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National Primary Drinking Water Regulations: Stage 2 Disinfectants and Disinfection Byproducts Rule; National Primary and Secondary Drinking Water Regulations: Approval of Analytical Methods for Chemical Contaminants; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141, 142 and 143

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National Primary Drinking Water Regulations: Stage 2 Disinfectants and Disinfection Byproducts Rule; National Primary and Secondary Drinking Water Regulations: Approval of Analytical Methods for Chemical Contaminants

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: In this document, the Environmental Protection Agency (EPA) is proposing maximum contaminant level goals (MCLGs) for chloroform, monochloroacetic acid (MCAA) and trichloroacetic acid (TCAA); National Primary Drinking Water Regulations (NPDWRs) which consist of maximum contaminant levels (MCLs) and monitoring, reporting, and public notification requirements for total trihalomethanes (TTHM—a sum of chloroform, bromodichloromethane, dibromochloromethane, and bromoform) and haloacetic acids (HAA5—a sum of mono-, di-, and trichloroacetic acids and mono- and dibromoacetic acids); and revisions to the reduced monitoring requirements for bromate. This document also specifies the best available technologies (BATs) for the proposed MCLs. EPA is also proposing additional analytical methods for the determination of disinfectants and disinfection byproducts (DBPs) in drinking water and proposing to extend approval of DBP methods for the determination of additional chemical contaminants. This set of regulations proposed today is known as the Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBPR). EPA's objective for the Stage 2 DBPR is to reduce the potential risks of reproductive and developmental health effects and cancer associated with disinfection byproducts (DBPs) by reducing peak and average levels of DBPs in drinking water supplies.

The Stage 2 DBPR applies to public water systems (PWS) that are community water systems (CWSs) or nontransient noncommunity water systems (NTNCWs) that add a primary or residual disinfectant other than ultraviolet light or deliver water that has been treated with a primary or residual disinfectant other than ultraviolet light.

DATES: The Agency requests comments on today's proposal. Comments must be received or post-marked by midnight November 17, 2003.

ADDRESSES: Comments may be submitted by mail to: Water Docket, Environmental Protection Agency, Mail Code 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OW–2002–0043. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions as provided in section I.C. of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: For technical inquiries, contact Tom Grubbs, Office of Ground Water and Drinking Water (MC 4607M), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone (202) 564–5262. For regulatory inquiries, contact Jennifer McLain at the same address; telephone (202) 564–5248. For general information contact the Safe Drinking Water Hotline, Telephone (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 9 a.m. to 5:30 p.m. Eastern Time.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Who Is Regulated by This Action?

Entities potentially regulated by the Stage 2 DBPR are community and nontransient noncommunity water systems that add a primary or residual disinfectant other than ultraviolet light or deliver water that has been treated with a primary or residual disinfectant other than ultraviolet light. Regulated categories and entities are identified in the following chart.

Category	Examples of regulated entities
Industry	Community and nontransient noncommunity water systems that add a primary or residual disinfectant other than ultraviolet light or deliver water that has been treated with a primary or residual disinfectant other than ultraviolet light.
State, Local, Tribal, or Federal Governments	Community and nontransient noncommunity water systems that add a primary or residual disinfectant other than ultraviolet light or deliver water that has been treated with a primary or residual disinfectant other than ultraviolet light.

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 of which EPA is now aware that could potentially be regulated by this action. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of ''public water system'' in § 141.2 and the section entitled ''coverage'' (§ 141.3) in Title 40 of the Code of Federal Regulations and applicability criteria in § 141.600 and 141.620 of today's proposal. If you have questions regarding the applicability of the Stage 2 DBPR to a particular entity, contact one of the persons listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. OW–2002–0043. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426. For access to docket material, please call (202) 566–2426 to schedule an appointment.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.B.1.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

a. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket,* and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in Docket ID No. OW–2002–0043. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

b. *E-mail.* Comments may be sent by electronic mail (e-mail) to *OW-Docket@epa.gov,* Attention Docket ID No. OW–2002–0043. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

c. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in section I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send three copies of your comments and any enclosures to: Water Docket, Environmental Protection Agency, Mail Code 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OW–2002–0043.

3. *By Hand Delivery or Courier.* Deliver your comments to: Water Docket, EPA Docket Center, Environmental Protection Agency, Room B102, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. OW–2002–0043. Such deliveries are only accepted during the Docket's normal hours of operation as identified in section I.B.1.

D. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period identified.
8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

Abbreviations Used in This Document

AIPC All Indian Pueblo Council
ALT Alanine aminotransferase
AST Aspartate aminotransferase
ASTM American Society for Testing and Materials
AWWA American Water Works Association
AwwaRF American Water Works Association Research Foundation
BAT Best available technology
BCAA Bromochloroacetic acid

BDCM Bromodichloromethane
CWS Community water system
DBAA Dibromoacetic acid
DBCM Dibromochloromethane
DBP Disinfection byproduct
DBPR Disinfectants and Disinfection Byproducts Rule
DCAA Dichloroacetic acid
DOC Dissolved organic carbon
EA Economic analysis
EC Enhanced coagulation
EDA Ethylenediamine
ED_{10} Maximum likelihood estimate of a dose producing effects in 10 percent of animals
EPA United States Environmental Protection Agency
FACA Federal Advisory Committee Act
FBRR Filter Backwash Recycling Rule
GAC Granular activated carbon
GC/ECD Gas chromatography using electron capture detection
GWUDI Ground water under the direct influence of surface water
HAA5 Haloacetic acids (five) (sum of monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid)
IC Ion chromatography
ICR Information Collection Request
IC/ICP–MS Ion chromatograph—coupled to an inductively coupled plasma mass spectrometer
IDSE Initial distribution system evaluation
ILSI International Life Sciences Institute
IESWTR Interim Enhanced Surface Water Treatment Rule
IPCS International Programme on Chemical Safety
IRIS Integrated Risk Information System (EPA)
kWh/yr Kilowatt hours per year
LED_{10} Lower 95 percent confidence bound of the maximum likelihood estimate of the dose producing effects in 10 percent of animals
LH Luteinizing hormone
LOAEL Lowest observed adverse effect level
LRAA Locational running annual average
LT1ESWTR Long Term 1 Enhanced Surface Water Treatment Rule
LT2ESWTR Long Term 2 Enhanced Surface Water Treatment Rule
MBAA Monobromoacetic acid
MCAA Monochloroacetic acid
MCL Maximum contaminant level
MCLG Maximum contaminant level goal
M-DBP Microbial and disinfection byproducts
mg/L Milligram per liter
MRL Minimum reporting level
MRDL Maximum residual disinfectant level
MRDLG Maximum residual disinfectant level goal
MTBE Methyl tertiary butyl ether
mWh Megawatt-hours
NATICH National Air Toxics Information Clearinghouse
NDIR Nondispersive infrared detection
NDMA N-nitrosodimethylamine
NDWAC National Drinking Water Advisory Council
NF Nanofiltration
NOAEL No Observed Adverse Effect Level
NODA Notice of data availability
NPDWR National primary drinking water regulation
NRWA National Rural Water Association
NTNCWS Nontransient noncommunity water system
NTP National Toxicology Program
NTTAA National Technology Transfer and Advancement Act
ODA o-dianisidine dihydrochloride
OMB Office of Management and Budget
OSTP Office of Science and Technology Policy
PAR Population attributable risk
PE Performance evaluation
PWS Public water system
QC Quality control
RAA Running annual average
RFA Regulatory Flexibility Act
RfD Reference dose
RSC Relative source contribution
RSD Relative standard deviation
SAB Science Advisory Board
SAC Selective anion concentration
SBAR Small Business Advisory Review
SBREFA Small Business Regulatory Enforcement Fairness Act
SDWA Safe Drinking Water Act, or the ''Act,'' as amended in 1996
SER Small Entity Representative
SGA Small for gestational age
SUVA Specific ultraviolet absorbance
SWAT Surface Water Analytical Tool
SWTR Surface Water Treatment Rule
TAME Tertiary amyl methyl ether
TCAA Trichloroacetic acid
TCR Total Coliform Rule
THM Trihalomethane
TOC Total organic carbon
TTHM Total trihalomethanes (sum of four THMs: chloroform, bromodichloromethane, dibromochloromethane, and bromoform)
TWG Technical work group
UMRA Unfunded Mandates Reform Act
USDOE EIA U.S. Department of Energy, Energy Information Administration
UV 254 Ultraviolet absorption at 254 nm
WTP Willingness To Pay

Table of Contents

I. Summary
A. Why is EPA Proposing the Stage 2 DBPR?
B. What Does the Stage 2 DBPR Require?
C. What are the Economic Impacts of the Stage 2 DBPR?
II. Background
A. What is the Statutory Authority for the Stage 2 DBPR?
B. What is the Regulatory History of the Stage 2 DBPR?
C. How were Stakeholders Involved in Developing the Stage 2 DBPR?
1. Federal Advisory Committee process
2. Other outreach processes
III. Public Health Risk
A. Reproductive and Developmental Epidemiology
1. Reif *et al.* 2000
a. Fetal growth
b. Fetal viability
c. Fetal malformations and other developmental anomalies
2. Bove *et al.* 2002
a. Fetal growth
b. Fetal viability
c. Fetal malformations
3. Nieuwenhuijsen *et al.* 2000
4. Additional epidemiology studies
B. Reproductive and Developmental Toxicology
1. EPA analysis and research
2. Tyl, 2000
a. Developmental defects
b. Whole litter resorption
c. Fetal toxicity
d. Male reproductive effects
3. World Health Organization review of the reproductive and developmental toxicology literature (2000)
4. New Studies
C. Conclusions Drawn from the Reproductive and Developmental Health Effects Data
D. Cancer Epidemiology
1. Population Attributable Risk analysis
2. New epidemiological cancer studies
a. New bladder cancer studies
b. New colon cancer studies
c. New rectal cancer studies
d. Other cancers
3. Review of the cancer epidemiology literature (WHO 2000)
E. Cancer and Other Toxicology
1. EPA criteria documents
2. Other byproducts with carcinogenic potential
a. 3-chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-furanone) (MX)—multisite cancer
b. N-nitrosodimethylamine (NDMA)—multisite cancer
3. Other toxicological effects
4. WHO review of the cancer toxicology literature (2000)
F. Conclusions Drawn from the Cancer Epidemiology and Toxicology
G. Request for Comment
IV. DBP Occurrence within Distribution Systems
A. Data Sources
1. Information Collection Rule Data
2. Other Data Sources Used to Support the Proposal
B. DBPs in Distribution Systems

1. DBPs above the MCL occur at some locations in a substantial number of plants
2. Specific locations in distribution systems are not protected to MCL levels
3. Stage 1 DBPR maximum residence time location may not reflect the highest DBP occurrence levels
C. Request for Comment
V. Discussion of Proposed Stage 2 DBPR Requirements
A. MCLG for Chloroform
1. What is EPA proposing today?
2. How was this proposal developed?
a. Background
b. Basis of the new chloroform MCLG
i. Mode of action
ii. Metabolism
c. How the MCLG is derived
i. Reference dose
ii. Relative source contribution
iii. Water ingestion and body weight assumptions
iv. MCLG calculation
v. Other considerations
d. Feasibility of other options
3. Request for comment
B. MCLGs for THMs and HAAs
1. What is EPA proposing today?
2. How was this proposal developed?
a. Trichloroacetic acid
b. Monochloroacetic acid
3. Request for comment
C. Consecutive Systems
1. What is EPA proposing today?
a. Definitions
b. Monitoring
c. Compliance schedules
d. Treatment
e. Violations
f. Public notice and consumer confidence reports
g. Recordkeeping and reporting
h. State special primacy conditions
2. How was this proposal developed?
3. Request for comment
D. MCLs for TTHM and HAA5
1. What is EPA proposing today?
2. How was this proposal developed?
a. Definition of an LRAA
b. Consideration of regulatory alternatives
c. Basis for the LRAA
d. Basis for phasing LRAA compliance
e. TTHM and HAA5 as Indicators
3. Request for comment
E. Requirements for Peak TTHM and HAA5 Levels
1. What is EPA proposing today?
2. How was this proposal developed?
3. Request for comment
F. BAT for TTHM and HAA5
1. What is EPA proposing today?
2. How was this proposal developed?
a. Basis for the BAT
i. BAT analysis using the Information Collection Rule treatment studies
ii. BAT analysis using the SWAT
b. Basis for the Consecutive System BAT
3. Request for comment
G. MCL, BAT, and Monitoring for Bromate
1. What is EPA proposing today?
2. How was this proposal developed?
a. Bromate MCL
b. Bromate in hypochlorite solutions
c. Criterion for reduced bromate monitoring
3. Request for comment
H. Initial Distribution System Evaluation (IDSE)
1. What is EPA proposing today?
a. Applicability
b. Data collection
i. Standard monitoring program
ii. System specific study
iii. 40/30 certification
c. Implementation
2. How was this proposal developed?
a. Applicability
b. Data collection
c. Implementation
3. Request for comment
a. Applicability
b. Data collection
c. Implementation
I. Monitoring Requirements and Compliance Determination for Stage 2A and Stage 2B TTHM and HAA5 MCLs
1. What is EPA proposing today?
a. Stage 2A
b. IDSE
c. Stage 2B
i. Subpart H systems serving 10,000 or more people
ii. Subpart H systems serving 500 to 9,999 people
iii. Subpart H systems serving fewer than 500 people
iv. Ground water systems serving 10,000 or more people
v. Ground water systems serving fewer than 10,000 people
vi. Consecutive systems
2. How was this proposal developed?
a. Sampling intervals for quarterly monitoring
b. Reduced monitoring frequency
c. Different IDSE sampling locations by disinfectant type
d. Population-based monitoring requirements for certain consecutive systems
3. Request for comment
a. Proposed IDSE and Stage 2B monitoring requirements
b. Plant-based vs. population-based monitoring requirements
i. Issues with plant-based monitoring requirements
ii. Approaches to addressing issues with plant-based monitoring
J. Compliance Schedules
1. What is EPA proposing?
2. How did EPA develop this proposal?
3. Request for comments
K. Public Notice Requirements
1. What is EPA proposing?
2. Request for comments
L. Variances and Exemptions
1. Variances
2. What are the affordable treatment technologies for small systems?
M. Requirements for Systems to Use Qualified Operators
N. System Reporting and Recordkeeping Requirements
1. Confirmation of applicable existing requirements
2. Summary of additional reporting requirements
3. Request for comment
O. Analytical Method Requirements
1. What is EPA proposing today?
2. How was this proposal developed?
3. Which new methods are proposed for approval?
a. EPA Method 327.0 for chlorine dioxide and chlorite.
b. EPA Method 552.3 for HAA5 and dalapon
c. ASTM D 6581–00 for bromate, chlorite, and bromide
d. EPA Method 317.0 revision 2 for bromate, chlorite, and bromide
e. EPA Method 326.0 for bromate, chlorite, and bromide
f. EPA Method 321.8 for bromate
g. EPA 415.3 for TOC and SUVA (DOC and UV_{254})
4. What additional regulated contaminants can be monitored by extending approval of EPA Method 300.1?
5. Which methods in the 20th edition and 2003 On-Line Version of Standard Methods are proposed for approval?
6. What is the updated citation for EPA Method 300.1?
7. How is the HAA5 sample holding time being standardized?
8. How is EPA clarifying which methods are approved for magnesium determinations?
9. Which methods can be used to demonstrate eligibility for reduced bromate monitoring?
10. Request for comments
P. Laboratory Certification and Approval
1. What is EPA proposing today?
2. What changes are proposed for the PE acceptance criteria?
3. What minimum reporting limits are being proposed?
4. What are the requirements for analyzing IDSE samples?
5. Request for comments
VI. State Implementation
A. State Primacy Requirements for Implementation Flexibility
B. State Recordkeeping Requirements
C. State Reporting Requirements
D. Interim Primacy
E. IDSE Implementation
F. State Burden
VII. Economic Analysis
A. Regulatory Alternatives Considered by the Agency
B. Rationale for the Proposed Rule Option
1. Reducing peak exposure
2. Reducing average exposure
C. Benefits of the Proposed Stage 2 DBPR
1. Non-quantifiable health and non-health related benefits
2. Quantifiable health benefits
3. Benefit sensitivity analyses
D. Costs of the Proposed Stage 2 DBPR
1. National cost estimates
2. Water system costs
3. State costs
4. Non-quantifiable
E. Expected System Treatment Changes
1. Pre-Stage 2 DBPR baseline conditions
2. Predicted technology distributions post-Stage 2 DBPR
F. Estimated Household Costs of the Proposed Rule
G. Incremental Costs and Benefits of the Proposed Stage 2 DBPR
H. Benefits From the Reduction of Co-Occurring Contaminants

I. Are there Increased Risks From Other Contaminants?
J. Effects on General Population and Subpopulation Groups
K. Uncertainties in Baseline, Risk, Benefit, and Cost Estimates
L. Benefit/Cost Determination for the Proposed Stage 2 DBPR
M. Request for Comment
VIII. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
G. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks
H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act
J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations or Low Income Populations
K. Consultations with the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services
L. Plain Language
IX. References

I. Summary

A. Why Is EPA Proposing the Stage 2 DBPR?

The Environmental Protection Agency is committed to ensuring that all public water systems provide clean and safe drinking water. Disinfectants are often an essential element of drinking water treatment because of the barrier they provide against harmful waterborne microbial pathogens. However, disinfectants react with naturally occurring organic and inorganic matter in source water and distribution systems to form disinfection byproducts (DBPs) that may pose health risks. The Agency is proposing the Stage 2 Disinfectants and Disinfection Byproduct Rule (DBPR) to reduce potential cancer, reproductive, and developmental risks from DBPs.

The Stage 2 DBPR augments the Stage 1 DBPR that was finalized in 1998. The proposed Stage 2 DBPR focuses on monitoring and reducing concentrations of two classes of DBPs: total trihalomethanes (TTHM) and haloacetic acids (HAA5). In part, these two groups of DBPs are used as indicators of the various byproducts that are present in disinfected water. This means that concentrations of TTHM and HAA5 are monitored for compliance, but their presence in drinking water is representative of many other DBPs that may also be present in the water; likewise, a reduction in TTHM and HAA5 indicates a reduction of total DBPs.

The Stage 2 DBPR is designed to reduce the level of exposure from disinfectants and DBPs without undermining the control of microbial pathogens. The Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) will be finalized and implemented simultaneously with the Stage 2 DBPR to ensure that drinking water is microbiologically safe at the limits set for disinfectants and DBPs.

New information on health effects, occurrence, and treatment has become available since the Stage 1 DBPR, which supports the need for the Stage 2 DBPR. Several reproductive and developmental studies have recently become available, and EPA has completed a more extensive analysis of reproductive and developmental effects associated with DBPs since the Stage 1 DBPR. Both human epidemiology studies and animal toxicology studies have shown associations between chlorinated drinking water and reproductive and developmental endpoints such as spontaneous abortion, stillbirth, neural tube defects, pre-term delivery, intrauterine growth retardation, and low birth weight. New epidemiology and toxicology studies evaluating bladder and rectal cancers have also increased the weight of evidence linking these health effects to DBP exposure. The large number of people (254 million Americans) exposed to DBPs and the identified potential cancer, reproductive, and developmental risks played a significant role in EPA's decision to move forward with regulatory changes that target lowering DBP exposures beyond the requirements of the Stage 1 DBPR.

While the Stage 1 DBPR provided a major reduction in DBP exposure, new national survey data suggest that some customers are receiving drinking water with elevated, or peak DBP concentrations even when their distribution systems are in compliance with the Stage 1 DBPR. Some of these peak concentrations can be substantially greater than the Stage 1 DBPR maximum contaminant levels (MCLs). The new survey results also showed that Stage 1 DBPR monitoring sites may not be representative of peak DBP concentrations that occur in distribution systems. In addition, the new information indicates that cost-effective technologies including ultraviolet light (UV) and granular activated carbon (GAC) may be very effective at lowering DBP levels. EPA's analysis of this new information concludes that significant public health benefits may be achieved through further cost-effective reduction of DBPs in distribution systems.

Congress required EPA to promulgate the Stage 2 DBPR as part of the 1996 Safe Drinking Water Act (SDWA) Amendments (section 1412(b)(2)(C)). Today's proposal reflects consensus recommendations from the Stage 2 Microbial/Disinfection Byproducts (M-DBP) Federal Advisory Committee (the Advisory Committee). These recommendations are set forth in the M-DBP Agreement in Principle (USEPA 2000g), which can be accessed on the edocket Web site (*www.epa.gov/edocket*).

After considering the new occurrence and health effects data and analyses, EPA has determined that there is an opportunity to further reduce potential risks from DBPs. The Stage 2 DBPR being proposed today presents a cost-effective, risk targeting approach to reduce risks from DBPs. The new requirements provide for more consistent protection from DBPs across the entire distribution system and the reduction of DBP peaks. New risk targeting provisions require only those systems with the greatest risk to make capital improvements. The Stage 2 DBPR, in conjunction with the LT2ESWTR, will help public water systems deliver safer water to Americans with the benefits of disinfection to control pathogens but with fewer risks from DBPs.

B. What Does the Stage 2 DBPR Require?

The Stage 2 DBPR applies to community or nontransient noncommunity water systems that add a primary or residual disinfectant other than ultraviolet light or deliver water that has been treated with a primary or residual disinfectant other than ultraviolet light. The TTHM and HAA5 MCL values will remain the same as in the Stage 1 DBPR, although compliance calculations will be different. The proposed Stage 2 DBPR includes new MCLGs for chloroform, monochloroacetic acid, and trichloroacetic acid, but these new MCLGs do not affect the MCLs for TTHM or HAA5.

The risk targeting components of the Stage 2 DBPR will focus the greatest amount of change where the greatest amount of risk may exist. The provisions of the Stage 2 DBPR focus on identifying and reducing exposure by reducing DBP peaks in distribution systems. The first provision, designed to address significant variations in exposure, is the Initial Distribution System Evaluation (IDSE). The purpose

of the IDSE is to identify Stage 2 DBPR compliance monitoring sites for capturing peaks. Because Stage 2 DBPR compliance will be determined at these new monitoring sites, distribution systems that identify elevated concentrations of TTHM and HAA5 will need to make treatment or process changes to bring the system into compliance with the Stage 2 DBPR. By identifying compliance monitoring sites with elevated concentrations of TTHM and HAA5, the IDSE will offer increased assurance that MCLs are being met across the distribution system. Both treatment changes and awareness of TTHM and HAA5 levels resulting from the IDSE will allow systems to better control for distribution system peaks.

The IDSE is designed to offer flexibility to public water systems. The IDSE requires TTHM and HAA5 monitoring for one year on a regular schedule that is determined by source water type and system size. Systems have the option of performing a site-specific study based on historical data, water distribution system models, or other data; and waivers are available under certain circumstances. The proposed IDSE requirements are discussed in sections V.H., V.I., and V.J. of this preamble and in subpart U of the proposed rule.

The second provision of the Stage 2 DBPR, which is designed to address variations in temporal and spatial exposure, is the new compliance calculation of the MCLs. The Stage 1 DBPR running annual average (RAA) calculation allows some locations within a distribution system to have higher DBP annual averages than others as long as the system-wide average is below the MCL. The Stage 2 DBPR will base compliance on a locational running annual average (LRAA) calculation where the annual average at each sampling location in the distribution system will be used to determine compliance with the MCLs. The LRAA will reduce exposures to peak DBP concentrations by ensuring that each monitoring site is in compliance with the MCLs as an annual average, and it will provide all customers drinking water that more consistently meets the MCLs.

EPA is proposing that systems comply with the Stage 2 DBPR MCLs in two phases, designated as Stage 2A and Stage 2B. In Stage 2A, beginning three years after the rule is final, all systems must comply with MCLs of 0.120 mg/L for TTHM and 0.100 mg/L for HAA5 as LRAAs at Stage 1 DBPR sampling sites, in addition to continuing to comply with the Stage 1 DBPR MCLs of 0.080 mg/L and 0.060 mg/L as RAAs for TTHM and HAA5, respectively. In Stage 2B, systems must comply with MCLs of 0.080 mg/L and 0.060 mg/L as LRAAs for TTHM and HAA5, respectively, based on sampling sites identified through the IDSE. A more detailed discussion of the proposed Stage 2 DBPR MCL requirements can be found in sections V.D., V.I., and V.J. of this preamble and in § 141.64(b)(2) and (3), and § 141.136, and subpart V of the rule language.

The IDSE and LRAA calculation will lead to overall reductions in DBP concentrations and reduce short term exposures to high DBP concentrations, but even with this strengthened approach to regulating DBPs it will be possible for individual DBP samples to exceed the MCLs when systems are in compliance with the Stage 2 DBPR. The Stage 2 DBPR requires systems that experience significant excursions to evaluate distribution system operational practices and identify opportunities to reduce DBP concentrations in the distribution system. This provision will curtail peaks and reduce exposure to high DBP levels. Significant excursions are discussed in greater detail in section V.E.

The Stage 2 DBPR also contains provisions for regulating consecutive systems, defined in the Stage 2 DBPR as public water systems that buy or otherwise receive some or all of their finished water from another public water system on a regular basis. Uniform regulation of consecutive systems provided by the Stage 2 DBPR will ensure that consecutive systems deliver drinking water that meets applicable DBP standards. More information on regulation of consecutive systems can be found in sections V.C., V.H., V.I. and V.J.

Today's document proposes plant-based monitoring requirements for non-consecutive systems and certain consecutive systems. Plant-based monitoring means that the number of compliance monitoring locations within a distribution system is based on the number of plants, population served, and type of source water used by the distribution system. EPA is proposing population-based monitoring for consecutive systems that buy all their finished water from other public water systems. EPA is also requesting comment on whether this approach should be extended to all systems covered by today's rule. Under a population-based monitoring structure, the number of compliance monitoring locations is based only on the population served and source water type. Section V.I. describes population-based monitoring and how it might affect systems complying with this rule.

C. What Are the Economic Impacts of the Stage 2 DBPR?

EPA quantified the potential benefits of the Stage 2 DBPR by estimating the reduction in bladder cancer cases that may result from the decrease in average DBP concentrations in disinfected water. Estimated reductions in DBP-related bladder cancers (including both fatal and non-fatal cases) result in annualized benefits ranging from $0 to $986 million (using a three percent discount rate), depending on the risk level assumed.

There may also be a number of important nonquantifiable benefits associated with reducing DBPs in drinking water, the primary ones being reduced potential risk of adverse reproductive and developmental effects including miscarriage, stillbirth, neural tube defects, heart defects, and cleft palate. Although a number of studies have found an association between reproductive and developmental endpoints and short-term exposure to elevated DBP levels, a causal link has not yet been established and information is not yet available to quantify potential effects. As a result, the Agency has not included an estimate of the potential benefits from reducing reproductive and developmental risks in its primary economic impact analysis of the Stage 2 DBPR. However, an illustrative calculation of potential fetal loss risk is discussed in Section VII and presented in more detail in the Economic Analysis (USEPA 2003i) to illustrate the benefits that could be associated with this rule. Reduction in other cancers potentially associated with DBP exposure represent additional unquantified health benefits.

EPA estimates the total annualized costs of the Stage 2 DBPR to be $54 to $64 million. This estimate includes costs associated with treatment changes, the Initial Distribution System Evaluation, changes in compliance monitoring, and rule implementation activities for both public water systems and States. EPA estimates that approximately 2.8 percent of all plants will need to convert to chloramines or add advanced treatment to comply with the Stage 2 DBPR.

Table I–1 presents the estimated quantified and unquantified benefits of the Stage 2 DBPR and the estimated costs. Analyses of unquantified benefits suggest that the total benefits associated with the Stage 2 DBPR might be much greater than these estimates. By targeting risks and building on the solid foundation of the Stage 1 DBPR, the

Stage 2 DBPR will deliver cost-effective reductions in DBP levels and associated potential public health risks.

TABLE I–1.—COSTS AND BENEFITS OF THE STAGE 2 DBPR BASED ON ANNUALIZATION DISCOUNT RATE OF 3%

Costs	Benefits	Unquantified benefits
$54–64 M	$0–986 M	Reduction in potential reproductive and developmental health effects, potential reduction in colon and rectal cancer, improved taste and odor of drinking water, control of contaminants that may be regulated in the future.

II. Background

A combination of factors have influenced the development of the proposed Stage 2 DBPR. These include the initial 1992–1994 Microbial and Disinfection Byproduct (M–DBP) stakeholder deliberations and EPA's Stage 1 DBPR proposal; the 1996 Safe Drinking Water Act (SDWA) Amendments; the 1996 Information Collection Rule; the 1998 Stage 1 DBPR; other new data, research, and analysis on disinfection byproduct (DBP) occurrence, treatment, and health effects since the Stage 1 DBPR; and the Stage 2 DBPR Microbial and Disinfection Byproducts Federal Advisory Committee. The following shows how EPA arrived at this proposal for regulating disinfection byproducts.

A. What Is the Statutory Authority for the Stage 2 DBPR?

The SDWA, as amended in 1996, authorizes EPA to promulgate a national primary drinking water regulation (NPDWR) and publish a maximum contaminant level goal (MCLG) for contaminants the Administrator determines ''may have an adverse effect on the health of persons,'' is ''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)). MCLGs are non-enforceable health goals set at a level at which ''no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety''. These health goals are published at the same time as the NPDWR (sections 1412(b)(4) and 1412(a)(3)).

The Agency may also consider additional health risks from other contaminants and establish an MCL ''at a level other than the feasible level, if the technology, treatment techniques, and other means used to determine the feasible level would result in an increase in the health risk from drinking water by—(i) increasing the concentration of other contaminants in drinking water; or (ii) interfering with the efficacy of drinking water treatment techniques or processes that are used to comply with other national primary drinking water regulations'' (section 1412(b)(5)(A)). When establishing an MCL or treatment technique under this authority, ''the level or levels of treatment techniques shall minimize the overall risk of adverse health effects by balancing the risk from the contaminant and the risk from other contaminants the concentrations of which may be affected by the use of a treatment technique or process that would be employed to attain the MCL or levels'' (section 1412(b)(5)(B)).

Finally, section 1412(b)(2)(C) of the Act requires EPA to promulgate a Stage 2 DBPR 18 months after promulgation of the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR). Consistent with statutory requirements for risk balancing (section 1412(b)(5)(B)), EPA will finalize the LT2ESWTR concurrently with the Stage 2 DBPR to ensure simultaneous protection from microbial and DBP risks.

B. What Is the Regulatory History of the Stage 2 DBPR?

The first rule to regulate DBPs was promulgated on November 29, 1979. The Total Trihalomethanes Rule (44 FR 68624) (USEPA 1979) set an MCL of 0.10 mg/L for total trihalomethanes (TTHMs). Compliance was based on the running annual average (RAA) of quarterly averages of all samples collected throughout the distribution system. This TTHM standard applied only to community water systems using surface water and/or ground water that served at least 10,000 people and added a disinfectant to the drinking water during any part of the treatment process.

Under the Surface Water Treatment Rule (SWTR) (54 FR 27486, June 29, 1989) (USEPA 1989a), EPA set MCLGs of zero for *Giardia lamblia,* viruses, and *Legionella;* and promulgated NPDWRs for all public water systems 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 other pathogenic organisms.

EPA also promulgated the Total Coliform Rule (TCR) on June 29, 1989 (54 FR 27544)(USEPA 1989b) to provide protection from microbial contamination in distribution systems of all types of public water supplies. The TCR established an MCLG of zero for total and fecal coliform bacteria, and an MCL based on the percentage of positive samples collected during a compliance period. Under the TCR, no more than 5 percent of distribution system samples collected in any month may contain coliform bacteria.

Together, the SWTR and the TCR were intended to address risks associated with microbial pathogens that might be found in source waters or associated with distribution systems. However, while reducing exposure to pathogenic organisms, the SWTR also increased the use of disinfectants in some public water systems and, as a result, exposure to DBPs in those systems.

In 1992, prompted by concerns about health risk tradeoffs between disinfection byproducts and microbial pathogens, EPA initiated a negotiated rulemaking with a wide range of stakeholders. The negotiators included representatives of State and local health and regulatory agencies, public water systems, elected officials, consumer groups, and environmental groups. The Regulatory Negotiating Committee met from November 1992 through June 1993. Following months of intensive discussions and technical analyses, the Regulatory Negotiating Committee recommended the development of three sets of rules: an Information Collection Rule, a two-staged approach for regulating DBPs, and an ''interim'' Enhanced Surface Water Treatment Rule (IESWTR) to be followed by a ''final'' Enhanced Surface Water Treatment Rule (USEPA 1996a, USEPA 1998c, USEPA 1998d). EPA took the first step towards implementing this strategy by proposing

the Stage 1 DBPR and IESWTR in 1994. Congress affirmed the phased microbial and disinfection byproduct rulemaking strategy in the 1996 SDWA Amendments by requiring that EPA develop these three sets of rules on a specific schedule that stipulates simultaneous promulgation of requirements governing microbial protection and DBPs.

In March 1997, the Agency established the Microbial and Disinfection Byproduct (M–DBP) Advisory Committee under the Federal Advisory Committee Act (FACA) to collect, share, and analyze new information and data available since the 1994 proposals of the Stage 1 DBPR and the IESWTR, as well as to build consensus on the regulatory implications of the new information. The Advisory 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 Advisory Committee met five times in March through July 1997 to discuss issues related to the IESWTR and the Stage 1 DBPR. The Advisory Committee reached consensus on a number of major issues that were incorporated into the Stage 1 DBPR and the IESWTR.

