which have 36 months to comply. These extended compliance dates will allow smaller systems to learn from the experience of larger systems on how to most cost effectively comply with the Stage 1 DBPR. In addition, larger systems will generate a significant amount of treatment and cost data from the ICR and in their efforts to achieve compliance with the Stage 1 requirements. EPA intends to summarize this information and make it available through guidance manuals (i.e., the Small Entities Guidance Manual). EPA believes this information will assist smaller systems in achieving compliance with the Stage 1 DBPR.

3. Summary of Comments

Several commenters expressed concern with the significant economic burden that the Stage 1 DBPR would place on small systems. Other commenters suggested more flexibility be given for small systems and that a longer compliance period for small systems should be included in the final Stage 1 DBPR. Several commenters suggested small systems should not be included in the final Stage 1 DBPR because the costs for implementing the rule would exceed the potential benefits for these systems.

EPA understands commenters' concerns with the potential significant economic burden on small systems. Because of this potential significant impact, EPA has provided several requirements which will reduce the burden on these systems. These requirements which are discussed above and also in greater detail in the RIA (EPA, 1998g) include: (1) less routine monitoring; and (2) extended compliance dates. EPA also believes small systems can reduce their economic burden by; (1) consolidation with larger systems; (2) using money from the State revolving fund loans; and (3) using variances and exemptions when needed. EPA considered an option in the development of the final rule for large systems to have MCLs of 80 ug/L for TTHMs and 60 ug/L for HAAs and for small systems to have a simple TTHM standard of 100 ug/L. This option was rejected because allowing small systems to comply with a different MCL level would not adequately protect the health of the population served by these systems. EPA did not consider excluding small systems from the Stage 1 DBPR, because these systems do not currently have any standards for DBPs and the Agency believed there was a public health concern that needed to be addressed. For a more detailed description of the alternatives considered in the development of the final rule see the final RIA (EPA, 1998g) or the final Unfunded Mandates Reform Act Analysis for the Stage 1 DBPR (EPA, 1998o).

B. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2040–0204.

The information collected as a result of this rule will allow the States and the EPA to evaluate PWS compliance with the rule. For the first three years after promulgation of the Stage 1 DBPR, the major information requirements pertain to preparation for monitoring activities, and for compliance tracking. Responses to the request for information are mandatory (Part 141). The information collected is not confidential.

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

EPA estimates that the annual burden on PWS and States for reporting and recordkeeping will be 314,471 hours. This is based on an estimate that there will be 4,631 respondents on average per year who will need to provide about 9,449 responses and that the average response will take 33 hours. The annual labor cost is estimated to be about $12 million. In the first 3 years after promulgation of the rule, only labor costs are incurred. The costs are incurred for the following activities: reading and understanding the rule; planning; and training.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15. EPA is amending the table in 40 CFR Part 9 of currently approved ICR control numbers issued by OMB for various regulations to list the information requirements contained in this final rule. This ICR was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is "good cause" under section 553 (b)(B) of the Administrative Procedures Act (5 U.S.C. 553 (b) (B)) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

C. Unfunded Mandates Reform Act

1. Summary of UMRA Requirements

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under UMRA section 202, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule, for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective or least burdensome alternative if the Administrator publishes with the final

rule an explanation on why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed, under section 203 of the UMRA, a small government agency plan. The plan must provide for notification to potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates; and informing, educating, and advising small governments on compliance with the regulatory requirements.

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

EPA has determined that this rule contains a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, and the private sector in any one year. Accordingly, EPA has prepared, under section 202 of the UMRA, a written statement addressing the following areas: (1) authorizing legislation; (2) cost-benefit analysis including an analysis of the extent to which the costs to State, local and Tribal governments will be paid for by the federal government; (3) estimates of future compliance costs and disproportionate budgetary effects; (4) macro-economic effects; and (5) a summary of EPA's consultation with State, local, and Tribal governments, and a summary of their concerns, and a summary of EPA's evaluation of their concerns. A more detailed description of this analysis is presented in EPA's Unfunded Mandates Reform Act Analysis for the Stage 1 DBP Rule (EPA, 1998o) which is included in the docket for this rule.

a. Authorizing Legislation. Today's rule is promulgated pursuant to Section 1412(b)(2) of the 1996 amendments to the SDWA; paragraph C of this section establishes a statutory deadline of November 1998 to promulgate this rule. This rule supersedes the TTHM Rule (EPA, 1979). In addition, the Stage 1 DBP rule is closely integrated with the IESWTR, which also has a statutory deadline of November 1998.

b. Cost Benefit Analysis. Section IV discusses the cost and benefits associated with the Stage 1 DBP rule. Also, the EPA's Regulatory Impact Analysis of the Stage 1 Disinfectants/Disinfection Byproducts Rule (EPA, 1998g) contains a detailed cost benefit analysis. Today's rule is expected to have a total annualized cost of approximately $701 million using a 7 percent cost of capital. The analysis includes both qualitative and monetized benefits for improvements to health and safety. Because of scientific uncertainty regarding the exposure assessment and the risk assessment for DBPs, the Agency has used five analytical approaches to assess the benefits of the Stage 1 DBP. These analyses were based on the quantification of bladder cancer health damages avoided. However, this rule may also reduce colon and rectal cancers, as well as decrease adverse reproductive and developmental effects. This would further increase the benefits of this rule.

Various Federal programs exist to provide financial assistance to State, local, and Tribal governments in complying with this rule. The Federal government provides funding to States that have primary enforcement responsibility for their drinking water programs through the Public Water Systems Supervision Grants program. Additional funding is available from other programs administered either by EPA or other Federal agencies. These include the Drinking Water State Revolving Fund (DWSRF) and Housing and Urban Development's Community Development Block Grant Program. For example, SDWA authorizes the Administrator of the EPA to award capitalization grants to States, which in turn can provide low cost loans and other types of assistance to eligible public water systems. The DWSRF assists public water systems with financing the costs of infrastructure needed to achieve or maintain compliance with SDWA requirements. Each State will have considerable flexibility to determine the design of its program and to direct funding toward its most pressing compliance and public health protection needs. States may also, on a matching basis, use up to ten percent of their DWSRF allotments for each fiscal year to assist in running the State drinking water program.

c. Estimates of Future Compliance Costs and Disproportionate Budgetary Effects. To meet the UMRA requirement in section 202, EPA analyzed future compliance costs and possible disproportionate budgetary effects. The Agency believes that the cost estimates, indicated above and discussed in more detail in Section IV of this rule, accurately characterize future compliance costs of the rule.

In regard to the disproportionate impacts, EPA considered available data sources in analyzing the disproportionate impacts upon geographic or social segments of the nation or industry. This analysis was difficult because impacts will most likely depend on a system's source water characteristics and this data is not available for all systems. However, it should be noted that the rule uniformly protects the health of all drinking water system users regardless of the size or type of system. Further analysis revealed that no geographic or social segment patterns were likely for this rule. One observation is that the historical pattern of development in this country led most large cities to be developed near rivers and other bodies of water useful for power, transportation, and drinking water. To the extent that this rule affects surface water, it in most ways reflects the distribution of population and geography of the nation. No rationale for disproportionate impacts by geography or social segment was identified. This analysis, therefore, developed three other measures: reviewing the impacts on small systems versus large systems; reviewing the costs to public versus private water systems; and reviewing the household costs of the final rule.

First, the national impacts on small systems (those serving fewer than 10,000 people) versus large systems (those serving 10,000 people or more) is indicated in Table V–1. The higher cost to the small ground water systems is mostly attributable to the large number of these types of systems (i.e. there are 68,171 small ground water systems, 1,320 large ground water systems, 5,165 small surface water systems, and 1,395 large surface water surface water systems).

TABLE V–1.—ANNUAL COST OF COMPLIANCE FOR SMALL AND LARGE SYSTEMS ($000)*

	Small systems (population <10,000)	Large systems (population ≥10,000)
Surface Water Systems (All)	$56,804	$278,321

TABLE V–1.—ANNUAL COST OF COMPLIANCE FOR SMALL AND LARGE SYSTEMS ($000)*—Continued

	Small systems (population <10,000)	Large systems (population ≥10,000)
Ground Water System (All)	218,062	130,651
Total	274,866	408,972

*Costs calculated at a 7 percent cost of capital and include one time start-up costs.

The second measure of disproportionate impact evaluated is the relative total costs to public versus private water systems, by size. EPA believes the implementation of the rule affects both public and private water systems equally, with the variance in total cost by system size merely a function of the number of affected systems.

The third measure, household costs, can also be used to gauge the impact of a regulation and to determine whether there are disproportionately high impacts in particular segments of the population. A detailed analysis of household cost impacts by system size and system type are presented in Section IV.E. In summary, for large surface water systems EPA estimates that 98 percent of households will incur costs of less than $1 per month while 0.3 percent of households will incur costs greater than $10 per month. For large groundwater systems, EPA estimates that 95 percent of households will incur costs of less than $1 per month while 1.0 percent of households will incur costs greater than $10 per month. For small surface water systems EPA estimates the 71 percent of households will incur costs of less than $1 per month while 1 percent of households will incur costs of greater than $10 per month. For small groundwater systems EPA estimates that 91 percent of households will incur costs of less than $1 per month while 4 percent of households will incur costs of greater than $10 per month.

The household analysis tends to overestimate the costs per household because of the structure and assumptions of the methodology. For example, the highest per-household cost would be incurred in a system using membrane technology. These systems, conversely, might seek less costly alternatives such as point-of-use devices, selection of alternative water sources, or connecting into a larger regional water system. The overall effect is that costs are higher in smaller systems, and a higher percentage of those systems are publicly owned. Smaller systems, however, represent a larger portion of systems that are not in compliance with existing regulations. EPA believes that smaller systems incurring the highest household costs may also incur the highest reduction in risk. This is because smaller systems have not had to previously comply with a TTHMs standard of 100 ug/L. In the RIA, EPA estimates that on average, small systems will achieve about twice as much reduction in risk as achieved by larger systems (EPA,1998g).

Based on the analysis above, EPA does not believe there will be disproportionate impacts on small systems, public versus private systems, or generally by household. A more detailed description of this analysis is presented in the EPA's Unfunded Mandates Reform Act Analysis for the Stage 1 DBP Rule (EPA,1998o).

d. Macro-economic Effects. As required under UMRA Section 202, EPA is required to estimate the potential macro-economic effects of the regulation. Macro-economic effects tend to be measurable in nationwide econometric models only if the economic impact of the regulation reaches 0.25 percent to 0.5 percent of Gross Domestic Product (GDP). In 1997, real GDP was $7,188 billion so a rule would have to cost at least $18 billion to have a measurable effect. A regulation with a smaller aggregate effect is unlikely to have any measurable impact unless it is highly focused on a particular geographic region or economic sector. The macro-economic effects on the national economy from the Stage 1 DBPR should be negligible based on the fact that the total annual costs are about $701 million per year (at a 7 percent cost of capital) and the costs are not expected to be highly focused on a particular geographic region or sector.

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

After the amendments to SDWA in 1996, the Agency initiated a second FACA process, similarly involving a broad range of stakeholders, and held meetings during 1997 to address the expedited deadline for promulgation of the Stage 1 DBPR in November 1998. EPA established the M–DBP Advisory Committee to collect, share, and analyze new data reviewed since the earlier Reg. Neg. process and also to build a consensus on the regulatory implications of this new information. The M–DBP Advisory Committee established a technical working group to assist them with the many scientific issues surrounding this rule. The Committee included representatives from organizations such as the National League of Cities, the National Association of City and County Health Officials, the Association of Metropolitan Water Agencies, the Association of State Drinking Water Administrators, and the National Association of Water Companies. In addition, the Agency invited the Native American Water Association to participate in the FACA process to develop this rule. Although they eventually decided not to take part, the Association continued to be informed of meetings and developments through a stakeholders mailing list.

Stakeholders who participated in the FACA processes, as well as all other interested members of the public, were invited to comment on the proposed rule and NODAs. Also, as part of the Agency's Communication Strategy, EPA sent copies of the proposed rule and NODAs to many stakeholders, including six tribal associations.

In addition, the Agency notified governmental entities and the private

sector of opportunities to provide input on this Stage 1 DBPR in the **Federal Register** on July 29, 1994 (59 FR 38668—EPA, 1994A), November 3, 1997 (62 FR 59485—EPA, 1997b), and on March 31, 1998 (63 FR 15974—EPA, 1998a). Additionally, EPA extended the comment period for the March 31, 1998 NODA and announced a public meeting to address new information. EPA received approximately 213 written comments on the July 29, 1994 notice, approximately 57 written comments on the November 3, 1997 notice, and approximately 41 written comments on the March 31, 1998 notice. Of the 213 comments received concerning the 1994 proposed rule, 11% were from States and 41% were from local governments. Also, one comment on the 1994 proposal was from a tribal group that represented 43 tribes. Of the 57 comments received concerning the 1997 Notice of Data Availability, 18% were from States and 37% were from local governments. Of the 41 comments received on the 1998 Notice of Data Availability prior to the close of the comment period, 5% were from States and 15% were from local governments.

The public docket for this rulemaking contains all comments received by the Agency and provides details about the nature of State, local, and tribal government's concerns. State and local governments raised several concerns including: the need for the Stage 1 DBPR; the high costs of the rule in relation to the uncertain benefits; the belief that not allowing predisinfection credit would increase the microbial risk; and the need for flexibility in implementing the Stage 1 DPBR and IESWTR to insure the rules are implemented simultaneously. The one tribal comment noted that compliance would come at a cost of diverting funds away from other important drinking water needs such as maintaining drinking water infrastructure.

EPA understands the State, local, and tribal governments concerns with the costs of the rule and the need to provide additional public health protection for the expenditure. The Agency believes the final Stage 1 DPBR will provide public health benefits to individuals by reducing their exposures to DBPs, while not requiring excessive capital expenditures. As discussed above, the majority of households will incur additional costs of less than $1 per month. As discussed in section III.E, the final rule maintains the existing predisinfection credit. Finally, in the 1997 DBP NODA (EPA, 1997b), EPA requested comment on four alternative schedules for complying with the Stage 1 DBPR. Most State and local commenters preferred the option which provides the maximum flexibility allowed under the SDWA for systems to comply with the Stage 1 DBPR, and this is the option EPA selected for the final rule.

f. Regulatory Alternatives Considered. As required under Section 205 of the UMRA, EPA considered several regulatory alternatives developed by the Reg Neg Committee and M–DBP Advisory Committee and suggested by stakeholders.