The Stage 1 DBPR and IESWTR, finalized in December 1998, were the first rules to be promulgated under the 1996 SDWA Amendments (USEPA 1998c and 1998d). The Stage 1 DBPR applies to all community and nontransient noncommunity water systems that add a chemical disinfectant to water. The rule established maximum residual disinfectant level goals (MRDLGs) and enforceable maximum residual disinfectant level (MRDL) standards for three chemical disinfectants—chlorine, chloramine, and chlorine dioxide; maximum contaminant level goals (MCLGs) for three THMs, two haloacetic acids (HAAs), bromate, and chlorite; and enforceable maximum contaminant level (MCL) standards for TTHM, five haloacetic acids (HAA5), chlorite, and bromate calculated as running annual averages (RAAs). The Stage 1 DBPR uses TTHMs and HAA5 as indicators of the various DBPs that are present in disinfected water. Under the Stage 1 DBPR, 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 (TOC), that may react with disinfectants to form DBPs. Removal is achieved through enhanced coagulation or enhanced softening, unless a system meets alternative compliance criteria.

EPA finalized the IESWTR at the same time as the Stage 1 DBPR to ensure simultaneous compliance and address risk tradeoff issues. The IESWTR applies to all water systems that use surface water or ground water under the direct influence of surface water that serve at least 10,000 people. The purpose of the IESWTR is to improve control of microbial pathogens in drinking water, specifically the protozoan *Cryptosporidium.*

The Filter Backwash Recycle Rule (FBRR) and the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR) round out the first group of regulations balancing microbial and DBP risks. EPA promulgated the FBRR in 2001 (USEPA 2001c) and the LT1ESWTR in 2002 (USEPA 2002b) to increase protection of finished drinking water supplies from contamination by *Cryptosporidium* and other microbial pathogens. The LT1ESWTR extends protection against *Cryptosporidium* and other disease-causing microbes to water systems that use surface water or ground water under the direct influence of surface water that serve fewer than 10,000 people. While the Ground Water Rule, proposed in May 2000, (USEPA 2000h) will add significant protection from pathogens in vulnerable ground water systems, it does not pose as many risk-risk tradeoff considerations as the surface water rules because only a small percentage of ground water systems subject to the Stage 2 DBPR have high DBP levels.

EPA reconvened the Advisory Committee in March 1999 to develop recommendations on issues pertaining to the Stage 2 DBPR and LT2ESWTR. The Advisory Committee collected, developed, and evaluated new information that became available after the Stage 1 DBPR was published. The Information Collection Rule provided new data on DBP exposure, and control; it also included new data on occurrence and treatment of pathogens. The unprecedented amount of information collected under the Information Collection Rule was supplemented by a survey conducted by the National Rural Water Association, data provided by various States, the Water Utility Database (which contains data collected by the American Water Works Association), and Information Collection Rule Supplemental Surveys. This large body of data allowed the Advisory Committee to reach new conclusions regarding DBP exposure and new treatment options.

After analyzing the data, the Advisory Committee reached three significant conclusions that led the Advisory Committee to recommending further control of DBPs in public water systems. The data from the Information Collection Rule show that the RAA compliance calculation allows elevated DBP levels to regularly occur at some locations in the system when the overall average at all locations is below the MCL. Customers served at those sampling locations that regularly exceed the MCLs are experiencing higher exposure compared to customers served at locations that consistently meet the MCLs.

Second, the new data demonstrated how single samples can be substantially above the MCLs. The new information showed that it is possible for customers to receive drinking water with concentrations of DBPs up to 75% above the MCLs even when their water system is in compliance with the Stage 1 DBPR. Studies have shown that DBP exposure during short, critical time windows may adversely impact reproductive and developmental health.

Third, data from the Information Collection Rule revealed that the highest TTHM and HAA5 levels are not always located at the maximum residence time monitoring sites specified by the Stage 1 DBPR. These sites were required for monitoring by the Stage 1 DBPR because previous data suggested that water in the distribution system for the maximum residence time would have the highest TTHM levels. The fact that the locations with the highest DBP levels varied in different public water systems indicates that the Stage 1 DBPR monitoring sites may not be representative of the high DBP concentrations that actually exist in distribution systems, and additional monitoring is needed to identify distribution system locations with elevated DBP levels. This information encouraged the Advisory Committee to recommend additional measures to identify locations with high LRAAs. Section IV provides a complete discussion of the new occurrence data.

The analysis of the new data also indicates that certain technologies are effective at reducing DBP concentrations. Bench- and pilot-scale studies for granular activated carbon (GAC) and membrane technologies required by the Information Collection Rule provided information on the effectiveness of the two technologies. Other studies found UV light to be highly effective for inactivating *Cryptosporidium* and *Giardia* at low doses without promoting the formation of DBPs (Malley *et al.* 1996; Zheng *et al.*

1999). This new treatment information added to the treatment options available to utilities for controlling DBPs beyond the requirements of the Stage 1 DBPR.

New data on the health effects of DBPs also influenced the Advisory Committee's recommendation to further regulate DBPs. Although bladder cancer risks were the focus of the Stage 1 M–DBP negotiations, potential reproductive and developmental health effects were central to the Stage 2 M–DBP Advisory Committee discussions. Recent human epidemiology studies and animal toxicology studies have both shown associations between chlorinated drinking water and reproductive and developmental health effects such as spontaneous abortion, stillbirth, neural tube defects, pre-term delivery, intrauterine growth retardation, and low birth weight. A critical review of the epidemiology literature pertaining to reproductive and developmental effects of exposure to DBPs completed in 2000 (Reif *et al.* 2000) concluded that ''the weight of evidence from the epidemiological studies also suggests that they [DBPs] are likely to be reproductive toxicants in humans under appropriate exposure conditions * * * and that measures aimed at reducing the concentrations of byproducts could have a positive impact on public health.''

While there has been substantial research to date, the Advisory Committee recognized that significant uncertainty remains regarding the risk associated with DBPs in drinking water. The Advisory Committee carefully considered the analyses described previously, as well as costs and potential impacts on public water systems, and concluded that a targeted protective public health approach should be taken to address exposure to DBPs beyond the requirements of the Stage 1 DBPR. After reaching this conclusion, the Advisory Committee developed an Agreement in Principle (USEPA 2000g) that laid out their recommendations on how to further control DBPs in public water systems.

In the Agreement in Principle, the Advisory Committee recommended maintaining the MCLs for TTHM and HAA5 at 0.080 mg/L and 0.060 mg/L respectively, but changing the compliance calculation in two phases to facilitate systems moving from the running annual average (RAA) calculation to a locational running annual average (LRAA) calculation. In the first phase, systems would continue to comply with the Stage 1 DBPR MCLs as RAAs and, at the same time, comply with MCLs of 0.120 mg/L for TTHM and 0.100 mg/L for HAA5 calculated as LRAAs. RAA calculations average all samples collected within a distribution system over a one-year period, but LRAA calculations average all samples taken at each individual sampling location in a distribution system during a one-year period. Systems would also carry out an Initial Distribution System Evaluation (IDSE) to select new compliance monitoring sites that more accurately reflect higher TTHM and HAA5 levels occurring in the distribution system. The second phase of compliance would require MCLs of 0.080 mg/L for TTHM and 0.060 mg/L for HAA5 calculated as LRAAs at individual monitoring sites identified through the IDSE.

The Agreement in Principle also provided recommendations for simultaneous compliance with the LT2ESWTR so that the reduction of potential health hazards of DBPs does not compromise microbial protection. The recommendations for the LT2ESWTR included treatment requirements for *Cryptosporidium* based on the results of source water monitoring, a toolbox of options for providing additional treatment at high risk facilities, use of microbial indicators to reduce *Cryptosporidium* monitoring burden on small systems, and future monitoring to determine if source water quality remains constant after completion of initial monitoring. The Agreement also encouraged EPA to develop guidance and criteria to facilitate the use of UV light for compliance with drinking water disinfection requirements. The complete text of the Agreement in Principle (USEPA 2000g) can be found at the edocket Web site *(http://www.epa.gov/edocket).*

After extensive analysis and investigation of available data and rule options considered by the Advisory Committee, EPA is proposing a Stage 2 DBPR control strategy that is consistent with the key elements of the Agreement in Principle signed in September 2000 by the participants in the Stage 2 M–DBP Advisory Committee. EPA determined that the risk-targeting measures recommended in the Agreement in Principle will require only those systems with the greatest risk to make treatment and operational changes and will maintain simultaneous protection from the potential health hazards of DBPs and microbial contaminants. EPA has carefully evaluated and expanded upon the recommendations of the Advisory Committee to more fully develop today's proposal. EPA also made simplifications where possible to minimize complications for public water systems as they transition to compliance with the Stage 2 DBPR while expanding public health protection. The proposed requirements of the Stage 2 DBPR are described in detail in section V of this preamble.

C. How Were Stakeholders Involved in Developing the Stage 2 DBPR?

1. Federal Advisory Committee Process

The Stage 2 M–DBP Advisory Committee consisted of 21 organizational members representing EPA, State and local public health and regulatory agencies, local elected officials, Native American Tribes, large and small drinking water suppliers, chemical and equipment manufacturers, environmental groups, and other stakeholders. Technical support for the Advisory Committee's discussions was provided by a technical working group established by the Advisory Committee. The Advisory Committee held ten meetings to discuss issues pertaining to the Stage 2 DBPR and LT2ESWTR from September 1999 to July 2000 which were open to the public. There was also an opportunity for public comment at each meeting.

In September 2000, the Advisory Committee signed the Agreement in Principle, a full statement of the consensus recommendations of the group. The agreement was published by EPA in a December 29, 2000 **Federal Register** notice (65 FR 83015), together with the list of committee members and their organizations. The Agreement is divided into Parts A and B. The recommendations in each part stand alone and are independent of one another. The entire Advisory Committee reached consensus on Part A, which contains provisions that directly apply to the proposed Stage 2 DBPR and LT2ESWTR. The full Advisory Committee, with the exception of the National Rural Water Association (NRWA), also agreed to Part B, which has recommendations for future activities by EPA in the areas of distribution systems and microbial water quality criteria.

2. Other Outreach Processes

EPA received valuable input from small system operators as part of an Agency outreach initiative under the Regulatory Flexibility Act (RFA). EPA also conducted outreach conference calls to solicit feedback and information from Small Entity Representatives (SERs) on issues related to Stage 2 DBPR impacts on small systems. The Agency consulted with State, local, and Tribal governments on the proposed Stage 2 DBPR. Section VIII includes a complete

description of the many stakeholder activities which contributed to the development of the Stage 2 DBPR.

The Agency held two meetings to discuss consecutive system issues relevant to the proposal (February 22–23, 2001 in Denver, CO and March 28, 2001 in Washington, DC). Representatives from States, EPA Regions, and public water systems participated in the discussions. EPA also briefed the National Drinking Water Advisory Committee at their November 2001 meeting on consecutive system issues associated with the rule to receive input on the implementation strategy selected. This Advisory Committee generally supported EPA's approach. Section V describes EPA's analysis of consecutive system issues, comments and input received during these sessions, and how the proposed requirements will apply to consecutive systems. EPA also consulted with the Science Advisory Board in December 2001 on the requirements of the Stage 2 DBPR.

Finally, EPA posted a pre-proposal draft of the Stage 2 DBPR preamble and regulatory language on an EPA Internet site *(http://www.epa.gov/safewater/mdbp/st2dis.html)* on October 17, 2001. This public review period allowed readers to comment on the Stage 2 DBPR's consistency with the Agreement in Principle of the Stage 2 M–DBP Advisory Committee. EPA received important suggestions on this pre-proposal draft from 14 commenters which included public water systems, State governments, laboratories, and other stakeholders. While EPA will not formally respond to these comments, EPA has carefully considered them in developing today's proposal.

III. Public Health Risk

Chlorine has been widely used as a chemical disinfectant, serving as a principal barrier to microbial contaminants in drinking water. However, the microbial risk reduction attributes of chlorination have been increasingly scrutinized due to concerns about potential increased health risks from exposure to disinfection byproducts, which are formed when certain disinfectants interact with organic and inorganic material in source waters. Since the discovery of chlorination byproducts in drinking water in 1974, numerous toxicological studies have shown several DBPs (*e.g.*, bromodichloromethane, bromoform, chloroform, dichloroacetic acid, trichloroacetic acid and bromate) to be carcinogenic in laboratory animals. These findings of carcinogenicity influenced EPA to promulgate the TTHM Rule in 1979 and the Stage 1 DBPR in 1998. The Stage 1 DBPR primarily addressed possible carcinogenic effects (*e.g.*, bladder, colon and rectal cancers) reported in both human epidemiology and laboratory animal studies. Since the Stage 1 DBPR, new health studies continue to support an association between bladder, colon and rectal cancers from long-term exposure to chlorinated surface water. In addition to cancer effects, recent studies have reported associations between use of chlorinated drinking water and a number of reproductive and developmental endpoints including spontaneous abortion, still birth, neural tube defect, pre-term delivery, low birth weight and intrauterine growth retardation (small for gestational age). Short-term, high-dose animal screening studies on individual byproducts (*e.g.*, bromodichloromethane (BDCM), and certain haloacetic acids) have also reported adverse reproductive and developmental effects (*e.g.*, whole litter resorption, reduced fetal body weight) that are similar to those reported in the human epidemiology studies. This section discusses the new studies that have become available since promulgation of the Stage 1 DBPR and how they contribute to the weight of evidence for an association between health effects and exposure to chlorinated surface water.

While the Stage 1 DBPR was targeted primarily at reducing long-term exposures to elevated levels of DBPs to address chronic health risks from cancer, the Stage 2 DBPR targets reducing short-term exposures to address potential reproductive and developmental health risks and cancer risks.

Based on the weight of evidence from both the human epidemiology and animal toxicology data on cancer and reproductive and developmental health effects and consideration of the large number of people exposed to chlorinated byproducts in drinking water (approximately 254 million), EPA concludes that: (1) Current reproductive and developmental health effects data support a hazard concern, (2) new cancer data strengthens the evidence of an association of chlorinated water with bladder cancer and suggests an association for colon and rectal cancers, and (3) the combined health data warrant regulatory action beyond the Stage 1 DBPR.

A. Reproductive and Developmental Epidemiology

The following section briefly discusses reproductive and developmental epidemiology information EPA analyzed, some conclusions of these studies and reports, and implications for the Stage 2 DBPR. Further discussion of the implications and EPA's conclusions can be found in the Stage 2 Economic Analysis (USEPA 2003i).

EPA has evaluated recently published epidemiological studies examining the relationship between exposure to contaminants in chlorinated surface water and adverse reproductive and developmental outcomes. EPA also considered critical reviews of the epidemiological literature by Reif *et al.* (2000), Bove *et al.* (2002), and Nieuwenhuijsen *et al.* (2000). Based on these evaluations, EPA believes that the reproductive and developmental epidemiology data contribute to the weight of evidence on the potential health risks from exposure to chlorinated drinking water. Although the data are not suitable for a quantitative risk assessment at this time, due in part to inconsistencies in the findings, they do suggest that exposure to DBPs is a potential reproductive and developmental health hazard.

1. Reif *et al.* 2000

Reif *et al.* (2000) completed a critical review of the epidemiology literature pertaining to reproductive and developmental effects of exposure to disinfection byproducts in drinking water as a report to Health Canada. The review focused on 16 peer-reviewed scientific manuscripts and published reports and evaluated associations between DBP exposure and outcomes grouped as effects on: (1) Fetal growth—low birth weight (<2500g); very low birth weight (<1500g); preterm delivery (<37 weeks of gestation) and intrauterine growth retardation (or small for gestational age); (2) fetal viability (spontaneous abortion and stillbirth) and (3) fetal malformations (all malformations, oral cleft defects, major cardiac defects, neural tube defects, and chromosomal abnormalities).

a. *Fetal growth.* Reif *et al.* (2000) found inconsistent epidemiological evidence for an association between DBPs and fetal growth. Some studies found weak but statistically significant associations (Gallagher *et al.* 1998; Bove *et al.* 1992 and 1995), while two studies found no association (Dodds *et al.* 1999; and Savitz *et al.* 1995) with fetal growth.

b. *Fetal viability.* Reif *et al.* 2000's review of the literature found inconsistencies in the epidemiological evidence for the association between DBP exposure and fetal viability. For instance, the study by Waller *et al.* 1998 found an apparent dose-dependent increase in rates of spontaneous

abortions associated with TTHMs in California. On the other hand, Savitz *et al.* (1995) found little evidence of an association using either the concentration of TTHM ≥81 μg/L or a dose estimate based on the amount of tap water consumed. An increased risk of stillbirth was reported for women in Nova Scotia by Dodds *et al.* 1999, but in New Jersey, Bove *et al.* (1992, 1995) found little evidence of an association with TTHM at 80 μg/L, but did report a weak association between stillbirth and use of surface water systems. Aschengrau *et al.* (1993) found an association between stillbirth and the use of a chlorinated vs. chloraminated surface water supply, but not for exposure to surface water.

c. *Fetal malformations and other developmental anomalies.* Reif *et al.* (2000) considered the data for congenital anomalies to be inconsistent across the six studies that have explored these outcomes. For example, two of the four studies on neural tube defects (Bove *et al.* 1995; Magnus *et al.* 1999) reported significant excess risks, but the remaining two studies (Dodds *et al.* 1999; Klotz and Pyrch *et al.* 1999) did not. These studies found lower risks or no evidence of an association with TTHM. However, those studies were conducted in locations with either very low or high concentrations of DBPs which may have limited the contrast in exposures, thereby reducing the ability to detect increased risks. An assessment of congenital anomalies is also difficult due to the relatively small number of cases available for evaluation.

Overall, Reif *et al.* (2000) conclude that the weight of evidence from the epidemiological studies suggest that ''DBPs are likely to be reproductive toxicants in humans under appropriate exposure conditions.'' Reif *et al.* comment that data from animal studies of individual DBPs provide biological plausibility for the effects observed in epidemiological studies. Although the authors recognize that the ''data are primarily at the stage of hazard identification,'' they conclude that ''measures aimed at reducing the concentrations of byproducts could have a positive impact on public health.''

2. Bove *et al.* 2002

Bove *et al.* (2002) conducted a qualitative review of 14 epidemiological studies that evaluated possible developmental and reproductive endpoints associated with exposure to chlorination byproducts in drinking water. Similar to Reif *et al.*, Bove *et al.* evaluated associations between DBP exposure and outcomes grouped as effects on (1) fetal growth—small for gestational age (SGA) as defined in each study (usually defined as the fifth or tenth percentile weight by gestational week of birth); (2) fetal viability—spontaneous abortion and stillbirth; and (3) fetal malformations (neural tube defects, oral clefts, and cardiac defects).

a. *Fetal growth.* Bove *et al.* found that, although the studies that evaluated SGA had several limitations, three studies out of eight (Kramer *et al.* 1992, Bove *et al.* 1995, and Gallagher *et al.* 1998) ''provided moderate evidence for a causal relationship between a narrow definition of SGA * * * and TTHM levels that could be found currently in some U.S. public water systems.'' They also concluded that the study with the best exposure assessment found the strongest association between SGA and TTHM exposure (Gallagher *et al.* 1998). One study found a very weak association (Dodds *et al.* 1999) and the other four did not observe an association (Yang *et al.* 2000, Kanitz *et al.* 1996, Kallen *et al.* 2000, and Jaakkola *et al.* 2001).

b. *Fetal viability.* Bove *et al.* evaluated three studies on spontaneous abortion and three studies on stillbirth. Again, Bove *et al.* found that the study employing the best methods found the strongest association between TTHM exposure and spontaneous abortions (Waller *et al.* 1998). The other two studies (Savitz *et al.* 1995 and Aschengrau *et al.* 1989) found weak associations. Two of the studies investigating stillbirths found an association between stillbirths and chlorinated surface water (Dodds *et al.* 2001 and Aschengrau *et al.* 1993). The third study (Bove *et al.* 1995) found no association, however this study did not evaluate individual THM levels or cause of death information.

c. *Fetal malformations.* Bove *et al.* evaluated seven studies that investigated the relationship between birth defects and DBP exposure. This evaluation found ''consistency among these studies in the findings for neural tube defects and oral cleft defects, but not for cardiac defects. Associations were found for neural tube defects in all three studies that examined neural tube defects. These studies also evaluated levels of THM exposure (Bove *et al.* 1995; Dodds *et al.* 1999; Klotz *et al.* 1999).'' Two studies evaluated oral cleft defects and levels of THMs; one found an association with TTHM (Bove *et al.* 1995) and the other found an association with chloroform (Dodds *et al.* 2001). A third study that did not evaluate THM levels did not identify an association with oral cleft defects (Jaakkola *et al.* 2001). Bove *et al.* 1995 found an association between cardiac defects and TTHM, but Dodds *et al.* 1999, 2001 and Shaw *et al.* 1991 did not. An association between chlorination and urinary tract defects was found in the three studies that evaluated that endpoint (Källén *et al.* 2000; Magnus *et al.* 1999; Aschengrau *et al.* 1993).

Bove *et al.* (2002) concluded that the current reproductive and developmental epidemiological database for exposure to chlorinated byproducts in drinking water presents moderate evidence for associations between DBP exposure and SGA, neural tube defects and spontaneous abortion. The authors acknowledged the difficulties in assessing exposure with any precision in the studies reviewed, but held the opinion that misclassification of exposure would tend to underestimate rather than overestimate the risk.

3. Nieuwenhuijsen *et al.* 2000

Nieuwenhuijsen *et al.* (2000) reviewed the toxicological and epidemiological literature and evaluated the potential risk of chlorination DBPs on human reproductive health. The authors state that ''some studies have shown associations for DBPs and other outcomes such as spontaneous abortions, stillbirths and birth defects, and although the evidence for these associations is weaker it is gaining weight.'' Nieuwenhuijsen *et al.* also concluded that, ''although studies report small risks that are difficult to interpret, the large number of people exposed to chlorinated water supplies constitutes a public health concern.''

4. Additional Epidemiology Studies

Three new reproductive and developmental epidemiological studies were completed that were not included in the Reif *et al.* 2000, Bove *et al.* 2002, or Nieuwenhuijsen *et al.* 2000 literature reviews.

Waller *et al.* 2001, recalculated the total trihalomethane exposures from their original publication (Waller *et al.* 1998) to evaluate two exposure assessment methods (closest site and utility-wide average). The new calculations were intended to reduce exposure misclassification by employing weighting factors and subset analyses. As in the 1998 publication, the new methods found a relationship between spontaneous abortion and THM exposure, although the unweighted utility-wide point estimate was lower than reported in the original manuscript.

Hwang *et al.* 2002, assessed the effect of water chlorination byproducts on specific birth defects in Norway by

classifying exposure on the basis of chlorination (yes/no) and amount of natural organic matter in the water. Statistically significant associations with exposure were found for risks of any birth defect, cardiac, respiratory, and urinary tract defects. For specific birth defects, a statistically significant association was found for a defect of the septum in the heart.

Windham *et al.*, 2003, assessed the relationship between exposure to THMs in drinking water and characteristics of the menstrual cycle among 403 women who provided daily urine samples for an average of 5.6 cycles. Women whose tap water had TTHM levels more than 0.060 mg/l had statistically significantly shorter menstrual cycles than women whose tap water had lower TTHMs. On average, the menstrual cycles of women with the higher levels of TTHMs were one day shorter than cycles of women with the lower levels (adjusted difference: −1.1 days, 95% confidence interval: −1.8 days to −0.4 days). This shortening occurred during the first half of the cycle, before ovulation (adjusted difference: −0.9 days; 95% confidence interval: −1.6 days to −0.2 days). There were no changes in bleed length or in the regularity of the cycles. Based on their study, Windham *et al.*, 2003, suggested that THM exposure may affect ovarian function, but since this is the first study to examine human menstrual cycle variation in relation to THM exposure, more research is needed to confirm the relationship. The public health implication of a small reduction in menstrual cycle length is not clear, but if THMs are related to disturbances in ovarian function, that might provide insight into the observed associations between THMs and a variety of adverse reproductive outcomes.

EPA's epidemiology research program continues to examine the relationship between exposure to DBPs and adverse developmental and reproductive effects. The Agency is supporting several studies using improved study designs to provide better information for characterizing potential risks. Details on EPA's epidemiology research program can be found at *http://cfint.rtpnc.epa.gov/dwportal/cfm/dwMDBP.cfm*.

B. Reproductive and Developmental Toxicology

Several new reproductive and developmental toxicology studies have become available since the December 1998 Stage 1 DBPR. This discussion presents some conclusions derived from these studies and reports, including hazard identification, as well as implications for the Stage 2 DBPR.

EPA conducted a literature search of animal toxicology studies on chronic and subchronic DBP exposures associated with reproductive and developmental health effects, evaluated the current reproductive and developmental toxicological database for several individual DBPs, and assessed two independent reviews (Tyl 2000 and WHO 2000). As a result of these analyses, EPA has concluded that although the database is not strong enough to quantify risk, it is sufficient to support a hazard concern. This hazard concern supports the need to address potential reproductive and developmental health effects in the Stage 2 DBPR. The following section describes how this conclusion was reached.

1. EPA Analysis and Research

Since the Stage 1 DBPR, EPA has continued to support reproductive and developmental toxicological research on various disinfection byproducts through extramural and intramural research programs. Information on EPA's toxicology programs can be found at *http://www.epa.gov/nheerl/*. These studies, along with data on several DBPs published after the 1998 Stage 1 DBPR, are summarized in the updated children's health document, ''Health Risks to Fetuses, Infants, and Children: A Review'' (USEPA 2003a).

In addition to this compilation of data, EPA has also prepared individual health criteria documents that provide detailed summaries of the relevant new information, as well as an overall characterization of the human health risks from exposure to certain DBPs (USEPA 2003b-USEPA 2003h, USEPA 2003l). From these new evaluations, EPA has concluded that several new studies on individual byproducts contribute to the weight of evidence for an association between DBP exposure and adverse effects on the developing fetus and reproduction. These effects include fetal loss, cardiovascular effects, and male reproductive effects and are associated with bromodichloromethane (BDCM), dichloroacetic acid (DCAA), trichloroacetic acid (TCAA), bromochloroacetic acid (BCAA), and dibromoacetic acid (DBAA). The data from these new studies do not change the MCLGs that were established as a part of the Stage 1 DBPR.

2. Tyl 2000

Tyl (2000) conducted a comprehensive review of the reproductive and developmental toxicology literature on DBPs representing over thirty-five studies. Adverse effects reported by these studies include developmental effects, whole litter resorption, reduced fetal body weights, and male reproductive effects (*e.g.*, inhibited spermiation, increased abnormal sperm). Many of these studies are categorized as high-dose, short-term screening studies that can be used to assess potential hazard (Table III–1), while the long term, two-generation reproduction studies could be an appropriate basis for quantitative risk assessment.

Disinfectant/DBP	Screening [1]	Developmental [2]	Two-generation [3] reproductive
Chlorine		✔	
Chlorine Dioxide	✔	✔	
Chloramine		✔	
Chloroform	✔	✔	✔
Bromoform	✔	✔	✔
Bromodichloromethane	✔	✔	in progress
Dibromochloromethane	✔	✔	
Monochloroacetic acid	✔	✔	
Dichloroacetic acid	✔	✔	
Trichloroacetic acid	✔	✔	
Monobromoacetic acid	✔	✔	
Dibromoacetic acid	✔	✔	in progress
Tribromoacetic acid	✔		
Bromochloroacetic acid	✔		in planning stage
Bromodichloroacetic acid	✔		
Dibromochloroacetic acid	✔		

Disinfectant/DBP	Screening [1]	Developmental [2]	Two-generation [3] reproductive
Chloroacetonitrile	✔		
Dichloroacetonitrile	✔	✔	
Trichloroacetonitrile	✔	✔	
Bromoacetonitrile	✔	✔	
Dibromoacetonitrile	✔		
Tribromoacetonitrile			
Bromochloroacetonitrile	✔	✔	
Propanal	✔	✔	
1,1 Dichloropropanone	✔		
Hexachloropropanone	✔		
Dichloromethane	✔		
MX	✔	✔	
Bromate	✔		
Chlorite	✔	✔	✔

✔ denotes the availability of at least one study in the following categories.
[1] Screening studies are for hazard identification. These types of studies include the following: whole embryo culture, NTP 35-day screening studies, Chernoff-Kavlock and its modified version, and short-term male reproductive toxicity screen.
[2] Developmental studies are used for dose-response determinations.
[3] Two-generation reproductive studies are multi-generation reproductive toxicity studies used for dose-response determinations.

Tyl concluded that, ''The screening studies, performed for a number of DBPs, are 'adequate' and 'sufficient' only to detect potent reproductive/developmental toxicants for hazard identification.'' Tyl further confirms that the database identifies certain DBPs with potential reproductive or developmental effects (Table III–2) and these are discussed further in the next section.

TABLE III–2.—POTENTIAL HAZARDS OF DBPS FOR REPRODUCTIVE AND DEVELOPMENTAL EFFECTS (ADAPTED FROM TYL, 2000)

Type of hazard	Disinfection byproducts
Developmental defects	TCAA, DCAA, MCAA and chlorite.
Whole litter resorption	Chloroform, bromoform, BDCM, DBCM, DCAA, TCAA, DCAN, and TCAN.
Fetotoxicity (reduced fetal body weights, increased variations)	Chloroform, BDCM, DBCM, DCAA, TCAA, DCAN, TCAN, DBAN, BCAN, MCAN.
Male reproductive effects (spermatotoxic)	DCAA, DBAA, BDCM.

a. *Developmental defects.* Tyl noted that adverse developmental effects that were reported from whole embryo culture tests on the developing heart, neural tube, eye, pharyngeal arch, and somites tended to be associated with haloacetic acids tested at high doses (Hunter *et al.* 1996; Saillenfait *et al.* 1995, Smith *et al.* 1989). Cardiovascular effects were also observed in vivo for TCAA and DCAA from developmental segment II toxicity studies at high doses (Smith *et al.* 1988, 1990).

b. *Whole litter resorption.* Whole litter resorption, likened to miscarriage or spontaneous abortion by Tyl 2000, was also observed at high doses in vivo for a range of DBPs as indicated in Table III–2 (Murray *et al.* 1979, Balster and Borzellca, 1982, Narotsky *et al.* 1992; 1997 a, b; Bielmeier *et al.* 2001; Smith *et al.* 1990; Smith *et al.* 1988). Tyl noted that similar effects were observed in several epidemiology studies.

c. *Fetal toxicity.* Fetal toxic effects such as reduced fetal body weights and increased variation were observed at high doses in vivo for a range of DBPs (*e.g.*, chloroform, BDCM, DBCM, DCAA, TCAA, DCAN, TCAN, DBAN, BCAN) (Thompson *et al.* 1974; Schwetz *et al.* 1974; Murray *et al.* 1979; Ruddick *et al.* 1983; Narotsky *et al.* 1992, Balster and Borzelleca, 1982; Smith *et al.* 1990). Again, Tyl noted a similarity in effects observed in epidemiology studies.

d. *Male reproductive effects.* Animal toxicology studies report increased risks of adverse effects on the male reproductive system from high doses of haloacetic acids and other DBPs that have not been studied in human epidemiology studies. Male reproductive effects (*e.g.*, inhibited spermiation, reduced epididymus, sperm number and motility, increased abnormal sperm, testicular damage and inhibited in vitro fertilization) were reported for DCAA, DBAA, TCAA and BDCM (Toth *et al.* 1992, Linder *et al.* 1997a, b; Linder *et al.* 1994a, b; Cosby and Dukelow 1992). Dr. Tyl noted that the adverse effects observed in the male reproductive toxicity screening studies (Toth *et al.* 1992; Linder *et al.* 1994a, b; 1997a, b) are confounded by a short dosing regimen and administration of test doses to only adult males.

From her review of the comprehensive animal toxicology database on reproductive and developmental health effects from DBP exposure, Dr. Tyl concludes that ''some DBPs have an intrinsic capacity to do harm, specifically to the developing conceptus and the male (and possibly the female) reproductive system''. She concludes that ''there is hazard to development from the haloacetic acids (TCAA, DCAA, MCAA) and acetate; to development from chloroform, bromoform, BDCM, DBCM, DCAA, TCAA, DCAN, and TCAN expressed as full litter resorption (which most likely indicates maternal endocrine/uterine effects); and fetotoxicity for chloroform, BDCM, DBCM, DCAA, TCAA, DCAN, TCAN, DBAN, BCAN, CAN, acetaldehyde, and possibly formaldehyde. Reproductive hazard exists for DCAA, DBAA, and possibly formaldehyde in males and for TCE and possibly formaldehyde in females.''

3. World Health Organization Review of the Reproductive and Developmental Toxicology Literature (2000)

The International Programme on Chemical Safety (IPCS) published an evaluation of Disinfectants and DBPs in its *Environmental Health Criteria* monograph series (WHO 2000). In this review of the toxicology data on reproductive and developmental effects from DBP exposure, the World Health Organization (WHO) concludes that although the data on these effects are not as robust as the cancer database, these effects are of potential health concern. The WHO concludes that reproductive effects in females have been principally embryolethality and fetal resorptions associated with the haloacetonitriles (trichloroacetonitrile, dichloroacetonitrile, bromochloroacetonitrile, and dibromoacetonitrile) and the dihaloacetates, while DCAA and DBAA have both been associated with adverse effects on male reproduction.