The Reg Neg Committee considered several options including a proposed TTHMs MCL of 80 μg/L and HAA5 MCL of 60 μg/L for large systems (and a simple standard of 100 μg/l for small systems). Another option called for the use of precursor removal technology to reduce the level of total organic carbon with alternative levels ranging from 4.0 to 0.5. Other options evaluated included a 80 μg/L for TTHMs, 60 μg/L for HAA5, and 4.0 for TOC. Finally, an option was evaluated of a 80 μg/L for TTHMs, 60 μg/L for HAA5, and 5.0 for TOC. The final consensus included a combination of MCLs which would be equal for all system size categories and a target TOC level. Allowing small systems to comply with a different MCL levels was rejected because the rule would not adequately protect the health of the population served by these systems. A more detailed description of these alternatives is discussed in the document Unfunded Mandates Reform Act Analysis for the Stage 1 DBPR Rule which can be found in the docket (EPA, 1998o).

Other regulatory alternatives were considered by the M–DBP Advisory Committee and these alternatives had the overall effect of reducing the cost of the final rule. For example, the M–DBP Advisory Committee recommended maintaining the predisinfection credit after reviewing data which suggested that many systems could probably meet the proposed MCLs for DBPs while maintaining current disinfection practices. This decision was important because systems would have had to incur large capital costs to remain in compliance with disinfection requirements if predisinfection credits were disallowed. Thus by allowing predisinfection, the overall cost of the rule was lowered.

Also, the Committee recommended exempting systems for the enhanced coagulation requirements based on their raw water quality. For example, systems with raw-water TOC of less than or equal to 2.0 mg/L and raw-water SUVA of less than or equal to 2.0 L/mg-m would be exempt from the enhanced coagulation requirements. This exclusion was intended to promote cost-effective enhanced coagulation (i.e., obtaining efficiencies of TOC removal without excessive sludge production and associated costs).

In conclusion, EPA believes that the alternative selected for the Stage 1 DBPR is the most cost-effective option that achieves the objectives of the rule. For a complete discussion of this issue see EPA's Regulatory Impact Analysis of the Stage 1 Disinfectants/Disinfection Byproducts Rule (EPA,1998g).

3. Impacts on Small Governments

The 1994 Stage 1 DBPR proposal was done without the benefit of the UMRA requirements. However, in preparation for the final rule, EPA conducted analysis on small government impacts and included small government officials or their designated representatives in the rule making process. The FACA processes gave a variety of stakeholders, including small governments, the opportunity for timely and meaningful participation in the regulatory development process. Representatives of small government organizations were on both the Reg. Neg. Committee and the M–DBP Advisory Committee and their representatives attended public stakeholder meetings. Groups such as the National Association of City and County Health Officials and the National League of Cities participated in the rulemaking process. Through such participation and exchange, EPA notified potentially affected small governments of requirements under consideration and provided officials of affected small governments with an opportunity to have meaningful and timely input into the development of regulatory proposals.

In addition, EPA will educate, inform, and advise small systems including those run by small government about DBPR requirements. One of the most important components of this process is the Small Entity Compliance Guide, as required by the Small Business Regulatory Enforcement Fairness Act of 1996. This plain-English guide will explain what actions a small entity must take to comply with the rule. Also, the Agency is developing fact sheets that concisely describe various aspects and requirements of the DBPR.

D. 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 OMB, an explanation of the reasons for not using such standards.

EPA's process for selecting the analytical test methods is consistent with section 12(d) of the NTTAA. EPA performed literature searches to identify analytical methods from industry, academia, voluntary consensus standards bodies, and other parties that could be used to measure disinfectants, DBPs, and other parameters. In addition, EPA's selection of the methods benefited from the recommendations of an Advisory Committee established under the FACA Act to assist the Agency with the Stage 1 DBPR. The Committee made available additional technical experts who were well-versed in both existing analytical methods and new developments in the field.

The results of these efforts form the basis for the analytical methods in today's rule which includes: eight methods for measuring different DBPs, of which five are EPA methods and three are voluntary consensus standards; nine methods for measuring disinfectants, all of which are voluntary consensus standards; three voluntary consensus methods for measuring TOC; two EPA methods for measuring bromide; one voluntary consensus method for measuring UV_{254}, and both governmental and voluntary consensus methods for measuring alkalinity. Where applicable voluntary consensus standards were not approved, this was due to their inability to meet the data quality objectives (e.g. accuracy, sensitivity, quality control procedures) necessary for demonstration of compliance with the relevant requirement.

In the 1997 NODA, EPA requested comment on voluntary consensus standards that had not been addressed and which should be considered for addition to the list of approved analytical methods in the final rule. No additional consensus methods were suggested by commenters.

E. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, (58 FR 41344—EPA, 1993c) the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

1. Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

3. Materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it will have an annual effect on the economy of $100 million or more. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the public record.

F. Executive Order 12898: Environmental Justice

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agency missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. The Agency has considered environmental justice related issues concerning the potential impacts of this action and has consulted with minority and low-income stakeholders.

Two aspects of today's rule comply with the Environmental Justice Executive Order which requires the Agency to consider environmental justice issues in the rulemaking and to consult with Environmental Justice (EJ) stakeholders. They can be classified as follows: (1) the overall nature of the rule, and (2) the convening of a stakeholder meeting specifically to address environmental justice issues. The Stage 1 DBPR applies to community water systems and nontransient noncommunity water systems that treat their water with a chemical disinfectant for either primary or residual treatment. Consequently, the health protection benefits this rule provides are equal across all income and minority groups within these communities.

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

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

In addition, EPA developed a plain-English guide specifically for this meeting to assist stakeholders in understanding the multiple and sometimes complex issues surrounding drinking water regulation.

Overall, EPA believes this rule will equally protect the health of all minority and low-income populations served by systems regulated under this rule from exposure to DBPs.

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

Executive Order 13045 applies to any rule initiated after April 21, 1997, or proposed after April 21, 1998, that (1) is determined to be "economically significant" as defined under E.O. 12866 and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

The final Stage 1 DBPR is not subject to the Executive Order because EPA published a notice of proposed rulemaking before April 21, 1998.

However, EPA's policy since November 1, 1995, is to consistently and explicitly consider risks to infants and children in all risk assessments generated during its decision making process including the setting of standards to protect public health and the environment.

EPA's Office of Water has historically considered risks to sensitive populations (including fetuses, infants, and children) in establishing drinking water assessments, advisories or other guidance, and standards (EPA, 1989c and EPA, 1991). The disinfection of public drinking water supplies to prevent waterborne disease is the most successful public health program in U.S. history. However, numerous chemical byproducts (DBPs) result from the reaction of chlorine and other disinfectants with naturally occurring organic and inorganic material in source water, and these may have potential health risks. Thus, maximizing health protection for sensitive subpopulations requires balancing risks to achieve the recognized benefits of controlling waterborne pathogens while minimizing risk of potential DBP toxicity. Human experience shows that waterborne disease from pathogens in drinking water is a major concern for children and other subgroups (elderly, immune compromised, pregnant women) because of their greater vulnerabilities (Gerba et al., 1996). Based on animal studies, there is also a concern for potential risks posed by DBPs to children and pregnant women (EPA, 1994a; EPA, 1998a).

In developing this regulation, risks to sensitive subpopulations (including fetuses and children) were taken into account in the assessments of disinfectants and disinfection byproducts. A description of the data available for evaluating risks to children and the conclusions drawn can be found in the public docket for this rulemaking (EPA, 1998h). In addition, the Agency has evaluated alternative regulatory options and selected the option that will provide the greatest benefits for all people including children. See the regulatory impact analysis for a complete discussion of the different options considered. It should also be noted that the IESTWR, which accompanies this final rule, provides better controls of pathogens and achieves the goal of increasing the protection of children.

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

In accordance with section 1412 (d) and (e) of the Act, the Agency submitted the proposed Stage 1 DBP rule to the Science Advisory Board, National Drinking Water Advisory Council (NDWAC), and the Secretary of Health and Human Services for their review. EPA has evaluated comments received from these organizations and considered them in developing the final Stage 1 DBP rule.

I. Executive Order 12875: Enhancing the Intergovernmental Partnership

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

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

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

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

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

EPA has concluded that this rule will significantly affect communities of Indian tribal governments. It will also impose substantial direct compliance costs on such communities, and the Federal government will not provide all the funds necessary to pay the direct costs incurred by the tribal governments in complying with the rule. In developing this rule, EPA consulted with representatives of tribal governments pursuant to both Executive Order 12875 and Executive Order 13084. EPA's consultation, the nature of the governments' concerns, and EPA's position supporting the need for this rule are discussed above in the preamble section that addresses compliance with Executive Order 12875. Specifically in developing this rule, the Agency invited the Native American Water Association to participate in the FACA process to develop this rule. Although they eventually decided not to take part, the Association continued to be informed of meetings and developments through a stakeholders mailing list. As described in Section V.C.2.e of the discussion on

UMRA, EPA held extensive meetings that provided the opportunity for meaningful and timely input in the development of the proposed rule. Summaries of the meetings have been included in the public docket for this rulemaking.

K. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective February 16, 1999.

L. Likely Effect of Compliance With the Stage 1 DBPR on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of the SDWA as amended requires that, in promulgating a NPDWR, the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, financial, and managerial capacity of public water systems. The following analysis has been performed to fulfill this statutory obligation.

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

Technical capacity is the physical and operational ability of a water system to meet SDWA requirements. Technical capacity refers to the physical infrastructure of the water system, including the adequacy of source water and the adequacy of treatment, storage, and distribution infrastructure. It also refers to the ability of system personnel to adequately operate and maintain the system and to otherwise implement requisite technical knowledge. A water system's technical capacity can be determined by examining key issues and questions, including:

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

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

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

- Ownership accountability. Are the system owner(s) clearly identified? Can they be held accountable for the system?
- Staffing and organization. Are the system operator(s) and manager(s) clearly identified? Is the system properly organized and staffed? Do personnel understand the management aspects of regulatory requirements and system operations? Do they have adequate expertise to manage water system operations? Do personnel have the necessary licenses and certifications?
- Effective external linkages. Does the system interact well with customers, regulators, and other entities? Is the system aware of available external resources, such as technical and financial assistance?

Financial capacity is a water system's ability to acquire and manage sufficient financial resources to allow the system to achieve and maintain compliance with SDWA requirements.

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

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

There are 76,051 systems affected by this rule. Of these, 12,998 will have to modify their treatment process and undertake disinfectant and DBP monitoring and reporting. Some of this smaller group may also be required to do DBP precursor monitoring and reporting. The other 63,063 systems will need to do disinfectant and DBP monitoring and reporting, but will not need to modify their treatment process. Some of this larger group may also be required to do DBP precursor monitoring and reporting.

Systems not modifying treatment are not generally expected to require significantly increased technical, financial, or managerial capacity to comply with these new requirements. Certainly some individual facilities may have weaknesses in one or more of these areas but overall, systems should have or be able to obtain the capacity needed for these activities.

Systems needing to modify treatment will employ one or more of a variety of steps. The steps expected to be employed by 50% or more of subpart H systems and by eight percent or more of ground water systems covered by the rule include a combination of low cost alternatives, including switching to chloramines for residual disinfection, moving the point of disinfectant application, and improving precursor removal. EPA estimates that less than seven percent of systems in any category will resort to higher cost alternatives, such as switching to ozone or chloramines for primary disinfection or using GAC or membranes for precursor removal. These higher cost alternatives may also provide other treatment benefits, so the cost may be somewhat offset by eliminating the need for technologies to remove other contaminants. Some of these systems may choose nontreatment alternatives such as consolidation with another system or changing to a higher quality water source.

Furthermore, there are a number of actions that are expected to be taken disproportionately by smaller sized systems (that is to say, a greater percentage of smaller sized systems will undertake than will larger sized systems). These steps include increased plant staffing and additional staff training to understand process control strategy. Small systems will be required to do this since larger systems have already undertaken these changes to

some extent for compliance with the 1979 TTHM rule.

For many systems serving less than 10,000 persons which need to make treatment modifications, an enhancement of technical, financial, and managerial capacity may likely be needed. As the preceding paragraph makes clear, these systems will be making structural improvements and enhancing laboratory and staff capacity. Larger sized systems have typically already made these improvements as part of normal operations. Meeting the requirements of the Stage 1 DBPR will require operating at a higher level of sophistication and in a better state of repair than some plants serving less than 10,000 people have considered acceptable in the past.

Certainly there will be exceptions in systems serving both below 10,000 persons and above. Some larger plants will doubtless find their technical, managerial, and financial capacity taxed by the new requirements. Likewise, some plants serving less than 10,000 persons will already have more than adequate technical, financial, and managerial capacity to meet these requirements. However, in general, the systems serving less than 10,000 persons needing to make treatment modifications will be the ones most needing to enhance their capacity.