4. New Studies

Christian *et al.* (2001) conducted a developmental toxicity study with pregnant New Zealand White rabbits exposed to BDCM in drinking water at concentrations of 0, 15, 150, 450, and 900 ppm in drinking water on gestation days 6–29. The no observed adverse effect level (NOAEL) and lowest observed adverse effect level (LOAEL) identified for maternal toxicity in this study were 13.4 mg/kg-day (150 ppm) and 35.6 mg/kg-day (450 ppm), respectively, based on decreased body weight gain. The developmental NOAEL was 55.3 mg/kg-day (900 ppm) based on absence of statistically significant, dose-related effects at any tested concentration. Christian *et al.* (2001) also conducted a developmental study of BDCM in a second species, Sprague-Dawley rats. Rats were exposed to BDCM in the drinking water at concentrations of 0, 50, 150, 450, and 900 ppm on gestation days 6 to 21. The concentration-based maternal NOAEL and LOAEL for this study were 150 ppm and 450 ppm, respectively, based on statistically significant, persistent reductions in maternal body weight and body weight gains. Based on the mean consumed dosage of bromodichloromethane, these concentrations correspond to doses of 18.4 mg/kg-day and 45.0 mg/kg-day, respectively. The concentration-based developmental NOAEL and LOAEL were 450 ppm and 900 ppm, respectively, based on a significantly decreased number of ossification sites per fetus for the forelimb phalanges (bones of the hand or the foot) and the hindlimb metatarsals and phalanges. These concentrations correspond to mean consumed doses of 45.0 mg/kg-day and 82.0 mg/kg-day, respectively.

Christian *et al.* (2002b) summarized the results of a two-generation reproductive toxicity study on bromodichloromethane conducted in Sprague-Dawley rats. Bromodichloromethane was continuously provided to test animals in the drinking water at concentrations of 0, 50, 150, or 450 ppm. Average daily doses estimated for the 50, 150, and 450 ppm concentrations were reportedly 4.1 to 12.6, 11.6 to 40.2, and 29.5 to 109 mg/kg-day, respectively. The parental NOAEL and LOAEL were 50 and 150 ppm, respectively, based on statistically significant reduced body weight and body weight gain; F1 and F2 generation pup body weights were reduced in the 150 and 450 ppm groups during the lactation period after the pups began to drink the water provided to the dams. Body weight and body weight gain were also reduced in the 150 and 450 ppm F1 generation males and females. A marginal effect on estrous cyclicity was observed in F1 females in the 450 ppm exposure group. Small (≤6%), but statistically significant, delays in F1 generation sexual maturation occurred at 150 (males) and 450 ppm (males and females) as determined by timing of vaginal patency or preputial separation. The study's authors considered these effects to be a secondary response associated with reduced body weight, which appears to be dehydration brought about by taste aversion to the compound. The results of this study identify NOAEL and LOAEL values for reproductive effects of 50 ppm (4.1 to 12.6 mg/kg-day) and 150 ppm (11.6 to 40.2 mg/kg-day), respectively, based on delayed sexual maturation.

Bielmeier *et al.* (2001) conducted a series of experiments to investigate the mode of action in bromodichloromethane-induced full litter resorption (FLR). The study included a strain comparison of F344 and Sprague-Dawley (SD) rats. In the strain comparison experiment, female SD rats (13 to 14/dose group) were dosed with 0, 75, or 100 mg/kg-day by aqueous gavage in 10% Emulphor® on GD 6 to 10. F344 rats (12 to 14/dose group) were dosed with 0 or 75 mg/kg-day administered in the same vehicle. The incidence of FLR in the bromodichloromethane-treated F344 rats was 62%, while the incidence of FLR in SD rats treated with 75 or 100 mg/kg-day of bromodichloromethane was 0%. Both strains of rats showed similar signs of maternal toxicity, and the percent body weight loss after the first day of dosing was comparable for SD rats and the F344 rats that resorbed their litters. The rats were allowed to deliver and pups were examined on postnatal days 1 and 6. Surviving litters appeared normal and no effect on post-natal survival, litter size, or pup weight was observed. The series of experiments conducted by Bielmeier *et al.* (2001) identified a LOAEL of 75 mg/kg-day (the lowest dose tested) based on FLR in F344 rats. A NOAEL was not identified. Mechanistic studies indicate that BDCM-induced pregnancy loss is likely to be luteinizing hormone (LH)-mediated (Bielmeier *et al.*, 2001). It is possible that BDCM alters LH levels by disrupting the hypothalamic-pituitary-gonadal axis or by altering the responsiveness of the corpora lutea to LH. Since these possible mechanisms are potentially relevant to pregnancy maintenance in humans, EPA believes the finding of BDCM-induced pregnancy loss in F344 rats is relevant to risk assessment, and may provide insight into the epidemiological finding of increased risk of spontaneous abortion associated with consumption of BDCM (Waller *et al.* 1998, 2001).

Christian *et al.* (2002a) recently completed a two-generation drinking water study of DBA in rats. Male and female Sprague-Dawley rats (30/sex/exposure group) were administered DBA in drinking water at concentrations of 0, 50, 250, or 650 ppm continuously from initiation of exposure of the parental (P) generation male and female rats through weaning of the F_2 offspring. Based on testicular histomorphology indicative of abnormal spermatogenesis in P and F_1 males, the parental and reproductive/developmental toxicity LOAEL and NOAEL are 250 and 50 ppm, respectively.

Previous studies by EPA have reported adverse effects of DBA, administered via oral gavage, on spermatogenesis that impacted male fertility (Linder *et al.* 1994a, 1995, 1997a) at doses-comparable to those achieved in the Christian *et al.* (2002a) study. Based on these studies collectively, it is clear that DBA is spermatotoxic. Moreover, Veeramachaneni *et al.* (2000) reported in an abstract that sperm from male rabbits exposed to DBA *in utero* from gestation days 15 and throughout life reduced the fertility of artificially inseminated females as evidenced by reduced conceptions. When published, this study may support the evidence that DBA is a male reproductive system toxicant .

In addition, research on DBA by Klinefelter *et al.* (2001) has

demonstrated statistically significant delays in both vaginal opening and preputial separation using the body weight on the day of acquisition (postnatal day 45) as the co-variant. This was not found by Christian *et al* (2002a) using the body weight at weaning as the statistical covariant. However, the authors analyzed the data for preputial separation and vaginal opening with body weight on the day of weaning as a co-variant rather than body weight on the day of acquisition, *i.e.*, the day that the prepuce separates or the day the vagina opens. It is likely that there was an increase in body weight from postnatal day 21 (weaning) until preputial separation (day 45) that was independent of the delay in sexual maturation.

Although the Christian *et al.* (2002a) study was conducted in accordance with EPA's 1998 testing guidelines, EPA has incorporated newer, more sophisticated measures into recent intramural and extramural studies that have not yet been incorporated into the testing guidelines. Such measures include measuring changes in specific proteins in the sperm membrane proteome and fertility assessments via in utero insemination. EPA believes that additional research is needed, utilizing these newer toxicological measures, to clarify the extent to which DBA poses human reproductive or developmental risk. The database on male reproductive effects from exposure to DBA is incomplete and is not suitable for quantitative risk assessment at this time. It does, however, identify reproductive effects as an area of concern.

C. Conclusions Drawn From the Reproductive and Developmental Health Effects Data

EPA believes that the weight of evidence of the best available science, in conjunction with the widespread exposure, supports regulatory changes that target peak DBP exposures specifically through the Stage 2 DBPR. Several epidemiology studies found statistically significant associations between exposure to chlorinated drinking water and fetal growth, spontaneous abortion, stillbirth, and neural tube defects. Although uncertainties remain and the current database does not support a quantitative reproductive and developmental risk assessment for most of the DBPs, the weight of evidence provides an indication of a hazard concern that warrants additional regulatory action beyond the Stage 1 DBPR.

Biological plausibility for the effects observed in epidemiological studies has been demonstrated through various toxicological studies. Tyl 2000 states that ''effects observed in animal studies included embryonic heart and neural tube defects from haloacetic acids in vitro and in vivo, and full litter resorption, reduced numbers of implants per litter, and reduced fetal body weight per litter were also observed from exposure to specific trihalomethanes. Comparable effects were also observed in children in some (but not all) epidemiological studies, with exposure to trihalomethanes (THMs) usually used as a surrogate for specific DBP classes or individual DBPs, as follows: increased incidences of cardiac defects (Bove *et al.* 1995) and of neural tube defects in children (Bove *et al.* 1995; Dodds *et al.* 1999; Klotz and Pyrch 1998) were reported. Intrauterine growth retardation (IUGR, approximately equivalent to reduced fetal body weights per litter) was reported to be associated with waterborne chloroform (Kramer *et al.* 1992; Bove *et al.* 1995; Gallagher *et al.* 1998). Miscarriage or spontaneous abortion, or stillbirth (approximately equivalent to whole litter resorption, reduced numbers of total and/or live implants per litter, and increased resorptions per litter) were observed by Waller *et al.*, 1998; Dodds *et al.*, 1999; and Bove *et al.*, 1995.''

Similarity of effects between animals and humans lends credence to and strengthens the weight of evidence for an association between adverse reproductive and developmental health effects and exposure to chlorinated surface water. EPA believes that the weight of evidence of both the reproductive and developmental toxicological and epidemiological databases suggests that exposure to DBPs may induce potential adverse health effects on reproduction and fetal development at some DBP exposures. However, additional toxicological work is necessary to identify the mode of action for the effects observed.

D. Cancer Epidemiology

Epidemiological studies on cancer provide valuable information that contributes to the overall evidence on the potential human health hazards from exposure to chlorinated drinking water. In the area of epidemiology, a number of 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, some studies have found an association between bladder, rectal and colon cancer and exposure to chlorinated surface water.

1. Population Attributable Risk Analysis

Some epidemiological studies have linked the consumption of chlorinated surface waters to an increased risk of two major causes of human mortality in the United States, colorectal and bladder cancers (Cantor 1998). Bladder cancer was chosen as the primary endpoint of concern in the Stage 1 DBPR (USEPA 1998f) economic analysis because it had the most consistent database for a possible association to chlorinated surface water exposure. More studies have considered bladder cancer than any other cancer. EPA used the published mean risk estimates from five studies to quantify the potential range of risk for bladder cancer from DBP exposure. These risks were expressed as a range of population attributable risks (PAR) of 2–17% (USEPA 1998f). This means that if the associations reported in the studies turn out to reflect a causal link, between 2 and 17% of new bladder cancer cases could be attributable to DBPs. This PAR range also represents that portion of the bladder cancer cases that would not have occurred if the exposure to chlorinated drinking water were absent. A complete discussion of the Stage 1 DBPR bladder cancer PAR evaluation, including uncertainties and assumptions, can be found in the Stage 2 DBPR Economic Analysis (USEPA 2003i).

While EPA recognized the limitations of the epidemiological database for making risk estimates, the Agency believed that it was useful for developing an estimate of bladder cancer risk. The PARs were derived from measured risks (Odds Ratios and Relative Risk) based on the number of years exposed to chlorinated surface water. The uncertainties associated with these PAR estimates are largely due to the common prevalence of both the disease (bladder cancer) and exposure (chlorinated drinking water). EPA recognizes that risks from chlorinated drinking water may be lower or higher than those estimated from the epidemiological literature, and that the PAR range could include zero or be higher than 17%.

Using the PARs of 2% and 17%, EPA estimated that the number of possible bladder cancer cases per year potentially associated with exposures to DBPs in chlorinated drinking water could range from 1,100 to 9,300 cases. This was based on the estimate of 54,500 new bladder cancer cases per year nationally, as projected by the National Cancer Institute for 1997. A thorough discussion of cancer studies published prior to 1998 and possible

associations with DBP exposure can be found in the Stage 1 DBPR (USEPA 1998c).

2. New Epidemiological Cancer Studies

New studies published since the Stage 1 DBPR continue to support an association between bladder, colon and rectal cancers and exposure to chlorinated surface water (Yang *et al.* 1998; Koivusalo *et al.* 1998; King *et al.* 2000b). Based on the weight of evidence provided by the cancer epidemiology database, EPA has chosen to use the same PAR analysis to estimate the primary benefits from bladder cancer cases potentially avoided as a consequence of reducing the DBP levels from the Stage 2 DBPR (*see* section VII). For the Stage 2 DBPR analysis, EPA updated the 1997 estimate of new bladder cancer cases per year nationally from 54,500 to 56,500 (projected by the American Cancer Society, 2002) and accounted for the reductions in DBP exposure that were projected for the Stage 1 DBPR.

a. *New bladder cancer studies.* Bladder cancer and chlorinated DBP exposure has historically been the most strongly supported association of all the possible cancers, based on human evidence. Two new studies (Yang *et al.* 1998 and Koivusalo *et al.* 1998) also suggest an association of DBP exposure with bladder cancer. Yang *et al.* 1998 found a positive association between consumption of chlorinated drinking water and bladder cancer. Koivusalo *et al.* (1998) found evidence of increased risk as a function of increasing DBP exposure duration. Long exposure durations (≥45 years for Koivusalo *et al.* 1998) were associated with about a two-fold increase in risk. The new bladder cancer studies continue to support an association and potential for a causal relationship between exposure to chlorination byproducts and risk for bladder cancer.

A new publication by C.M. Villanueva *et al.* (Villanueva *et al.* 2003) reports on their meta-analysis of case-control and cohort studies. This meta-analysis may be useful for improving the estimate of national population attributable risk (fraction of bladder cancer cases in the U.S. that may be attributed to chlorinated drinking water). Compared to EPA's current approach (*i.e.*, providing a range of population attributable risks (PAR)), use of the meta-estimate would provide a more stable result because:

- It provides a single (meta) estimate of the odds ratio from which to calculate the PAR, thereby summarizing the results across studies, thus reducing the influence of geographic and temporal differences.
- It uses three additional high-quality studies not included in the PAR range analysis conducted by EPA (*i.e.*, studies by Koivusalo *et al.* 1998, Doyle *et al.* 1997, and Vena *et al.* 1993).
- It weights the individual studies according to their precision, so more precise estimates (due principally to greater numbers of cases) carry greater statistical weight and therefore have greater influence on the meta-estimate.
- In addition to the primary analysis, the authors conducted an evaluation of the robustness of their conclusions. They examined the sensitivity of estimates to decisions made with respect to exposure definitions, cut points defining exposure groups, inclusion/exclusion of individual studies, and potential publication bias.

The meta-analysis provided at least two meta-estimates that may be useful for estimating national population attributable risk:

- A combined odds ratio for ever-exposure, with confidence intervals and
- A combined dose-response regression slope coefficient, relating increasing odds ratios to additional years of chlorinated drinking water consumption.

EPA conducted an estimate of the impact of using the meta-analysis to provide a perspective on the national population attributable risk. This estimate is based on the author's correction of a minor transcription error in their published manuscript (the appropriate estimate for the King study yields corrected over-all odds ratio for ever-consumers of 1.2 with 95% confidence interval of 1.091 to 1.320, personal communication from M. Kogevinas to M. Messner, 5/19/2003). Assuming 70% of the U.S. population is in the ever-consumed category (based on the chlorinated surface water exposed population), a point estimate of the population attributable risk using the odds ratio from the meta-analysis is 12% (95% interval 6% to 18%). Although EPA's population attributable risk range (2% to 17%) was not intended to convey a quantified level of confidence, it is not vastly different from the meta-analysis' 95% confidence range of 6% to 18%. EPA regards the meta-range as additional support for EPA's population attributable risk range. The meta-analysis provides continued support for an association between exposure to chlorinated surface water and bladder cancer.

EPA requests comment on the use of a meta-estimated odds ratios to estimate national population attributable risk for the purpose of supporting the benefit analysis for this rule, either based specifically on the Villanueva *et al.* publication or on the application of a similar approach. EPA also solicits comments and suggestions for use of the combined dose-response regression slope coefficient associated with the increased risk of bladder cancer for each additional year's exposure to DBPs in drinking water for estimating the drop in risk associated with a reduction in DBPs as part of the benefit analysis of this rule. EPA provides further discussion and solicitation of comment on how the slope factor might further be considered in estimating the benefits of this rule in the economic section of this preamble.

b. *New colon cancer studies.* Colorectal cancer is the third most common type of new cancer cases and deaths in both men and women in the U.S. It is estimated that 148,300 new colorectal cancer cases will be diagnosed in 2002, with 56,600 resulting in deaths (American Cancer Society, 2002). Human epidemiology studies on chlorinated surface water have reported associations with colorectal cancer. Since the Stage 1 DBPR, two new human epidemiology studies (Yang *et al.* 1998 and King *et al.* 2000b) have been conducted to investigate the relationship between colon cancer and exposure to chlorinated surface water. Yang *et al.* 1998 did not identify an association between consumption of chlorinated drinking water and colon cancer. The King *et al.* (2000b) study found evidence of a DBP association with colon cancer among males, but no association was observed among females.

Similarity of effects reported in animal toxicity and human epidemiology studies strengthen the weight of evidence for an association between DBP exposure and colon cancer. Effects observed in animal studies which included tumors in BDCM exposed rats and mice at several sites (NTP 1987); colon tumors in bromoform exposed rats (NTP 1989); and development of aberrant crypt foci, a preneoplastic lesion of colon cancer in animals exposed to DBP mixtures (DeAngelo *et al.* 2002), are comparable to observations in some cancer epidemiological studies showing an association with colorectal cancer and consumption of chlorinated water (King *et al.* 2000b).

Even with the additional study showing an association, the epidemiological database on colon cancer as a whole is not as strong as that for bladder cancer. However, this new study increases the weight of evidence of an association between DBP exposure

and colon cancer. The Stage 1 DBPR (USEPA 1998c) includes additional discussion of colon cancer risks associated with DBP exposure.

c. *New rectal cancer studies.* The evidence for an association between DBPs and rectal cancer is stronger than for colon cancer. Yang *et al.* (1998) and Hildesheim *et al.* (1998) both found associations between chlorinated drinking water exposure and rectal cancer, and the associations had a similar magnitude in both sexes. Hildesheim *et al.* also found an association in both sexes with lifetime average THM concentration. The consistency of the dose-response trends, the consistency between sexes, and the apparent control of important potential confounders in this study all support the observed associations.

d. *Other cancers.* Two new human epidemiology studies support the possibility of an association between DBPs and kidney cancer. Yang *et al.* (1998) found a positive association for both males and females between consumption of chlorinated drinking water and kidney cancer. Koivusalo *et al.* (1998) found a small, statistically significant, exposure-related excess risk for kidney cancer for males. The association for females was not significant in the Koivusalo *et al.* 1998 study. The current database for this endpoint of cancer, however, is insufficient to conclude an association.

Cantor *et al.* (1999) studied brain cancer, focusing on gliomas. None of the exposure variables were related to brain cancer among females, but males showed a statistically significant, monotonically increasing risk associated with duration of exposure to chlorinated surface water. This study suggests a possible association between chlorination byproducts and gliomas; however, the evidence from this study is not strong enough to support a conclusion of a causal association.

Infante-Rivard *et al.* (2001) conducted a population-based case-control study in Quebec Province, Canada, to examine possible associations between childhood acute lymphoblastic leukemia and THMs. There were no associations with leukemia for any of the exposure indices for total THM, or specific THMs. Therefore, the study does not provide evidence of an association between any of the exposure variables and childhood leukemia.

3. Review of the Cancer Epidemiology Literature (WHO 2000)

The International Programme on Chemical Safety (IPCS) report on disinfectants and disinfection byproducts (WHO 2000) concludes that results of analytical epidemiological cancer studies are insufficient to support a causal relationship for bladder, colon, rectal, or any other cancer and chlorinated drinking water or THMs. The report notes that there is better evidence for an association between exposure to chlorinated surface water and bladder cancer than for other types of cancer. The WHO also concludes that based on the large number of people exposed to chlorinated drinking water, there is a need to address this potential health concern.

E. Cancer and Other Toxicology

Few new cancer toxicology studies have been completed since the Stage 1 DBPR was finalized in December 1998. The information provided in the following sections adds to the toxicology database and provides additional support for the Stage 2 DBPR to control DBP peaks (e.g, high TTHM and HAA5 levels) throughout distribution systems, but does not change the quantitative assessment of the MCLGs.

1. EPA Criteria Documents

To date, EPA has established lifetime cancer risk levels for four DBPs (bromoform, bromodichloromethane, bromate, and dichloroacetic acid) classified as ''probable'' carcinogens, as promulgated in the Stage 1 DBPR and reported in the Integrated Risk Information System (IRIS). Although researchers have continued to assess the cancer risks of DBPs, there has been little change in the overall DBP carcinogenicity database since the Stage 1 DBPR.

The most significant new publication since the Stage 1 DBPR was a study of DCAA tumorigenicity in mice by DeAngelo *et al.* (1999). The Agency has used the data from this study to revise the slope factor for DCAA and a drinking water 10^{-6} lifetime cancer risk concentration. The slope factor is a measure of the potency of a carcinogen while the 10^{-6} lifetime cancer risk concentration provides an estimate of the concentration of a contaminant in drinking water that is associated with an estimated excess lifetime cancer risk of one in a million (Table III–3).

Another significant advancement beyond the Stage 1 DBPR was the evaluation of the chloroform tumorigenicity data on the basis of its nonlinear mode of action following the draft 1999 proposed Guidelines for Carcinogen Risk Assessment (USEPA 1999a). The new chloroform assessment became available on IRIS (2001) in October, 2001 (see section V for a more detailed discussion).

The Criteria Documents for bromoform, bromodichloromethane, dibromochloromethane, and dichloroacetic acid that support the Stage 2 proposal include cancer slope factors and 10^{-6} lifetime cancer risk concentrations that have been modified from their Stage 1 values in order to reflect the methodology proposed in the 1996/1999 draft cancer guidelines (USEPA 1999a) (Table III–3). These include the values based on the Maximum Likelihood Estimate of the dose producing effects in 10 percent of the animals (ED_{10}) and from the lower 95 percent confidence bound on that value (LED_{10}). Except for dibromochloromethane, which is classified as a possible human carcinogen, the DBPs in Table III–3 (and bromate as noted previously) are classified as probable human carcinogens.

TABLE III—3.—QUANTIFICATION OF CANCER RISK

Disinfection byproduct	Risk factors from LED_{10}		Risk factors from ED_{10}	
	Slope factor $(mg/kg/day)^{-1}$	10^{-6} Risk concentration (mg/L)	Slope factor $(mg/kg/day)^{-1}$	10^{-6} Risk concentration (mg/L)
Bromodichloromethane	0.034	0.001	0.022	0.002
Bromoform	0.0045	0.008	0.0034	0.01
Dibromochloromethane	0.04	0.0009	0.017	0.002
Dichloroacetic Acid	0.048	0.0007	0.014	0.003

EPA believes that it is important to pursue additional research on cancer from DBPs. EPA has several ongoing studies in addition to a collaboration with the National Toxicology Program of the National Institute of Environmental Health Sciences. More information on EPA's toxicology research program can be found at *http://www.epa.gov/nheerl.*

2. Other Byproducts with Carcinogenic Potential

a. *3-chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-furanone) (MX)—multisite cancer.* MX is a byproduct of chlorination that is typically found at very low concentrations (approximately <0.000067 mg/L) in drinking water. The information available on MX was recently compiled in the *Quantitative Cancer Assessment for MX and chlorohydroxyfuranones* (USEPA 2000i). Overall, the weight of evidence indicates that MX is a direct-acting genotoxicant in mammals, with the ability to induce tumors in multiple sites. The primary sites for tumor formation are the thyroid and liver.

b. *N-nitrosodimethylamine (NDMA)—multisite cancer.* Health effects data indicate that NDMA is a probable human carcinogen, as described on IRIS (1991). Risk assessments have estimated that the 10^{-6} lifetime cancer risk level is 0.000007 mg/L based on induction of tumors at multiple sites. Recent studies have produced new information on the occurrence and mechanism of formation of NDMA but there is not enough information at this time to draw conclusions. More research is underway to determine the mechanism by which NDMA is formed in drinking water, and the extent of its occurrence in chloraminated systems.

3. Other Toxicological Effects

The Agency has modified the reference dose (RfD) values for 2 of the chlorinated acetic acids since the Stage 1 DBPR. Under the Stage 1 DBPR there was no established RfD for monochloroacetic acid (MCAA). Data from a drinking water exposure study of MCAA in rats by DeAngelo *et al.* (1997) were used to establish an RfD of 0.004 mg/kg/day based on observed increases in spleen weight. Data from DeAngelo (1997) were also used to calculate a new RfD of 0.03 mg/kg/day for trichloroacetic acid (TCAA) based on observed effects on body weight and liver effects. Detailed discussions of the new reference doses are located in section V of this preamble.

4. WHO Review of the Cancer Toxicology Literature (2000)

The IPCS report on Disinfectants and Disinfection Byproducts (WHO 2000) emphasizes that the bulk of the toxicology data focuses primarily on carcinogenesis. The Task Group found BDCM to be of particular interest because it produces tumors in both rats and mice at several sites. Although the HAAs appear to be without significant genotoxic activity, the brominated HAAs appear to induce oxidative damage to DNA, leading to tumor formation.

F. Conclusions Drawn From the Cancer Epidemiology and Toxicology

EPA believes that the cancer epidemiology and toxicology databases provide important information that contributes to the weight of evidence evaluation of the potential health risks from exposure to chlorinated drinking water. At this time the cancer epidemiology studies are insufficient to establish a causal relationship between exposure to chlorinated drinking water and cancer, but EPA does believe there is a potential association. The current database is sufficient for quantitative analysis on the endpoint of bladder cancer, as presented previously in the PAR analysis.

The association between DBP exposure and colon cancer remains more tenuous than the link to bladder cancer, although similarity of effects reported in animal toxicity and human epidemiology studies strengthens the weight of evidence for an association between DBP exposure and colon cancer. Studies finding potential relationships between exposure to chlorinated drinking water and rectal, kidney, and brain cancer also add to the weight of evidence for a public health concern. EPA believes that the overall cancer epidemiology and toxicology data support the decision to pursue additional DBP control measures as reflected in the Stage 2 DBPR.

G. Request for Comment

EPA requests comment on the conclusions drawn from the new health information summarized in this section. EPA requests comment on the weight of evidence evaluation of the potential reproductive and developmental hazards from DBPs and its potential implications for the regulatory provisions for the final Stage 2 DBPR. EPA solicits any additional data on the reproductive or developmental effects from DBPs that need to be considered for the final Stage 2 DBPR.

EPA requests comment on EPA's conclusions regarding cancer epidemiology and toxicology, and the new studies discussed in today's proposal. EPA solicits any additional cancer epidemiology and toxicology data that need to be considered for the final Stage 2 DBPR.

EPA also solicits any health information available to further assess risk to sensitive subpopulations, especially children and the elderly.

IV. DBP Occurrence Within Distribution Systems

New information on the occurrence of DBPs in distribution systems raises issues about the protection provided by the Stage 1 DBPR. This section presents the new information used to identify key issues and to support the development of the Stage 2 DBPR. For a more detailed discussion see the *Stage 2 Occurrence Assessment for Disinfectants and Disinfection Byproducts* (USEPA 2003o).

Under the Stage 1 DBPR, compliance with the DBP MCLs is determined by averaging, annually and system-wide, all DBP measurements. The following discussion shows that compliance based on system averages of DBP concentrations allows a significant number of sampling locations within distribution systems to have DBP levels above the MCLs. These peak DBP occurrences are masked by averaging with lower distribution system occurrence levels. The populations served by portions of the distribution system with higher DBP concentrations are not receiving the same level of health protection.

The new information also shows that the highest DBP levels often do not occur at distribution system sites identified as representing maximum residence time. The information further shows that the highest TTHM and HAA5 levels often do not occur at the same site within the distribution system. These two findings suggest that it is appropriate to reevaluate the Stage 1 DBPR compliance monitoring sites in order to target those sites with high DBP levels. EPA believes that distribution system compliance monitoring sites need to be reevaluated to ensure identification of sites that reflect both high TTHM and HAA5 occurrence.

A. Data Sources

1. Information Collection Rule Data

The Information Collection Rule (USEPA 1996a) established monitoring and data reporting requirements for large public water systems. Under the Information Collection Rule, systems serving at least 100,000 people were required to conduct DBP and DBP-

related monitoring. The 18 months of required monitoring, which began in July 1997 and ended in December 1998, applied to 296 public water systems (500 treatment plants).

The Information Collection Rule data show the national occurrence of: (1) Influent water quality parameters; (2) primary and secondary disinfectant use by the large plants; (3) occurrence of DBPs and DBP precursors in treatment plants, finished waters, and distributions systems; (4) microbial occurrence (in subpart H systems only); and (5) treatment plant monthly operation, and initial as well as final treatment plant design. The data were gathered after the Stage 1 DBPR was finalized (USEPA 1998c) but well before systems were required to meet Stage 1 DBPR requirements.

The Information Collection Rule required a significant investment for the water treatment industry, as well as for the EPA to analyze the data. Overall, the occurrence and treatment data collected under the Information Collection Rule, excluding microbial data, was estimated to cost systems $54 million (USEPA 1996a). In addition, systems using source waters with high DBP precursor levels were required to conduct bench and pilot studies to evaluate the effectiveness of granular activated carbon (GAC) and membrane technology to control for DBPs. The estimated cost for these studies totaled approximately $57 million (USEPA 1996a).

In addition to the analysis of DBPs in distribution systems, EPA used occurrence data from the Information Collection Rule to confirm selection of TTHM and HAA5 as appropriate contaminants for monitoring DBPs. EPA also used occurrence data from the Information Collection Rule to confirm differences in monitoring requirements for systems using surface water versus those using ground water, as stipulated under the Stage 1 DBR. Analysis of the Information Collection Rule data indicates that TTHM and HAA5 comprise on average, across all systems, about 50% of the total mixture of chlorinated DBPs and that TTHM and HAA5 concentrations are much lower and less variable in ground water systems than in surface water systems. These results support the basis for continuing the use of TTHM and HAA5 as indicators for controlling chlorinated DBPs. The data also reconfirmed that ground water systems require less monitoring than surface water systems based on lower and less variable DBP occurrence. For detailed analysis, see *Stage 2 Occurrence Assessment for Disinfectants and Disinfection Byproducts* (USEPA 2003o).

2. Other Data Sources Used To Support the Proposal

Table IV–1 summarizes the data sources other than the Information Collection Rule used to support the Stage 2 DBPR. The data from the Information Collection Rule is from large systems. To validate the conclusions drawn from analysis of the Information Collection Rule for small and medium systems, EPA compared these other data sources with the Information Collection Rule data. EPA found that there are significant similarities between large systems and medium and small systems with regard to source water quality (affecting DBP formation) and use of treatment technologies. Because of these similarities, EPA expects that small and medium systems would find DBP distribution system levels similar to those found in large systems following compliance with the Stage 1 DBPR requirements. For detailed discussion of this analysis, see *Stage 2 Occurrence Assessment for Disinfectants and Disinfection Byproducts* (USEPA 2003o) and *Economic Analysis for the Stage 2 Disinfection Byproducts Rule* (USEPA 2003i).

TABLE IV–1.—SUMMARY OF NON-INFORMATION COLLECTION RULE OCCURRENCE SURVEY DATA

Data source	Data collected	Geographic representation	Number of plants (By population served)
Information Collection Rule Supplemental Survey.	Raw source water-(Large Systems) TOC Raw source water-(Small & Medium Survey Systems) TOC, UV 254, bromide, turbidity, pH, & temperature.	Random national distribution by SW source type [1].	47 serving 100,000 or more. 40 serving 10,000–99,999. 40 serving fewer than 10,000.
WaterStats	Population served and flows Raw source water—Water Quality Parameters (WQPs), Source water type. Finished water-WQPs, TTHM, HAAs Treatment-unit processes, disinfectant used.	Random national distribution.	219 serving 100,000 or more. 623 serving 10,000–99,999. 30 serving fewer than 10,000.
National Rural Water Association Survey (NRWAS).	Population served and flows Raw source water-temperatures, turbidity, pH, and source water type, bromide, TOC, UV 254, alkalinity, calcium, and total hardness. Finished water-residence time estimate, total and individual THMs, individual HAAs and HAA5, HAA6, HAA9,TOC, UV 254, Bromide, Temperature, pH, free and total chlorine residual levels. Treatment-unit processes, disinfectant used.	Random national distribution.	117 serving fewer than 10,000.
State Data-Surface Water ..	Distribution system TTHM occurrence data.	AK, CA, IL, MN, MS, NC, TX, WA [2].	562 serving fewer than 10,000.
State Data-Ground Water ..	Distribution system TTHM occurrence data.	AK, CA, FL, IL, NC, TX, WA [2].	2336 serving fewer than 10,000.
Ground Water Supply Survey.	TOC and TTHM (one sample for each parameter at the entry point to distribution system.)	Random national distribution.	979 total.

[1] Source type designations include flowing stream and lake/reservoir (Except for 7 large plants pre-selected).

[2] Over 50 percent of each State's systems are represented. EPA believes that the data reasonably represent a full range of source water quality in small systems at the national level.

B. DBPs in Distribution Systems

EPA wanted to understand DBP occurrence in distribution systems likely to exist after implementation of the Stage 1 DBPR. Such an understanding would enable EPA to recognize options on how to improve protection under the Stage 2 DBPR. The analysis of occurrence data to support the Stage 2 DBPR is complicated because available national occurrence data do not reflect the changes in occurrence resulting from the implementation of the Stage 1 DBPR. Many utilities have only recently changed their treatment to comply with the Stage 1 DBPR (subpart H systems serving 10,000 people or more were required to comply beginning January 2002) or are about to make changes in treatment to comply with this rule (subpart H systems serving fewer than 10,000 people and ground water systems are required to comply beginning January 2004).