VI. References

1. APHA. 1992. Standard Methods for the Examination of Water and Wastewater, 18th Edition. American Public Health Association, Washington, DC.
2. APHA. 1995. Standard Methods for the Examination of Water and Wastewater, 19th Edition. American Public Health Association, Washington DC.
3. APHA. 1996. Standard Methods for the Examination of Water and Wastewater, 19th Edition, Supplement. American Public Health Association, Washington DC.
4. ASTM. 1993. Methods D-1067-88B, D-2035-80. Annual Book of ASTM Standards. Vol. 11.01, American Society for Testing and Materials.
5. ASTM. 1994. Methods D-1067-92B. Annual Book of ASTM Standards. Vol. 11.01, American Society for Testing and Materials.
6. ASTM. 1996. Methods D-1253-86. Annual Book of ASTM Standards. Vol. 11.01, American Society for Testing and Materials.
7. Bove, F.J., et al. 1995. Public Drinking Water Contamination and Birth Outcomes. Amer. J. Epidemiol., 141(9), 850-862.
8. Bull, R.J. and Kopfler, F.C. 1991. Health Effects of Disinfectants and Disinfection Byproducts. Prepared for the American Water Works Research Foundation.
9. Cantor K. P., Hoover R., Hartge P., et al. 1985. Drinking Water Source and Bladder Cancer: A Case-Control Study. In Jolley R.L., Bull R.J., Davis W.P., et al. (eds), Water Chlorination: Chemistry, Environmental Impact and Health Effects, Vol. 5. Lewis Publishers, Inc., Chelsea, MI pp 145-152.
10. Cantor K.P., Hoover R., Hartge P. et al. 1987. Bladder Cancer, Drinking Water Source and Tap Water Consumption: A Case Control Study. JNCI; 79:1269-79.
11. Cantor K.P., Lunch C.F., Hildesheim M., Dosemeci M., Lubin J., Alavanja M., Craun G.F.. 1998. Drinking Water Source and Chlorination Byproducts. I. Risk of Bladder Cancer. Epidemiology; 9:21-28.
12. Chowdhury, Z. 1997. Presentation to Technical Work Group January, 1997. Cincinnati, OH.
13. Clark, S.C., J. Wiginton, and J.T. Musgrove. 1994. Enhanced Lime Softening: Is Your TOC Removal Maxed Out? AWWA Enhanced Coagulation Workshop, December 1994.
14. CMA. 1996. Sodium Chlorite: Drinking Water Rat Two-Generation Reproductive Toxicity Study. Chemical Manufacturers Association. Quintiles Report Ref. CMA/17/96.
15. CMA. 1998. Letter to Michael Cox, U.S. EPA, OGWDW. From Marian K. Stanley, Chemical Manufacturers Association. Regarding the two-generation reproduction/developmental neurotoxicity study with sodium chlorite. January 26, 1998. 20 pp.
16. DeAngelo, A. B., Daniel, F. B., Most, B. M. and G. R. Olsen. 1997. The Failure of Monochloroacetic Acid and Trichloroacetic Acid Administered in the Drinking Water to Produce Liver Cancer in Male F344/N rats. J. Toxicol. Environ. Health (in press).
17. DeAngelo A. B., George M. H., Kilburn S. R., Moore T. M., Wolf D. C. 1998. Carcinogenicity of Potassium Bromate Administered in the Drinking Water to Make B6C3F1 Mice and F344/N Rats, Toxicologic Pathology vol.26, No.4 (in press).
18. Doyle T. J., Sheng W., Cerhan J. R., Hong C. P., Sellers T. A., Kushi, L. H., Folsom A. R. 1997. The Association of Drinking Water Source and Chlorination By-products with Cancer Incidence Among Postmenopausal Women in Iowa: A Prospective Cohort Study. American Journal of Public Health. 87:7.
19. Edwards, M. 1997. Predicting DOC Removal During Enhanced Coagulation. Jour. AWWA (89:5:78).
20. Edzwald, J. K., and J. E. Van Benschoten. 1990. Aluminum Coagulation of Natural Organic Matter. Proc. Fourth Int'l Gothenburg Symposium on Chemical Treatment, Madrid, Spain (Oct. 1990).
21. Federal Focus. 1996. Principles for Evaluating Epidemiological Data in Regulatory Risk Assessment. Developed By An Expert Panel at a Conference in London, England October 1995. Appendix B: The "Bradford Hill" or "Surgeon General's" Criteria for Judging the Causal Significance of an Exposure-Effect Association Indicated by an Epidemiological Study or Studies. August 1996. Federal Focus, Inc. Washington, DC.
22. Freedman M., Cantor K. P., Lee N. L., Chen L. S., Lei H. H., Ruhl C. E., and Wang S. S. 1997. Bladder cancer and drinking water: a population-based case-control study in Washington County, Maryland (United States). Cancer Causes and Control. 8, pp 738-744.
23. Gerba, CP., J.B Rose, and C.N Haas. 1996. Sensitive Populations: Who is at the Greatest Risk. Int. J. Food and Microbiology. 30:113-123.
24. Heywood R., Sortwell R.J., Noel PRB, Street AE, Prentice DE, Roe FJC, Wadsworth PF, Worden AN, Van Abbe NJ. 1979. Safety Evaluation of Toothpaste Containing Chloroform. III. Long-term Study in Beagle Dogs. J. Environ. Pathol. Toxicol. 2:835-851.
25. Hildesheim M.E., Cantor K.P., Lynch C.F., Dosemeci M., Lubin J., Alavanja M., and Craun G.F. 1998. Drinking Water Source and Chlorination Byproducts: Risk of Colon and Rectal Cancers. Epidemiology. 9:1, pp: 29-35.
26. ILSI. 1997. An Evaluation of EPA's Proposed Guidelines for Carcinogen Risk Assessment Using Chloroform and Dichloroacetate as Case Studies: Report of an Expert Panel. International Life Sciences Institute, Health and Environmental Sciences Institute November, 1997.
27. Jorgenson T.A., Meierhenry E.F., Rushbrook C.J. Bull RJ, Robinson M. 1985. Carcinogenicity of Chloroform in Drinking Water to Male Osborne-Mendel Rats and Female B6C3F1 Mice. Fundam. Appl. Toxicol. 5:760-769.
28. Kanitz, S. et al. 1996. Association Between Drinking Water Disinfection and Somatic Parameters at Birth. Environ. Health Perspectives, 104(5), 516-520.
29. Kaplan, L.A. 1992. Comparison of High Temperature and Persulfate Oxidation Methods for Determination of Dissolved Organic Carbon in Freshwaters. Limnol. Oceanogr. 37 (5): 1119-25.
30. King, W. D. and L. D. Marrett. 1996. Case-Control Study of Water Source and Bladder Cancer. Cancer Causes and Control, 7:596-604.
31. Klotz, J. B. and Pyrch, L. A. 1998. A Case-Control Study of Neural Tube Defects and Drinking Water Contaminants. New Jersey Department of Health and Senior Services.
32. Krasner, Stuart. April 1997. Issue Paper on Enhanced Coagulation to the M-DBP Advisory Committee.

33. Kurokawa et al. 1986a. Dose-response Studies on the Carcinogenicity of Potassium Bromate in F344 Rats after Long-term Oral Administration. J. Natl. Cancer Inst. 77:977–982.
34. Kurokawa et al. 1986b. Long-term *in vitro* Carcinogenicity Tests of Potassium Bromate, Sodium Hypochlorite and Sodium Chlorite Conducted in Japan. Environ. Health Perspect. 69:221–236.
35. McGeehin, M.A. et al. 1993. Case-Control Study of Bladder Cancer and Water Disinfection Methods in Colorado. Am. J. Epidemiology, 138:492–501.
36. Mobley, S. A., D. H. Taylor, R. D. Laurie, and R. J. Pfohl. 1990. Chlorine dioxide depresses T3 uptake and delays development of locomotor activity in young rats. In: Water Chlorination: Chemistry, Environmental Impact and Health Effects. Vol 6. Lolley, Condie, Johnson, Katz, Mattice and Jacobs, ed. lewis Publ., Inc. Chelsea MI., pp 347–360.
37. Morris, R. D. et al. 1992. Chlorination, Chlorination By-products, and Cancer: A Meta-Analysis. American Journal of Public Health, 82(7): 955–963.
38. Moser, G. September 9, 1997. Letter to Yogi Patel, U.S. EPA, OW. Regarding the Neurodevelopment Section of the CMA Study of Chlorite.
39. NTP. 1985. National Toxicology Program. Toxicology and carcinogenesis studies of chlorodibromomethane in F344/N rats and B6C3F$_1$ mice (gavage studies). Tech. Rep. Ser. No. 282.
40. NTP. 1987. National Toxicology Program. Toxicity and carcinogenesis studies of bromodichloromethane in F344/N rats and B6C3F$_1$ mice (gavage studies). Technical Report Series No. 321.
41. NTP. 1989. National Toxicology Program. Toxicology and carcinogenesis studies of bromoform in F344/N rats and B6C3F$_1$ mice (gavage studies). Tech. Rep. Ser. No. 350.
42. NTP. 1990. National Toxicology Program. NTP Technical Report on the Toxicology and Carcinogenesis studies of chlorinated and chloraminated water in F344/N rats and B6C3F$_1$ mice (drinking water studies). NTP TR 392, National Institutes of Health, 474pp.
43. Orme, J. D.H. Taylor, R.D. Laurie, and R.J. Bull. 1985. Effects of Chlorine Dioxide on Thyroid Function in Neonatal Rats. J. Tox. and Environ. Health. 15:315–322.
44. OSTP. 1985. Chemical Carcinogens; A Review of the Science and Its Associated Principles, February 1985. Presented in Risk Analysis: A guide to Principles and Methods for Analyzing Health and Environmental Risks. Appendix G. **Federal Register**, March 14, 1985. Pages 10371–10442.
45. Owen, D. M.; Amy, G. L. and Z. K. Chowdhury. 1993. Characterization of Natural Organic Matter and Its Relationship to Treatability. AWWA Research Foundation & AWWA, Denver, CO.
46. Poole, C. 1997. Analytical Meta-Analysis of Epidemiological Studies of Chlorinated Drinking Water and Cancer: Quantitative Review and Reanalysis of the Work Published by Morris et al., Am J Public Health 1992:82:955–963. National Center for Environmental Assessment, Office of Research and Development, September 30, 1997.
47. Randtke, S. J.; Hoehn, R. C.; Knocke, W. R.; Dietrich, A. M.; Long, B. W.; and N. A. Wang. 1994. Comprehensive Assessment of DBP Precursor Removal by Enhanced Coagulation and Softening. Proc. AWWA Ann. Conf. (Water Quality), New York, NY, pp. 737–777.
48. Reif, J. S. et al. 1996. Reproductive and Developmental Effects of Disinfection By-products in Drinking Water. Environmental Health Prospectives. 104(10):1056–1061.
49. Sanders, V.M., B.M. Kauffman, K.L. White, K.A. Douglas, D.W. Barnes, L.E. Sain, T.J. Bradshaw, J.F. Borzelleca and A.E. Munson. 1982. Toxicology of chloral hydrate in the mouse. Environ. Health Perspect. 44:137–146.
50. Savitz, D. A., Andrews, K. W. and L. M. Pastore. 1995. Drinking Water and Pregnancy Outcome in Central North Carolina: Source, Amount, and Trihalomethane levels. Environ. Health Perspectives. 103(6), 592–596.
51. Shorney, H. L., Randtke, S. J., Hargette, P. H., Mann, P. D., Hoehn, R.C., Knocke, W. R., Dietrich, A. M. and B. W. Long. 1996. The Influence of Raw Water Quality on Enhanced Coagulation and Softening for the Removal of NOM and DBP Formation Potential, Proceedings 1996 AWWA Annual Conference, Toronto, Ontario, Canada.
52. Singer, P. C., Harrington, G. W., Thompson, J. D. and M. C. White. 1995. Enhanced Coagulation and Enhanced Softening for the Removal of Disinfection By-Product Precursors: An Evaluation. Report prepared for the AWWA Government Affairs Office, Washington, DC, by the Dept. of Environmental Sciences and Engineering, UNC, Chapel Hill, NC.
53. Singer, P. C., Harrington, G. W., Thompson, J. and M. White. 1996. Enhanced Coagulation and Enhanced Softening for the Removal of Disinfection By-Product Precursors: An Evaluation, Report to AWWA Disinfectants/ Disinfection By-Products Technical Advisory Workgroup of the Water Utility Council, December 1996.
54. Smith, M.K., Randall, J.L., Read, E.J., and Stober, J.A. 1989. Teratogenic activity of trichloroacetic acid in the rat. Teratology 40:445–451.
55. Summers, R.S., G. Solarik, V.A. Hatcher, R.S. Isabel, and J.F. Stile. 1997. Analyzing the Impacts of Predisinfection Through Jar Testing, Proceedings, AWWA Water Quality Technology Conference, Denver, CO.
56. Tseng, T. and M. Edwards. 1997. Considerations in Optimizing Coagulation. Proc. 1996 AWWA Water Qual. Technol. Conf., Boston, Mass.
57. U.S. EPA. 1979. National Interim Primary Drinking Water Regulations; Control of Trihalomethanes in Drinking Water. Fed. Reg., 44:231:68624. (November 29, 1979)
58. U.S. EPA. 1983. EPA Method 310.1. Methods of Chemical Analysis of Water and Wastes. Envir. Monitoring Systems Laboratory, Cincinnati, OH. EPA 600/4–79–020. 460 pp.
59. U.S. EPA. 1986. Guidelines for Carcinogen Risk Assessment, Fed. Reg. 51(185):33992–34003. EPA/600/8–87/045. NTIS PB88–123997.
60. U.S. EPA. 1987. Drinking Water Regulations; Public Notification; Final Rule. Federal Register. Vol. 52, No. 208, Wednesday, Oct. 28, 1987—Part II. pp. 41534–41550.
61. U.S. EPA. 1988. EPA Method 502.2. Methods for the Determination of Organic Compounds in Drinking Water. EPA 600/4–88–039. PB91–231480. Revised July 1991.
62. U.S. EPA. 1989a. National Primary Drinking Water Regulations; Filtration, Disinfection; Turbidity, Giardia lamblia, Viruses, Legionella, and Heterotrophic Bacteria; Final Rule. Part II. Fed. Reg., 54:124:27486. (June 29, 1989)
63. U.S. EPA 1989b. National Primary Drinking Water Regulations; Total Coliforms (Including Fecal Coliform and E. Coli); Final Rule. Fed. Reg., 54:124:27544. (June 29, 1989)
64. U.S. EPA. 1989c. Review of Environmental Contaminants and Toxicology. USEPA. Office of Drinking Water Health Advisories, Volume 106. 225pp.
65. U.S. EPA. 1990. EPA Methods 551, 552. Methods for the Determination of Organic Compounds in Drinking Water—Supplement I. EPA 600/4–90–020. PB91–146027.
66 U.S. EPA. 1991. National Primary Drinking Water Regulations: Final Rule. Fed, reg., 56:20, January 30, 1991 3526–3597.
67. U.S. EPA. 1992. EPA Methods 524.2, 552.1. Methods for the Determination of Organic Compounds in Drinking Water—Supplement II. EPA 600/R–92/129. PB92–207703.
68. U.S. EPA. 1993a. Draft Drinking Water Health Criteria Document for Bromate. Office of Science and Technology, Office of Water. Sep. 30, 1993.
69. U.S. EPA. 1993b. EPA Method 300.0. The Determination of Inorganic Anions by Ion Chromatography in the Manual "Methods for the Determination of Inorganic Substances in Environmental Samples," EPA/600/R/93/100. NTIS, PB94120821.
70. U.S. EPA. 1993c. Executive Order 12866: Regulatory Planning and Review. **Federal Register.** Vol. 58, No. 190. October 4, 1993. 51735–51744.
71. U.S. EPA/ILSI. 1993. A Review of Evidence on Reproductive and Developmental Effects of Disinfection By-Products in Drinking Water. Washington: U.S. Environmental Protection Agency and International Life Sciences Institute.

72. U.S. EPA. 1994a. National Primary Drinking Water Regulations; Disinfectants and Disinfection Byproducts; Proposed Rule. Fed. Reg., 59:145:38668. (July 29, 1994).
73. U.S. EPA. 1994b. National Primary Drinking Water Regulations; Enhanced Surface Water Treatment Requirements; Proposed Rule. Fed. Reg., 59:145:38832. (July 29, 1994).
74. U.S. EPA. 1994c. National Primary Drinking Water Regulations; Monitoring Requirements for Public Drinking Water Supplies; Proposed Rule. Fed. Reg., 59:28:6332. (February 10, 1994).
75. U.S. EPA. 1994d. Final Draft Drinking Water Health Criteria Document for Chlorine Dioxide, Chlorite and Chlorate. Office of Science and Technology, Office of Water. March 31, 1994.
76. U.S. EPA. 1994e. Draft Drinking Water Health Criteria Document for Chlorine, Hypochlorous Acid and Hypochlorite Ion. Office of Science and Technology, Office of Water.
77. U.S. EPA. 1994f. Health and Ecological Criteria Div., OST. Final Draft for the Drinking Water Criteria Document on Trihalomethanes. Apr. 8. 1994.
78. U.S. EPA. 1994g. Draft Drinking Water Health Criteria Document for Chlorinated Acetic Acids/Alcohols/ Aldehydes and Ketones. Office of Science and Technology, Office of Water.
79. U.S. EPA. 1994h. Draft Drinking Water Health Criteria Document for Chloramines. Office of Science and Technology, Office of Water.
80. U.S. Environmental Protection Agency. 1994i. Regulatory Impact Analysis of Proposed Disinfectant/Disinfection Byproduct Regulations. Washington, DC. EPA-68-C3-0368.
81. U.S. EPA. 1995. Methods for the Determination of Organic Compounds in Drinking Water. Supplement III. EPA-600/R-95/131. NTIS, PB95261616.
82. U.S. EPA. 1996a. National Primary Drinking Water Regulations: Monitoring Requirements for Public Drinking Water Supplies; Final Rule. Fed. Reg., 61:94:24354. (May 14, 1996)
83. U.S. EPA. 1996b. Proposed Guidelines for Carcinogen Risk Assessment. U.S. EPA, April 23, 1996.
84. U.S. EPA. 1997a. National Primary Drinking Water Regulations; Interim Enhanced Surface Water Treatment Rule; Notice of Data Availability; Proposed Rule. Fed. Reg., 62 (No. 212): 59486-59557. (November 3, 1997).
85. U.S. EPA. 1997b. National Primary Drinking Water Regulations; Disinfectants and Disinfection Byproducts; Notice of Data Availability; Proposed Rule. Fed. Reg., 62 (No. 212): 59388-59484. (November 3, 1997).
86. U.S. EPA. 1997c. Summaries of New Health Effects Data. Office of Science and Technology, Office of Water. October 1997.
87. U.S. EPA. 1997d. External Peer Review of CMA Study -2- Generation, EPA Contract No. 68-C7-0002, Work Assignment B-14, The Cadmus Group, Inc., October 9, 1997.
88. U.S. EPA. 1997e. Method 300.1. Determination of Inorganic Anions in Drinking Water by Ion Chromatography. Revision 1.0. USEPA National Exposure Research Laboratory, Cincinnati OH.
89. U.S. EPA. 1997f. Performance Based Measurement System. Notice of Intent. Federal Register, October 6, 1997. Vol. 62, No. 193., 52098-52100.
90. U.S. EPA. 1997g. Manual for the Certification of Laboratories Analyzing Drinking Water, Fourth Edition, Office of Water Resource Center (RC-4100), EPA 815-B-97-001. March 1997.
91. U.S. EPA. 1998a. National Primary Drinking Water Regulations; Disinfectants and Disinfection Byproducts; Notice of Data Availability; Proposed Rule. Fed. Reg., 63 (No. 61): 15606-15692. (March 31, 1998).
92. U.S. EPA. 1998b. Dichloroacetic acid: Carcinogenicity Identification Characterization Summary. National Center for Environmental Assessment—Washington Office. Office of Research and Development. March 1998. EPA 815-B-98-010. PB 99-111387.
93. U.S. EPA. 1998c. Quantification of Bladder Cancer Risk from Exposure to Chlorinated Surface Water. Office of Science and Technology, Office of Water. November 9, 1998.
94. U.S. EPA. 1998d. Health Risk Assessment/Characterization of the Drinking Water Disinfection Byproduct Chlorine Dioxide and the Degradation Byproduct Chlorite. Office of Science and Technology, Office of Water. October 15, 1998. EPA 815-B-98-008. PB 99-111361.
95. U.S. EPA. 1998e. Health Risk Assessment/Characterization of the Drinking Water Disinfection Byproduct Bromate. Office of Science and Technology, Office of Water. September 30, 1998. EPA 815-B-98-007. PB 99-111353.
96. U.S. EPA. 1998f. Panel Report and Recommendation for Conducting Epidemiological Research on Possible Reproductive and Developmental Effects of Exposure to Disinfected Drinking Water. Office of Research and Development. February 12, 1998.
97. U.S. EPA. 1998g. Regulatory Impact Analysis of Final Disinfectant/ Disinfection By-Products Regulations. Washington, D.C. EPA Number 815-B-98-002. PB 99-111304.
98. U.S. EPA. 1998h. Health Risks to Fetuses, Infants, and Children (final Stage 1 DBP Rule). Office of Science and Technology. Office of Water. November 19, 1998. EPA 815-B-98-009. PB 99-111379.
99. U.S. EPA. 1998i. Revisions to State Primacy Requirements To Implement Safe Drinking Water Act Amendments: Final Rule. **Federal Register**, Tuesday, April 28, 1998, Vol. 63, No.81, 23362-23368.
100. U.S. EPA. 1998j. Revision of Existing Variance and Exemption Regulations to Comply with Requirements of the Safe Drinking Water Act; Final Rule. **Federal Register**, Vol 63, No. 157. Friday, Aug. 14, 1998. pp. 43833-43851.
101. U.S. EPA. 1998k. Cost and Technology Document for Controlling Disinfectants and Disinfection Byproducts. Office of Ground Water and Drinking Water. Washington, DC. EPA 815-R-98-014. PB 99-111486.
102. U.S. EPA. 1998l. Synthesis of the Peer-Review of Meta-analysis of Epidemiologic Data on Risks of Cancer from Chlorinated Drinking Water. National Center for Environmental Assessment, Office of Research and Development, February 16, 1998.
103. U.S. EPA. 1998m. NCEA Position Paper Regarding Risk Assessment Use of the Results from the Published Study: Morris et al. Am J Public Health 1992;82:955-963. National Center for Environmental Assessment, Office of Research and Development, October 7, 1997.
104. U.S. EPA. 1998n. A Suggested Approach for Using the Current Epidemiologic Literature to Estimate the Possible Cancer Risk from Water Chlorination, for the Purposes of the Regulatory Impact Analysis. ORD, National Center for Environmental Assessment. August 27, 1998.
105. U.S. EPA. 1998o. Unfunded Mandates Reform Act Analysis for the Stage 1 Disinfectant and Disinfection Byproduct Rule. Office of Groundwater and Drinking Water.
106. U.S. EPA. 1998p. Health Risk Assessment/Characterization of the Drinking Water Disinfection Byproduct Chloroform. Office of Science and Technology, Office of Water. November 4, 1998. EPA 815-B-98-006. PB 99-111346.
107. U.S. EPA. 1998q. Small System Compliance Technology List for the Stage 1 DBP Rule. Office of Groundwater and Drinking Water. EPA 815-R-98-017. PB 99-111510.
108. U.S. EPA. 1998r. Technologies and Costs for Point-of-Entry (POE) and Point-of-Use (POU) Devices for Control of Disinfection Byproducts. Office of Groundwater and Drinking Water. EPA 815-R-98-016. PB 99-111502.
109. U.S. EPA. 1998s. National-Level Affordability Criteria Under the 1996 Amendments to the Safe Drinking Water Act. Office of Groundwater and Drinking Water. August 19, 1998.
110. U.S. EPA. 1998t. Variance Technology Findings for Contaminants Regulated Before 1996. Office of Water. September 1998. EPA 815-R-98-003.
111. U.S. EPA. 1998u. Occurrence Assessment for Disinfectants and Disinfection Byproducts in Public Drinking Water Supplies. Office of Groundwater and Drinking Water. EPA 815-B-98-004. November 13, 1998. PB 99-111320.
112. USGS. 1989. Method I-1030-85. Techniques of Water Resources Investigations of the U.S. Geological Survey. Book 5, Chapter A-1, 3rd ed., U.S. Government Printing Office.
113. Waller K., Swan S. H., DeLorenze G., Hopkins B., 1998. Trihalomethanes in drinking water and spontaneous abortion. Epidemiology. 9(2):134-140.

114. White, M. C., Thompson, D., Harrington, G. W., and P.S. Singer. 1997. Evaluating Criteria for Enhanced Coagulation Compliance. *AWWA*, 89:5:64.
115. Xie, Yuefeng. 1995. Effects of Sodium Chloride on DBP Analytical Results, Extended Abstract, Division of Environmental Chemistry, American Chemical Society Annual Conference, Chicago, IL, Aug. 21–26, 1995.

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Parts 141 and 142

Analytical methods, Drinking water, Environmental protection, Incorporation by reference, Intergovernmental relations, Public utilities, Reporting and recordkeeping requirements, Utilities, Water supply.

Dated: November 30, 1998.

Carol M. Browner,

Administrator.

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

PART 9—[AMENDED]

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

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

2. In § 9.1 the table is amended by adding under the indicated heading: the new entries in numerical order to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
National Primary Drinking Water Regulations	
* * * * *	
141.130–141.132	2040–0204
141.134–141.135	2040–0204
* * * * *	

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

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

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

4. Section 141.2 is amended by adding the following definitions in alphabetical order to read as follows:

§ 141.2 Definitions.

* * * * *

Enhanced coagulation means the addition of sufficient coagulant for improved removal of disinfection byproduct precursors by conventional filtration treatment.

* * * * *

Enhanced softening means the improved removal of disinfection byproduct precursors by precipitative softening.

* * * * *

GAC10 means granular activated carbon filter beds with an empty-bed contact time of 10 minutes based on average daily flow and a carbon reactivation frequency of every 180 days.

* * * * *

Haloacetic acids (five) (HAA5) mean the sum of the concentrations in milligrams per liter of the haloacetic acid compounds (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid), rounded to two significant figures after addition.

* * * * *

Maximum residual disinfectant level (MRDL) means a level of a disinfectant added for water treatment that may not be exceeded at the consumer's tap without an unacceptable possibility of adverse health effects. For chlorine and chloramines, a PWS is in compliance with the MRDL when the running annual average of monthly averages of samples taken in the distribution system, computed quarterly, is less than or equal to the MRDL. For chlorine dioxide, a PWS is in compliance with the MRDL when daily samples are taken at the entrance to the distribution system and no two consecutive daily samples exceed the MRDL. MRDLs are enforceable in the same manner as maximum contaminant levels under Section 1412 of the Safe Drinking Water Act. There is convincing evidence that addition of a disinfectant is necessary for control of waterborne microbial contaminants. Notwithstanding the MRDLs listed in § 141.65, operators may increase residual disinfectant levels of chlorine or chloramines (but not chlorine dioxide) in the distribution system to a level and for a time necessary to protect public health to address specific microbiological contamination problems caused by circumstances such as distribution line breaks, storm runoff events, source water contamination, or cross-connections.

* * * * *

Maximum residual disinfectant level goal (MRDLG) means the maximum level of a disinfectant added for water treatment at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. MRDLGs are nonenforceable health goals and do not reflect the benefit of the addition of the chemical for control of waterborne microbial contaminants.

* * * * *

Subpart H systems means public water systems using surface water or ground water under the direct influence of surface water as a source that are subject to the requirements of subpart H of this part.

* * * * *

SUVA means Specific Ultraviolet Absorption at 254 nanometers (nm), an indicator of the humic content of water. It is a calculated parameter obtained by dividing a sample's ultraviolet absorption at a wavelength of 254 nm (UV_{254}) (in m^{-1}) by its concentration of dissolved organic carbon (DOC) (in mg/L).

* * * * *

Total Organic Carbon (TOC) means total organic carbon in mg/L measured using heat, oxygen, ultraviolet irradiation, chemical oxidants, or combinations of these oxidants that convert organic carbon to carbon dioxide, rounded to two significant figures.

* * * * *

5. Section 141.12 is revised to read as follows:

§ 141.12 Maximum contaminant levels for total trihalomethanes.

The maximum contaminant level of 0.10 mg/L for total trihalomethanes (the sum of the concentrations of bromodichloromethane, dibromochloromethane, tribromomethane (bromoform), and trichloromethane (chloroform)) applies to subpart H community water systems which serve a population of 10,000 people or more until December 16, 2001. This level applies to community water systems that use only ground water not under the direct influence of surface water and serve a population of 10,000 people or more until December

16, 2003. Compliance with the maximum contaminant level for total trihalomethanes is calculated pursuant to § 141.30. After December 16, 2003, this section is no longer applicable.

6. Section 141.30 is amended by revising the the first sentences in paragraphs (d) and (f) and adding paragraph (h) to read as follows:

§ 141.30 Total trihalomethanes sampling, analytical and other requirements.

* * * * *

(d) Compliance with § 141.12 shall be determined based on a running annual average of quarterly samples collected by the system as prescribed in paragraph (b)(1) or (2) of this section. * * *

* * * * *

(f) Before a community water system makes any significant modifications to its existing treatment process for the purposes of achieving compliance with § 141.12, such system must submit and obtain State approval of a detailed plan setting forth its proposed modification and those safeguards that it will implement to ensure that the bacteriological quality of the drinking water served by such system will not be adversely affected by such modification. * * *

* * * * *

(h) The requirements in paragraphs (a) through (g) of this section apply to subpart H community water systems which serve a population of 10,000 or more until December 16, 2001. The requirements in paragraphs (a) through (g) of this section apply to community water systems which use only ground water not under the direct influence of surface water that add a disinfectant (oxidant) in any part of the treatment process and serve a population of 10,000 or more until December 16, 2003. After December 16, 2003, this section is no longer applicable.

7. Section 141.32 is amended by revising the heading in paragraph (a) introductory text, the first sentence of paragraph (a)(1)(iii) introductory text, and the first sentence of paragraph (c), and adding paragraphs (a)(1)(iii)(E) and (e) (76) through (81), to read as follows:

§ 141.32 Public notification.

* * * * *

(a) *Maximum contaminant levels (MCLs), maximum residual disinfectant levels (MRDLs).* * * *

(1) * * *

(iii) For violations of the MCLs of contaminants or MRDLs of disinfectants that may pose an acute risk to human health, by furnishing a copy of the notice to the radio and television stations serving the area served by the public water system as soon as possible but in no case later than 72 hours after the violation. ***

* * * * *

(E) Violation of the MRDL for chlorine dioxide as defined in § 141.65 and determined according to § 141.133(c)(2).