To address the above issue, EPA evaluated Stage 1 DBPR implications by using Information Collection Rule data from plants that would not exceed the Stage 1 DBPR TTHM and HAA5 MCLs as an annual average. The TTHM and HAA5 data consist of quarterly measurements in four locations in distribution systems associated with each Information Collection Rule treatment plant. Two samples were collected at sites representing average residence time (AVG1 and AVG2), one sample at a site intended to represent the maximum residence time (MAX), and one sample was reported as a distribution system equivalent (DSE). The DSE sample was generally representative of average residence times. EPA believes that the monitoring locations of the Information Collection Rule, while not necessarily being the same as the Stage 1 DBPR compliance monitoring sites, provide a close approximation of monitoring under the Stage 1 DBPR. EPA recognizes, however, that data for plants that are in compliance with Stage 1 MCLs even without installing additional treatment (perhaps because of low source water TOC) are not necessarily reflective of plants that make treatment changes to comply with the Stage 1 DBPR.

1. DBPs Above the MCL Occur at Some Locations in a Substantial Number of Plants

Figure IV–1 compares the TTHM running annual average (RAA) levels with the single highest TTHM concentration in the distribution system. Twenty one percent (60 of 290) of the Information Collection Rule plants had single TTHM concentrations higher than the 0.080 mg/L MCL. Figure IV–2 makes the same comparison for HAA5. Fourteen percent (40 of 290) of the plants meeting the Stage 1 DBPR MCL had single HAA5 concentrations higher than the 0.060 mg/L MCL. In systems with a low RAA for TTHM and HAA5, the highest single TTHM and HAA5 values are generally not much higher than the respective Stage 1 DBPR MCLs. However, as the RAAs increase, there is a greater likelihood of having peak levels above the MCLs. As the RAAs approach the Stage 1 DBPR MCLs, some of the distribution system single highest concentrations approach levels that are double the Stage 1 DBPR MCLs.

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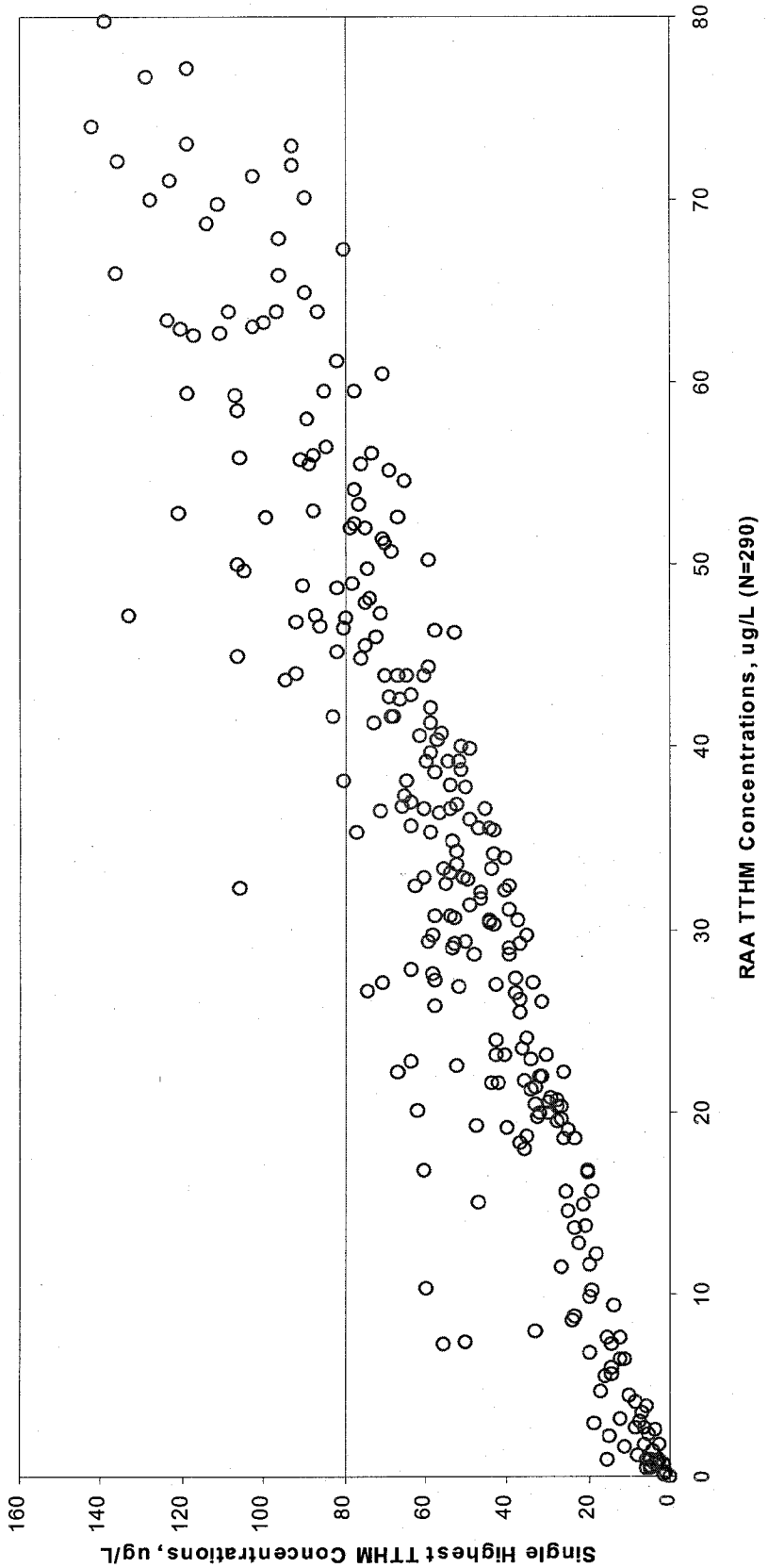
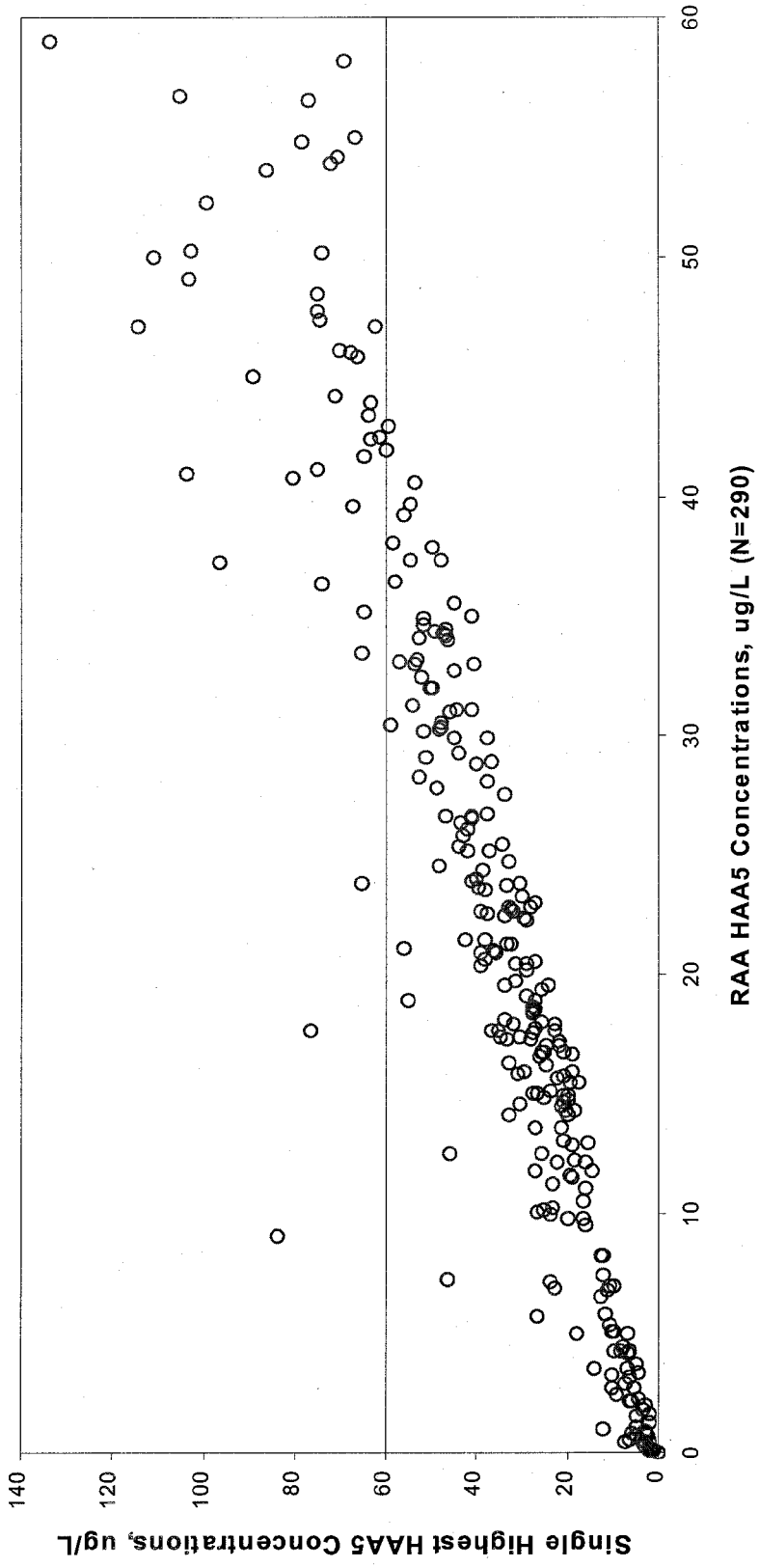
Figure IV-1. Single Highest TTHM Concentrations Versus TTHM RAA Concentrations for Plants Meeting Stage 1 DBPR MCLs



[1] Includes only the Information Collection Rule plants with at least 3 quarters of data and with each quarter having at least 3 sampling locations for both TTHM and HAA5 during the last 4 quarters of the Information Collection Rule sampling period.

Figure IV-2 Single Highest HAA5 Concentrations Versus HAA5 RAA Concentrations for Plants Meeting Stage 1 DBPR MCLs



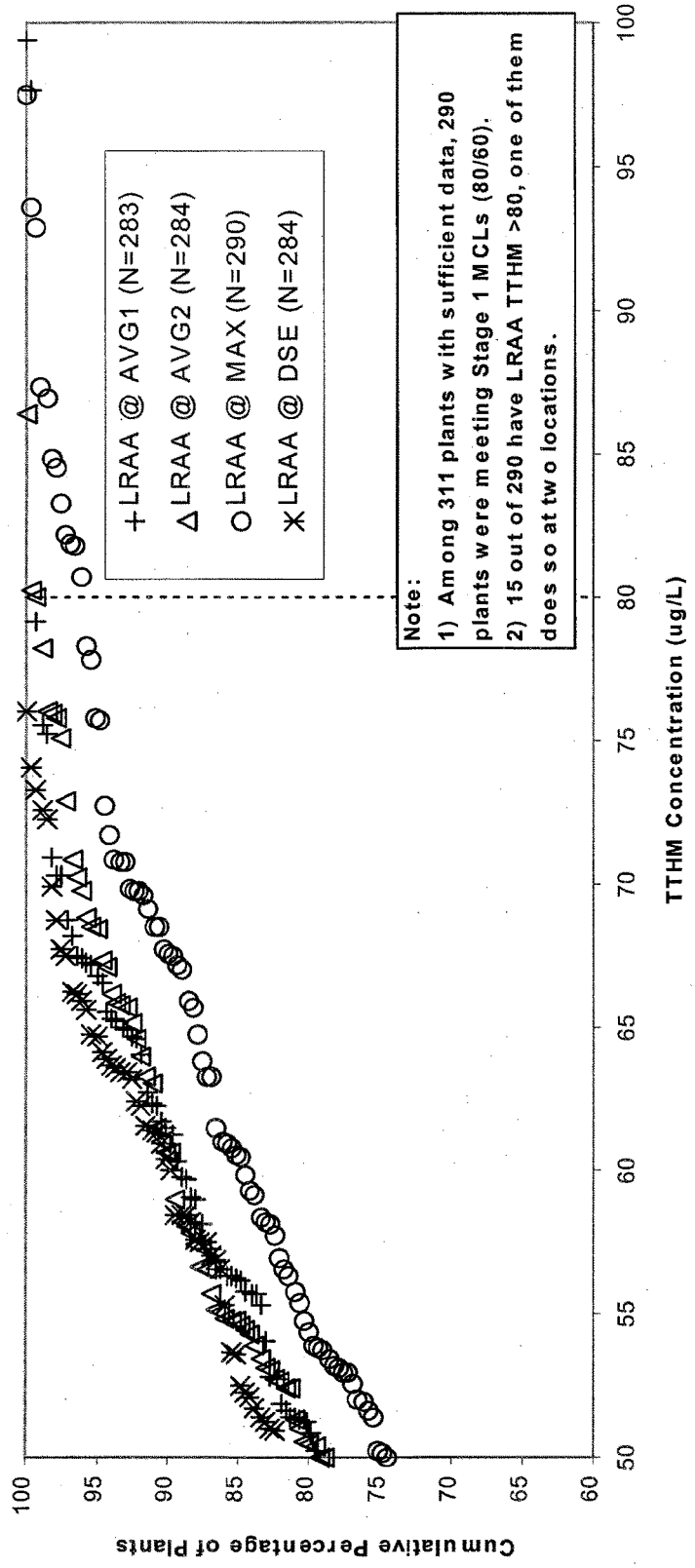
[1] Includes only the Information Collection Rule plants with at least 3 quarters of data and with each quarter having at least 3 sampling locations for both TTHM and HAA5 during the last 4 quarters of the Information Collection Rule sampling period.

2. Specific Locations in Distribution Systems Are Not Protected to MCL Levels

Data from the Information Collection Rule show that the RAA compliance calculation may allow specific locations in a distribution system to regularly receive water with DBP levels that exceed the MCL. Figure IV–3 shows that five percent of plants (15 out of 290) had one or more locations that, on average, exceeded 0.080 mg/L as a TTHM LRAA for that same year. One of the 15 plants that exceeded a TTHM LRAA of 0.080 mg/L did so at two locations. Of the 15 plants, the highest LRAA was between 0.080 and 0.090 mg/L at 10 plants, and between 0.090 and 0.100 mg/L at 5 plants. Customers served at these locations regularly received water with TTHM concentrations somewhat higher than the MCL.

Figure IV–4 shows similar results based on Information Collection Rule HAA5 data. Three percent of plants (eight of 290) exceeded 0.060 mg/L as an LRAA, and three of these eight plants did so at two or three locations. Of the 8 plants, the highest LRAA was between 0.060 and 0.070 mg/L at 5 plants, and between 0.070 and 0.075 mg/L at 3 plants. Among the 290 plants in the Information Collection Rule database meeting the Stage 1 MCLs, 19 plants have a maximum TTHM LRAA of 0.080 mg/l or greater or a maximum HAA5 LRAA of 0.060 mg/l or greater (four plants exceeded both MCLs), though in no case did DBP levels at a given location consistently exceed the MCL by more than 20%.

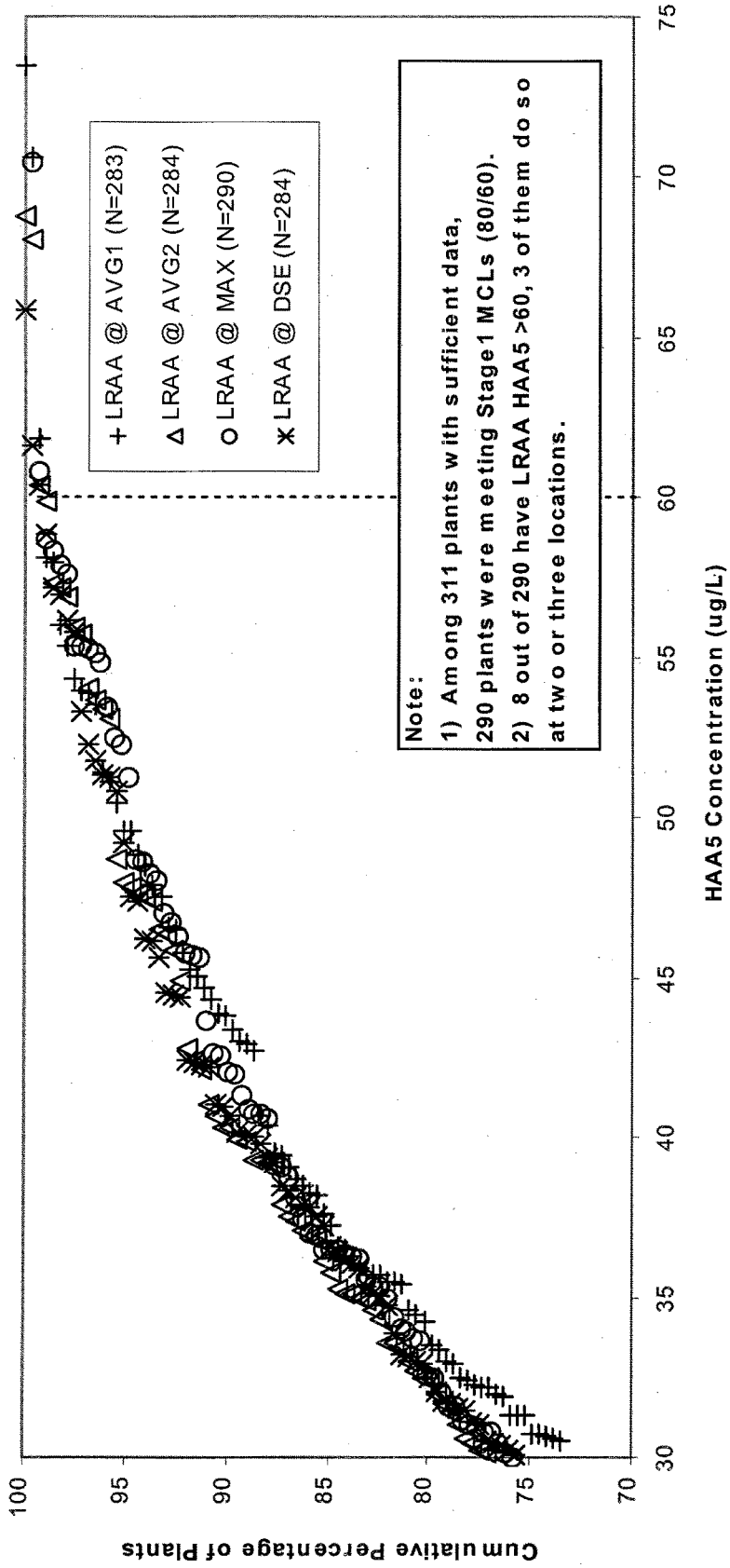
Figure IV-3. Cumulative Percentage of TTHM LRAAs for Surface Water Plants[1,2]



The data shown are for surface water plants that would not exceed the Stage 1 DBPR TTHM and HAA5 MCLs when calculated using the last 4 quarters of Information Collection Rule data.

[2] Includes only the Information Collection Rule plants with at least 3 quarters of data and with each quarter having at least 3 sampling locations for both TTHM and HAA5 during the last 4 quarters of the Information Collection Rule sampling period.

Figure IV-4. Cumulative Percentage of HAA5 LRAAs for Surface Water Plants[1,2].



[1] The data shown are for surface water plants that would not exceed the Stage 1 DBPR TTHM and HAA5 MCLs when calculated using the last 4 quarters of Information Collection Rule data.

[2] Includes only the Information Collection Rule plants with at least 3 quarters of data and with each quarter having at least 3 sampling locations for both TTHM and HAA5 during the last 4 quarters of the Information Collection Rule sampling period.

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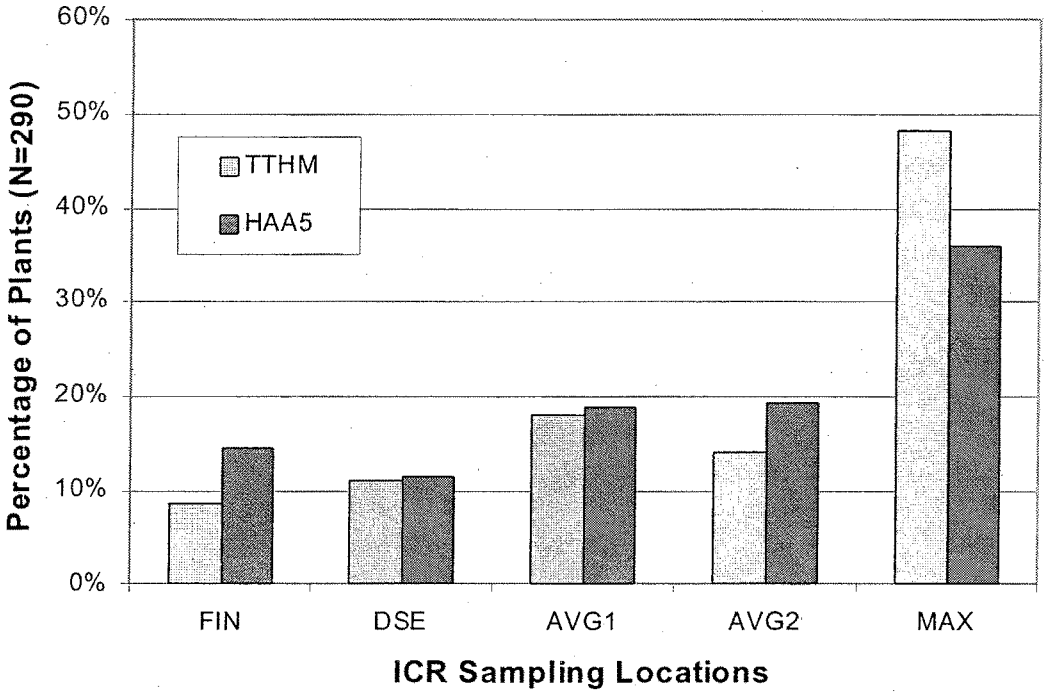
3. Stage 1 DBPR Maximum Residence Time Location May Not Reflect the Highest DBP Occurrence Levels

The 1979 TTHM rule and Stage 1 DBPR monitoring locations must include a site reflection maximum residence time in the distribution system with the intent of capturing the highest DBP levels in the distribution system. The Information Collection rule referred to this specific location as MAX. The Information Collection rule data indicate two important results: (1) that monitoring locations identified as the maximum residence time locations often did not represent those locations with the highest DBP levels and (2) the highest TTHM and HAA5 level often occurred at different points in the distribution system.

Figure IV–5 illustrates that the highest TTHM and HAA5 LRAAs could be at any of the four Information Collection Rule sample locations in the distribution system or, in some cases, at the finished water location. Fifty percent of the plants evaluated have the highest TTHM LRAA concentration occurring at a site other than the maximum residence time monitoring site. over 60% of plants evaluated had the highest HAA5 LRAA at a location other than the maximum residence time monitoring site.

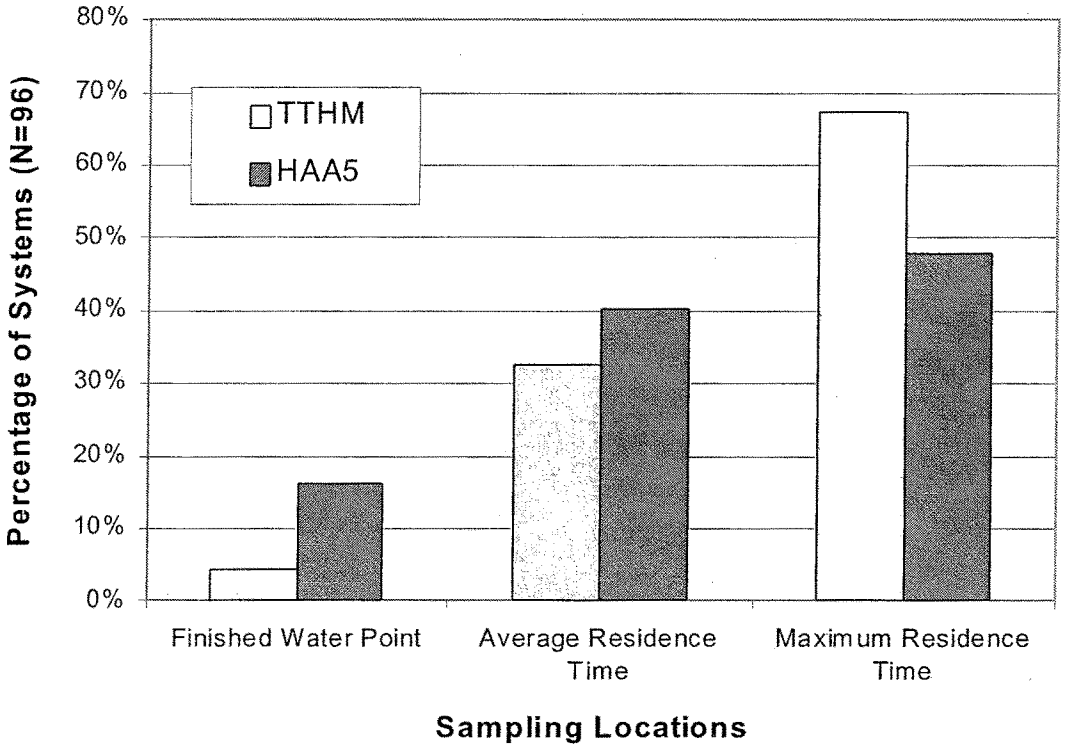
Figure IV–6, based on data from the National Rural Water Survey (NRWS), indicates that systems serving fewer than 10,000 people also frequently have their highest TTHM and HAAS levels at locations other than those intended to represent maximum residence time. The occurrence patterns indicated in Figures IV–5 and IV–6 may be due to several factors, such as HHA5 degrading over time in the distribution system, maximum residence time monitoring sites not actually representing the maximum residence time, or that using a simple estimation of maximum residence time cannot characterize a complex distribution system.

Figure IV-5. Frequency at Which Highest TTHM or HAA5 Locational Annual Average Concentrations Occurred at Each Information Collection Rule Sampling Location for plants meeting Stage 1 MCLs[1]



[1] Includes only the Information Collection Rule plants with at least 3 quarters of data and with each quarter having at least 3 sampling locations for both TTHM and HAA5 during the last 4 quarters of the Information Collection Rule sampling period.

Figure IV-6 Frequency at Which Highest TTHM or HAA5 Locational Annual Average Concentrations Occurred at Each Monitoring Location in NRWA Survey



Note: LRAA calculation is based on the results from two sampling events at each of sampling locations in the NRWA survey (winter and summer months). Only plants having monitoring results for both winter and summer months are included in the data set.

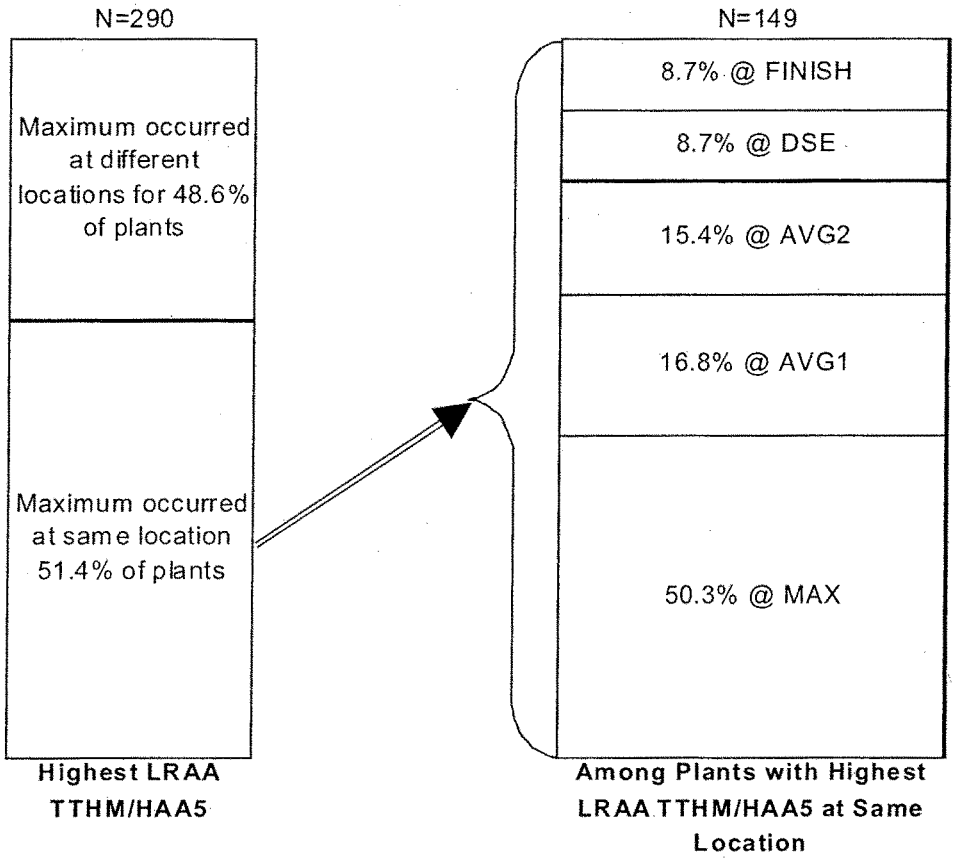
EPA also analyzed whether the highest LRAA for TTHM and HAA5 occurred at the same location. If TTHM and HAA5 occur at the same location rather than different locations, fewer monitoring sites would be needed to represent TTHM and HAA5 occurrence. However, this is not the case. The Information Collection Rule and NRWA data sets, respectively, indicate that 49% and 44% of plants experienced their highest LRAA TTHM and HAA5 concentrations at different locations in the distribution system.

For plants that did have their highest LRAA TTHM and HAA5 concentrations at the same location, it was not necessarily the maximum residence time monitoring location. Figure IV–7 illustrates that for the Information Collection Rule plants with the highest TTHM and HAA5 levels occurring at the same location, the highest TTHM and HAA5 LRAA simultaneously occurred at the maximum residence time monitoring location in 50% of the cases. Figure IV–8 illustrates that for the NRWA plants with the highest TTHM and HAA5 levels occurring at the same location, the highest TTHM and HAA5 LRAA simultaneously occurred at the maximum residence time (MAX) monitoring location in 64% of the cases.

C. Request for Comment

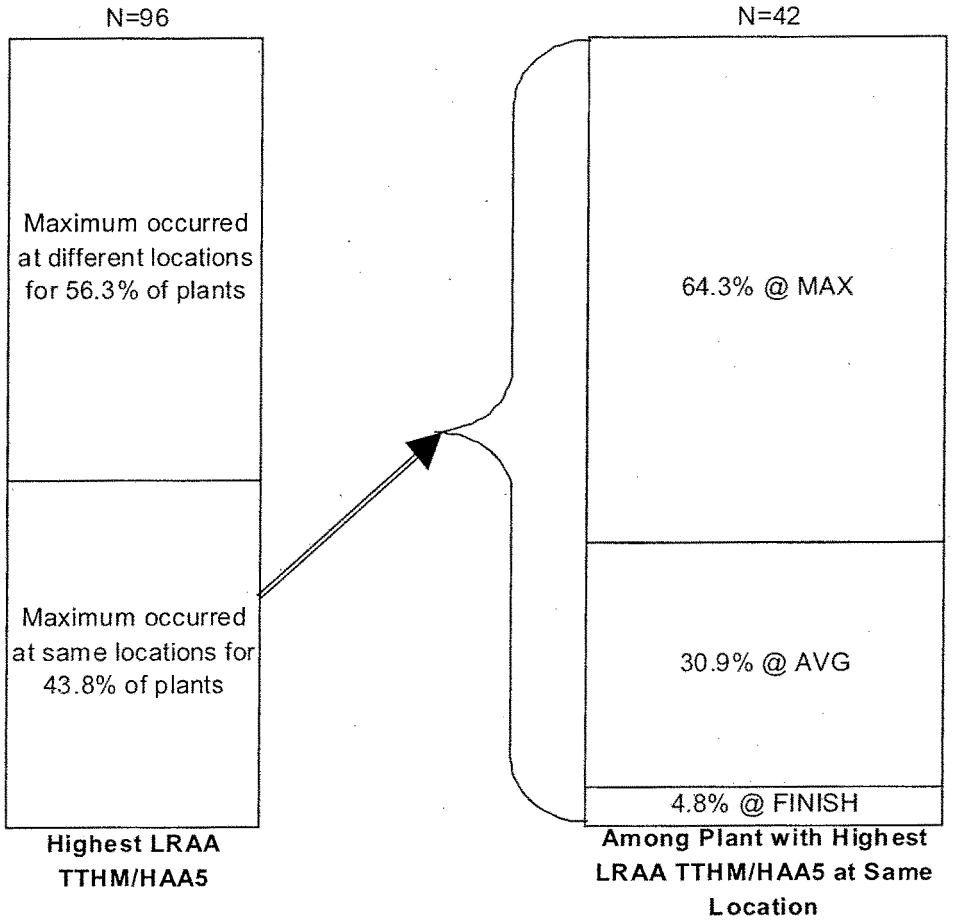
EPA requests comment on the analysis presented in this section. Is EPA's approach for representing post Stage 1 DBPR occurrence appropriate? What other approaches might be used? Are the conclusions that EPA derives from the analysis appropriate?

Figure IV-7. Frequency at Which Highest TTHM/HAA5 LRAAs Occurred at Same Sampling Location (Based on the Information Collection Rule data) for plants meeting Stage 1 MCLs. [1]



[1]Includes only the Information Collection Rule plants with at least 3 quarters of data and with each quarter having at least 3 sampling locations for both TTHM and HAA5 during the last 4 quarters of the Information Collection Rule sampling period.

Figure IV-8. Frequency at Which Highest TTHM/HAA5 LRAAs Occurred at Same Sampling Location (Based on the data from NRWA Survey)



Note: LRAA calculation is based on the results from two sampling events at each of sampling locations in the NRWA survey (winter and summer months). Only plants having monitoring results for both winter and summer months are included in the data set.

V. Discussion of Proposed Stage 2 DBPR Requirements

A. MCLG for Chloroform

1. What Is EPA Proposing Today?

EPA is proposing an MCLG for chloroform of 0.07 mg/L based on a cancer reference dose (RfD), an assumption that a person drinks 2 liters of water per day (the 90th percentile of intake rate for the U.S. population), and a relative source contribution (RSC) of 20 percent. The MCLG is proposed at a level at which no adverse effects on the health of persons is anticipated with an adequate margin of safety. This conclusion is based on toxicological evidence that the carcinogenic effects of chloroform are an ultimate consequence of sustained tissue toxicity. The MCLG is set at a daily dose for a lifetime at which no adverse effects will occur because the sustained tissue toxicity, which is a key event in the cancer mode of action of chloroform, will not occur (USEPA 2001b).

EPA believes that the RfD used for chloroform is protective of sensitive groups, including children. This RfD was developed by the EPA current method for developing RfDs based on animal data. The method is designed to be protective by taking human variability into account and assuming that the average human will be as sensitive as the most responsive animal species. EPA's understanding of the mode of action for chloroform does not indicate a uniquely sensitive subgroup or an increased sensitivity in children.

2. How Was This Proposal Developed?

a. *Background.* EPA proposed a zero MCLG for chloroform in the 1994 Stage 1 DBPR proposal (USEPA 1994b). Following the proposal, numerous toxicological studies on chloroform were published and were discussed in two Notices of Data Availability (NODAs) (USEPA 1997a; USEPA 1998e). The 1998 NODA presented substantial scientific data related to the mode of action as part of the chloroform risk assessment and requested comment on a chloroform MCLG of 0.3 mg/L that reflected a nonlinear mode of action. After considering comments on the NODAs, EPA determined that further deliberations with the Science Advisory Board (SAB) and stakeholders were needed before changing the MCLG for chloroform. Thus, EPA promulgated a chloroform MCLG of zero in the final Stage 1 DBPR (USEPA 1998c) and committed to conducting additional deliberations with the SAB and factoring the SAB's review into the Agency's Stage 2 DBPR rulemaking

process. The Agency consulted with the SAB in October 1999 (USEPA 2000f).

The Stage 1 DBPR MCLG of zero for chloroform was challenged, and the U.S. Court of Appeals for the District of Columbia Circuit issued an order vacating the zero MCLG (*Chlorine Chemistry Council and Chemical Manufacturers Association* v. *EPA,* 206 f.3d 1286 (D.C. Circuit 2000)). EPA committed to the Court to propose a non-zero MCLG for chloroform in the upcoming proposed Stage 2 Disinfectants and Disinfection Byproducts Rule. EPA removed the MCLG for chloroform from its Stage 1 DBP NPDWR (USEPA 2000e). No other provision of the Stage 1 DBPR was affected.

b. *Basis of the new chloroform MCLG.* Based on an analysis of all the available scientific data on chloroform discussed in more detail below, EPA believes that chloroform dose-response is nonlinear and that chloroform is likely to be carcinogenic only under high exposure conditions. EPA's assessment of the cancer risk associated with chloroform exposure (USEPA 2001b) uses the principles of the 1999 EPA Proposed Guidelines for Carcinogen Risk Assessment (USEPA 1999a).

The Proposed Guidelines for Carcinogen Risk Assessment, as reviewed by the public and the EPA SAB, reflect new science and are consistent with, and an extension of, the existing 1986 Guidelines for Carcinogen Risk Assessment (USEPA 1986). The 1986 guidelines provide for departures from default assumptions such as low dose linear extrapolation. For example, the 1986 EPA guidelines reflect the position of the Office of Science and Technology Policy (OSTP) that (OSTP 1985; Principle 26) ''[N]o 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 1985 guidelines go on to 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.''

i. *Mode of action.* EPA has fully evaluated the science on chloroform and concludes that chloroform is likely to be carcinogenic to humans under high exposure conditions that lead to cytotoxicity and regenerative hyperplasia in susceptible tissue; chloroform is not likely to be carcinogenic to humans at a dose level that does not cause cytotoxicity and cell regeneration (USEPA 1998e, USEPA 1998b, USEPA 2001b).

Chloroform's carcinogenic potential is indicated by animal tumor evidence (liver tumors in mice and renal tumors in both mice and rats) from inhalation and oral exposure. Data on metabolism, toxicity, mutagenicity and cellular proliferation contribute to an understanding of the mode of carcinogenic action. For chloroform, sustained or repeated cytotoxicity with secondary regenerative hyperplasia precedes, and is a key event for, hepatic and renal neoplasia.

EPA believes that a DNA reactive mutagenic mode of action is not likely to be the predominant influence of chloroform on the carcinogenic process. EPA has concluded that the predominant mode of action involves cytotoxicity produced by the oxidative generation of highly reactive metabolites, followed by regenerative cell proliferation (USEPA 2001b). EPA further believes that the chloroform dose-response is nonlinear. The SAB final report states ''(t)he Subcommittee agrees with EPA that sustained or repeated cytotoxicity with secondary regenerative hyperplasia in the liver and/or kidney of rats and mice precedes, and is probably a causal factor for, hepatic and renal neoplasia'' (USEPA 2000f).

ii. *Metabolism.* The cytochrome P450 isoenzyme CYP 2E1 is the primary enzyme catalyzing chloroform metabolism at low concentrations. Chloroform's carcinogenic effects involve oxidative generation of reactive and toxic metabolites (phosgene and hydrochloric acid [HCl]) and thus are related to its noncancer toxicities (*e.g.*, liver or kidney toxicities). The electrophilic metabolite phosgene could react with macromolecules such as phosphotidyl inositols or tyrosine kinases which in turn could potentially lead to interference with signal transduction pathways (*i.e.*, chemical messages controlling cell division), thus leading to carcinogenesis. Likewise, it is also plausible that phosgene reacts with cellular phospholipids, peptides and proteins resulting in generalized tissue injury. Glutathione, free cysteine, histidine, methionine and tyrosine are all potential reactants for electrophilic agents.

At high concentrations, chloroform may undergo reductive metabolism which forms reactive dichloromethyl free radicals. These free radicals can contribute to lipid peroxidation and cause cytotoxicity.

c. *How the MCLG is derived.* EPA continues to recognize the strength of the science in support of a nonlinear approach for estimating the carcinogenicity of chloroform. This science was affirmed by the Chloroform Risk Assessment Review Subcommittee of the EPA SAB Executive Committee which met on October 27–28, 1999 (USEPA 2000f). The SAB Subcommittee agreed that the nonlinear approach is most appropriate for the risk assessment of chloroform.

Nonzero MCLGs are scientifically and statutorily supported. The statute requires that the MCLG be set where no known or anticipated adverse effects occur, allowing for an adequate margin of safety (56 FR 3533; USEPA 1991b). Historically, EPA 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. If there is substantial scientific evidence, however, that indicates there is a ''safe threshold'', then a nonzero MCLG can be established with an adequate margin of safety (56 FR 3533; USEPA 1991a)).

EPA would ideally like to use the delivered dose (i.e., the amount of key chloroform metabolites that actually reach the liver and cause cell toxicity) for calculating an RfD to support the MCLG. However, the required toxicokinetic data are not currently available. Thus, the RfD is calculated using the applied dose (i.e., the amount of chloroform ingested). The RfD is based on both the benchmark dose and the traditional no observed adverse effect level/lowest observed adverse effect level (NOAEL/LOAEL) approaches for hepatotoxicity in the most sensitive species, the dog. The MCLG is based on the RfD and calculated as follows:

$$\text{MCLG} = \frac{\text{RfD} \times \text{body weight} \times \text{RSC}}{\text{daily water consumption}}$$

i. *Reference dose.* The RfD for chloroform was estimated based on noncancer effects using both the benchmark dose and the traditional NOAEL/LOAEL approaches. For benchmark analysis, five relevant data sets including target organ toxicity, labeling index, histopathology in rodents, and liver toxicity in dogs (Heywood 1979) were evaluated. The effects seen in dogs are considered to be early signs of liver toxicity, preceding cytotoxicity, cytolethality and regenerative hyperplasia. Thus, the Heywood (1979) study, provides the most sensitive end point in the most sensitive species and is the most appropriate basis for the RfD.

The 95% confidence lower bound on the dose associated with a 10% extra risk (LED10) is based on the prevalence of animals demonstrating liver toxicity. After an exposure adjustment to the LED10 (1.2 mg/kg/day), an RfD of 0.01 mg/kg/day was calculated using an overall uncertainty factor of 100 (10 for interspecies extrapolation and 10 for protection of sensitive individuals) (USEPA 2001b).

Coincidentally, the benchmark dose and the traditional NOAEL/LOAEL approaches yield the same RfD number (USEPA 2001b). The NOAEL/LOAEL approach is also based on the Heywood study (1979) which had a LOAEL of 15 mg/kg/day for evidence of liver toxicity. After an exposure adjustment to the LOAEL (yielding 12.9 mg/kg/day), an RfD of 0.01 mg/kg/day was calculated using an overall uncertainty factor of 1000 (10 for interspecies extrapolation, 10 for protection of sensitive individuals, and 10 for using a LOAEL instead of a NOAEL) (USEPA 2001b).

ii. *Relative source contribution.* Another factor in determining the MCLG is the relative source contribution (RSC). The RSC is used when the MCLG is set at a level above zero. Its purpose is to ensure that the contribution to exposure from drinking tap water does not cause the lifetime daily exposure of persons to a contaminant to exceed RfD. The RSC is thus a factor used to make sure that the MCLG is protective even if persons are exposed to the contaminant by other routes (inhalation, dermal absorption) or other sources (*e.g.*, food). If sufficient quantitative data are not available on exposure by other routes and sources, EPA has historically assumed that the RSC from drinking water is 20 percent of the total exposure, a value considered protective. If data indicate that contributions from other routes and sources are not significant, EPA has historically assumed a less conservative RSC of 80 percent (54 FR 22,062, 22,069 (May 22, 1989)(USEPA 1989a), 56 FR at 3535 (Jan 30, 1990)(USEPA 1991a), 59 FR 38,668, 38,678 (July 29, 1994)(USEPA 1994b)).

Today, EPA is proposing an assumption of a 20 percent RSC. This is in consideration of data which indicate that exposure to chloroform by other routes and sources of exposure may potentially contribute a substantial percentage of the overall exposure to chloroform.

In the 1998 Stage 1 DBPR NODA, EPA considered an MCLG of 0.3 mg/L that was calculated using an RSC of 80 percent, based on the assumption that most exposure to chloroform is likely to come from ingestion of drinking water. In the final Stage 1 DBPR, EPA reconsidered this assumption in response to comments and in the light of data which indicate that exposure to chloroform by inhalation and dermal exposure may potentially contribute a substantial percentage of the overall exposure to chloroform depending on the activity patterns of individuals (USEPA 1998e) *e.g.,* during showering, bathing, swimming, boiling water, clothes washing, and dishwashing. There is also potential exposure to chloroform by the dietary route. There are uncertainties regarding other possible highly exposed sub-populations, *e.g.*, swimmers, those who use humidifiers, hot-tubs, and outdoor misters, persons living near industrial sources, people working in laundromats, and persons working with pesticides employing chloroform as a solvent (USEPA 1998b).

A 1998 International Life Sciences Institute (ILSI) report evaluated the uptake of drinking water contaminants through the skin and by inhalation. The report noted that ''(i)n the case of chloroform, its high volatility leads to its rapid movement from liquid to air. Large water-use sources, such as showers, become dominant sources with respect to exposure'' and ''(t)he inhalation route is demonstrated to be the primary route for higher-volatility compounds (*e.g.,* chloroform)'' (ILSI 1998). Weisel and Jo (1996) found that ''approximately equivalent amounts of chloroform from water can enter the body by three different exposure routes, inhalation, dermal absorption, and ingestion, for typical daily activities of drinking and bathing.''

Chloroform has been found in beverages, especially soft drinks, and food, particularly dairy products (Wallace, 1997). Wallace states that ''ingestion (drinking tap water and soft drinks and eating certain dairy foods), inhalation (breathing peak amounts of chloroform emitted during showers or baths, and lower levels in indoor air from other indoor sources), and dermal absorption (during showers, baths, and swimming)'' each ''appear to be potentially substantial contributors to total exposure''.

EPA estimates that for the median individual, ingestion of total tap water (assuming certain activity patterns, habits, and home characteristics) can contribute roughly 28 percent of the total dose of chloroform (USEPA 2001a). With assumptions as described, tap water ingestion is a portion of exposure through fluid intake which contributes about 34 percent of the total dose, inhalation accounts for about 31 percent of the total dose, ingestion of foods contributes another 27 percent of the overall dose, and dermal absorption (primarily during showering) adds slightly less than 8 percent of the total dose. These exposure percentages are based on average daily doses (mean chloroform intake for adults) for each source and route of exposure under specific conditions. They do not take into account the considerable variability in several factors across the population. For instance, intake of drinking water or particular foods and length of shower varies from day-to-day, as do home air turnover rates and ventilation. Different areas in the United States vary with respect to these factors and chloroform concentrations in food. Thus, although the 28 percent for the median individual is based on reasonable assumptions, uncertainty remains.

Given the uncertainties of estimation, EPA believes available analyses point to the RSC of 20 percent as the appropriate default (*i.e.,* 20 percent of exposure to chloroform comes from drinking tap water alone). EPA also believes that this default is protective of public health and is a more reasonable choice than choosing any particular estimate because of the assumptions and uncertainties involved with each estimation. Hence, EPA is proposing the MCLG based on the RSC default of 20 percent which supports the adequacy of the margin of safety associated with the MCLG.

iii. *Water ingestion and body weight assumptions.* In MCLG calculations, EPA assumes the 90th percentile water ingestion of 2 liters (roughly equivalent to a half gallon) per day (USEPA 2000a). The use of a conservative consumption estimate is consistent with the objective of setting an MCLG that is protective. EPA also uses a default adult body weight of 70 kg (equal to 154 pounds) for the RfD since dose is calculated from lifetime studies of animals and compared to lifetime exposure for humans.

iv. *MCLG calculation.* The MCLG is calculated to be 0.07 mg/L using the following assumptions: an adult tap water consumption of 2 L per day for a 70 kg adult, and a relative source contribution of 20%:

$$\text{MCLG for Chloroform} = \frac{0.01\ \text{mg/kg/d} \times 70\ \text{kg} \times 0.2}{2\text{L/day}} = 0.07\ \text{mg/L (rounded)}$$

EPA concludes that an MCLG of 0.07 mg/L based on protection against liver toxicity will be protective against carcinogenicity given that the mode of action for chloroform involves cytotoxicity as a key event preceding tumor development. Therefore, the recommended MCLG for chloroform is 0.07 mg/L.

v. *Other considerations.* The evidence supports similarity of potential response in children and adults. The basic biology of toxicity caused by cell damage due to oxidative damage is expected to be the same. There is nothing about the incidence and etiology of liver and kidney cancer in children to indicate that they would be inherently more sensitive to this mode of action. Most importantly in this case, children appear to be no different quantitatively in ability to carry out the oxidative metabolism step for the induction of toxicity and cancer and may, as fetuses, be less susceptible (USEPA 1999c).

Some commenters on the March 1998 NODA were concerned that EPA did not take drinking water epidemiology studies into account in its evaluation of chloroform risk. EPA believes that while the epidemiologic evidence suggests that chlorinated drinking water may be associated with certain cancers and reproductive, developmental effects pertinent to the risk of disinfectant byproduct mixtures, it does not provide insight into the risk from chloroform specifically. The SAB noted that ''(t)he goal of the draft risk assessment (the isolation of the effect of chloroform in drinking water) makes the extensive epidemiologic evidence on drinking water disinfection byproducts largely irrelevant'' to the specific question of chloroform health risks because, in the available studies, chloroform cannot be isolated from other disinfection byproducts that may be in the drinking water (USEPA 2000f). The SAB noted that ''the epidemiologic evidence is quite pertinent to the broader question of most direct regulatory concern, namely disinfection byproducts in the aggregate''.

d. *Feasibility of other options.* During the development of the MCLG for chloroform, EPA considered a number of options for both the chloroform MCLG and the TTHM MCL. Today, EPA is proposing the preferred option of a 0.07 mg/L MCLG for chloroform. EPA primarily considered two other options which are discussed in more detail later: a 0.07 mg/L MCLG for chloroform in conjunction with developing MCLs for each of the individual TTHMs (*i.e.,* 4 MCLs and 4 MCLGs for the THMs); and developing a single combined MCLG for TTHM rather than developing a separate MCLG for each of the THMs.

EPA considered developing separate MCLGs and MCLs for each THM. Under this strategy, EPA would determine an MCL as close to the individual MCLGs as is technically feasible, taking cost into consideration, for each THM. EPA would propose an MCLG of 0.07 mg/L for chloroform and maintain the Stage 1 DBPR MCLGs for BDCM, DBCM, and bromoform (USEPA 1998c). EPA analyzed the impact such an MCL strategy would have and ultimately rejected this option. This approach represents a fundamental shift from the TTHM strategy agreed to by stakeholders and EPA as part of the M–DBP negotiation process and reflected in the 1998 Stage 1 DBPR. In addition, one important component of the existing single MCL is that TTHMs are an indicator for other DBPs. Developing a separate MCL for each THM would move away from this indicator approach. Because precursor and DBP occurrence measurements are highly variable, both temporally and geographically, determining technical feasibility for best available technology (BAT) would be difficult. Compliance with individual THM standards would be very different from compliance based on a sum of the four THMs and it is not clear what treatment technology shifts would be needed. This problem would be particularly exacerbated in areas with high bromide, such as California. EPA also projected that States would have a difficult time overseeing (*e.g.*, variances, exemptions, *etc.*) the more complicated rule that would result from this option.

EPA considered establishing a single combined MCLG for TTHM. There is precedent for using a toxicity equivalency quotient (analogous to a combined MCLG) for dioxin and coplanar PCBs (USEPA 2000o, Draft Dioxin Reassessment). From a scientific standpoint, a combined MCLG approach requires that the chemicals have a similar mode of action and health endpoint. Chemicals within each of the dioxin and coplanar PCB classes have the same mode of action and endpoint (target tissue). Within the PCB class, noncoplanar PCBs have a different mode of action than the coplanar PCBs. Noncoplanar PCBs are, therefore, not included in the toxicity equivalency quotient for coplanar PCBs. In the case of the disinfection byproducts, EPA believes that the THMs have different modes of action and health endpoints. One of the THMs is a liver carcinogen (chloroform) with a mode of action dependent on cytolethality; two are DNA-reactive carcinogens (bromodichloromethane—large intestine and kidney tumors, and bromoform—large intestine tumors); and one is a nonlinear non-carcinogen (dibromochloromethane) which is a liver toxicant. EPA therefore, chose not to develop a combined MCLG for TTHM. Consequently, after considering this alternative option in some detail, EPA is today proposing an MCLG of 0.07 mg/L for chloroform.

3. Request for Comment

Based on the information presented previously, EPA is proposing an MCLG for chloroform of 0.07 mg/L. EPA requests comments on the MCLG and on EPA's cancer assessment for chloroform. EPA also requests comments on the RfD, the default RSC of 20 percent, and the tap water consumption and body weight assumptions used in the MCLG calculation. EPA solicits additional data on chloroform exposure via other sources and routes. EPA requests comment on the other options for developing the chloroform MCLG that the Agency considered.

B. MCLGs for THMs and HAAs

1. What Is EPA Proposing Today?

Today EPA is proposing new MCLGs of 0.02 mg/L for TCAA and 0.03 mg/L for MCAA based on new toxicological data. As a part of the Stage 1 DBPR, EPA finalized an MCLG of 0.3 mg/L for TCAA. The Stage 1 DBPR did not include an MCLG for MCAA (although it was included as one of the five haloacetic acids in the HAA5 MCL). With the exception of chloroform, discussed above, and these two HAAs, EPA is not revising any of the other MCLGs that were finalized in the Stage 1 DBPR. No significant new studies that would change EPA's MCLG estimates for BDCM, DBCM, bromoform, or DCAA have been published since the Stage 1 DBPR. See section III for a summary of new health effects data.

2. How Was This Proposal Developed?

EPA reviewed the available literature on BDCM, DBCM, bromoform, DCAA and determined that there was no new

information that would cause EPA to revise its MCLG estimates. New toxicology studies on reproductive and developmental effects and cancer are summarized in sections III.B. and III.D. of today's proposal.

EPA is proposing new MCLGs for TCAA and MCAA. The health effects information and studies described in the following two sections that support the proposed MCLGs are summarized from the Addendum to the Criteria Document for Monochloroacetic Acid and Trichloroacetic Acid (USEPA 2003b). The occurrence of MCAA and TCAA are discussed in the *Stage 2 Occurrence Assessment for Disinfectants and Disinfection Byproducts* (USEPA 2003o). a. Trichloroacetic acid. In the final Stage 1 DBPR, EPA based its health effects assessment of TCAA on developmental toxicity and limited evidence of carcinogenicity (USEPA 1998c). Since then, the Agency has decided that the RfD based on a developmental LOAEL yields a less conservative RfD than that based on liver toxicity derived from the study by DeAngelo *et al.* (1997). Thus, the Agency has reassessed the health effects of TCAA based on liver toxicity and revised the RfD and MCLG.

TCAA induces systemic, noncancer effects in animals and humans that can be grouped into three categories: metabolic alterations, liver toxicity; and developmental toxicity. The primary site of TCAA toxicity is the liver (USEPA1994a; Dees and Travis, 1994; Acharya *et al.* 1995; Acharya *et al.* 1997; DeAngelo *et al.*1997).

The liver has consistently been identified as a target organ for TCAA toxicity in short-term (Goldsworthy and Popp, 1987; DeAngelo *et al.* 1989; Sanchez and Bull, 1990) and longer-term (Bull *et al.* 1990; Mather *et al.* 1990; Bhat *et al.* 1991) studies. Peroxisome proliferation has been a primary endpoint evaluated, with mice reported to be more sensitive to this effect than rats. More recent studies have confirmed these earlier findings. TCAA-induced peroxisome proliferation was observed in B6C3F1 mice exposed for 10 weeks to doses as low as 25 mg/kg/day (Parrish *et al.* 1996), while in rats exposed to TCAA for up to 104 weeks (DeAngelo *et al.* 1997), peroxisome proliferation was observed at 364 mg/kg/day, but not at 32.5 mg/kg/day. Increased liver weight and significant increases in hepatocyte proliferation have been observed in short-term studies in mice at doses as low as 100 mg/kg/day (Dees and Travis, 1994), but no increase in hepatocyte proliferation was noted in rats given TCAA at similar doses (DeAngelo *et al.* 1997). More clearly adverse liver toxicity endpoints, including increased serum levels of liver enzymes (indicating leakage from cells) or histopathological evidence of necrosis, have been reported in rats, but generally only at high doses. For example, in a rat chronic drinking water study, increased hepatocyte necrosis was observed at a dose of 364 mg/kg/day (DeAngelo *et al.* 1997).

In the DeAngelo *et al.*(1997) study, groups of 50 male F344 rats were administered TCAA in drinking water, at 0, 50, 500, or 5000 mg/L, resulting in time-weighted mean daily doses of 0, 3.6, 32.5, or 364 mg/kg for 104 weeks. There were no significant differences in water consumption or survival between the control and treatment groups. Exposure to the high dose of TCAA resulted in a significant decrease in body weight of 11% at the end of the study. The absolute but not relative liver weight was decreased at the high dose. Complete necropsy and histopathology examination showed mild hepatic cytoplasmic vacuolization in the two low-dose groups, but not in the high-dose group. The severity of hepatic necrosis was increased mildly in the high-dose animals. Analyses of serum aspartate aminotransferase (AST) and alanine aminotransferase (ALT) activities at the end of exposure showed a significant decrease in AST activity in the mid-dose group and a significant increase in ALT level in the high-dose group. Since increased serum ALT or AST levels reflect hepatocellular necrosis, the increased ALT at the high dose is considered an adverse effect, while a non-dose related decrease of AST is not. Peroxisome proliferation was increased significantly in the high-dose animals. There was no evidence of any exposure-related increase in hepatocyte proliferation. Based on the significant decrease in body weight (≥10%), minimal histopathology changes, and increased serum ALT level, the high dose of 364 mg/kg/day is considered the LOAEL and the mid dose of 32.5 mg/kg/day is considered the NOAEL.

There are no reproductive toxicity studies of TCAA. The results of an *in vitro* fertilization assay indicated that TCAA might decrease fertilization (Cosby and Dukelow, 1992). The available data suggest that TCAA is a developmental toxicant. TCAA increased resorptions, decreased implantations, and increased fetal cardiovascular malformations when administered to pregnant rats at 291 mg/kg/day (Johnson *et al.* 1998) on gestation days 1–22. In another study, decreased fetal weight and length, and increased cardiovascular malformations were observed when pregnant rats were administered 330 mg/kg/day TCAA by gavage during gestation days 6 to 15 (Smith *et al.* 1989). Neither of these studies identified a NOAEL. The results of *in vitro* developmental toxicity assays, including mouse and rat whole-embryo culture (Saillenfait *et al.* 1995; Hunter *et al.* 1996) and frog embryo teratogenesis assay—*Xenopus* (FETAX) (Fort *et al.* 1993) yielded positive results. The *Hydra* test system (Fu *et al.* 1990) produced negative results.

TCAA has been reported to induce liver tumors in mice but not in rats (USEPA 1994a). This observation has also been made in more recent drinking water studies. Pereira (1996) observed an increased incidence of hepatocellular adenomas and carcinomas in female B6C3F1 mice at doses of 262 mg/kg/day and higher after 82 weeks. In contrast, no increase in neoplastic liver lesions were found in F344 rats given doses up to 364 mg/kg/day for 104 weeks (DeAngelo *et al.* 1997). In addition, a variety of recent mechanistic studies have observed that TCAA either induced or promoted liver tumors in mice (Ferreira-Gonzalez *et al.* 1995; Pereira and Phelps, 1996; Tao *et al.* 1996; Latendresse and Pereira, 1997; Stauber and Bull, 1997; Tao *et al.* 1998).

Recent mutagenicity data have provided mixed results (Giller *et al.* 1997; DeMarini *et al.* 1994; Harrington-Brock *et al.* 1998). TCAA did not induce oxidative DNA damage in mice following dosing for either 3 or 10 weeks (Parrish *et al.* 1996). Studies on DNA strand breaks and chromosome damage produced mixed results (Nelson and Bull, 1988; Chang *et al.* 1991; Mackay *et al.* 1995; Harrington-Brock *et al.* 1998).

According to the 1999 Draft Guidelines for Carcinogen Risk Assessment (USEPA 1999a), a compound is appropriately classified as ''Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential'' when ''the evidence from human or animal data is suggestive of carcinogenicity, which raises a concern for carcinogenic effects but is judged not sufficient for a conclusion as to human carcinogenic potential''. Based on uncertainty surrounding the relevance of the liver tumor data in B6C3F1 mice, TCAA can best be described as ''Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential'' under the 1999 Draft Guidelines for Carcinogen Risk Assessment. Thus a quantitative estimate of cancer potency is not supported.

The RfD for TCAA of 0.03 mg/kg/day is based on the NOAEL of 32.5 mg/kg/day for liver histopathological changes identified by DeAngelo *et al.* (1997). The RfD includes an uncertainty factor of 1000 (composite uncertainty factor consisting of three factors of 10 chosen to account for extrapolation from a NOAEL in animals, inter-individual variability in humans, and insufficiencies in the database, including the lack of full histopathological data in a second species, the lack of a developmental toxicity study in second species, and the lack of a multi-generation reproductive study).

The MCLG is calculated to be 0.02 mg/L using the following assumptions: an adult tap water consumption of 2 L of tap water per day for a 70 kg adult, a relative source contribution (RSC) of 20%, and an additional safety factor to account for possible carcinogenicity. EPA has traditionally applied an additional safety factor of 1–10 beyond the uncertainty factors included in the RfD to the MCLG to account for possible carcinogenicity in cases where there is limited evidence of carcinogenicity from drinking water, considering weight of evidence, pharmacokinetics, potency and exposure (USEPA 1994b, p.38678). EPA is proposing this additional safety factor of 10 for TCAA for the following reasons: TCAA causes liver tumors in mice but does not do so in rats. In addition, although peroxisome proliferation (a mode of action of limited relevance to humans) may play a role in the development of the mouse tumors, rats also exhibit a peroxisomal proliferative response after exposure to TCA, yet do not develop tumors. Other data suggest that promotion of initiated cells and/or disrupted cell signaling may be involved in the mode of action for the mouse tumors. Together these factors argue against quantification of the mouse liver tumors using linear extrapolation from the dose-response curve, but are not sufficient to rule out concern for a tumorigenic response. Accordingly, EPA has employed the ten-fold additional safety factor in determination of the Lifetime Health Advisory for TCAA. EPA requests comment on the use of 10 as the additional safety factor for possible carcinogenicity.

$$\text{MCLG for TCAA} = \frac{(0.03\ \text{mg/kg/day})(70\ \text{kg})(20\%)}{(2\ \text{L/day})(10)} = 0.02\ \text{mg/L (rounded)}$$

An RSC factor of 20% is used to account for exposure to TCAA in sources other than tap water, such as ambient air and food. Although TCAA is nonvolatile and inhalation while showering is not expected to be a major contribution to total dose, rain waters contain 0.01–1.0 µg/L of TCAA (Reimann *et al.* 1996) and it can be assumed to be detected in the atmosphere. Limited data on concentrations of TCAA in air (NATICH 1993) indicate inhalation of TCAA in ambient air may contribute to overall exposure. Concentrations of TCAA that have been measured in a limited selection of foods including vegetables, fruits, grain and bread (Reimann *et al.* 1996) are comparable to that in water. About 3 to 33% of TCAA in cooking water have been reported to be taken up by the food during cooking in a recent research summary (Raymer *et al.* 2001). In addition, there are uses of chlorine in food production and processing, and TCAA may occur in food as a byproduct of chlorination (USEPA 1994a). Therefore, ingestion of TCAA in food may also contribute to the overall exposure. A recent dermal absorption study of DCAA and TCAA from chlorinated water suggested that the dermal contribution to the total doses of DCAA and TCAA from routine household uses of drinking water is less than 1% (Kim and Weisel, 1998).

b. *Monochloroacetic acid.* Subchronic and chronic oral dosing studies suggest that the primary targets for MCAA-induced toxicity include the heart and nasal epithelium. In a 13-week oral gavage study, decreased heart weight was observed at 30 mg/kg/day and cardiac lesions progressed in severity with increasing dose. Liver and kidney toxicity were only observed at higher doses (NTP 1992). In a two-year study, decreased survival and nasal and forestomach hyperplasia were observed in mice at 50 mg/kg/day (NTP 1992). A more recent study confirms the heart and nasal cavities as target sites for MCAA. DeAngelo *et al.* (1997) noted decreased body weight at 26.1 mg/kg/day and myocardial degeneration and inflammation of the nasal cavities in rats exposed to doses of 59.9 mg/kg/day for up to 104 weeks.

No studies were located on the reproductive toxicity of MCAA and the potential developmental toxicity of MCAA has not been adequately tested. Two developmental toxicity studies were identified. Johnson *et al.* (1998) reported markedly decreased maternal weight gain, but no developmental effects, in rats exposed to 193 mg/kg/day MCAA through gestation days 1–22, only fetal heart was examined. In contrast, in a published abstract, Smith *et al.* (1990) reported an increase in cardiovascular malformations when pregnant rats were exposed to 140 mg/kg/day; this was also the LOAEL for maternal toxicity, based on marked decreases in weight gain. MCAA was noted as a potential developmental toxicant in *in vitro* screening assays using *Hydra* (Fu *et al.* 1990; Ji *et al.* 1998).

MCAA has yielded mixed results in genotoxicity assays (USEPA 1994a; Giller *et al.* 1997), but has not induced a carcinogenic response in chronic rodent bioassays (NTP 1992; DeAngelo *et al.* 1997). In chronic oral gavage studies, a LOAEL of 15 mg/kg/day (the lowest dose tested) for decreased survival was identified in rats. In mice the NOAEL was 50 mg/kg/day and the LOAEL was 100 mg/kg/day for nasal and forestomach epithelium hyperplasia (NTP 1992). In a more recent chronic study, DeAngelo *et al.* (1997) reported a LOAEL of 3.5 mg/kg/day in rats given MCAA in their drinking water, based on increased absolute and relative spleen weight. Although spleen weight was decreased at the mid and high doses, this might reflect the masking effect of overt toxicity. As evidence for this, decreased body weight (>10%), liver, kidney, and testes weight changes were reported beginning at the next higher dose of 26.1 mg/kg/day. No increased spleen weight was reported in the NTP (1992) bioassays, but the lowest dose in rats caused severe toxicity, and the lowest dose in mice was more than an order of magnitude higher than the LOAEL in the DeAngelo *et al.* (1997) study.