* * * * *

(c) * * * The owner or operator of a community water system must give a copy of the most recent public notice for any outstanding violation of any maximum contaminant level, or any maximum residual disinfectant level, or any treatment technique requirement, or any variance or exemption schedule to all new billing units or new hookups prior to or at the time service begins.

* * * * *

(e) * * *

(76) *Chlorine.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that chlorine is a health concern at certain levels of exposure. Chlorine is added to drinking water as a disinfectant to kill bacteria and other disease-causing microorganisms and is also added to provide continuous disinfection throughout the distribution system. Disinfection is required for surface water systems. However, at high doses for extended periods of time, chlorine has been shown to affect blood and the liver in laboratory animals. EPA has set a drinking water standard for chlorine to protect against the risk of these adverse effects. Drinking water which meets this EPA standard is associated with little to none of this risk and should be considered safe with respect to chlorine.

(77) *Chloramines.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that chloramines are a health concern at certain levels of exposure. Chloramines are added to drinking water as a disinfectant to kill bacteria and other disease-causing microorganisms and are also added to provide continuous disinfection throughout the distribution system. Disinfection is required for surface water systems. However, at high doses for extended periods of time, chloramines have been shown to affect blood and the liver in laboratory animals. EPA has set a drinking water standard for chloramines to protect against the risk of these adverse effects. Drinking water which meets this EPA standard is associated with little to none of this risk and should be considered safe with respect to chloramines.

(78) *Chlorine dioxide.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that chlorine dioxide is a health concern at certain levels of exposure. Chlorine dioxide is used in water treatment to kill bacteria and other disease-causing microorganisms and can be used to control tastes and odors. Disinfection is required for surface water systems. However, at high doses, chlorine dioxide-treated drinking water has been shown to affect blood in laboratory animals. Also, high levels of chlorine dioxide given to laboratory animals in drinking water have been shown to cause neurological effects on the developing nervous system. These neurodevelopmental effects may occur as a result of a short-term excessive chlorine dioxide exposure. To protect against such potentially harmful exposures, EPA requires chlorine dioxide monitoring at the treatment plant, where disinfection occurs, and at representative points in the distribution system serving water users. EPA has set a drinking water standard for chlorine dioxide to protect against the risk of these adverse effects.

Note: In addition to the language in this introductory text of paragraph (e)(78), systems must include either the language in paragraph (e)(78)(i) or (e)(78)(ii) of this section. Systems with a violation at the treatment plant, but not in the distribution system, are required to use the language in paragraph (e)(78)(i) of this section and treat the violation as a nonacute violation. Systems with a violation in the distribution system are required to use the language in paragraph (e)(78)(ii) of this section and treat the violation as an acute violation.

(i) The chlorine dioxide violations reported today are the result of exceedances at the treatment facility only, and do not include violations within the distribution system serving users of this water supply. Continued compliance with chlorine dioxide levels within the distribution system minimizes the potential risk of these violations to present consumers.

(ii) The chlorine dioxide violations reported today include exceedances of the EPA standard within the distribution system serving water users. Violations of the chlorine dioxide standard within the distribution system may harm human health based on short-term exposures. Certain groups, including pregnant women, infants, and young children, may be especially susceptible to adverse effects of excessive exposure to chlorine dioxide-treated water. The purpose of this notice is to advise that such persons should consider reducing their risk of adverse effects from these chlorine dioxide violations by seeking alternate sources of water for human consumption until such exceedances are rectified. Local

and State health authorities are the best sources for information concerning alternate drinking water.

(79) *Disinfection byproducts and treatment technique for DBPs.* The United States Environmental Protection Agency (EPA) sets drinking water standards and requires the disinfection of drinking water. However, when used in the treatment of drinking water, disinfectants react with naturally-occurring organic and inorganic matter present in water to form chemicals called disinfection byproducts (DBPs). EPA has determined that a number of DBPs are a health concern at certain levels of exposure. Certain DBPs, including some trihalomethanes (THMs) and some haloacetic acids (HAAs), have been shown to cause cancer in laboratory animals. Other DBPs have been shown to affect the liver and the nervous system, and cause reproductive or developmental effects in laboratory animals. Exposure to certain DBPs may produce similar effects in people. EPA has set standards to limit exposure to THMs, HAAs, and other DBPs.

(80) *Bromate.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that bromate is a health concern at certain levels of exposure. Bromate is formed as a byproduct of ozone disinfection of drinking water. Ozone reacts with naturally occurring bromide in the water to form bromate. Bromate has been shown to produce cancer in rats. EPA has set a drinking water standard to limit exposure to bromate.

(81) *Chlorite.* The United States Environmental Protection Agency (EPA) sets drinking water standards and has determined that chlorite is a health concern at certain levels of exposure. Chlorite is formed from the breakdown of chlorine dioxide, a drinking water disinfectant. Chlorite in drinking water has been shown to affect blood and the developing nervous system. EPA has set a drinking water standard for chlorite to protect against these effects. Drinking water which meets this standard is associated with little to none of these risks and should be considered safe with respect to chlorite.

* * * * *

8. Subpart F is amended by revising the subpart heading and adding §§ 141.53 and 141.54 to read as follows:

Subpart F—Maximum Contaminant Level Goals and Maximum Residual Disinfectant Level Goals

* * * * *

§ 141.53—Maximum contaminant level goals for disinfection byproducts.

MCLGs for the following disinfection byproducts are as indicated:

Disinfection byproduct	MCLG (mg/L)
Chloroform	Zero
Bromodichloromethane	Zero
Bromoform	Zero
Bromate	Zero
Dichloroacetic acid	Zero
Trichloroacetic acid	0.3
Chlorite	0.8
Dibromochloromethane	0.06

§ 141.54 Maximum residual disinfectant level goals for disinfectants.

MRDLGs for disinfectants are as follows:

Disinfectant residual	MRDLG(mg/L)
Chlorine	4 (as Cl_2).
Chloramines	4 (as Cl_2).
Chlorine dioxide	0.8 (as ClO_2)

9. Subpart G is amended by revising the subpart heading and adding §§ 141.64 and 141.65 to read as follows:

Subpart G—National Revised Primary Drinking Water Regulations: Maximum Contaminant Levels and Maximum Residual Disinfectant Levels

* * * * *

§ 141.64 Maximum contaminant levels for disinfection byproducts.

(a) The maximum contaminant levels (MCLs) for disinfection byproducts are as follows:

Disinfection byproduct	MCL (mg/L)
Total trihalomethanes (TTHM)	0.080
Haloacetic acids (five) (HAA5)	0.060
Bromate	0.010
Chlorite	1.0

(b) *Compliance dates.* (1) *CWSs and NTNCWSs.* Subpart H systems serving 10,000 or more persons must comply with this section beginning December 16, 2001. Subpart H systems serving fewer than 10,000 persons and systems using only ground water not under the direct influence of surface water must comply with this section beginning December 16, 2003.

(2) A system that is installing GAC or membrane technology to comply with this section may apply to the State for an extension of up to 24 months past the dates in paragraphs (b)(1) of this section, but not beyond December 16, 2003. In granting the extension, States must set a schedule for compliance and may specify any interim measures that the system must take. Failure to meet the schedule or interim treatment requirements constitutes a violation of a National Primary Drinking Water Regulation.

(c) The Administrator, pursuant to Section 1412 of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for disinfection byproducts identified in paragraph (a) of this section:

Disinfection by-product	Best available technology
TTHM	Enhanced coagulation or enhanced softening or GAC10, with chlorine as the primary and residual disinfectant
HAA5	Enhanced coagulation or enhanced softening or GAC10, with chlorine as the primary and residual disinfectant.
Bromate	Control of ozone treatment process to reduce production of bromate.
Chlorite	Control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.

§ 141.65 Maximum residual disinfectant levels.

(a) Maximum residual disinfectant levels (MRDLs) are as follows:

Disinfectant residual	MRDL (mg/L)
Chlorine	4.0 (as Cl_2).
Chloramines	4.0 (as Cl_2).
Chlorine dioxide	0.8 (as ClO_2).

(b) Compliance dates.

(1) CWSs and NTNCWSs. Subpart H systems serving 10,000 or more persons must comply with this section beginning December 16, 2001. Subpart H systems serving fewer than 10,000 persons and systems using only ground water not under the direct influence of surface water must comply with this subpart beginning December 16, 2003.

(2) Transient NCWSs. Subpart H systems serving 10,000 or more persons and using chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning December 16, 2001. Subpart H systems serving fewer than 10,000 persons and using chlorine dioxide as a disinfectant or oxidant and systems using only ground water not under the direct influence of surface water and using chlorine dioxide as a disinfectant or oxidant must comply with the

chlorine dioxide MRDL beginning December 16, 2003.

(c) The Administrator, pursuant to Section 1412 of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum residual disinfectant levels identified in paragraph (a) of this section: control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.

10. A new subpart L is added to read as follows:

Subpart L—Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors

Sec.
141.130 General requirements.
141.131 Analytical requirements.
141.132 Monitoring requirements.
141.133 Compliance requirements.
141.134 Reporting and recordkeeping requirements.
141.135 Treatment technique for control of disinfection byproduct (DBP) precursors.

§ 141.130 General requirements.

(a) The requirements of this subpart L constitute national primary drinking water regulations.

(1) The regulations in this subpart establish criteria under which community water systems (CWSs) and nontransient, noncommunity water systems (NTNCWSs) which add a chemical disinfectant to the water in any part of the drinking water treatment process must modify their practices to meet MCLs and MRDLs in §§ 141.64 and 141.65, respectively, and must meet the treatment technique requirements for disinfection byproduct precursors in § 141.135.

(2) The regulations in this subpart establish criteria under which transient NCWSs that use chlorine dioxide as a disinfectant or oxidant must modify their practices to meet the MRDL for chlorine dioxide in § 141.65.

(3) EPA has established MCLs for TTHM and HAA5 and treatment technique requirements for disinfection byproduct precursors to limit the levels of known and unknown disinfection byproducts which may have adverse health effects. These disinfection byproducts may include chloroform; bromodichloromethane; dibromochloromethane; bromoform; dichloroacetic acid; and trichloroacetic acid.

(b) *Compliance dates.* (1) *CWSs and NTNCWSs.* Unless otherwise noted, systems must comply with the requirements of this subpart as follows. Subpart H systems serving 10,000 or more persons must comply with this subpart beginning December 16, 2001. Subpart H systems serving fewer than 10,000 persons and systems using only ground water not under the direct influence of surface water must comply with this subpart beginning December 16, 2003.

(2) *Transient NCWSs.* Subpart H systems serving 10,000 or more persons and using chlorine dioxide as a disinfectant or oxidant must comply with any requirements for chlorine dioxide and chlorite in this subpart beginning December 16, 2001. Subpart H systems serving fewer than 10,000 persons and using chlorine dioxide as a disinfectant or oxidant and systems using only ground water not under the direct influence of surface water and using chlorine dioxide as a disinfectant or oxidant must comply with any requirements for chlorine dioxide and chlorite in this subpart beginning December 16, 2003.

(c) Each CWS and NTNCWS regulated under paragraph (a) of this section must be operated by qualified personnel who meet the requirements specified by the State and are included in a State register of qualified operators.

(d) *Control of disinfectant residuals.* Notwithstanding the MRDLs in § 141.65, systems may increase residual disinfectant levels in the distribution system of chlorine or chloramines (but not chlorine dioxide) to a level and for a time necessary to protect public health, to address specific microbiological contamination problems caused by circumstances such as, but not limited to, distribution line breaks, storm run-off events, source water contamination events, or cross-connection events.

§ 141.131 Analytical requirements.

(a) *General.* (1) Systems must use only the analytical method(s) specified in this section, or otherwise approved by EPA for monitoring under this subpart, to demonstrate compliance with the requirements of this subpart. These methods are effective for compliance monitoring February 16, 1999.

(2) The following documents are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at EPA's Drinking Water Docket, 401 M Street, SW, Washington, DC 20460, or at the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington DC. EPA Method 552.1 is in *Methods for the Determination of Organic Compounds in Drinking Water-Supplement II*, USEPA, August 1992, EPA/600/R-92/129 (available through National Information Technical Service (NTIS), PB92-207703). EPA Methods 502.2, 524.2, 551.1, and 552.2 are in *Methods for the Determination of Organic Compounds in Drinking Water-Supplement III*, USEPA, August 1995, EPA/600/R-95/131. (available through NTIS, PB95-261616). EPA Method 300.0 is in *Methods for the Determination of Inorganic Substances in Environmental Samples*, USEPA, August 1993, EPA/600/R-93/100. (available through NTIS, PB94-121811). EPA Method 300.1 is titled *USEPA Method 300.1, Determination of Inorganic Anions in Drinking Water by Ion Chromatography, Revision 1.0*, USEPA, 1997, EPA/600/R-98/118 (available through NTIS, PB98-169196); also available from: Chemical Exposure Research Branch, Microbiological & Chemical Exposure Assessment Research Division, National Exposure Research Laboratory, U.S. Environmental Protection Agency, Cincinnati, OH 45268, Fax Number: 513-569-7757, Phone number: 513-569-7586. Standard Methods 4500-Cl D, 4500-Cl E, 4500-Cl F, 4500-Cl G, 4500-Cl H, 4500-Cl I, 4500-ClO_2 D, 4500-ClO_2 E, 6251 B, and 5910 B shall be followed in accordance with *Standard Methods for the Examination of Water and Wastewater, 19th Edition*, American Public Health Association, 1995; copies may be obtained from the American Public Health Association, 1015 Fifteenth Street, NW, Washington, DC 20005. Standard Methods 5310 B, 5310 C, and 5310 D shall be followed in accordance with the *Supplement to the 19th Edition of Standard Methods for the Examination of Water and Wastewater*, American Public Health Association, 1996; copies may be obtained from the American Public Health Association, 1015 Fifteenth Street, NW, Washington, DC 20005. ASTM Method D 1253-86 shall be followed in accordance with the *Annual Book of ASTM Standards*, Volume 11.01, American Society for Testing and Materials, 1996 edition; copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohoken, PA 19428.