According to the 1999 Draft Guidelines for Carcinogen Risk Assessment (USEPA 1999a), a compound is appropriately classified as ''Not Likely to be Carcinogenic to Humans'' when it has ''been evaluated in at least two well-conducted studies in two appropriate animal species without demonstrating carcinogenic effects.'' MCAA can best be described as ''Not Likely to be Carcinogenic to Humans'' under the 1999 Draft Guidelines for Carcinogen Risk Assessment.

The RfD for MCAA of 0.004 mg/kg/day is based on a LOAEL of 3.5 mg/kg/day for increased spleen weight in rats (DeAngelo *et al.* 1997) and application of an uncertainty factor of 1000 (composite uncertainty factor consisting of two factors of 10 chosen to account for extrapolation from an animal study, and inter-individual variability in humans; as well as two factors of 3 for extrapolation from a minimal effect LOAEL, and insufficiencies in the database, including the lack of adequate developmental toxicity studies in two species, and the lack of a multi-generation reproductive study). Two developmental toxicity studies have been reported (Johnson *et al.* 1998; Smith *et al.* 1990), but the NOAELs yielded less conservative RfDs. The study by DeAngelo et al (1997) is the most appropriate for derivation of the RfD because it identifies the lowest LOAEL, and dosing was in drinking water, which is more appropriate for human health risk assessment.

The MCLG is calculated to be 0.03 mg/L using the following assumptions: an adult tap water consumption of 2 L of tap water per day for a 70 kg adult, and a relative source contribution of 20 %.

$$\text{MCLG for MCAA} = \frac{(0.004\ \text{mg/kg/day})(70\ \text{kg})(20\%)}{(2\ \text{L/day})} = 0.03\ \text{mg/L (rounded)}$$

An RSC factor of 20% is used to account for exposure to MCAA in other sources in addition to tap water. Although MCAA is nonvolatile and inhalation while showering is not expected to be a major contribution to total dose, rain waters contain 0.05–9 μg/L of MCAA (Reimann *et al.* 1996) and it can be assumed to be detected in the atmosphere. Presence of MCAA has also been reported in rain waters; thus, inhalation of MCAA in ambient air may contribute to overall exposure. Concentrations of MCAA that have been measured in a limited selection of foods including vegetables, fruits, grain and bread (Reimann *et al.* 1996) are comparable to that in water. About 2.5 to 62% of MCAA in cooking water has been reported to be taken up by food during cooking in a recent research summary (Raymer *et al.* 2001). In addition, there are uses of chlorine in food production and processing, and MCAA may occur in food as a byproduct of chlorination (USEPA 1994a). Therefore, ingestion of MCAA in food may also contribute to the overall exposure. Assuming dermal absorption rate of MCAA is similar to DCAA, dermal contribution to the total doses of MCAA from routine household uses of drinking water should be minor (*see* V.B.2.a.).

3. Request for Comment

EPA requests comment on the new MCLGs for TCAA (0.02 mg/L) and MCAA (0.03 mg/L) and all the factors incorporated in the derivation of the MCLGs, including the RfDs and RSCs. EPA also solicits health effect information on DBAA and monobromoacetic acid (MBAA), for which MCLGs have not yet been established.

C. Consecutive Systems

Today's proposal includes provisions for consecutive systems, which are public water systems that purchase or otherwise receive finished water from another water system (a wholesale system). As described in this section, consecutive systems face particular challenges in providing water that meets regulatory standards for DBPs and other contaminants whose concentration can increase in the distribution system. Moreover, current regulation of DBP levels in consecutive systems varies widely among States. In consideration of these factors, EPA is proposing monitoring, compliance schedule, and other requirements specifically for consecutive systems. These requirements are intended to facilitate compliance by consecutive systems with MCLs for TTHM and HAA5 under the Stage 2 DBPR. Further, this approach will help to ensure that consumers in consecutive systems receive equivalent public health protection. This section begins with a summary of how EPA proposes to regulate consecutive systems under the Stage 2 DBPR. The intent of this section is to provide an overview of all consecutive system requirements in today's proposal. Detailed explanations of these requirements are provided in later sections of this preamble. The overview of consecutive system requirements is followed by an explanation of why EPA has taken this approach to consecutive systems in today's proposal, including recommendations from the Stage 2 M–DBP Federal Advisory Committee.

1. What Is EPA Proposing Today?

As public water systems, consecutive systems must provide water that meets the MCLs for TTHM and HAA5 under the proposed Stage 2 DBPR, and must carry out associated monitoring, reporting, recordkeeping, public notification, and other requirements. The following discussion summarizes how the Stage 2 DBPR requirements apply to consecutive systems, beginning with a series of definitions. Later sections of this preamble provide further details as noted.

a. *Definitions.* To address consecutive systems in the Stage 2 DBPR, the Agency must define them, along with a number of related terms.

EPA is proposing to define a *consecutive system* in the Stage 2 DBPR as a public water system that buys or otherwise receives some or all of its finished water from one or more wholesale systems for at least 60 days per year. In addition to buying finished water, some consecutive systems also operate a treatment plant (meaning a plant that treats source water to produce finished water). As described in section V.I., monitoring requirements under the Stage 2 DBPR proposal differ depending on whether a consecutive system buys all of its finished water year-round or, alternatively, produces some of its finished water through treating source water.

EPA proposes to define finished water as water that has been introduced into the distribution system of a public water system and is intended for distribution without further treatment, except that necessary to maintain water quality (such as booster disinfection). With this definition, water entering the distribution system is finished water even if a system subsequently applies additional treatment like booster disinfection to maintain a disinfectant residual throughout the distribution system.

In today's proposal, EPA defines a *wholesale system* as a public water system that treats source water and then sells or otherwise delivers finished water to another public water system for at least 60 days per year. Delivery may be through a direct connection or through the distribution system of another consecutive system. Under this definition, a consecutive system that passes water from a wholesaler to another consecutive system, and that does not also treat source water, is not

a wholesale system. Rather, the system that actually produces the finished water is responsible for wholesale system requirements under the proposed Stage 2 DBPR.

A *consecutive system entry point* is defined as a location at which finished water is delivered at least 60 days per year from a wholesale system to a *consecutive system*. Section V.I. presents the relationship between consecutive system entry points and proposed Stage 2 DBPR monitoring requirements. The *combined distribution system* is the interconnected distribution system consisting of the distribution systems of wholesale systems and of the consecutive systems that receive finished water from those wholesale system(s).

b. *Monitoring.* For consecutive systems that both purchase finished water and treat source water to produce finished water for at least part of the year, EPA is proposing monitoring requirements under a treatment plant-based approach, described in section V.I. This is the approach proposed for non-consecutive systems under the Stage 2 DBPR as well. Under this approach, the sampling requirements for consecutive systems will be influenced by both the number of treatment plants operated by the system and the number of consecutive system entry points, as well as population served and source water type.

For consecutive systems that purchase all of their finished water year-round, EPA is proposing monitoring requirements under a population-based approach, also described in section V.I. Under the population-based approach, the population of the consecutive system will determine the sampling requirements. EPA believes this approach is more appropriate than plant-based monitoring because these consecutive systems do not have treatment plants. As noted in section V.I., EPA is requesting comment on extending population-based monitoring to all systems, including non-consecutive systems. EPA has prepared draft guidance for implementing the IDSE monitoring requirements (described in section V.H.) using the population-based approach (USEPA 2003j).

EPA is also proposing that States have the opportunity to specify alternative monitoring requirements for multiple consecutive systems in a combined distribution system. This option allows States to consider complex consecutive system configurations for which alternative monitoring strategies might be more appropriate. As a minimum under such an approach, each consecutive system must collect at least one sample among the total number of samples required for the combined distribution system and will base compliance on samples collected within its distribution system. The consecutive system is responsible for ensuring that required monitoring is completed and the system is in compliance. The consecutive system may conduct the monitoring itself or arrange for the monitoring to be done by the wholesale system or another outside party. Whatever approach it chooses, the consecutive system must document its monitoring strategy as part of its DBP monitoring plan.

Finally, EPA is proposing that consecutive systems not conducting disinfectant residual monitoring comply with the monitoring requirements and MRDLs for chlorine and chloramines.

c. Compliance schedules. EPA is proposing that consecutive systems of any size comply with the requirements of the Stage 2 DBPR on the same schedule as required for the largest system in the combined distribution system. This includes the schedule for carrying out the IDSE, described in section V.H, and for meeting the Stage 2B MCLs for TTHM and HAA5, described in section V.D. As discussed later in this section, EPA is proposing simultaneous compliance schedules under the Stage 2 DBPR for all systems (both wholesalers and consecutive systems) in a combined distribution system because this may allow for more cost-effective compliance with TTHM and HAA5 MCLs. This is also consistent with the recommendations of the Stage 2 M–DBP Advisory Committee. See section V.J for details of compliance schedule requirements.

d. *Treatment.* While consecutive systems often do not need to treat finished water received from a wholesale system, they may need to implement procedures to control the formation of DBPs in the distribution system. For consecutive systems, EPA is proposing that the BAT for meeting TTHM and HAA5 MCLs is chloramination with management of hydraulic flow and storage to minimize residence time in the distribution system. This BAT stems from the recognition that treatment to remove already-formed DBPs or minimize further formation is different from treatment to prevent or reduce their formation. See section V.F for additional information on BATs and their role in compliance with MCLs.

e. *Violations.* Under this proposal, monitoring and MCL violations are assigned to the PWS where the violation occurred. Several examples are as follows:

—If a consecutive system has hired its wholesale system under contract to monitor in the consecutive system and the wholesale system fails to monitor, the consecutive system is in violation because it has the legal responsibility for monitoring under State/EPA regulations.

—If monitoring results in a consecutive system indicate an MCL violation, the consecutive systems is in violation because it has the legal responsibility for complying with the MCL under State/EPA regulations. The consecutive system may set up a contract with its wholesale system that details water quality delivery specifications.

—If a wholesale system has a violation and provides that water to a consecutive system, the wholesale system is in violation. Whether the consecutive system is in violation will depend on the situation. The consecutive system will also be in violation unless it conducted monitoring that showed that the violation was not present in the consecutive system.

f. *Public notice and consumer confidence reports.* The responsibilities for public notification and consumer confidence reports rest with the individual system. Under the Public Notice Rule and Consumer Confidence Report Rule, the wholesale system is responsible for notifying the consecutive system of analytical results and violations related to monitoring conducted by the wholesale system. Consecutive systems are required to conduct appropriate public notification after a violation (whether in the wholesale system or the consecutive system). In their consumer confidence report, consecutive systems must include results of the testing conducted by the wholesale system unless the consecutive system conducted equivalent testing that indicated the consecutive system was in compliance, in which case the consecutive system reports its own compliance monitoring results.

g. *Recordkeeping and reporting.* Consecutive systems are required to keep all records required of PWSs regulated under this rule. They are also required to report to the State monitoring results, violations, and other actions, and are required to consult with the State after a significant excursion.

h. *State special primacy conditions.* EPA is aware that due to the complicated wholesale system-consecutive system relationships that

exist nationally, there will be cases where the standard monitoring framework proposed today will be difficult to implement. Therefore, the Agency is proposing to allow States to develop, as a special primacy condition, a program under which the State can modify monitoring requirements for consecutive systems. These modifications must not undermine public health protection and all systems, including consecutive systems, must comply with the TTHM and HAA5 MCLs based on the LRAA. However, such a program would allow the State to establish monitoring requirements that account for complicated distribution system relationships, such as where neighboring systems buy from and sell to each other regularly throughout the year, water passes through multiple consecutive systems before it reaches a user, or a large group of interconnected systems have a complicated combined distribution system. EPA intends to develop a guidance manual to address development of a State program and other consecutive system issues.

2. How Was This Proposal Developed?

The practice of public water systems buying and selling water to each other has been commonplace for many years. Reasons include saving money on pumping, treatment, equipment, and personnel; assuring an adequate supply during peak demand periods; acquiring emergency supplies; selling surplus supplies; delivering a better product to consumers; and meeting Federal and State water quality standards. EPA estimates that there are at least 8500 consecutive systems nationally, based on the definitions being proposed today.

Consecutive systems face particular challenges in providing water that meets regulatory standards for contaminants that can increase in the distribution system. Examples of such contaminants include coliforms, which can grow if favorable conditions exist, and some DBPs, including THMs and HAAs, which can increase when a disinfectant and DBP precursors continue to react in the distribution system.

EPA is proposing requirements specifically for consecutive systems because States have taken widely varying approaches to regulating DBPs in consecutive systems. For example, some States do not regulate DBP levels in consecutive systems that deliver disinfected water but do not add a disinfectant. Other States determine compliance with DBP standards based on the combined distribution system that includes both the wholesaler and consecutive systems. In this case, sites in consecutive systems are treated as monitoring sites within the combined distribution system. Once fully implemented, this proposed rule will ensure similar protection for consumers in consecutive systems.

EPA is proposing that consecutive systems and wholesale systems be on the same compliance schedule because generally the most cost-effective way to achieve compliance with TTHM and HAA5 MCLs is to treat at the source, typically through precursor removal or alternative disinfectants. For a wholesale system to make the best decisions concerning the treatment steps necessary to meet TTHM and HAA5 LRAAs under the Stage 2 DBPR, both in its own distribution system and in the distribution systems of consecutive systems it serves, the wholesale system must know the DBP levels throughout the combined distribution system. Without this information, the wholesale system may design treatment changes that allow the wholesale system to achieve compliance, but leave the consecutive system out of compliance. EPA also recognizes that there may be cases where a consecutive system needs to add treatment even after a wholesale system has optimized its own treatment train.

In consideration of these issues, the Stage 2 M–DBP Advisory Committee recognized two principles related to consecutive systems: (1) Consumers in consecutive systems should be just as well protected as customers of all systems, and (2) monitoring provisions should be tailored to meet the first principle. Accordingly, the Advisory Committee recommended that all wholesale and consecutive systems comply with provisions of the Stage 2 DBPR on the same schedule required of the wholesale or consecutive system serving the largest population in the combined distribution system. In addition, the Advisory Committee recommended that EPA solicit comments on issues related to consecutive systems that the Advisory Committee had not fully explored (USEPA 2000g). EPA agrees with these recommendations and they are reflected in today's proposal.

3. Request for Comment

EPA requests comment on all consecutive system issues related to this rule. Specifically, EPA requests comment on the following:

—Whether the proposed definitions adequately address various wholesale system-consecutive system relationships and issues.
—Whether any additional terms need to be defined and, if so, what the definition should be.
—Whether the criteria for States' use of the special primacy criteria and other State responsibilities are appropriate and adequate.
—Whether it is necessary to require that consecutive system treatment be installed on the same compliance schedule as the wholesale system in cases where the size of the consecutive system might otherwise allow it a longer compliance time frame and the consecutive system treatment does not affect water quality in any other system.

D. MCLs for TTHM and HAA5

1. What Is EPA Proposing Today?

Today, EPA is proposing use of locational running annual averages (LRAAs) to determine compliance with the MCLs for TTHM and HAA5. Consistent with the Stage 2 M-DBP Advisory Committee recommendation, EPA is proposing a phased approach for LRAA implementation to allow systems to identify compliance monitoring locations for Stage 2B while facilitating transition to the new compliance strategy and maintaining simultaneous compliance schedules for the Stage 2 DBPR and the LT2ESWTR.

In Stage 2A, all systems must comply with MCLs of 0.120 mg/L for TTHM and 0.100 mg/L for HAA5 as LRAAs using Stage 1 DBPR compliance monitoring sites. In addition, during this time period, all systems must continue to comply with the Stage 1 DBPR MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as RAAs.

In Stage 2B, all systems, including consecutive systems, must comply with MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as LRAAs using sampling sites identified under the Initial Distribution System Evaluation (IDSE) (discussed in section V.H.).

Details of proposed monitoring requirements and compliance schedules are discussed in preamble sections V.I. and V.J., respectively, and may be found in § 141.136 and subpart V of today's rule.

2. How Was This Proposal Developed?

a. *Definition of an LRAA.* The primary objective of the LRAA is to reduce exposure to high DBP levels. For an LRAA, an annual average must be computed at each monitoring site. The RAA compliance basis of the 1979 TTHM rule and the Stage 1 DBPR allows a system-wide annual average under which high DBP concentrations in one or more locations are averaged with, and

dampened by, lower concentrations elsewhere in the distribution system. Figure V–1 illustrates the difference in calculating compliance with the MCLs for TTHM between a Stage 1 DBPR RAA, and the proposed Stage 2 DBPR LRAA.

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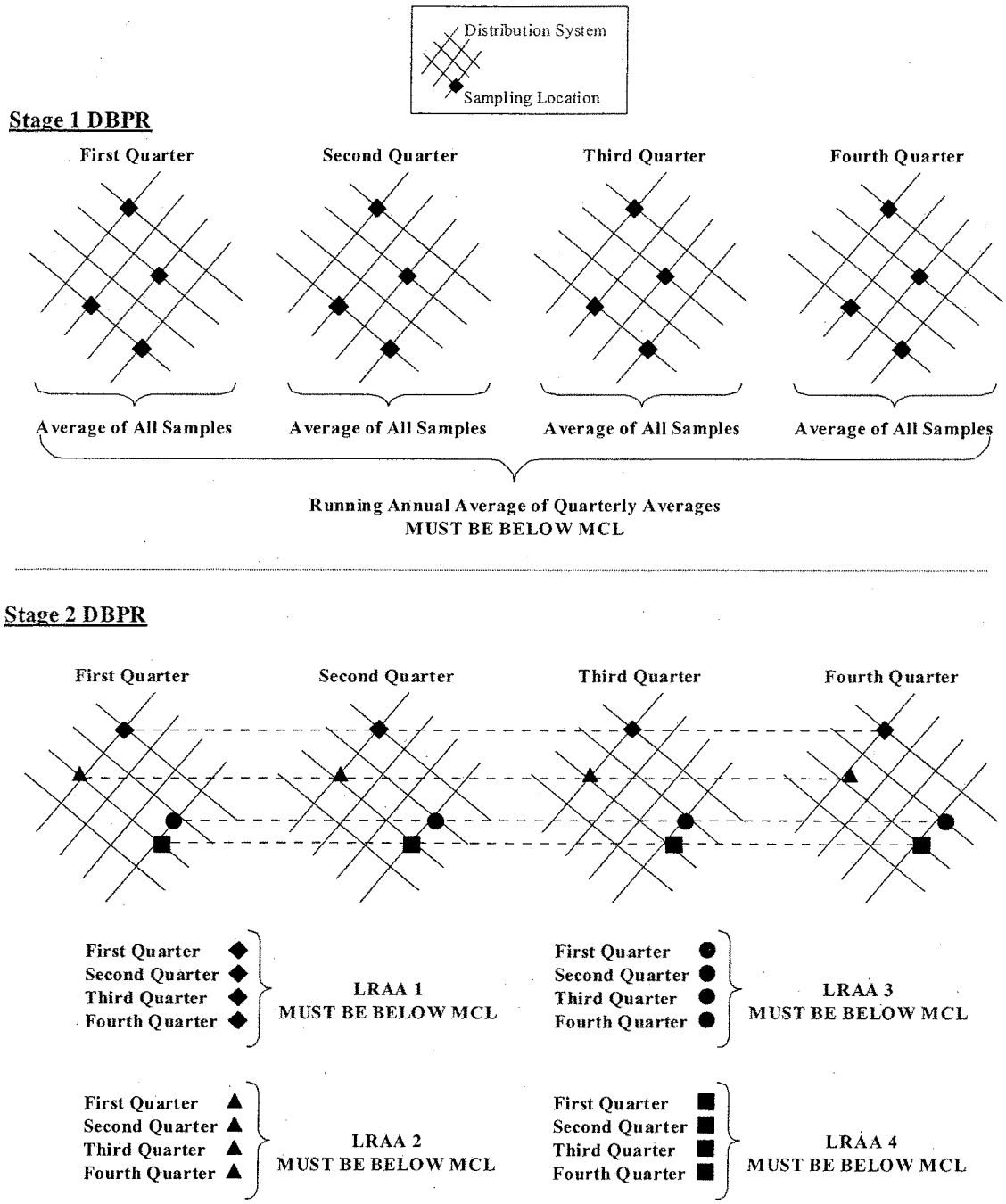
Figure V-1. Comparison of RAA and LRAA compliance calculations[1].



[1]Stage 2 DBPR sampling locations will be selected based on the results of an IDSE study and may occur at locations different from Stage 1 DBPR sampling sites.

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b. *Consideration of regulatory alternatives.* This section will discuss EPA's and the Stage 2 M-DBP Advisory Committee's decision-making process as an array of alternative MCL strategies were considered. EPA believes that the MCL alternative proposed today (MCLs of 0.080 mg/L TTHM, 0.060 mg/L HAA5 as LRAAs) is supported by the best available research, data, and analysis. The science related to cancer and reproductive and developmental health effects that may be associated with DBPs, in conjunction with occurrence data that show that a significant number of high DBP levels occur under current regulatory scenarios, justify a change in regulation. EPA believes that this proposal achieves an appropriate balance between the available science and the uncertainties. EPA believes that regulatory action is necessary and prudent in the interest of further public health protection and that the LRAA alternative in combination with the IDSE is a balanced and reasonable approach. Although it will not remove all DBP peaks (individual samples with values greater than the MCL), this proposed regulation will ensure that DBP exposures across a system's distribution system are further reduced, are more equitable, and may reduce cancer and reproductive and developmental risk.

The Advisory Committee discussions primarily focused on the relative magnitude of exposure reduction versus the expected impact on the water industry and its customers. Initially, this analysis compared expected reductions in DBP levels and predictions of treatment technology changes associated with a wide variety of Stage 2 DBPR MCL alternatives.

After initial discussions, EPA and the Advisory Committee primarily focused on four types of alternative rule scenarios.

Preferred Alternative.—MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as LRAAs. Bromate MCL of 0.010 mg/L.

Alternative 1.—MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as LRAAs. Bromate MCL of 0.005 mg/L.

Alternative 2.—MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as individual sample maximums (*i.e.*, no single sample could exceed the MCL). Bromate MCL of 0.010 mg/L.

Alternative 3.—MCLs of 0.040 mg/L TTHM and 0.030 mg/L HAA5 as RAAs. Bromate MCL of 0.010 mg/L.

EPA and the Advisory Committee, with assistance from the Technical Workgroup, conducted an in-depth analysis of these regulatory alternatives. In the process of evaluating alternatives, EPA and the Advisory Committee reviewed vast quantities of data and many analyses that addressed health effects, DBP occurrence, predicted reductions in DBP levels, predicted technology changes, and capital, annual, and household costs. Details of the compliance, occurrence, and cost forecasts for the four alternative rule scenarios are described in the Stage 2 DBPR Economic Analysis (EA) (USEPA 2003i) and the Stage 2 DBPR Occurrence Document (USEPA 2003o).

In the end, the Advisory Committee recommended the Preferred Alternative in combination with the IDSE which they believed would reduce exposure to high levels of DBPs. Today, EPA is proposing the Preferred Alternative in combination with the IDSE.

The only difference between the Preferred Alternative and Alternative 1 is the bromate MCL. The Advisory Committee's recommendation to maintain the Stage 1 DBPR bromate MCL of 0.010 mg/L is discussed in section V.G. of today's proposal.

Alternatives 2 and 3 are significantly more stringent than the Stage 1 DBPR with respect to the TTHM and HAA5 requirements. Alternative 2 would require that all samples be below the MCL. Because DBP occurrence is variable across the distribution system and over time (as discussed in section IV), systems would have to base their disinfectant and treatment strategies on controlling their highest DBP occurrence levels. Alternative 3 maintains the Stage 1 DBPR RAA compliance calculation, but reduces the Stage 1 DBPR MCLs by 50 percent. Both alternatives 2 and 3 would cause significant changes in treatment for a large number of systems. The estimated costs for Alternatives 2 and 3 are approximately an order of magnitude above the costs for the Preferred Alternative (see section VII.B.).

Consistent with this greater stringency of alternatives 2 and 3, the predicted DBP reductions and the resulting health benefits for them are greater than those predicted for the Preferred Alternative. Although all members of the Advisory Committee believed that the science showing reproductive and developmental health effects that have been associated with DBPs was sufficient to cause concern and warrant regulatory action, the Advisory Committee did not believe that the association was certain enough to justify the substantial change in treatment technologies that would be required to meet these alternatives. Thus, the Advisory Committee rejected Alternatives 2 and 3.

c. *Basis for the LRAA.* This section discusses the data and information EPA used to determine that the LRAA is an appropriate compliance strategy for today's proposed rule. EPA has chosen compliance based on an LRAA due to concerns about levels of DBPs above the MCL in some portions of the distribution system. The LRAA standard will eliminate system-wide averaging. The individuals served in areas of the distribution system with above average DBP occurrence levels masked by averaging under an RAA are not receiving the same level of health protection. Although an LRAA standard still allows averaging at a single location over an annual period, EPA believes that changing the basis of compliance from an RAA to an LRAA will result in decreased exposure to above average DBP levels (*see* section VII.A. for predictions of DBP reductions under the LRAA MCLs). This conclusion is based on three considerations:

(1) There is considerable evidence that under the current RAA MCL compliance monitoring requirements a small but significant proportion of monitoring locations experience high DBP levels. As summarized in section IV of this preamble, 14 and 21% of Information Collection Rule systems currently meeting the Stage 1 DBPR RAA MCLs had TTHM and HAA5 single sample concentrations greater than the Stage 1 MCLs and ranged up to 140 μg/L and 130 μg/L respectively (Figures IV–1 and IV–2), though most of these exceedences were below 100 μg/L.

(2) In some situations, the populations served by certain portions of the distribution system consistently receive water that exceeds the MCL even though the system is in compliance. As discussed in section IV of this preamble, some Information Collection Rule systems meeting the Stage 1 DBPR RAA MCLs had monitoring locations that exceeded 0.080 mg/L TTHM and/or 0.060 mg/L HAA5 as an annual average (*i.e.*, as LRAAs) by up to 25% (Figures IV–3 and IV–4). Five percent of plants that achieved compliance with the Stage 1 TTHM MCL of 0.080 mg/L based on an RAA had a particular sampling location that exceeded 0.080 mg/L as an LRAA (Figure IV–3). Figure IV–4 shows similar results based on Information Collection Rule HAA5 data. Three percent of plants that met the Stage 1 HAA5 MCL of 0.060 mg/L as an RAA had a sampling location that exceeded 0.060 mg/L as an LRAA. Customers served at these locations consistently received water with TTHM and/or HAA5 concentrations higher than the system-wide MCL.

(3) Compliance based on an LRAA will remove the opportunity for systems to average out samples from high and low quality water sources. Some systems are able to comply with an RAA MCL even if they have a plant with a poor quality water source (that thus produces high concentrations of DBPs) because they have another plant that has a better quality water source (and thus lower concentrations of DBPs). Individuals served by the plant with the poor quality source will usually have higher DBP exposure than individuals served by the other plant.

d. *Basis for phasing LRAA compliance.* EPA believes that a phased approach for LRAA implementation will facilitate transition to the new compliance requirements. Stage 2A of this proposed rule does not require systems to conduct any additional monitoring. They will continue to monitor at Stage 1 DBPR locations. Because the LRAA calculation is the same as the RAA calculation if there is only one site, Stage 2A compliance only applies to systems that monitor at more than one site and will only affect medium and large surface water systems (serving at least 10,000 people) or systems with multiple plants. Thus, the majority of ground water systems, small surface water systems, and some consecutive systems are not affected by the proposed Stage 2A requirements.

e. *TTHM and HAA5 as Indicators.* In part, both the TTHM and HAA5 classes are regulated because they occur at high levels and represent chlorination byproducts that are produced from source waters with a wide range of water quality. The combination of TTHM and HAA5 represent a wide variety of compounds resulting from bromine substitution and chlorine substitution reactions (*i.e.*, bromoform has 3 bromines, TCAA has 3 chlorines, BDCM has one bromine and two chlorines, etc). EPA believes that the TTHM and HAA5 classes serve as an indicator for unidentified and unregulated DBPs. EPA believes that controlling the occurrence levels of TTHM and HAA5 will control the levels of all chlorination DBPs to some extent.

3. Request for Comment

EPA requests comment on the alternative MCL strategies that were considered by the Advisory Committee and the determination to propose the Preferred Alternative in combination with the IDSE as the preferred regulatory strategy. EPA also requests comment on whether the proposed approach will reduce peak DBP levels.

EPA requests comment on the phased MCL strategy and whether or not it will facilitate compliance with the LRAA. EPA also requests comment on the Stage 2A MCLs of 0.120 mg/L TTHM and 0.100 mg/L HAA5 as LRAAs and on the long-term MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as LRAAs.

E. Requirements for Peak TTHM and HAA5 Levels

1. What Is EPA Proposing Today?

Today, EPA is proposing that, concurrent with Stage 2B, systems must specifically document occurrences of peak DBP levels, termed significant excursions. In support of this provision, EPA is proposing that States, as a special primacy condition, develop criteria for determining whether a system has a significant excursion. EPA has developed draft guidance for systems and States on how systems may determine whether they have significant excursions. EPA is also proposing that a system that has a significant excursion must: (1) Evaluate distribution system operational practices to identify opportunities to reduce DBP levels (such as tank management to reduce residence time and flushing programs to reduce disinfectant demand), (2) prepare a written report of the evaluation, and (3) no later than the next sanitary survey, review the evaluation with their State. This review will take place under the sanitary survey components calling for the State to review monitoring, reporting, and data verification and system management and operation.

2. How Was This Proposal Developed?

Because individual measurements from a location are averaged over a four-quarter period to determine compliance, there may be occurrence levels that exceed the MCL even when a system is in compliance with an LRAA MCL. EPA and the Advisory Committee were concerned about these exposures to peak levels of DBPs and the possible risk they might pose. This concern was clearly reflected in the Agreement in Principle, which states,

''Recognizing that significant excursions of DBP levels will sometimes occur, even when systems are in full compliance with the enforceable MCL, public water systems that have significant excursions during peak periods are to refer to EPA guidance on how to conduct peak excursion evaluations, and how to reduce such peaks. Such excursions will be reviewed as part of the sanitary survey process. EPA guidance on DBP level excursions will be issued prior to promulgation of the final rule and will be developed in consultation with stakeholders.''

In evaluating this recommendation, EPA believes that the Advisory Committee's intent was clear with regard to the need for guidance on how to evaluate and reduce significant excursions. However, the Agreement is less clear on how, and where, to define what constitutes a significant excursion, and how to define the scope of the evaluation. EPA draft guidance recommends several approaches for determining whether significant excursions have occurred. While today's proposal requires an evaluation only of distribution system operational practices, EPA believes that many systems would benefit from a broader evaluation that includes treatment plant and other system operations.

EPA recognizes that different stakeholders have different points of view on whether specific criteria that initiate the evaluation of significant excursions should be included in the rule or in guidance. EPA also recognizes that different stakeholders may have different perspectives on how to identify a significant excursion. For this proposal, EPA has prepared draft guidance for systems and States on how to (1) determine whether a significant excursion has occurred, using several different options, (2) conduct significant excursion evaluations, and (3) reduce significant excursion occurrence.

3. Request for Comment

EPA requests comment on the proposed approach for addressing significant excursions and on the draft guidance. Is a special primacy condition the appropriate means for allowing flexibility in identifying significant excursions while ensuring that such evaluations occur? Is the sanitary survey the appropriate mechanism for reviewing significant excursion data with the State? Should a system be required to take corrective action when significant excursions occur? Should the required scope of the evaluation be expanded beyond distribution system operations?

EPA also requests comment on whether specific criteria that initiate the evaluation of significant excursions should be included in the rule or in guidance. EPA requests comment on how to identify significant excursions (regardless of whether the criteria are in the rule or in guidance). For example, should the significant excursion be based on an individual measurement, *e.g.*, any measurement being 25 or 50% over either the TTHM or HAA5 MCLs? Alternatively, should the determination of a significant excursion be based on a certain level of variability among multiple measurements? For example,

should the significant excursion be based on the standard deviation of the LRAA exceeding specific numerical values for either TTHM (*e.g.*, 0.020 mg/l) or HAA5 (*e.g.*, 0.015 mg/L)? Or should the excursion be based on a relative measure of variability (*e.g.*, a relative standard deviation exceeding 25% or 50%) with the condition of a threshold average concentration also being exceeded (*e.g.*, an LRAA needing to be at least 0.040 mg/l for TTHM or 0.030 mg/l for HAA5)? EPA requests comment on the above approaches or alternative approaches for determining whether a significant excursion has occurred. EPA also requests comment on whether different approaches may be appropriate for large and small systems.

F. BAT for TTHM and HAA5

1. What Is EPA Proposing Today?

Today, EPA is proposing that the best available technology (BAT) for the TTHM and HAA5 LRAA MCLs (0.080 mg/L and 0.060 mg/L respectively) be one of the three following technologies:

(1) GAC adsorbers with at least 10 minutes of empty bed contact time and an annual average reactivation/replacement frequency no greater than 120 days, plus enhanced coagulation or enhanced softening.

(2) GAC adsorbers with at least 20 minutes of empty bed contact time and an annual average reactivation/replacement frequency no greater than 240 days.

(3) Nanofiltration (NF) using a membrane with a molecular weight cut off of 1000 Daltons or less (or demonstrated to reject at least 80% of the influent TOC concentration under typical operating conditions).

EPA is proposing a different BAT for consecutive systems than for wholesale systems to meet the TTHM and HAA5 LRAA MCLs. The proposed consecutive system BAT is chloramination with management of hydraulic flow and storage to minimize residence time in the distribution system.

2. How Was This Proposal Developed?

a. *Basis for the BAT.* The Safe Drinking Water Act directs EPA to specify BAT for use in achieving compliance with the MCL. Systems unable to meet the MCL after application of BAT can get a variance (*see* section V.L. for a discussion of variances). Systems are not required to use BAT in order to comply with the MCL. They can use other technologies as long as they meet all drinking water standards and are approved by the State.

EPA examined BAT using two different methods: (1) EPA analyzed data from the Information Collection Rule treatment studies and (2) EPA used the Surface Water Analytical Tool (SWAT), a model developed to compare alternative regulatory strategies. Both analyses support the BAT options proposed today. The results of each analyses are presented in the following two sections.

i. BAT analysis using the Information Collection Rule treatment studies. EPA analyzed data from the Information Collection Rule treatment studies (Information Collection Rule Treatment Study Database CD–ROM, Version 1.0, USEPA 2000m; Hooper and Allgeier 2002). The treatment studies were designed to evaluate the technical feasibility of using GAC and NF to remove DBP precursors prior to the addition of chlorine-based disinfectants. Systems were required to conduct an Information Collection Rule treatment study based on TOC levels in the source or finished water. Specifically, surface water plants with annual average source water TOC concentrations greater than 4 mg/L and ground water plants with annual average finished water TOC concentrations greater than 2 mg/L were required to conduct treatment studies. Thus, the plants required to conduct treatment studies generally had waters with organic DBP precursor levels that were significantly higher than the Information Collection Rule national plant medians of 2.7 mg/L for source water at surface water plants and 0.2 mg/L for finished water at ground water plants (USEPA 2003o).

Plants that conducted GAC studies typically evaluated performance at two empty bed contact times, 10 and 20 minutes, over a wide range of operational run times to evaluate the variable nature of TOC removal by GAC. This allowed GAC performance to be assessed with respect to empty bed contact time as well as reactivation/replacement frequency. Plants that conducted membrane treatment studies evaluated one or two nanofiltration membranes with molecular weight cutoffs less than 1000 Daltons. Regardless of the technology evaluated, all treatment studies evaluated DBP formation in the effluent from the advanced process under simulated distribution system conditions representative of the average residence time and using free chlorine as the primary and residual disinfectant. (For more information on the Information Collection Rule treatment study requirements and testing protocols, see USEPA 1996 a and b.)

Based on the treatment study results, GAC is effective for controlling DBP formation for waters with influent TOC concentrations below approximately 6 mg/L (based on the Information Collection Rule and NRWA data, over 90 percent of plants have average influent TOC levels below 6 mg/L (USEPA 2003o)). Of the plants that conducted an Information Collection Rule GAC treatment study, approximately 70% of the surface water plants studies could meet the 0.080 mg/L TTHM and 0.060 mg/L HAA5 MCLs, with a 20% safety factor (*i.e.*, 0.064 mg/L and 0.048 mg/L, respectively) using GAC with 10 minutes of empty bed contact time and a 120 day reactivation frequency, and 78% of the plants could meet the MCLs with a 20% safety factor using GAC with 20 minutes of empty bed contact time and a 240 day reactivation frequency. As discussed previously, the treatment studies were conducted at plants with poorer water quality than the national average. Therefore, EPA believes that much higher percentages of plants nationwide could meet the MCLs with the proposed GAC BATs.

Among plants using GAC, larger systems would likely realize an economic benefit from on-site reactivation, which could allow them to use smaller, 10-minute empty bed contact time contactors with more frequent reactivation (*i.e.*, 120 days or less). Most small systems would not find it economically advantageous to install on-site carbon reactivation facilities, and thus would opt for larger, 20-minute empty bed contact time contactors, with less frequent carbon replacement (*i.e.*, 240 days or less).

The proposed reactivation/replacement interval for the 20 minute contactor (*i.e.*, 240 days) is double the reactivation/replacement interval for 10 minute contactor (*i.e.*, 120 days). This is based on the assumption of a linear relationship between empty bed contact time and the reactivation interval (*e.g.*, a doubling of the empty bed contact time will result in a doubling of the reactivation interval). The data from the Information Collection Rule treatment studies indicates that this linear relationship may not always hold and that doubling the empty bed contact time generally results in more than a doubling of the reactivation interval. While there may be some operational advantage in using larger empty bed contact times, the larger contactors will result in additional capital expenditures. Furthermore, the economic optimization of a GAC process must also consider the number of smaller contactors in parallel, since it may be advantageous to operate a larger number of smaller contactors in parallel, allowing each individual contactor to be

operated for a longer period of time. Based on these considerations, and the analysis of subject matter experts, it was concluded that the proposed combination of GAC empty bed contact times and reactivation/replacement intervals were reasonable for BAT.

The Information Collection Rule treatment study results also demonstrated that nanofiltration was the better DBP control technology for ground water sources with high TOC concentrations (*i.e.*, above approximately 6 mg/L). The results of the membrane treatment studies showed that all ground water plants could meet the 0.080 mg/L TTHM and 0.060 mg/L HAA5 MCLs, with a 20% safety factor (*i.e.*, 0.064 mg/L and 0.048 mg/L, respectively) at the average distribution system residence time using nanofiltration. Nanofiltration would be less expensive than GAC for high TOC ground waters, which generally require minimal pretreatment prior to the membrane process. Also, nanofiltration is an accepted technology for treatment of high TOC ground waters in Florida and parts of the Southwest, areas of the country with elevated TOC levels in ground waters.

ii. *BAT analysis using the SWAT.* The second method that EPA used to examine alternatives for BAT was the SWAT model that was developed to compare alternative regulatory strategies. EPA modeled the following BAT options: enhanced coagulation/softening with chlorine (the Stage 1 DBPR BAT); enhanced coagulation/softening with chlorine and no predisinfection; enhanced coagulation and GAC10; enhanced coagulation and GAC20; and enhanced coagulation and chloramines. Enhanced coagulation/softening is required under the Stage 1 DBPR at subpart H conventional filtration plants. In the model, GAC10 was defined as granular activated carbon with an empty bed contact time of 10 minutes and a reactivation or replacement interval of 90 days or longer. GAC20 was defined as granular activated carbon with an empty bed contact time of 20 minutes and a reactivation or replacement interval of 90 days or longer. EPA assumed that systems would be operating to achieve both the Stage 2B MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as an LRAA and the SWTR removal and inactivation requirements of 3-log for *Giardia* and 4-log for viruses. EPA also evaluated the BAT options under the assumption that plants operate to achieve DBP levels 20% below the MCL (safety factor). These assumptions along with other inputs for the SWAT runs are consistent with those used in the Economic Analysis of today's proposed rule (USEPA 2003i).

The compliance percentages forecasted by the SWAT model are indicated in Table V–1. EPA estimates that more than 97% of large systems will be able to achieve the Stage 2B MCLs regardless of post-disinfection choice if they were to apply one of the proposed GAC BATs, *i.e.*, enhanced coagulation (EC) and GAC10 (Seidel Memo, 2001). As shown in the Stage 2 DBPR Occurrence document (USEPA 2003o), the source water quality (*e.g.*, DBP precursor levels) in medium and small systems is expected to be comparable to or better than that for the large systems. Based on the large system estimate, EPA believes it is conservative to assume that at least 90% of medium and small systems will be able to achieve the Stage 2B MCLs if they were to apply one of the proposed GAC BATs. EPA assumes that small systems may adopt GAC20 in a replacement mode (with replacement every 240 days) over GAC10 because it may not be economically feasible for some small systems to install and operate an on-site GAC reactivation facility. Moreover, some small systems may find nanofiltration cheaper than the GAC20 in a replacement mode if their specific geographic locations cause a relatively high cost for routine GAC shipment.

TABLE V–1.—SWAT MODEL PREDICTIONS OF PERCENT OF LARGE PLANTS IN COMPLIANCE WITH TTHM AND HAA5 STAGE 2B MCLS AFTER APPLICATION OF SPECIFIED TREATMENT TECHNOLOGIES

Technology *	Compliance with 0.080 mg/L (TTHM)/0.060 mg/L (HAA5) LRAAs			Compliance with 0.064 mg/L (TTHM)/0.048 mg/L (HAA5) LRAAs (MCLs with 20% safety factor)		
	Residual disinfectant		All systems	Residual disinfectant		All systems
	Chlorine	Chloramine		Chlorine	Chloramine	
Enhanced Coagulation (EC)	73.5	76.9	74.8	57.2	65.4	60.4
EC (no predisinfection)	73.4	88.0	78.4	44.1	62.7	50.5
EC & GAC10	100	97.1	99.1	100	95.7	98.6
EC & GAC20	100	100	100	100	100	100
EC & All Chloramines	NA	83.9	NA	NA	73.6	NA

* Enhanced coagulation/softening is required under the Stage 1 DBPR for conventional plants.

b. *Basis for the Consecutive System BAT.* EPA believes that the best compliance strategy for consecutive systems is to collaborate with wholesalers on the water quality they need. For consecutive systems that are having difficulty meeting the MCLs, EPA is proposing a BAT of chloramination with management of hydraulic flow and storage to minimize residence time in the distribution system. EPA is proposing a different BAT than for wholesale systems because a consecutive system's source water has already been disinfected and contains DBPs that cannot be effectively removed or controlled with the BATs proposed for wholesale systems. EPA believes the proposed consecutive system BAT is an effective means for consecutive systems to meet the MCLs.

Chloramination has been used for residual disinfection for many years to minimize the formation of chlorination DBPs, including TTHM and HAA5 (Stage 2 Technology and Cost Document, USEPA 2003k). The BAT provision to manage hydraulic flow and minimize residence time in the distribution system is to facilitate the maintenance of the chloramine residual and minimize the likelihood for nitrification. Nitrification, the process by which microbes convert free ammonia to nitrate and nitrite, is a concern for systems using chloramines. Nitrification, however, can be controlled with appropriate chlorine to ammonia ratios, increasing flow in low demand areas, and increasing storage tank turnover. EPA proposes that systems implementing the consecutive system BAT must do the following: (1) Maintain a chloramine residual throughout the distribution system, (2) develop and submit a plan that indicates actions that will be taken to minimize the residence time of water

within the distribution system, (3) have the plan approved by the Primacy Agency, and (4) implement the plan as approved by the Primacy Agency. Minimum components of the management plan would include periodic scheduled flushing of all dead end pipes and storage vessels through which water is delivered to customers, and hydraulic flow control procedures that routinely circulate water in all storage vessels within the distribution system.

EPA believes that the BATs proposed for wholesale systems are not appropriate for consecutive systems because each of these BATs, when applied to water with DBPs, raises other concerns. GAC is not cost-effective for removing DBPs. In addition, dioxin, a carcinogen, may be formed during GAC regeneration if GAC has been used to adsorb chlorinated DBPs. Nanofiltration is only moderately effective at removing THMs or HAAs if membranes that have a very low molecular weight cutoff and very high cost of operation are employed. Therefore, GAC and nanofiltration are not appropriate BATs for consecutive systems.

3. Request for Comment

EPA requests comment on the proposed BATs including the BAT for consecutive systems.

G. MCL, BAT, and Monitoring for Bromate

1. What Is EPA Proposing Today?

EPA is proposing today that the MCL for bromate for systems using ozone remain at 0.010 mg/L as an RAA for samples taken at the entrance to the distribution system as established by the Stage 1 DBPR and as provided for under the risk-balancing provisions of section 1412(b)(5) of the SDWA. EPA's proposal is consistent with the recommendation of the Stage 2 M–DBP Advisory Committee, which considered the potential that reducing the bromate MCL could both increase the concentration of other DBPs in the drinking water and interfere with the efficacy of microbial pathogen inactivation. In addition, as required by the SDWA and as recommended by the Advisory Committee, EPA will review the bromate MCL as part of the 6-year review process and determine whether the MCL should remain at 0.010 mg/L or be reduced to a lower level. As a part of that review, EPA will consider the increased utilization of alternative technologies, such as UV, and whether the risk/risk concerns reflected in today's proposal remain valid.

Because EPA is not revising the Stage 1 DBPR bromate MCL, EPA is not proposing a revised BAT for bromate. The Stage 1 DBPR BAT for bromate is defined as control of ozone treatment processes to reduce production of bromate. EPA also determined that it was not necessary to regulate bromate in non-ozone systems that use hypochlorite.

Finally, EPA is proposing to modify the criterion for a system that uses ozone (and therefore must monitor for bromate) to qualify for reduced bromate monitoring from one sample per ozone plant per month to one sample per plant per quarter.

2. How Was This Proposal Developed?

a. *Bromate MCL.* Bromate is a principal byproduct from ozonation of bromide-containing source waters. As described in more detail later, making the bromate MCL more stringent has the potential to decrease current levels of microbial protection, impair the ability of systems to control resistant pathogens like *Cryptosporidium,* and increase levels of DBPs from other disinfectants that may be used instead of ozone.

EPA estimates that the 1 in 10,000 excess lifetime cancer risk level for bromate is 0.005 mg/L. EPA proposed and ultimately finalized an MCL of 0.010 mg/L in the Stage 1 DBPR, primarily because available analytical detection methods for bromate could only reliably measure to 0.01 mg/L (USEPA 1994b). Analytical methods for bromate are now available to quantify bromate concentrations as low as 0.001 mg/L. Due to the availability of lower detection methods for bromate, as part of the Stage 2 M–DBP Advisory Committee deliberations, EPA considered revising the MCL to 0.005 mg/L or lower.

As a disinfectant, ozone is highly effective against a broad range of microbial pathogens including bacteria, viruses, and protozoa. Moreover, ozone is one of the few disinfectants available in water treatment that is capable of inactivating *Cryptosporidium,* a protozoan which can cause severe intestinal disorders and can be deadly to those with compromised immune systems. The oxidizing properties of ozone are also valuable for treatment objectives like control of tastes and odors and removal of iron and manganese. In contrast, chlorine, the most common disinfectant and oxidant in water treatment, is substantially less effective for controlling *Cryptosporidium.* Chlorine dioxide, while capable of providing low levels of inactivation for *Cryptosporidium,* typically cannot be used at high doses without violating the MCL for chlorite, a byproduct of chlorine dioxide. UV light is highly effective against *Cryptosporidium* and *Giardia* and most viruses, but has not been used extensively to treat drinking water in the United States.

As of early 2000, there were 332 plants of various sizes using ozone (Overbeck 2000) and 58 plants that were planning to install ozonation (Rice 2000—personal communication: email 7/14/2000). A significant percent of current ozone plants use ozone for some portion of their disinfection objective (Rice, 2000—personal communication: email 7/14/2000). An ozone system that could not meet a 0.005 mg/L bromate MCL would have three primary options: decrease the ozone dose; switch to a different disinfectant; or install an advanced filtration process such as membranes, sometimes in combination with the first two options. Of these three options, the third is likely effective but very expensive, while the first two create the risk either of reducing microbial protection for a wide range of microbial pathogens, or of increasing formation of DBPs other than bromate.

In an attempt to achieve a lower level of bromate, some systems might be driven to reduce the applied ozone dose to the minimum necessary for regulatory compliance or switch to other treatment processes. Many systems currently achieve more disinfection than is required by the SWTR and if a system were to simply lower the ozone dose, protection from pathogens may be compromised. In addition, since inactivation of *Cryptosporidium* requires much higher ozone doses than *Giardia* inactivation, systems cannot achieve *Cryptosporidium* inactivation with low ozone doses.

If a system were to lower the ozone dose and supplement with an additional disinfectant, or switch entirely to a different disinfectant, the system may not achieve the same level of microbial protection as is afforded by ozonation. Also, other potentially harmful byproducts from the different disinfectant would be produced.

During the Stage 2 M–DBP Advisory Committee discussions, the TWG evaluated the impact of reducing the bromate MCL from 0.010 mg/L to 0.005 mg/L as an annual average. The TWG concluded that many systems currently using ozone or predicted to install ozone to inactivate microbial pathogens would have significant difficulty maintaining bromate levels at or below 0.005 mg/L. In the Information Collection Rule survey of systems serving greater than 100,000 people, all of the ozone plants had annual average

bromate concentrations below the 0.010 mg/L level (USEPA 2003o). However, approximately 20% of these ozone plants did not meet the 0.005 mg/L level. Using the assumption that systems operate their plants using a safety margin of 20% below the MCL, about 30% of ozone plants did not reliably attain this level (0.004 mg/L). During the Information Collection Rule, for the first half of 1998, much of the U.S. was wetter than normal (NOAA 1998). This hydrogeological condition often leads to lower than normal bromide concentrations due to dilution by higher water flows. In the second half of 1998, California continued to experience El Nino rains (40% of Information Collection Rule ozone plants were located in California) but many other areas of the country such as Texas and Florida experienced a drought. The percentage of ozone systems unable to achieve 0.005 mg/L bromate would likely increase during years in which bromide concentrations in California were elevated as consequence of drought.

The ability of systems to use ozone to meet *Cryptosporidium* treatment requirements proposed under the LT2ESWTR would be diminished if the bromate MCL was decreased from 0.010 to 0.005 mg/L. The proposed LT2ESWTR will require a subset of systems, based on source water pathogen levels, to provide from 1.0 to 2.5 logs of additional treatment for *Cryptosporidium*. Ozone doses required to inactivate *Cryptosporidium* are substantially greater than those required for Giardia and viruses. To assess the potential impact of a lower bromate MCL on the ability of systems to treat for *Cryptosporidium*, the TWG estimated the percentage of treatment plants that could use ozone to inactivate from 0.5 to 2.5 log of *Cryptosporidium* without exceeding a bromate MCL of either 0.005 or 0.010 mg/L (USEPA 2003i). These estimations were based on analyses of Information Collection Rule source water quality data, coupled with projected ozone dose requirements for *Cryptosporidium*. This analysis suggests that 88% of systems could use ozone to achieve 1 log of *Cryptosporidium* inactivation and 47% could inactivate 2 log while complying with a bromate MCL of 0.010 mg/L. With the bromate MCL reduced to 0.005 mg/L, though, these estimates drop to 67% of systems able to inactivate 1 log of *Cryptosporidium* with ozone and only 14% able to inactivate 2 log. The number of plants predicted to be able to treat for *Cryptosporidium* with ozone and meet a 0.005 mg/L standard was further reduced when periods of higher bromide levels, similar to drought conditions, were modeled. This trend is further exacerbated since the proposed LT2ESWTR would require more stringent ozone operating conditions (such as higher ozone doses and longer contact times) than under current surface water treatment requirements for the subset of plants with higher *Cryptosporidium* concentrations in their source water and would thus result in higher bromate formation than assumed by the TWG. Thus, as systems are required to meet more stringent inactivation requirements, a large number of systems would be forced to select treatment processes other than ozone if the bromate standard were lowered to 0.005 mg/L.

The Stage 2 M–DBP Advisory Committee considered that reducing the bromate MCL to 0.005 mg/L could both increase the concentration of other DBPs in the drinking water and interfere with the efficacy of microbial pathogen inactivation. Therefore, the Advisory Committee recommended, for purposes of the Stage 2 DBPR, that the bromate MCL remain at 0.010 mg/L. EPA will review the bromate MCL as part of the ongoing 6-year review process and determine whether the MCL should remain at 0.010 mg/L or be reduced to a lower concentration based on new information.

Today, EPA is proposing to leave the bromate MCL at 0.010 mg/L, consistent with the Advisory Committee's recommendation. EPA believes that this is a prudent step at this time, in order to preserve microbial protection. EPA will continue to analyze any new bromate health effects data as they become available. It is possible that EPA may determine that the bromate MCL should be decreased to 0.005 mg/L or lower in a future rulemaking.

b. *Bromate in hypochlorite solutions.* The Stage 2 M–DBP Advisory Committee also discussed the issue of hypochlorite solutions contaminated with bromate. This contamination can occur during the production of hypochlorite solutions from natural salt deposits. The range of bromate concentrations in hypochlorite stock solutions varies widely (Bolyard *et al.* 1992; Chlorine Institute 1999, 2000). Moreover, the bromate contained in the stock solution is diluted upon addition to the drinking water. From data on Information Collection Rule ozone systems that used hypochlorite versus those that used gaseous chlorine, the TWG estimated that hypochlorite solutions contributed an average of 0.001 mg/L bromate.

The Advisory Committee discussed these results and, since the bromate level resulting from hypochlorite solutions was small compared to the MCL, did not recommend regulating bromate at systems not using ozone (non-ozone systems). The Advisory Committee recognized that ozone systems also using hypochlorite will have to be careful about the quality of their stock solution.

c. *Criterion for reduced bromate monitoring.* Because more sensitive bromate methods are now available, EPA is proposing a new criterion for reduced bromate monitoring. In the Stage 1 DBPR, EPA required ozone systems to demonstrate that source water bromide levels, as a running annual average, did not exceed 0.05 mg/L. EPA elected to use bromide as a surrogate for bromate in determining eligibility for reduced monitoring because the available analytical method for bromate was not sensitive enough to quantify levels well below the bromate MCL of 0.010 mg/L.

In section V.O., EPA is proposing several new analytical methods for bromate that are far more sensitive than the existing method. Since these methods can measure bromate to levels of 0.001 mg/L or lower, EPA is proposing to replace the criterion for reduced bromate monitoring (source water bromide running annual average not to exceed 0.05 mg/L) with a bromate running annual average not to exceed 0.0025 mg/L.

In the past, EPA has often set the criterion for reduced monitoring eligibility at 50% of the MCL, which would be 0.005 mg/L. However, as discussed before, EPA is proposing that the MCL for bromate remain at 0.010 mg/L, a level that is higher than EPA's usual excess cancer risk range of 10(-4) to 10(-6) at 2x10(-4) because of risk tradeoff considerations. EPA believes that the decision for reduced monitoring is separate from these risk tradeoff considerations. Risk tradeoff considerations influence the selection of the MCL, while reduced monitoring requirements are designed to ensure that the MCL, once established, is reliably and consistently achieved. Requiring a running annual average of 0.0025 mg/L for the reduced monitoring criterion allows greater confidence that the system is achieving the MCL and thus ensuring public health protection.

3. Request for Comment

EPA requests comment on the decision to maintain the Stage 1 DBPR bromate BAT and MCL of 0.010 mg/L. EPA also requests comment on the decision not to require bromate

monitoring at non-ozone systems that use hypochlorite.

EPA requests comment on whether the criterion for reduced bromate monitoring should be set at a level other than 0.0025 mg/L, and a rationale for setting it at that level.

H. Initial Distribution System Evaluation (IDSE)

The IDSE is an important part of today's proposed regulation that is intended to identify sample locations for Stage 2B compliance monitoring that represent distribution system sites with high DBP concentrations.

1. What is EPA Proposing Today?

EPA is proposing a requirement for systems to perform an Initial Distribution System Evaluation (IDSE). Systems will collect data on DBP levels throughout their distribution system, evaluate these data to determine which sampling locations are most representative of high DBP levels and compile this information into a report for submission to the primacy agency.

a. *Applicability.* All community water systems, and large nontransient noncommunity water systems (those serving at least 10,000 people) that add a primary or residual disinfectant other than ultraviolet light, or that deliver water that has been treated with a primary or residual disinfectant other than ultraviolet light (*i.e.*, consecutive systems) are required to conduct an IDSE under the proposed rule. The IDSE requirement for systems serving fewer than 500 people may be waived if the State determines that the monitoring site approved for Stage 1 DBPR compliance is sufficient to represent both high HAA5 and high TTHM concentrations. The State must submit criteria for this waiver determination to EPA as part of their primacy application. States may decide to waive the IDSE requirement for all systems serving fewer than 500 or some subset of all systems serving fewer than 500 if the State determines that it is appropriate. EPA is developing an IDSE Guidance Manual that will include guidance to States on situations for which a waiver would be appropriate (USEPA 2003j).

b. *Data collection.* IDSEs are intended to help identify and select Stage 2B compliance monitoring sites that represent high concentrations of TTHMs and HAA5. To be able to identify these sites, systems and States must have monitoring data collected from throughout their distribution systems. Therefore, under today's proposed rule, systems are required to collect monitoring data on the concentrations of these DBPs. There are three possible approaches by which a system can meet the IDSE requirement.

i. *Standard monitoring program.* The standard monitoring program requires one year of monitoring on a specified schedule throughout the distribution system. The frequency and number of samples required under the standard monitoring program is determined by source water type, number of treatment plants, and system size (see section V.J. for a more detailed discussion of the specific monitoring requirements). Prior to commencing the standard monitoring program, systems must prepare a monitoring plan. EPA's IDSE Guidance Manual will provide guidance on selecting monitoring sites and conducting the standard monitoring program (USEPA 2003j). As recommended by the Advisory Committee, EPA is proposing that the standard monitoring program results are not to be used for determining compliance with MCLs and that systems will not be required to report IDSE results in the Consumer Confidence Report.

ii. *System specific study.* Under this approach, systems may choose to perform a system-specific study based on earlier monitoring studies or other data analysis in lieu of the standard monitoring program. These studies must provide equivalent or better information than the standard monitoring program for selecting sites that represent high TTHM and HAA5 levels. Examples of alternative studies are: (1) Recent TTHM and HAA5 monitoring data that encompass a wide range of sample sites representative of the distribution system, including those judged to represent high TTHM and HAA5 concentrations and (2) hydraulic modeling studies that simulate water movement in the distribution system. Historical TTHM and HAA5 results submitted by systems must have been generated by certified laboratories and must include the system's most recent data. Treatment plant and distribution system characteristics at the time of historical data collection must reflect the current plant operations and distribution system. EPA's IDSE Guidance Manual will include a guidance for system-specific studies and how to determine whether site-specific data could be sufficient to meet the IDSE requirements (USEPA 2003j).

iii. *40/30 certification.* Under this approach, systems certify to their primacy agency that all required Stage 1 DBPR compliance samples were properly collected and analyzed during the two years prior to the start of the IDSE, and all individual compliance samples were ≤ 0.040 mg/L for TTHM and ≤0.030 mg/L for HAA5. Properly collected and analyzed compliance samples are those taken at required locations at times specified in the system's Stage 1 DBPR monitoring plan and analyzed by certified laboratories. Systems not required to collect Stage 1 DBPR compliance samples can not utilize the 40/30 certification approach because they do not have data to determine sampling locations that represent high concentrations of TTHMs and HAA5. Systems that qualify for reduced monitoring for the Stage 1 DBPR during the two years prior to the start of the IDSE, may use results of both routine and reduced Stage 1 DBPR monitoring to prepare the 40/30 certification. Large ground water systems may not have two years of HAA5 data to evaluate due to the timing of the Stage 1 DBPR and the IDSE requirements. EPA is proposing that, if two years worth of HAA5 data are not available, large ground water systems evaluate the most recent two years of TTHM data including data collected in accordance with the 1979 TTHM rule and all available HAA5 compliance data collected up to nine months following promulgation of this rule when making the 40/30 certification. Similarly, small wholesale and consecutive systems required to submit their IDSE report no later than two years after publication of the final rule will evaluate all available Stage 1 DBPR compliance data collected up to nine months following promulgation.

c. *Implementation.* All systems subject to the IDSE requirement under the proposed rule (except those receiving a very small system waiver from the State) must submit a report to the primacy agency. The requirements for the report depend upon the IDSE data collection alternative that the system selects and are listed in Table V–2.

TABLE V–2.—IDSE REPORT REQUIREMENTS

IDSE data collection alternative	IDSE report requirements
Standard Monitoring Program.	• All standard monitoring program TTHM and HAA5 analytical results, the original monitoring plan, and an explanation of any deviations from that plan. • A schematic of the distribution system. • Recommendations and justification for where and during what month(s) Stage 2B monitoring should be conducted.
System Specific Study	• All studies, reports, analytical results and modeling. • A schematic of the distribution system. • Recommendations and justification for where and during what month(s) Stage 2B monitoring should be conducted
40/30 Certification	• A certification that all required compliance samples were properly collected and analyzed during the two years prior to the start of the IDSE and all individual compliance samples were ≤ 0.040 mg/L for TTHM and ≤0.030 mg/L for HAA5. • Results of compliance samples taken after the IDSE was scheduled to begin and before the IDSE report was submitted. • Recommendations for where and during what month(s) Stage 2B monitoring should be conducted.

All IDSE reports must include recommendations for the location and schedule for the Stage 2B monitoring. The number of sampling locations and the criteria for their selection are described in § 141.605 of today's proposed rule, and in section V.I. Generally, a system must recommend locations with the highest LRAAs unless it provides a rationale (such as ensuring geographical coverage of the distribution system instead of clustering all sites in a particular section of the distribution system) for selecting other locations. Systems must consider both their compliance data and IDSE data in making this determination. In addition to specifying a protocol for identifying recommended monitoring sites in the rule language, EPA will provide guidance for recommending compliance monitoring sites (including rationales for systems to recommend sites that do not have the highest LRAA concentrations) and preparing the IDSE report. EPA will also provide a process to address IDSE implementation issues during the period prior to State primacy. At the time that systems serving fewer than 10,000 people conduct their monitoring or analyze their site-specific data, many States may have primacy.

The compliance schedules for the IDSE and other requirements of the proposed rule are described in detail in section V.J. Systems serving at least 10,000 people (and those smaller wholesale and consecutive systems associated with larger systems) will be collecting data for their IDSE prior to State primacy. EPA intends to have an IDSE Guidance Manual available to assist systems in performing the IDSE (USEPA 2003j). Primacy agencies will specify requirements for systems that do not submit an IDSE report, or that have not, in the determination of the primacy agency, conducted an adequate IDSE, in addition to giving the system a monitoring and reporting violation. These requirements may include repeating the IDSE while conducting compliance monitoring at Stage 1 monitoring sites or conducting Stage 2 compliance monitoring at sites selected by the State.

Consecutive systems are subject to the IDSE requirements of today's proposed rule. IDSE requirements for consecutive systems are largely the same as for other systems, but with two differences. First, the schedule for completion of the IDSE by a consecutive system is dependent upon the population of the wholesale system. If a consecutive system serving fewer than 10,000 buys water from a system that serves 10,000 or more people, then this consecutive system must comply within the same schedule as that for systems ≥ 10,000. Conversely, if a wholesale system serves < 10,000 but sells water to a consecutive system serving ≥ 10,000, then both the wholesale system and the consecutive system must complete the IDSE within the same schedule as that for systems ≥ 10,000. The second difference for consecutive systems is that the procedure for recommending Stage 2B compliance monitoring locations is modified for consecutive systems purchasing or receiving all of their finished water from a wholesale system. These modified procedures are described in § 141.605 of today's proposed rule, and in section V.I.

2. How Was This Pr oposal Developed?

The IDSE was recommended by the Stage 2 M–DBP Advisory Committee. The Advisory Committee believed that maintaining Stage 1 DBPR sampling sites for the Stage 2 DBPR would not accomplish the objective of providing consistent and equitable protection across the distribution system.

a. *Applicability.* The M–DBP Advisory Committee recommended that an IDSE be performed on all community systems to help to identify the locations in the distribution system that represent high DBP concentrations. EPA believes that large nontransient noncommunity water systems (those serving at least 10,000 people) also have distribution systems that require further evaluation to determine the most representative locations of high DBP levels. Therefore, large nontransient noncommunity systems and all community systems are required to perform an IDSE under today's proposal.

States may waive the IDSE requirement for those very small systems (systems that serve fewer than 500 people) that monitor for Stage 1 DBPR compliance at the maximum residence time site if the State determines their maximum residence time Stage 1 compliance monitoring site is likely to capture both the high TTHM and high HAA5 levels within the distribution system. The Advisory Committee recommended this waiver be included because many very small systems have small distribution systems and the high TTHM and high HAA5 site is at the same location. The Advisory Committee also recognized that not all very small systems have a single monitoring site that would represent both high TTHM and high HAA5 levels (*e.g.*, some rural systems with large distribution systems) and thus did not recommend a blanket IDSE waiver for all very small systems.

b. *Data collection.* The data collection requirements of the IDSE are designed to find both high TTHM and high HAA5 sites (*see* section V.I. for IDSE monitoring site locations). The IDSE is intended as a one-time requirement. High TTHM and HAA5 concentrations often occur at different locations in the

distribution system. The Stage 1 DBPR monitoring sites identified as the maximum location are selected according to residence time. Because HAAs can degrade in the distribution system in the absence of sufficient disinfectant residual (Baribeau *et al.* 2000), residence time alone is not an ideal criterion for identifying high HAA5 sites. The Information Collection Rule data show that of the four monitoring locations sampled per system, the one identified as the maximum residence time location was often not the location where the highest DBP levels were found. In fact, over 60 percent of the highest HAA5 LRAAs and 50 percent of the highest TTHM LRAAs were found at sampling locations in the system other than the maximum residence time location (*see* section IV). Thus the method and assumptions used to select the Information Collection Rule monitoring sites, and the Stage 1 DBPR compliance monitoring sites, are not sufficiently reliable to select Stage 2 DBPR compliance monitoring sites that will capture high DBP levels.