(b) *Disinfection byproducts.* (1) Systems must measure disinfection byproducts by the methods (as modified by the footnotes) listed in the following table:

APPROVED METHODS FOR DISINFECTION BYPRODUCT COMPLIANCE MONITORING

Methodology [2]	EPA method	Standard method	Byproduct measured [1]			
			TTHM	HAA5	Chlorite [4]	Bromate
P&T/GC/EICD & PID	[3]502.2		X			
P&T/GC/MS	524.2		X			
LLE/GC/ECD	551.1		X			
LLE/GC/ECD		6251 B		X		
SPE/GC/ECD	552.1			X		
LLE/GC/ECD	552.2			X		
Amperometric Titration		4500-ClO_2 E			X	
IC	300.0				X	
IC	300.1				X	X

[1] X indicates method is approved for measuring specified disinfection byproduct.
[2] P&T = purge and trap; GC = gas chromatography; EICD = electrolytic conductivity detector; PID = photoionization detector; MS = mass spectrometer; LLE = liquid/liquid extraction; ECD = electron capture detector; SPE = solid phase extractor; IC = ion chromatography.
[3] If TTHMs are the only analytes being measured in the sample, then a PID is not required.
[4] Amperometric titration may be used for routine daily monitoring of chlorite at the entrance to the distribution system, as prescribed in § 141.132(b)(2)(i)(A). Ion chromatography must be used for routine monthly monitoring of chlorite and additional monitoring of chlorite in the distribution system, as prescribed in § 141.132(b)(2)(i)(B) and (b)(2)(ii).

(2) Analysis under this section for disinfection byproducts must be conducted by laboratories that have received certification by EPA or the State. To receive certification to conduct analyses for the contaminants in § 141.64(a), the laboratory must carry out annual analyses of performance evaluation (PE) samples approved by EPA or the State. In these analyses of PE samples, the laboratory must achieve quantitative results within the acceptance limit on a minimum of 80% of the analytes included in each PE sample. The acceptance limit is defined as the 95% confidence interval calculated around the mean of the PE study data between a maximum and minimum acceptance limit of +/−50% and +/−15% of the study mean.

(c) *Disinfectant residuals.* (1) Systems must measure residual disinfectant concentrations for free chlorine, combined chlorine (chloramines), and chlorine dioxide by the methods listed in the following table:

APPROVED METHODS FOR DISINFECTANT RESIDUAL COMPLIANCE MONITORING

Methodology	Standard method	ASTM method	Residual Measured [1]			
			Free chlorine	Combined chlorine	Total chlorine	Chlorine dioxide
Amperometric Titration	4500-Cl D	D 1253–86	X	X	X	
Low Level Amperometric Titration	4500-Cl E				X	
DPD Ferrous Titrimetric	4500-Cl F		X	X	X	
DPD Colorimetric	4500-Cl G		X	X	X	
Syringaldazin e (FACTS)	4500-Cl H		X			
Iodometric Electrode	4500-Cl I				X	
DPD	4500-ClO_2 D					X
Amperometric Method II	4500-ClO_2 E					X

[1] X indicates method is approved for measuring specified disinfectant residual.

(2) If approved by the State, systems may also measure residual disinfectant concentrations for chlorine, chloramines, and chlorine dioxide by using DPD colorimetric test kits.

(3) A party approved by EPA or the State must measure residual disinfectant concentration.

(d) *Additional analytical methods.* Systems required to analyze parameters not included in paragraphs (b) and (c) of this section must use the following methods. A party approved by EPA or the State must measure these parameters.

(1) *Alkalinity.* All methods allowed in § 141.89(a) for measuring alkalinity.

(2) *Bromide.* EPA Method 300.0 or EPA Method 300.1.

(3) *Total Organic Carbon (TOC).* Standard Method 5310 B (High-Temperature Combustion Method) or Standard Method 5310 C (Persulfate-Ultraviolet or Heated-Persulfate Oxidation Method) or Standard Method 5310 D (Wet-Oxidation Method). TOC samples may not be filtered prior to analysis. TOC samples must either be analyzed or must be acidified to achieve pH less than 2.0 by minimal addition of phosphoric or sulfuric acid as soon as practical after sampling, not to exceed 24 hours. Acidified TOC samples must be analyzed within 28 days.

(4) *Specific Ultraviolet Absorbance (SUVA).* SUVA is equal to the UV absorption at 254nm (UV_{254}) (measured in m^{-1} divided by the dissolved organic carbon (DOC) concentration (measured as mg/L). In order to determine SUVA, it is necessary to separately measure UV_{254} and DOC. When determining SUVA, systems must use the methods stipulated in paragraph (d)(4)(i) of this section to measure DOC and the method stipulated in paragraph (d)(4)(ii) of this section to measure UV_{254}. SUVA must be determined on water prior to the addition of disinfectants/oxidants by the system. DOC and UV_{254} samples used to determine a SUVA value must be taken at the same time and at the same location.

(i) Dissolved Organic Carbon (DOC). Standard Method 5310 B (High-Temperature Combustion Method) or Standard Method 5310 C (Persulfate-Ultraviolet or Heated-Persulfate Oxidation Method) or Standard Method

5310 D (Wet-Oxidation Method). Prior to analysis, DOC samples must be filtered through a 0.45 µm pore-diameter filter. Water passed through the filter prior to filtration of the sample must serve as the filtered blank. This filtered blank must be analyzed using procedures identical to those used for analysis of the samples and must meet the following criteria: DOC < 0.5 mg/L. DOC samples must be filtered through the 0.45 µm pore-diameter filter prior to acidification. DOC samples must either be analyzed or must be acidified to achieve pH less than 2.0 by minimal addition of phosphoric or sulfuric acid as soon as practical after sampling, not to exceed 48 hours. Acidified DOC samples must be analyzed within 28 days.

(ii) Ultraviolet Absorption at 254 nm (UV_{254}). Method 5910 B (Ultraviolet Absorption Method). UV absorption must be measured at 253.7 nm (may be rounded off to 254 nm). Prior to analysis, UV_{254} samples must be filtered through a 0.45 µm pore-diameter filter. The pH of UV_{254} samples may not be adjusted. Samples must be analyzed as soon as practical after sampling, not to exceed 48 hours.

(5) *pH.* All methods allowed in § 141.23(k)(1) for measuring pH.

§ 141.132 Monitoring requirements.

(a) *General requirements.* (1) Systems must take all samples during normal operating conditions.

(2) Systems may consider multiple wells drawing water from a single aquifer as one treatment plant for determining the minimum number of TTHM and HAA5 samples required, with State approval in accordance with criteria developed under § 142.16(f)(5) of this chapter.

(3) Failure to monitor in accordance with the monitoring plan required under paragraph (f) of this section is a monitoring violation.

(4) Failure to monitor will be treated as a violation for the entire period covered by the annual average where compliance is based on a running annual average of monthly or quarterly samples or averages and the system's failure to monitor makes it impossible to determine compliance with MCLs or MRDLs.

(5) Systems may use only data collected under the provisions of this subpart or subpart M of this part to qualify for reduced monitoring.

(b) *Monitoring requirements for disinfection byproducts.* (1) *TTHMs and HAA5.* (i) *Routine monitoring.* Systems must monitor at the frequency indicated in the following table:

ROUTINE MONITORING FREQUENCY FOR TTHM AND HAA5

Type of system	Minimum monitoring frequency	Sample location in the distribution system
Subpart H system serving at least 10,000 persons.	Four water samples per quarter per treatment plant.	At least 25 percent of all samples collected each quarter at locations representing maximum residence time. Remaining samples taken at locations representative of at least average residence time in the distribution system and representing the entire distribution system, taking into account number of persons served, different sources of water, and different treatment methods.[1]
Subpart H system serving from 500 to 9,999 persons.	One water sample per quarter per treatment plant.	Locations representing maximum residence time.[1]
Subpart H system serving fewer than 500 persons.	One sample per year per treatment plant during month of warmest water temperature.	Locations representing maximum residence time.[1] If the sample (or average of annual samples, if more than one sample is taken) exceeds MCL, system must increase monitoring to one sample per treatment plant per quarter, taken at a point reflecting the maximum residence time in the distribution system, until system meets reduced monitoring criteria in paragraph (c) of this section.
System using only ground water not under direct influence of surface water using chemical disinfectant and serving at least 10,000 persons.	One water sample per quarter per treatment plant[2].	Locations representing maximum residence time.[1]
System using only ground water not under direct influence of surface water using chemical disinfectant and serving fewer than 10,000 persons.	One sample per year per treatment plant[2] during month of warmest water temperature.	Locations representing maximum residence time.[1] If the sample (or average of annual samples, if more than one sample is taken) exceeds MCL, system must increase monitoring to one sample per treatment plant per quarter, taken at a point reflecting the maximum residence time in the distribution system, until system meets criteria in paragraph (c) of this section for reduced monitoring.

[1] If a system elects to sample more frequently than the minimum required, at least 25 percent of all samples collected each quarter (including those taken in excess of the required frequency) must be taken at locations that represent the maximum residence time of the water in the distribution system. The remaining samples must be taken at locations representative of at least average residence time in the distribution system.

[2] Multiple wells drawing water from a single aquifer may be considered one treatment plant for determining the minimum number of samples required, with State approval in accordance with criteria developed under § 142.16(f)(5) of this chapter.

(ii) Systems may reduce monitoring, except as otherwise provided, in accordance with the following table:

Reduced Monitoring Frequency for TTHM and HAA5

If you are a . . .	You may reduce monitoring if you have monitored at least one year and your . . .	To this level
Subpart H system serving at least 10,000 persons which has a source water annual average TOC level, before any treatment, ≤4.0 mg/L.	TTHM annual average ≤0.040 mg/L and HAA5 annual average ≤0.030 mg/L.	One sample per treatment plant per quarter at distribution system location reflecting maximum residence time.
Subpart H system serving from 500 to 9,999 persons which has a source water annual average TOC level, before any treatment, ≤4.0 mg/L.	TTHM annual average ≤0.040 mg/L and HAA5 annual average ≤0.030 mg/L.	One sample per treatment plant per year at distribution system location reflecting maximum residence time during month of warmest water temperature. NOTE: Any Subpart H system serving fewer than 500 persons may not reduce its monitoring to less than one sample per treatment plant per year.
System using only ground water not under direct influence of surface water using chemical disinfectant and serving at least 10,000 persons.	TTHM annual average ≤0.040 mg/L and HAA5 annual average ≤0.030 mg/L.	One sample per treatment plant per year at distribution system location reflecting maximum residence time during month of warmest water temperature
System using only ground water not under direct influence of surface water using chemical disinfectant and serving fewer than 10,000 persons.	TTHM annual average ≤0.040 mg/L and HAA5 annual average ≤0.030 mg/L for two consecutive years OR TTHM annual average ≤0.020 mg/L and HAA5 annual average ≤0.015 mg/L for one year.	One sample per treatment plant per three year monitoring cycle at distribution system location reflecting maximum residence time during month of warmest water temperature, with the three-year cycle beginning on January 1 following quarter in which system qualifies for reduced monitoring.

(iii) Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year (for systems which must monitor quarterly) or the result of the sample (for systems which must monitor no more frequently than annually) is no more than 0.060 mg/L and 0.045 mg/L for TTHMs and HAA5, respectively. Systems that do not meet these levels must resume monitoring at the frequency identified in paragraph (b)(1)(i) of this section in the quarter immediately following the quarter in which the system exceeds 0.060 mg/L and 0.045 mg/L for TTHMs and HAA5, respectively.

(iv) The State may return a system to routine monitoring at the State's discretion.

(2) *Chlorite.* Community and nontransient noncommunity water systems using chlorine dioxide, for disinfection or oxidation, must conduct monitoring for chlorite.

(i) *Routine monitoring.* (A) *Daily monitoring.* Systems must take daily samples at the entrance to the distribution system. For any daily sample that exceeds the chlorite MCL, the system must take additional samples in the distribution system the following day at the locations required by paragraph (b)(2)(ii) of this section, in addition to the sample required at the entrance to the distribution system.

(B) *Monthly monitoring.* Systems must take a three-sample set each month in the distribution system. The system must take one sample at each of the following locations: near the first customer, at a location representative of average residence time, and at a location reflecting maximum residence time in the distribution system. Any additional routine sampling must be conducted in the same manner (as three-sample sets, at the specified locations). The system may use the results of additional monitoring conducted under paragraph (b)(2)(ii) of this section to meet the requirement for monitoring in this paragraph.

(ii) *Additional monitoring.* On each day following a routine sample monitoring result that exceeds the chlorite MCL at the entrance to the distribution system, the system is required to take three chlorite distribution system samples at the following locations: as close to the first customer as possible, in a location representative of average residence time, and as close to the end of the distribution system as possible (reflecting maximum residence time in the distribution system).

(iii) *Reduced monitoring.* (A) Chlorite monitoring at the entrance to the distribution system required by paragraph (b)(2)(i)(A) of this section may not be reduced.

(B) Chlorite monitoring in the distribution system required by paragraph (b)(2)(i)(B) of this section may be reduced to one three-sample set per quarter after one year of monitoring where no individual chlorite sample taken in the distribution system under paragraph (b)(2)(i)(B) of this section has exceeded the chlorite MCL and the system has not been required to conduct monitoring under paragraph (b)(2)(ii) of this section. The system may remain on the reduced monitoring schedule until either any of the three individual chlorite samples taken quarterly in the distribution system under paragraph (b)(2)(i)(B) of this section exceeds the chlorite MCL or the system is required to conduct monitoring under paragraph (b)(2)(ii) of this section, at which time the system must revert to routine monitoring.

(3) *Bromate.* (i) *Routine monitoring.* Community and nontransient noncommunity systems using ozone, for disinfection or oxidation, must take one sample per month for each treatment plant in the system using ozone. Systems must take samples monthly at the entrance to the distribution system while the ozonation system is operating under normal conditions.

(ii) *Reduced monitoring.* Systems required to analyze for bromate may reduce monitoring from monthly to once per quarter, if the system demonstrates that the average source water bromide concentration is less than 0.05 mg/L based upon representative monthly bromide measurements for one year. The system may remain on reduced bromate monitoring until the running annual average source water bromide concentration, computed quarterly, is equal to or greater than 0.05 mg/L based upon representative monthly measurements. If the running annual average source water bromide concentration is ≥0.05 mg/L, the system must resume routine monitoring

required by paragraph (b)(3)(i) of this section.

(c) *Monitoring requirements for disinfectant residuals.* (1) *Chlorine and chloramines.* (i) *Routine monitoring.* Systems must measure the residual disinfectant level at the same points in the distribution system and at the same time as total coliforms are sampled, as specified in § 141.21. Subpart H systems may use the results of residual disinfectant concentration sampling conducted under § 141.74(b)(6)(i) for unfiltered systems or § 141.74(c)(3)(i) for systems which filter, in lieu of taking separate samples.

(ii) *Reduced monitoring.* Monitoring may not be reduced.

(2) *Chlorine dioxide.* (i) *Routine monitoring.* Community, nontransient noncommunity, and transient noncommunity water systems that use chlorine dioxide for disinfection or oxidation must take daily samples at the entrance to the distribution system. For any daily sample that exceeds the MRDL, the system must take samples in the distribution system the following day at the locations required by paragraph (c)(2)(ii) of this section, in addition to the sample required at the entrance to the distribution system.

(ii) *Additional monitoring.* On each day following a routine sample monitoring result that exceeds the MRDL, the system is required to take three chlorine dioxide distribution system samples. If chlorine dioxide or chloramines are used to maintain a disinfectant residual in the distribution system, or if chlorine is used to maintain a disinfectant residual in the distribution system and there are no disinfection addition points after the entrance to the distribution system (i.e., no booster chlorination), the system must take three samples as close to the first customer as possible, at intervals of at least six hours. If chlorine is used to maintain a disinfectant residual in the distribution system and there are one or more disinfection addition points after the entrance to the distribution system (i.e., booster chlorination), the system must take one sample at each of the following locations: as close to the first customer as possible, in a location representative of average residence time, and as close to the end of the distribution system as possible (reflecting maximum residence time in the distribution system).

(iii) *Reduced monitoring.* Chlorine dioxide monitoring may not be reduced.

(d) *Monitoring requirements for disinfection byproduct precursors (DBPP).* (1) *Routine monitoring.* Subpart H systems which use conventional filtration treatment (as defined in § 141.2) must monitor each treatment plant for TOC no later than the point of combined filter effluent turbidity monitoring and representative of the treated water. All systems required to monitor under this paragraph (d)(1) must also monitor for TOC in the source water prior to any treatment at the same time as monitoring for TOC in the treated water. These samples (source water and treated water) are referred to as paired samples. At the same time as the source water sample is taken, all systems must monitor for alkalinity in the source water prior to any treatment. Systems must take one paired sample and one source water alkalinity sample per month per plant at a time representative of normal operating conditions and influent water quality.

(2) *Reduced monitoring.* Subpart H systems with an average treated water TOC of less than 2.0 mg/L for two consecutive years, or less than 1.0 mg/L for one year, may reduce monitoring for both TOC and alkalinity to one paired sample and one source water alkalinity sample per plant per quarter. The system must revert to routine monitoring in the month following the quarter when the annual average treated water TOC ≥2.0 mg/L.

(e) *Bromide.* Systems required to analyze for bromate may reduce bromate monitoring from monthly to once per quarter, if the system demonstrates that the average source water bromide concentration is less than 0.05 mg/L based upon representative monthly measurements for one year. The system must continue bromide monitoring to remain on reduced bromate monitoring.

(f) *Monitoring plans.* Each system required to monitor under this subpart must develop and implement a monitoring plan. The system must maintain the plan and make it available for inspection by the State and the general public no later than 30 days following the applicable compliance dates in § 141.130(b). All Subpart H systems serving more than 3300 people must submit a copy of the monitoring plan to the State no later than the date of the first report required under § 141.134. The State may also require the plan to be submitted by any other system. After review, the State may require changes in any plan elements. The plan must include at least the following elements.

(1) Specific locations and schedules for collecting samples for any parameters included in this subpart.

(2) How the system will calculate compliance with MCLs, MRDLs, and treatment techniques.

(3) If approved for monitoring as a consecutive system, or if providing water to a consecutive system, under the provisions of § 141.29, the sampling plan must reflect the entire distribution system.

§ 141.133 Compliance requirements.

(a) *General requirements.* (1) Where compliance is based on a running annual average of monthly or quarterly samples or averages and the system's failure to monitor for TTHM, HAA5, or bromate, this failure to monitor will be treated as a monitoring violation for the entire period covered by the annual average. Where compliance is based on a running annual average of monthly or quarterly samples or averages and the system's failure to monitor makes it impossible to determine compliance with MRDLs for chlorine and chloramines, this failure to monitor will be treated as a monitoring violation for the entire period covered by the annual average.

(2) All samples taken and analyzed under the provisions of this subpart must be included in determining compliance, even if that number is greater than the minimum required.

(3) If, during the first year of monitoring under § 141.132, any individual quarter's average will cause the running annual average of that system to exceed the MCL, the system is out of compliance at the end of that quarter.

(b) *Disinfection byproducts.* (1) *TTHMs and HAA5.* (i) For systems monitoring quarterly, compliance with MCLs in § 141.64 must be based on a running annual arithmetic average, computed quarterly, of quarterly arithmetic averages of all samples collected by the system as prescribed by § 141.132(b)(1). If the running annual arithmetic average of quarterly averages covering any consecutive four-quarter period exceeds the MCL, the system is in violation of the MCL and must notify the public pursuant to § 141.32, in addition to reporting to the State pursuant to § 141.134. If a PWS fails to complete four consecutive quarters' monitoring, compliance with the MCL for the last four-quarter compliance period must be based on an average of the available data.

(ii) For systems monitoring less frequently than quarterly, compliance must be based on an average of samples taken that year under the provisions of § 141.132(b)(1). If the average of these samples exceeds the MCL, the system must increase monitoring to once per quarter per treatment plant.

(iii) Systems on a reduced monitoring schedule whose annual average exceeds the MCL will revert to routine monitoring immediately. These systems

will not be considered in violation of the MCL until they have completed one year of routine monitoring.

(2). *Bromate.* Compliance must be based on a running annual arithmetic average, computed quarterly, of monthly samples (or, for months in which the system takes more than one sample, the average of all samples taken during the month) collected by the system as prescribed by § 141.132(b)(3). If the average of samples covering any consecutive four-quarter period exceeds the MCL, the system is in violation of the MCL and must notify the public pursuant to § 141.32, in addition to reporting to the State pursuant to § 141.134. If a PWS fails to complete 12 consecutive months' monitoring, compliance with the MCL for the last four-quarter compliance period must be based on an average of the available data.

(3) *Chlorite.* Compliance must be based on an arithmetic average of each three sample set taken in the distribution system as prescribed by § 141.132(b)(2)(i)(B) and § 141.132(b)(2)(ii). If the arithmetic average of any three sample set exceeds the MCL, the system is in violation of the MCL and must notify the public pursuant to § 141.32, in addition to reporting to the State pursuant to § 141.134.

(c) *Disinfectant residuals.* (1) *Chlorine and chloramines.* (i) Compliance must be based on a running annual arithmetic average, computed quarterly, of monthly averages of all samples collected by the system under § 141.132(c)(1). If the average of quarterly averages covering any consecutive four-quarter period exceeds the MRDL, the system is in violation of the MRDL and must notify the public pursuant to § 141.32, in addition to reporting to the State pursuant to § 141.134.

(ii) In cases where systems switch between the use of chlorine and chloramines for residual disinfection during the year, compliance must be determined by including together all monitoring results of both chlorine and chloramines in calculating compliance. Reports submitted pursuant to § 141.134 must clearly indicate which residual disinfectant was analyzed for each sample.

(2) *Chlorine dioxide.* (i) *Acute violations.* Compliance must be based on consecutive daily samples collected by the system under § 141.132(c)(2). If any daily sample taken at the entrance to the distribution system exceeds the MRDL, and on the following day one (or more) of the three samples taken in the distribution system exceed the MRDL, the system is in violation of the MRDL and must take immediate corrective action to lower the level of chlorine dioxide below the MRDL and must notify the public pursuant to the procedures for acute health risks in § 141.32(a)(1)(iii)(E). Failure to take samples in the distribution system the day following an exceedance of the chlorine dioxide MRDL at the entrance to the distribution system will also be considered an MRDL violation and the system must notify the public of the violation in accordance with the provisions for acute violations under § 141.32(a)(1)(iii)(E).

(ii) *Nonacute violations.* Compliance must be based on consecutive daily samples collected by the system under § 141.132(c)(2). If any two consecutive daily samples taken at the entrance to the distribution system exceed the MRDL and all distribution system samples taken are below the MRDL, the system is in violation of the MRDL and must take corrective action to lower the level of chlorine dioxide below the MRDL at the point of sampling and will notify the public pursuant to the procedures for nonacute health risks in § 141.32(e)(78). Failure to monitor at the entrance to the distribution system the day following an exceedance of the chlorine dioxide MRDL at the entrance to the distribution system is also an MRDL violation and the system must notify the public of the violation in accordance with the provisions for nonacute violations under § 141.32(e)(78).

(d) *Disinfection byproduct precursors (DBPP).* Compliance must be determined as specified by § 141.135(b). Systems may begin monitoring to determine whether Step 1 TOC removals can be met 12 months prior to the compliance date for the system. This monitoring is not required and failure to monitor during this period is not a violation. However, any system that does not monitor during this period, and then determines in the first 12 months after the compliance date that it is not able to meet the Step 1 requirements in § 141.135(b)(2) and must therefore apply for alternate minimum TOC removal (Step 2) requirements, is not eligible for retroactive approval of alternate minimum TOC removal (Step 2) requirements as allowed pursuant to § 141.135(b)(3) and is in violation. Systems may apply for alternate minimum TOC removal (Step 2) requirements any time after the compliance date.

§ 141.134 Reporting and recordkeeping requirements.

(a) Systems required to sample quarterly or more frequently must report to the State within 10 days after the end of each quarter in which samples were collected, notwithstanding the provisions of § 141.31. Systems required to sample less frequently than quarterly must report to the State within 10 days after the end of each monitoring period in which samples were collected.

(b) *Disinfection byproducts.* Systems must report the information specified in the following table:

If you are a...	You must report...[1]
System monitoring for TTHM and HAA5 under the requirements of §§ 141.132(b) on a quarterly or more frequent basis.	(1) The number of samples taken during the last quarter. (2) The location, date, and result of each sample taken during the last quarter. (3) The arithmetic average of all samples taken in the last quarter. (4) The annual arithmetic average of the quarterly arithmetic averages of this section for the last four quarters. (5) Whether the MCL was exceeded.
System monitoring for TTHMs and HAA5 under the requirements of §§ 141.132(b) less frequently than quarterly (but at least annually).	(1) The number of samples taken during the last year. (2) The location, date, and result of each sample taken during the last quarter. (3) The arithmetic average of all samples taken over the last year (4) Whether the MCL was exceeded.
System monitoring for TTHMs and HAA5 under the requirements of § 141.132(b) less frequently than annually.	(1) The location, date, and result of the last sample taken. (2) Whether the MCL was exceeded.

If you are a...	You must report...[1]
System monitoring for chlorite under the requirements of § 141.132(b) ..	(1) The number of samples taken each month for the last 3 months. (2) The location, date, and result of each sample taken during the last quarter. (3) For each month in the reporting period, the arithmetic average of all samples taken in the month. (4) Whether the MCL was exceeded, and in which month it was exceeded.
System monitoring for bromate under the requirements of § 141.132(b)	(1) The number of samples taken during the last quarter. (2) The location, date, and result of each sample taken during the last quarter. (3) The arithmetic average of the monthly arithmetic averages of all samples taken in the last year. (4) Whether the MCL was exceeded.

(c) *Disinfectants.* Systems must report the information specified in the following table:

If you are a...	You must report...[1]
System monitoring for chlorine or chloramines under the requirements of § 141.132(c).	(1) The number of samples taken during each month of the last quarter. (2) The monthly arithmetic average of all samples taken in each month for the last 12 months. (3) The arithmetic average of all monthly averages for the last 12 months. (4) Whether the MRDL was exceeded.
System monitoring for chlorine dioxide under the requirements of § 141.132(c).	(1) The dates, results, and locations of samples taken during the last quarter. (2) Whether the MRDL was exceeded. (3) Whether the MRDL was exceeded in any two consecutive daily samples and whether the resulting violation was acute or nonacute.

[1] The State may choose to perform calculations and determine whether the MRDL was exceeded, in lieu of having the system report that information.

(d) *Disinfection byproduct precursors and enhanced coagulation or enhanced softening.* Systems must report the information specified in the following table:

If you are a . . .	You must report . . .[1]
System monitoring monthly or quarterly for TOC under the requirements of § 141.132(d) and required to meet the enhanced coagulation or enhanced softening requirements in § 141.135(b)(2) or (3).	(1) The number of paired (source water and treated water, prior to continuous disinfection) samples taken during the last quarter. (2) The location, date, and result of each paired sample and associated alkalinity taken during the last quarter. (3) For each month in the reporting period that paired samples were taken, the arithmetic average of the percent reduction of TOC for each paired sample and the required TOC percent removal. (4) Calculations for determining compliance with the TOC percent removal requirements, as provided in § 141.135(c)(1). (5) Whether the system is in compliance with the enhanced coagulation or enhanced softening percent removal requirements in § 141.135(b) for the last four quarters.
System monitoring monthly or quarterly for TOC under the requirements of § 141.132(d) and meeting one or more of the alternative compliance criteria in § 141.135(a)(2) or (3).	(1) The alternative compliance criterion that the system is using. (2) The number of paired samples taken during the last quarter. (3) The location, date, and result of each paired sample and associated alkalinity taken during the last quarter. (4) The running annual arithmetic average based on monthly averages (or quarterly samples) of source water TOC for systems meeting a criterion in §§ 141.135(a)(2)(i) or (iii) or of treated water TOC for systems meeting the criterion in § 141.135(a)(2)(ii).

If you are a . . .	You must report . . .[1]
	(5) The running annual arithmetic average based on monthly averages (or quarterly samples) of source water SUVA for systems meeting the criterion in § 141.135(a)(2)(v) or of treated water SUVA for systems meeting the criterion in § 141.135(a)(2)(vi). (6) The running annual average of source water alkalinity for systems meeting the criterion in § 141.135(a)(2)(iii) and of treated water alkalinity for systems meeting the criterion in § 141.135(a)(3)(i). (7) The running annual average for both TTHM and HAA5 for systems meeting the criterion in § 141.135(a)(2)(iii) or (iv). (8) The running annual average of the amount of magnesium hardness removal (as $CaCO_3$, in mg/L) for systems meeting the criterion in § 141.135(a)(3)(ii). (9) Whether the system is in compliance with the particular alternative compliance criterion in § 141.135(a)(2) or (3).

[1] The State may choose to perform calculations and determine whether the treatment technique was met, in lieu of having the system report that information.

§ 141.135 Treatment technique for control of disinfection byproduct (DBP) precursors.

(a) *Applicability.* (1) Subpart H systems using conventional filtration treatment (as defined in § 141.2) must operate with enhanced coagulation or enhanced softening to achieve the TOC percent removal levels specified in paragraph (b) of this section unless the system meets at least one of the alternative compliance criteria listed in paragraph (a)(2) or (a)(3) of this section.

(2) *Alternative compliance criteria for enhanced coagulation and enhanced softening systems.* Subpart H systems using conventional filtration treatment may use the alternative compliance criteria in paragraphs (a)(2)(i) through (vi) of this section to comply with this section in lieu of complying with paragraph (b) of this section. Systems must still comply with monitoring requirements in § 141.132(d).

(i) The system's source water TOC level, measured according to § 141.131(d)(3), is less than 2.0 mg/L, calculated quarterly as a running annual average.

(ii) The system's treated water TOC level, measured according to § 141.131(d)(3), is less than 2.0 mg/L, calculated quarterly as a running annual average.

(iii) The system's source water TOC level, measured as required by § 141.131(d)(3), is less than 4.0 mg/L, calculated quarterly as a running annual average; the source water alkalinity, measured according to § 141.131(d)(1), is greater than 60 mg/L (as $CaCO_3$), calculated quarterly as a running annual average; and either the TTHM and HAA5 running annual averages are no greater than 0.040 mg/L and 0.030 mg/L, respectively; or prior to the effective date for compliance in § 141.130(b), the system has made a clear and irrevocable financial commitment not later than the effective date for compliance in § 141.130(b) to use of technologies that will limit the levels of TTHMs and HAA5 to no more than 0.040 mg/L and 0.030 mg/L, respectively. Systems must submit evidence of a clear and irrevocable financial commitment, in addition to a schedule containing milestones and periodic progress reports for installation and operation of appropriate technologies, to the State for approval not later than the effective date for compliance in § 141.130(b). These technologies must be installed and operating not later than June 16, 2005. Failure to install and operate these technologies by the date in the approved schedule will constitute a violation of National Primary Drinking Water Regulations.

(iv) The TTHM and HAA5 running annual averages are no greater than 0.040 mg/L and 0.030 mg/L, respectively, and the system uses only chlorine for primary disinfection and maintenance of a residual in the distribution system.

(v) The system's source water SUVA, prior to any treatment and measured monthly according to § 141.131(d)(4), is less than or equal to 2.0 L/mg-m, calculated quarterly as a running annual average.

(vi) The system's finished water SUVA, measured monthly according to § 141.131(d)(4), is less than or equal to 2.0 L/mg-m, calculated quarterly as a running annual average.

(3) *Additional alternative compliance criteria for softening systems.* Systems practicing enhanced softening that cannot achieve the TOC removals required by paragraph (b)(2) of this section may use the alternative compliance criteria in paragraphs (a)(3)(i) and (ii) of this section in lieu of complying with paragraph (b) of this section. Systems must still comply with monitoring requirements in § 141.132(d).

(i) Softening that results in lowering the treated water alkalinity to less than 60 mg/L (as $CaCO_3$), measured monthly according to § 141.131(d)(1) and calculated quarterly as a running annual average.

(ii) Softening that results in removing at least 10 mg/L of magnesium hardness (as $CaCO_3$), measured monthly and calculated quarterly as an annual running average.

(b) *Enhanced coagulation and enhanced softening performance requirements.* (1) Systems must achieve the percent reduction of TOC specified in paragraph (b)(2) of this section between the source water and the combined filter effluent, unless the State approves a system's request for alternate minimum TOC removal (Step 2) requirements under paragraph (b)(3) of this section.

(2) Required Step 1 TOC reductions, indicated in the following table, are based upon specified source water parameters measured in accordance with § 141.131(d). Systems practicing softening are required to meet the Step 1 TOC reductions in the far-right column (Source water alkalinity >120 mg/L) for the specified source water TOC:

STEP 1 REQUIRED REMOVAL OF TOC BY ENHANCED COAGULATION AND ENHANCED SOFTENING FOR SUBPART H SYSTEMS USING CONVENTIONAL TREATMENT [1, 2]

Source-water TOC, mg/L	Source-water alkalinity, mg/L as $CaCO_3$		
	0–60 (percent)	≤60–120 (percent)	>120 [3] (percent)
>2.0–4.0	35.0	25.0	15.0
>4.0–8.0	45.0	35.0	25.0
>8.0	50.0	40.0	30.0

[1] Systems meeting at least one of the conditions in paragraph (a)(2)(i)–(vi) of this section are not required to operate with enhanced coagulation.
[2] Softening systems meeting one of the alternative compliance criteria in paragraph (a)(3) of this section are not required to operate with enhanced softening.
[3] Systems practicing softening must meet the TOC removal requirements in this column.

(3) Subpart H conventional treatment systems that cannot achieve the Step 1 TOC removals required by paragraph (b)(2) of this section due to water quality parameters or operational constraints must apply to the State, within three months of failure to achieve the TOC removals required by paragraph (b)(2) of this section, for approval of alternative minimum TOC (Step 2) removal requirements submitted by the system. If the State approves the alternative minimum TOC removal (Step 2) requirements, the State may make those requirements retroactive for the purposes of determining compliance. Until the State approves the alternate minimum TOC removal (Step 2) requirements, the system must meet the Step 1 TOC removals contained in paragraph (b)(2) of this section.

(4) *Alternate minimum TOC removal (Step 2) requirements.* Applications made to the State by enhanced coagulation systems for approval of alternative minimum TOC removal (Step 2) requirements under paragraph (b)(3) of this section must include, as a minimum, results of bench- or pilot-scale testing conducted under paragraph (b)(4)(i) of this section and used to determine the alternate enhanced coagulation level.

(i) *Alternate enhanced coagulation level is defined as* coagulation at a coagulant dose and pH as determined by the method described in paragraphs (b)(4)(i) through (v) of this section such that an incremental addition of 10 mg/L of alum (as aluminum) (or equivalent amount of ferric salt) results in a TOC removal of ≤ 0.3 mg/L. The percent removal of TOC at this point on the "TOC removal versus coagulant dose" curve is then defined as the minimum TOC removal required for the system. Once approved by the State, this minimum requirement supersedes the minimum TOC removal required by the table in paragraph (b)(2) of this section. This requirement will be effective until such time as the State approves a new value based on the results of a new bench- and pilot-scale test. Failure to achieve State-set alternative minimum TOC removal levels is a violation of National Primary Drinking Water Regulations.

(ii) Bench- or pilot-scale testing of enhanced coagulation must be conducted by using representative water samples and adding 10 mg/L increments of alum (as aluminum) (or equivalent amounts of ferric salt) until the pH is reduced to a level less than or equal to the enhanced coagulation Step 2 target pH shown in the following table:

ENHANCED COAGULATION STEP 2 TARGET pH

Alkalinity (mg/L as $CaCO_3$)	Target pH
0–60	5.5
>60–120	6.3
>120–240	7.0
>240	7.5

(iii) For waters with alkalinities of less than 60 mg/L for which addition of small amounts of alum or equivalent addition of iron coagulant drives the pH below 5.5 before significant TOC removal occurs, the system must add necessary chemicals to maintain the pH between 5.3 and 5.7 in samples until the TOC removal of 0.3 mg/L per 10 mg/L alum added (as aluminum) (or equivalant addition of iron coagulant) is reached.

(iv) The system may operate at any coagulant dose or pH necessary (consistent with other NPDWRs) to achieve the minimum TOC percent removal approved under paragraph (b)(3) of this section.

(v) If the TOC removal is consistently less than 0.3 mg/L of TOC per 10 mg/L of incremental alum dose (as aluminum) at all dosages of alum (or equivalant addition of iron coagulant), the water is deemed to contain TOC not amenable to enhanced coagulation. The system may then apply to the State for a waiver of enhanced coagulation requirements.

(c) *Compliance calculations.* (1) Subpart H systems other than those identified in paragraph (a)(2) or (a)(3) of this section must comply with requirements contained in paragraph (b)(2) of this section. Systems must calculate compliance quarterly, beginning after the system has collected 12 months of data, by determining an annual average using the following method:

(i) Determine actual monthly TOC percent removal, equal to:

(1—(treated water TOC/source water TOC)) × 100

(ii) Determine the required monthly TOC percent removal (from either the table in paragraph (b)(2) of this section or from paragraph (b)(3) of this section).

(iii) Divide the value in paragraph (c)(1)(i) of this section by the value in paragraph (c)(1)(ii) of this section.

(iv) Add together the results of paragraph (c)(1)(iii) of this section for the last 12 months and divide by 12.

(v) If the value calculated in paragraph (c)(1)(iv) of this section is less than 1.00, the system is not in compliance with the TOC percent removal requirements.

(2) Systems may use the provisions in paragraphs (c)(2)(i) through (v) of this section in lieu of the calculations in paragraph (c)(1)(i) through (v) of this section to determine compliance with TOC percent removal requirements.

(i) In any month that the system's treated or source water TOC level, measured according to § 141.131(d)(3), is less than 2.0 mg/L, the system may assign a monthly value of 1.0 (in lieu of the value calculated in paragraph (c)(1)(iii) of this section) when calculating compliance under the provisions of paragraph (c)(1) of this section.

(ii) In any month that a system practicing softening removes at least 10 mg/L of magnesium hardness (as $CaCO_3$), the system may assign a

monthly value of 1.0 (in lieu of the value calculated in paragraph (c)(1)(iii) of this section) when calculating compliance under the provisions of paragraph (c)(1) of this section.

(iii) In any month that the system's source water SUVA, prior to any treatment and measured according to § 141.131(d)(4), is ≤2.0 L/mg-m, the system may assign a monthly value of 1.0 (in lieu of the value calculated in paragraph (c)(1)(iii) of this section) when calculating compliance under the provisions of paragraph (c)(1) of this section.

(iv) In any month that the system's finished water SUVA, measured according to § 141.131(d)(4), is ≤2.0 L/mg-m, the system may assign a monthly value of 1.0 (in lieu of the value calculated in paragraph (c)(1)(iii) of this section) when calculating compliance under the provisions of paragraph (c)(1) of this section.

(v) In any month that a system practicing enhanced softening lowers alkalinity below 60 mg/L (as $CaCO_3$), the system may assign a monthly value of 1.0 (in lieu of the value calculated in paragraph (c)(1)(iii) of this section) when calculating compliance under the provisions of paragraph (c)(1) of this section.

(3) Subpart H systems using conventional treatment may also comply with the requirements of this section by meeting the criteria in paragraph (a)(2) or (3) of this section.

(d) *Treatment technique requirements for DBP precursors.* The Administrator identifies the following as treatment techniques to control the level of disinfection byproduct precursors in drinking water treatment and distribution systems: For Subpart H systems using conventional treatment, enhanced coagulation or enhanced softening.

11. Section 141.154 is amended by adding paragraph (e) to read as follows:

§ 141.154 Required additional health information.

* * * * *

(e) Community water systems that detect TTHM above 0.080 mg/l, but below the MCL in § 141.12, as an annual average, monitored and calculated under the provisions of § 141.30, must include health effects language prescribed by paragraph (73) of appendix C to subpart O.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

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

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

13. Section 142.14 is amended by adding new paragraphs (d)(12), (d)(13), (d)(14), (d)(15), and (d)(16) to read as follows.

§ 142.14 Records kept by States.

* * * * *

(d) * * *

(12) Records of the currently applicable or most recent State determinations, including all supporting information and an explanation of the technical basis for each decision, made under the following provisions of 40 CFR part 141, subpart L for the control of disinfectants and disinfection byproducts. These records must also include interim measures toward installation.

(i) States must keep records of systems that are installing GAC or membrane technology in accordance with § 141.64(b)(2) of this chapter. These records must include the date by which the system is required to have completed installation.

(ii) States must keep records of systems that are required, by the State, to meet alternative minimum TOC removal requirements or for whom the State has determined that the source water is not amenable to enhanced coagulation in accordance with § 141.135(b)(3) and (4) of this chapter, respectively. These records must include the alternative limits and rationale for establishing the alternative limits.

(iii) States must keep records of subpart H systems using conventional treatment meeting any of the alternative compliance criteria in § 141.135(a)(2) or (3) of this chapter.

(iv) States must keep a register of qualified operators that have met the State requirements developed under § 142.16(f)(2).

(13) Records of systems with multiple wells considered to be one treatment plant in accordance with § 141.132(a)(2) of this chapter and § 142.16(f)(5).

(14) Monitoring plans for subpart H systems serving more than 3,300 persons in accordance with § 141.132(f) of this chapter.

(15) List of laboratories approved for analyses in accordance with § 141.131(b) of this chapter.

(16) List of systems required to monitor for disinfectants and disinfection byproducts in accordance with part 141, subpart L of this chapter. The list must indicate what disinfectants and DBPs, other than chlorine, TTHM, and HAA5, if any, are measured.

* * * * *

14. Section 142.16 is amended by adding paragraph (h) to read as follows.

§ 142.16 Special primacy requirements.

* * * * *

(h) *Requirements for States to adopt 40 CFR part 141, subpart L.* In addition to the general primacy requirements elsewhere in this part, including the requirement that State regulations be at least as stringent as federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subpart L, must contain a description of how the State will accomplish the following program requirements:

(1) Section 141.64(b)(2) of this chapter (interim treatment requirements). Determine any interim treatment requirements for those systems electing to install GAC or membrane filtration and granted additional time to comply with § 141.64 of this chapter.

(2) Section 141.130(c) of this chapter (qualification of operators). Qualify operators of public water systems subject to 40 CFR part 141, subpart L. Qualification requirements established for operators of systems subject to 40 CFR part 141, subpart H—Filtration and Disinfection may be used in whole or in part to establish operator qualification requirements for meeting 40 CFR part 141, subpart L requirements if the State determines that the 40 CFR part 141, subpart H requirements are appropriate and applicable for meeting subpart L requirements.

(3) Section 141.131(c)(2) of this chapter (DPD colorimetric test kits). Approve DPD colorimetric test kits for free and total chlorine measurements. State approval granted under § 141.74(a)(2) of this chapter for the use of DPD colorimetric test kits for free chlorine testing is acceptable for the use of DPD test kits in measuring free chlorine residuals as required in 40 CFR part 141, subpart L.

(4) Sections 141.131(c)(3) and (d) of this chapter (State approval of parties to conduct analyses). Approve parties to conduct pH, bromide, alkalinity, and residual disinfectant concentration measurements. The State's process for approving parties performing water quality measurements for systems subject to 40 CFR part 141, subpart H requirements in paragraph (b)(2)(i)(D) of this section may be used for approving parties measuring water quality parameters for systems subject to subpart L requirements, if the State determines the process is appropriate and applicable.

(5) Section 141.132(a)(2) of this chapter (multiple wells as a single source). Define the criteria to use to determine if multiple wells are being drawn from a single aquifer and therefore be considered a single source for compliance with monitoring requirements.

(6) Approve alternate minimum TOC removal (Step 2) requirements, as allowed under the provisions of § 141.135(b) of this chapter.

[FR Doc. 98–32887 Filed 12–15–98; 8:45 am]
BILLING CODE 6560–50–U

EPA
United States
Environmental Protection Agency
(4607)
Washington, DC 20460

Official Business
Penalty for Private Use
$300