This data analysis reveals that a reevaluation of monitoring sites is necessary at many systems to capture sites with high DBP levels. The Advisory Committee recommended sample locations (based on distribution disinfectant type) at widely distributed sites (*see* section V.I. for details on IDSE monitoring requirements). Monitoring at additional sites across the distribution system increases the chance of finding sites with high DBP levels and targets both DBPs that degrade, and DBPs that form, as residence time increases in the distribution system. EPA believes that the required number of monitoring locations plus Stage 1 monitoring results provides an adequate recharacterization of DBP levels throughout the distribution system, at a reasonable cost. With a recharacterization of distribution systems that focuses on both high TTHM and HAA5 occurrence, EPA believes that high occurrence sites will be better represented in this standard monitoring program. Systems will be required to take steps to address high DBP levels at points that might otherwise have gone undetected. EPA believes that the decrease in DBP exposure anticipated to result from the transition from an RAA to an LRAA will be augmented by the IDSE.

The frequency and number of samples required for the standard monitoring program decrease as system size (population served) decreases and depend on source water type. The Advisory Committee believed that the number of samples required for large and medium surface water systems was not necessary for small surface water systems and ground water systems. The majority of small systems have distribution systems with simpler designs than large systems. DBP occurrence in ground water systems is generally lower and less variable than in surface water systems due to lower and less variable precursor levels and much less temperature variation (*see* section IV).

Committee members recognized that some systems have detailed knowledge of their distribution systems by way of hydraulic modeling and/or ongoing widespread monitoring plans (well beyond that required for compliance monitoring) that would provide equivalent or superior monitoring site selection compared to IDSE monitoring. Therefore, the Advisory Committee recommended that such systems be allowed to determine new monitoring sites using system-specific data such as historical monitoring data.

Systems that certify to their State that all compliance samples taken in the two years prior to the start of the IDSE were ≤ 0.040 mg/L TTHM and ≤ 0.030 mg/L HAA5 are not required to collect additional DBP monitoring data because the Advisory Committee determined that these systems most likely would not have high peak DBP levels. EPA determined that this provision needed to be more specific for three groups of systems: (1) Those performing Stage 1 DBPR reduced monitoring, (2) large ground water systems, and (3) small systems required to conduct an early IDSE. Today's proposal clarifies that these systems may use a 40/30 certification. EPA recognizes that these systems may have less compliance data on which to base their 40/30 certifications. However, EPA believes that the data that will be available are sufficient to make a determination on the most appropriate Stage 2B monitoring locations.

c. *Implementation.* Systems are required to submit an IDSE report so that primacy agencies may review the system's IDSE data collection efforts and the Stage 2B monitoring locations recommended by the system. Systems serving at least 10,000 must submit their IDSE report two years after rule promulgation (which may be prior to primacy for some States). The M–DBP Advisory Committee recommended an implementation schedule that would allow systems sufficient time to make site-specific risk determinations and decisions regarding the simultaneous implementation of the Stage 2 DBPR and LT2ESWTR but not stretch out the compliance time frame too far into the future. This provision requires that medium and large systems conduct and complete site-specific risk determinations (*i.e.*, the IDSE and LT2ESWTR *Cryptosporidium* monitoring) as soon as possible after rule promulgation. Since small systems cannot begin their microbial monitoring until after the results from the large system microbial monitoring have been analyzed, small systems have a longer compliance time frame.

Systems that submit a 40/30 certification are required to submit that certification as part of the IDSE report and to include a recommended Stage 2B monitoring plan. The monitoring plan is required for these systems because the Stage 2B MCL compliance monitoring sites proposed today have fundamentally different objectives than the Stage 1 DBPR monitoring sites. Additionally, many systems are required to have more Stage 2 compliance monitoring sites than Stage 1 sites because high HAA5 site may be different than high TTHM sites.

3. Request for Comment

EPA requests comments on the IDSE requirement and whether it is a good tool to identify sites representative of high TTHM and high HAA5 levels.

a. *Applicability.* EPA requests comment on requiring large (serving 10,000 or more people) nontransient noncommunity water systems to perform an IDSE. Should NTNCWSs serving fewer than 10,000 people be required to conduct an IDSE? EPA also requests comment upon whether States should be able to waive IDSE requirements for very small systems (serving fewer than 500 people). Are there objective criteria that the State should use in waiving the requirement? Should the State be allowed to grant very small system waivers based on some other criterion other than serving a population <500? For example, should the State be allowed to choose a higher population cutoff? Should the State be allowed to use a non-population criterion such as simplicity of distribution system to grant a very small system waiver? If so, what should this criterion be and how should qualification be demonstrated?

b. *Data collection.* EPA requests comment on the requirements for each of the alternatives for data collection under the proposed IDSE including: the standard monitoring program, the system-specific study, and the 40/30 certification. EPA requests comment on whether systems with less than two years of routine monitoring data should be considered to have sufficient data to utilize the 40/30 certification.

Specifically EPA requests comment on whether systems on reduced monitoring, large ground water systems, and small systems required to conduct an IDSE within the first two years after promulgation should be prohibited from submitting a 40/30 certification.

c. *Implementation.* EPA requests comment on the requirement that large and medium systems must collect data and prepare their IDSE report prior to State primacy. EPA requests comment from the States regarding whether they intend to be involved in the consultations with systems collecting data for IDSE or in the review of IDSE reports that are submitted prior to State primacy. EPA is developing a plan to implement the IDSE during the period prior to State primacy. EPA requests comment on any issues that should be addressed during this period to facilitate the IDSE.

I. Monitoring Requirements and Compliance Determination for Stage 2A and Stage 2B TTHM and HAA5 MCLs

1. What Is EPA Proposing Today?

Today's proposal includes new requirements for how systems must monitor TTHM and HAA5 levels in their distribution systems and how systems must assess their monitoring results to determine compliance with TTHM and HAA5 MCLs. The new monitoring requirements are associated with the IDSE (described in section V.H) and Stage 2B of the proposed rule. The new compliance determination requirements relate to use of the locational running annual average (LRAA) for meeting proposed Stage 2A and Stage 2B MCLs for TTHM and HAA5 (described in section V.D). This section presents these proposed monitoring and compliance determination requirements for Stage 2A, the IDSE, and Stage 2B.

An important aspect of the proposed TTHM and HAA5 monitoring requirements is the use of two different approaches for determining the number of samples a system is required to collect. One approach is plant-based. Under the plant-based approach, a system's TTHM and HAA5 sampling requirements are determined by the number of treatment plants in the system and, in the case of consecutive systems, the number of consecutive system entry points. The second approach is population-based. Under the population-based approach, a system's sampling requirements are influenced by the number of people served, but not by the number of treatment plants. EPA is proposing population-based sampling requirements only for IDSE and Stage 2B monitoring by consecutive systems that purchase all of their finished water year-round. However, EPA is requesting comment on applying a population-based approach to all systems for the IDSE and Stage 2B compliance. The discussion of monitoring requirements in this section provides details on these two approaches.

A number of factors affect DBP formation, including the 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, and because DBP levels can be highly variable throughout the distribution system (as discussed in section IV), today's proposal requires systems to collect IDSE and Stage 2B samples at specific locations in the distribution system and in accordance with a sampling schedule. For purposes of determining the number of required samples, EPA intends to maintain the provision in the Stage 1 DBPR (§ 141.132(a)(2)) that multiple wells drawing raw water from a single aquifer may, with State approval, be considered one plant, and prior approvals will remain in force unless withdrawn.

a. *Stage 2A.* For Stage 2A of the proposed rule, compliance will be based on the compliance sampling sites and frequency established under the existing Stage 1 DBPR. Systems must continue to monitor for TTHM and HAA5 using a plant-based approach, as required under 40 CFR 141.132. Using these monitoring results, systems must continue to demonstrate compliance with Stage 1 MCLs of 0.080 mg/L for TTHM and 0.060 mg/L for HAA5, based on a running annual average (see 40 CFR 141.133). In addition, systems must comply with the Stage 2A MCLs of 0.120 mg/L for TTHM and 0.100 mg/L for HAA5, based on the LRAA at each Stage 1 DBPR monitoring location. Stage 1 DBPR provisions for systems to reduce the frequency of TTHM and HAA5 monitoring will still apply.

Stage 2A will primarily affect surface water systems serving at least 10,000 people or systems with multiple plants, because these systems are required to monitor at more than one location in the distribution system. Most other systems take compliance samples at only one location under Stage 1 and in these cases, the calculated LRAA will be equal to the calculated RAA.

b. *IDSE.* IDSE monitoring requirements are designed to identify locations within the distribution system with high TTHM and HAA5 levels, which will serve as Stage 2B monitoring sites. The following discussion provides details on the IDSE standard monitoring program. Section V.H identifies other approaches by which systems can meet IDSE requirements of the rule.

For IDSE monitoring, subpart H systems serving at least 10,000 people must collect samples approximately every 60 days at eight distribution system sites per plant (these are in addition to Stage 1 DBPR compliance monitoring sites). The distribution system residual disinfectant type determines the location of the eight sites, as shown in Table V–3.

Subpart H systems serving fewer than 10,000 people and all ground water systems must collect IDSE samples at two distribution system sites per plant (at sites that are in addition to the Stage 1 DBPR compliance monitoring sites) as shown in Table V–3. Subpart H systems serving 500–9,999 people and ground water systems serving at least 10,000 people must sample quarterly (approximately every 90 days); subpart H systems serving fewer than 500 people and ground water systems serving fewer than 10,000 people must sample semi-annually (approximately every 180 days).

EPA is also proposing IDSE monitoring requirements for consecutive systems. For consecutive systems that both purchase finished water and treat source water to produce finished water, IDSE requirements are the same as for non-consecutive systems with the same population and source water type (*see* Table V–3). For these consecutive systems, each consecutive system entry point (defined in section V.C) is counted as one treatment plant for purposes of determining sampling requirements. However, the State may allow a system to consider multiple consecutive system entry points to be considered a single point.

As noted previously, for consecutive systems that purchase all of their finished water year-round, EPA is proposing a population-based monitoring approach (*see* Table V–4) instead of a plant-based approach. Under the population-based approach, monitoring requirements are not influenced by the number of consecutive system entry points, but are based solely on the population served and the type of source water used. EPA believes the population-based approach is equitable and will provide representative DBP concentrations throughout distribution systems.

TABLE V–3.—PROPOSED IDSE MONITORING REQUIREMENTS

System type and population served	Distribution system disinfectant type	Number of monitoring periods	Distribution system sample locations per plant per monitoring period [1]				
			Total	Near entry point	Average residence time	High TTHM locations	High HAA5 locations
Subpart H ≥10,000	Chloramines	[2]6	8	2	2	2	2
	Chlorine	[2]6	8	1	2	3	2
Subpart H 500–9,999 or Ground Water ≥10,000.	Any	[3]4	2	0	0	1	1
Subpart Any H <500 or Ground Water <10,000.	Any	[2]4	2	0	0	1	1
Consecutive Systems	Any	—Consecutive systems that purchase 100% of their finished water year-round—see Table V.4. —Consecutive systems that also treat source water to produce finished water—plant-based monitoring at same location and frequency as a non-consecutive system with the same population and source water.					

[1] Samples must be taken at locations other than the existing Stage 1 DBPR monitoring locations. Dual sample sets (*i.e.*, a TTHM and an HAA5 sample) must be taken at each site. Sampling locations should be distributed throughout the distribution system.
[2] Approximately every 60 days.
[3] Approximately every 90 days.
[4] Approximately every 180 days.

TABLE V–4. POPULATION-BASED MONITORING FREQUENCIES AND LOCATIONS UNDER IDSE FOR CONSECUTIVE SYSTEMS THAT PURCHASE 100% OF FINISHED WATER YEAR-ROUND

Source water type	Population size category	Monitoring periods and frequency	Distribution system sample locations [1]				
			Total	Near entry points [2]	Average residence time	High TTHM locations	High HAA5 locations
Subpart H	0–499	Two 2 every 180 days)	2	.....	.....	1	1
	500–4,999	Four (every 90 days)	2	.....	.....	1	1
	5,000–9,999		4	.....	1	2	1
	10,000-24,999	Six (every 60 days)	8	1	2	3	2
	25,000-49,999		12	2	3	4	3
	50,000-99,999		16	3	4	5	4
	100,000-499,999		24	4	6	8	6
	500,000-1,499,000		32	6	8	10	8
	1,500,000-4,999,999		40	8	10	12	10
	≥5,000,000		48	10	12	14	12
Ground Water	0–499	Two (every 180 days)	2	.....	.....	1	1
	500–9,999		2	.....	.....	1	1
	10,000-99,999	Four (every 90 days)	6	1	1	2	2
	100,000-499,999		8	1	1	3	3
	≥500,000		12	2	2	4	4

[1] Samples must be taken at locations other than the existing Stage 1 DBPR monitoring locations. Dual sample sets (*i.e.*, a TTHM and an HAA5 sample) must be taken at each site. Sampling locations should be distributed throughout the distribution system.
[2] If the number of entry points to the distribution system is less than the specified number of sampling locations, additional samples must be taken equally at high TTHM and HAA5 locations. If there is an odd extra location number, a sample at a high TTHM location must be taken. If the number of entry points to the distribution system is more than the specified number of sampling locations, samples must be taken at entry points to the distribution system having the highest water flows.

As a part of the monitoring schedule, all systems conducting IDSE monitoring must collect samples during the peak historical month for TTHM levels or water temperature. EPA will provide guidance to assist systems in choosing IDSE monitoring locations, including criteria for selecting high TTHM and HAA5 monitoring locations.

c. *Stage 2B.* For those systems required to conduct an IDSE, Stage 2B monitoring sites are based on the system's IDSE results and Stage 1 DBPR compliance monitoring results. For those systems not required to conduct an IDSE, Stage 2B monitoring locations are based on the system's Stage 1 DBPR compliance monitoring results and an evaluation of the distribution system characteristics to identify additional monitoring locations, if required.

Consistent with the Advisory Committee recommendations, the monitoring frequency for Stage 2B is structured so that systems that monitor quarterly under the Stage 1 DBPR will continue to monitor quarterly. In addition, the monitoring schedule must include the month with the highest historical DBP concentrations.

Many systems on reduced monitoring under the Stage 1 DBPR will conduct Stage 2B compliance monitoring at different or additional locations than those used for Stage 1 compliance monitoring. Such systems must conduct routine monitoring for at least one year before being eligible for reduced monitoring under Stage 2B. Those systems that monitor at the same locations under both the Stage 1 DBPR and Stage 2B DBPR and have qualified for reduced monitoring under Stage 1 may remain on reduced monitoring at the beginning of Stage 2B.

EPA is proposing to require all systems to develop and maintain a DBP monitoring plan that must include the following information: monitoring locations, monitoring dates, compliance calculation procedures, and copies of any permits, contracts, or other agreements with third parties to sample, analyze, report, or perform any other monitoring requirement. Each system in a combined distribution system (as discussed in section V.C) must develop and maintain its own monitoring plan.

To comply with the requirement for a monitoring plan, systems may develop a new plan or update the monitoring plan required under the Stage 1 DBPR (see § 141.132(f)). In either case, the system must follow the monitoring plan, which will be based on the IDSE report submitted to the State, modified by any changes required by the State.

Table V–5 summarizes proposed routine and reduced monitoring requirements for Stage 2B of today's rule for non-consecutive systems and for consecutive systems that also treat source water. Tables V–6 and V–7 summarize proposed routine and reduced Stage 2B monitoring requirements for consecutive systems that purchase all of their finished water year-round. The proposed reduced monitoring requirements are consistent with the approach taken in the Stage 1 DBPR.

TABLE V–5.—PROPOSED STAGE 2B ROUTINE AND REDUCED MONITORING REQUIREMENTS FOR NON-CONSECUTIVE SYSTEMS AND FOR CONSECUTIVE SYSTEMS THAT ALSO TREAT SOURCE WATER TO PRODUCE FINISHED WATER [1]

System size and source water type	Routine monitoring (per plant) [2]	Requirements to qualify for reduced monitoring	Reduced monitoring (per plant)	Trigger for returning to routine monitoring
Subpart H systems serving ≥10,000 people.	Four dual sample sets per quarter.	One year of completed routine monitoring and all TTHM and HAA5 LRAAs are no more than 0.040 mg/L and 0.030 mg/L, respectively, and TOC running annual average ≤4.0 mg/L.	Two dual sample sets per quarter.	TOC >4.0 mg/L as an RAA, or TTHM LRAA >0.040 mg/L or HAA5 LRAA >0.030 mg/L.
Subpart H systems serving 500 to 9,999 people.	Two dual sample sets per quarter [3].	One year of completed routine monitoring and all TTHM and HAA5 LRAAs are no more than 0.040 mg/L and 0.030 mg/L, respectively, and TOC running annual average ≤4.0 mg/L.	Two dual sample sets per year [4].	TOC >4.0 mg/L as an RAA, or Single Sample of TTHM >0.060 mg/L or HAA5 >0.045 mg/L.[5]
Subpart H systems serving <500 people.	One dual sample set per year [5 6].	Monitoring may not be reduced	NA	NA.
Ground water systems serving ≥10,000 people [7].	Two dual sample sets per quarter [3].	One year of completed routine monitoring and all TTHM and HAA5 LRAAs are no more than 0.040 mg/L and 0.030 mg/L, respectively.	Two dual sample sets per year [4].	Single Sample of TTHM >0.060 mg/L or HAA5 >0.045 mg/L.[5]
Ground water systems serving 500 to 9,999 people [7].	Two dual sample sets per year [3 5].	One year of completed routine monitoring and all TTHM and HAA5 LRAAs are no more than 0.040 mg/L and 0.030 mg/L, respectively.	Two dual samples every third year [4].	Single sample of TTHM >0.040 mg/L or HAA5 >0.030 mg/L.[5]
Ground water systems serving <500 people [7].	One dual sample set per year [5 6].	One year of completed routine monitoring and all TTHM and HAA5 LRAAs are no more than 0.040 mg/L and 0.030 mg/L, respectively.	Two dual samples every third year [4].	Single sample of TTHM >0.040 mg/L or HAA5 >0.030 mg/L [5]
Consecutive systems that also treat source water.	System must meet the routine and reduced monitoring requirements of a non-consecutive system with the same population and source water. Monitoring may be reduced to the level required of that non-consecutive system.			

[1] Samples must be taken during representative operating conditions. Quarterly samples must be taken approximately every 90 days.
[2] Systems will use the results of their IDSEs and Stage 1 DBPR compliance monitoring to recommend Stage 2B monitoring locations representative of high TTHM and HAA5 concentrations to the State in their IDSE reports. Systems must monitor at the recommended locations unless the State requires other locations.
[3] If site and quarter of highest individual TTHM and HAA5 measurement are the same, monitoring is only required at one location if State approves.
[4] If site and quarter of highest individual TTHM and HAA5 measurement are the same, monitoring is only required at one location.
[5] If any single sample of TTHM >0.080 mg/L or HAA5 >0.060 mg/L, system must go to increased monitoring of quarterly dual samples at each routine monitoring location and can return to routine monitoring when TTHM ≤0.060 mg/L and HAA5 ≤0.045 mg/L as LRAAs.
[6] If the site or month of highest TTHM is not the same as the site or month of highest HAA5, the system must monitor for TTHM at the location of the highest TTHM LRAA during the month of highest TTHM single measurement and for HAA5 at the location of the highest HAA5 LRAA during the month of highest HAA5 single measurement.
[7] Ground water systems are those not under the direct influence of surface water. For the purpose of determining the required number of samples, multiple wells drawing water from a single aquifer may, with State approval, be considered one treatment plant.

i. Subpart H systems serving 10,000 or more people.

Routine monitoring: Systems must take four dual sample sets (*i.e.*, a TTHM and an HAA5 sample must be taken at each sampling site) per treatment plant per quarter. Systems must monitor at locations recommended in the IDSE report, unless the State has required other locations. Most systems must take samples at each plant in the system as follows: One dual sample set at the existing Stage 1 DBPR average residence time monitoring location with the highest TTHM or HAA5 LRAA, one dual sample set at a point representative of the highest HAA5 levels, and two dual sample sets at points representative of the highest TTHM levels.

Systems must schedule monitoring so that one quarter's monitoring is conducted during the peak historical month for high TTHM concentration and the other quarterly monitoring is

conducted approximately every 90 days on a predetermined schedule included in the system's monitoring plan.

Reduced monitoring: Only systems with source water TOC ≤4.0 mg/L as an RAA that have completed at least one year of routine monitoring may qualify for reduced monitoring (*see* Table V–5). Systems that have a TTHM LRAA ≤0.040 mg/L and an HAA5 LRAA ≤0.030 mg/L at all sites, in addition to a source water TOC RAA ≤ 4.0 mg/L, may reduce the monitoring frequency for TTHM and HAA5 to two dual sample sets (one each at sites representative of the highest HAA5 and TTHM LRAAs) per treatment plant per quarter. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the LRAA of all samples taken in the year is no more than 0.040 mg/L for TTHM and 0.030 mg/L for HAA5 or if source water TOC exceeds 4.0 mg/L as an RAA. Systems must revert to routine monitoring in the quarter immediately following any quarter in which the LRAA for any monitoring location exceeds 0.040 mg/L for TTHM or 0.030 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 Stage 2B when the TTHM and HAA5 LRAAs for each sample location, computed quarterly, are less than or equal to the Stage 2B MCLs of 0.080 mg/L and 0.060 mg/L, respectively. Otherwise, the system is out of compliance.

ii. Subpart H systems serving 500 to 9,999 people. Routine monitoring: Systems must monitor quarterly for each treatment plant by taking two dual sample sets, one each at sites representative of high HAA5 levels and high TTHM levels (as recommended in the IDSE report). However, if the State determines that the sites representative of the high TTHM and HAA5 levels are at the same location, the State may determine that the system is only required to monitor at one site per treatment plant.

Systems must conduct quarterly monitoring during the peak historical month for TTHM with quarterly samples taken approximately every 90 days on a predetermined schedule specified in the system's monitoring plan. All samples must be taken as dual sample sets (*i.e.*, a TTHM and an HAA5 sample must be taken at each site).

Reduced monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (*see* Table V–5). Systems eligible for reduced monitoring may reduce the monitoring frequency from quarterly to annually. Samples must be taken during the month(s) of peak historical TTHM and HAA5 levels at the same locations specified under routine monitoring. Systems that have their highest TTHM and HAA5 levels in the same month must take dual sample sets at both the high TTHM and high HAA5 sites. If the high months for TTHM and HAA5 are not the same, the system must take dual sample sets in both the high TTHM and high HAA5 months. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the annual sample taken at each location is no more than 0.060 mg/L for TTHM and 0.045 mg/L for HAA5 or if source water TOC exceeds 4.0 mg/L as an RAA. 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 Stage 2B when the LRAAs of each sample location, computed quarterly, are less than or equal to the MCLs. Otherwise, the system is out of compliance. If the annual sample taken under reduced monitoring exceeds the MCL, the system must resume quarterly monitoring but is not immediately in violation of the MCL. The system is out of compliance if the LRAA of the quarterly sample for the past four quarter exceeds the MCL.

iii. Subpart H systems serving fewer than 500 people. Routine monitoring: Systems are required to sample annually for each treatment plant at the location with high TTHM and HAA5 values during the month of peak historical TTHM levels. The system must take one dual sample set at the site representative of the high HAA5 and TTHM levels (at the Stage 1 DBPR monitoring site or as recommended in the IDSE report), unless the State determines that the highest TTHM site and the highest HAA5 site are not at the same location or are not during the same quarter. If the State determines that the highest TTHM and highest HAA5 do not occur in the same location, the system is required to take two samples, an HAA5 sample at the site representative of the high HAA5 levels and a TTHM sample at the site representative the high TTHM levels. If the State determines that the highest TTHM and highest HAA5 do not occur in the same quarter, the systems is required to take one sample in the high TTHM quarter and one sample in the high HAA5 quarter. If the annual sample exceeds the MCL for either TTHM or HAA5, the system must monitor quarterly at the previously determined monitoring locations.

Reduced monitoring: These systems may not reduce monitoring to less frequently than annually. Systems on increased (quarterly) monitoring may return to routine monitoring if the LRAAs of quarterly samples are 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 LRAA of quarterly samples, if increased or additional monitoring is conducted) is less than or equal to the MCL. If the annual sample exceeds the MCL, the system must conduct increased (quarterly) monitoring but is not immediately in violation of the MCL. The system is out of compliance if the LRAA of the quarterly samples for the past four quarters exceeds the MCL.

iv. Ground water systems serving 10,000 or more people. Routine monitoring: Systems are required to monitor quarterly for each treatment plant in the system by taking two dual sample sets, one each at sites representative of high HAA5 levels and high TTHM levels (as recommended in the IDSE report). However, if the State determines that the sites representative of the high TTHM and HAA5 levels are the same, the State may determine that the system only has to monitor at one site per treatment plant. One quarterly sample must be taken during the peak historical month for TTHM, with subsequent quarterly samples taken approximately every 90 days.

Reduced monitoring: To qualify for reduced monitoring, systems must meet certain requirements (*see* Table V–5). Systems eligible for reduced monitoring may reduce the monitoring frequency from quarterly to annually. Samples must be taken during the month(s) of peak historical TTHM and HAA5 levels at the same locations specified under routine monitoring. Systems that have their highest TTHM and HAA5 levels in the same quarter must take dual sample sets at both the high TTHM and high HAA5 sites. If the quarter for high TTHM and high HAA5 are not the same, the system must take dual sample sets in both the high TTHM and high HAA5 quarters. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the annual sample taken at each location 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 Stage 2B when the locational running annual average of each sample location, computed quarterly, is less than or equal to the MCL. Otherwise, the system is out of compliance. If the annual sample exceeds the MCL, the system must conduct increased (quarterly) monitoring but is not immediately in violation of the MCL. The system is out of compliance if the LRAA of the quarterly sample for the past four quarter exceeds the MCL.

v. Ground water systems serving fewer than 10,000 people. Routine monitoring: Systems serving 500 to 9,999 people are required to take two dual sample sets annually, one each at sites representative of high HAA5 levels and high TTHM levels (as recommended in the IDSE report). However, if the State determines that the sites representative of the high TTHM and HAA5 levels are the same, the State may allow the system to monitor at only one site per treatment plant. If the State makes a determination that high TTHM and high HAA5 occur in different quarters, the system must monitor accordingly. If the annual sample exceeds the MCL for either TTHM or HAA5, the system must monitor quarterly at the previously determined monitoring locations.

Systems serving fewer than 500 people are required to take one dual sample set at the site representative of both high HAA5 and TTHM levels, unless the State determines that the high TTHM site and the high HAA5 site are not at the same location. If the State makes this determination, the system is required to take samples at two locations, an HAA5 sample at the site representative of the high HAA5 levels and a TTHM sample at the site representative of the high TTHM levels. If the State makes a determination that high TTHM and high HAA5 occur in different quarters, the system must monitor accordingly. If the annual sample exceeds the MCL for either TTHM or HAA5, the system must monitor quarterly at the previously determined monitoring locations.

Reduced monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (*see* Table V–5). Systems eligible for reduced monitoring may reduce the monitoring frequency for TTHM and HAA5 to every third year. Systems are required to take two water samples, at sites representative of high HAA5 and TTHM levels (as discussed under routine monitoring) during the month of peak TTHM levels. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the sample taken every third year is no more than 0.040 mg/L for TTHM and 0.030 mg/L for HAA5. Systems that do not meet these levels must resume routine annual monitoring until their annual average is no more than 0.040 mg/L for TTHM and 0.030 mg/L for HAA5.

Compliance determination: A PWS is in compliance when the annual sample (or LRAA of quarterly samples, if increased or additional monitoring is conducted) is less than or equal to the MCL. If the annual sample exceeds the MCL, the system must conduct increased (quarterly) monitoring but is not immediately in violation of the MCL. The system is out of compliance if the LRAA of the quarterly samples for the past four quarters exceeds the MCL.

vi. *Consecutive systems.* Routine monitoring: Monitoring requirements are determined by whether the consecutive system purchases all of its finished water year-round or also treats source water, along with the population served and source water type of the wholesale system (unless the consecutive system also has a surface water or ground water under the direct influence of surface water (GWUDI) source and the wholesale system is only ground water, in which case the consecutive system is classified as a subpart H system). Section V.C. of today's document provides a more detailed discussion of consecutive system issues.

As noted earlier, for consecutive systems that purchase all their finished water year-round, EPA is proposing population-based monitoring. The proposed number of monitoring locations is based on the source water type of the wholesale system and consecutive system population. Proposed Stage 2B compliance monitoring requirements for consecutive systems that purchase all their finished water are contained in Table V–6. Consecutive systems that also treat source water to produce finished water must monitor at the same locations and same frequency as a non-consecutive system with the wholesale system's source water type and the consecutive system's population.

TABLE V–6.—PROPOSED POPULATION-BASED ROUTINE MONITORING ROUTINE FREQUENCIES AND LOCATIONS UNDER STAGE 2B FOR CONSECUTIVE SYSTEMS THAT PURCHASE ALL THEIR FINISHED WATER YEAR-ROUND

Source water type	Population size category	Monitoring frequency [1]	Distribution system sample location [2]			
			Total	Highest TTHM locations	Highest HAA5 locations	Existing stage 1 compliance locations [3]
Subpart H	0–499	per year	2 [4]	1	1	.....
	500–4,999	per quarter	2 [4]	1	1	.....
	5,000–9,999	per quarter	2	1	1	.....
	10,000–24,999	per quarter	4	2	1	1
	25,000–49,999	per quarter	6	3	2	1
	50,000–99,999	per quarter	8	4	2	2
	100,000–499,999	per quarter	12	6	3	3
	500,000–1,499,000	per quarter	16	8	4	4
	1,500,000–4,999,999	per quarter	20	10	5	5
	≥5,000,000	per quarter	24	12	6	6
Ground Water	0–499	per year	2 [4]	1	1	.....
	500–9,999	per year	2	1	1	.....
	10,000–99,999	per quarter	4	2	1	1
	100,000–499,999	per quarter	6	3	2	1
	≥500,000	per quarter	8	4	2	2

[1] All systems must take at least one dual sample set during month of highest DBP concentrations. Systems on quarterly monitoring must take dual sample sets approximately every 90 days.

[2] Locations based on system recommendations for Stage 2B monitoring locations in IDSE report to the State, unless State requires different or additional locations. Locations should be distributed through distribution system to the extent possible.

[3] Alternate between highest HAA5 LRAA and highest TTHM LRAA locations among the existing Stage 1 compliance locations. If the number of existing Stage 1 compliance locations is fewer than the specified number for Stage 2B, alternate between highest HAA5 LRAA locations and highest TTHM LRAA locations from the IDSE.

[4] System is required to take individual TTHM and HAA5 samples at the locations with the highest TTHM and HAA5 concentrations, respectively. Only one location with a dual sample set per monitoring period is needed if highest TTHM and HAA5 concentrations occur at the same location.

Reduced monitoring: Consecutive systems can qualify for reduced monitoring if the LRAA at each location is ≤0.040 mg/L for TTHM and ≤0.030 mg/L for HAA5 based on at least one year of monitoring at Stage 2B locations. Consecutive systems that purchase all of their finished water year-round may reduce their monitoring as specified in Table V–7. Consecutive systems that also treat source water to produce finished must conduct reduced monitoring at the same locations and same frequency as a non-consecutive system with the wholesale system's source water type and the consecutive system's population.

TABLE V–7.—REDUCED MONITORING FREQUENCY FOR CONSECUTIVE SYSTEMS THAT BUY ALL THEIR WATER

Population served	Reduced monitoring frequency and location
Subpart H systems	
<500	Monitoring may not be reduced.
500 to 4,999	1 TTHM and 1 HAA5 sample per year at different locations or during different quarters if the highest TTHM and HAA5 occurred at different locations or different quarters or 1 dual sample per year if the highest TTHM and HAA5 occurred at the same location and quarter.
5,000 to 9,999	2 dual sample sets per year; one at the location with the highest TTHM single measurement during the quarter that the highest single TTHM measurement occurred, one at the location with the highest HAA5 single measurement during the quarter that the highest single HAA5 measurement occurred.
10,000 to 24,999	2 dual sample sets per quarter at the locations with the highest TTHM and highest HAA5 LRAAs.
25,000 to 49,999	2 dual sample sets per quarter at the locations with the highest TTHM and highest HAA5 LRAAs.
50,000 to 99,000	4 dual sample sets per quarter at the locations with the two highest TTHM and two highest HAA5 LRAAs.
100,000 to 499,999	4 dual sample sets per quarter at the locations with the two highest TTHM and two highest HAA5 LRAAs.
500,000 to 1,499,999	6 dual sample sets per quarter at the locations with the three highest TTHM and three highest HAA5 LRAAs.
1,500,000 to 4,999,999	6 dual sample sets per quarter at the locations with the three highest TTHM and three highest HAA5 LRAAs.
>=5,000,000	8 dual sample sets per quarter at the locations with the four highest TTHM and four highest HAA5 LRAAs.
Ground water systems	
<500	1 TTHM and 1 HAA5 sample every third year at different locations or during different quarters if the highest TTHM and HAA5 occurred at different locations or different quarters or 1 dual sample every third year if the highest TTHM and HAA5 occurred at the same location and quarter.
500 to 9,999	1 TTHM and 1 HAA5 sample every year at different locations or during different quarters if the highest TTHM and HAA5 occurred at different locations or different quarters or 1 dual sample every year if the highest TTHM and HAA5 occurred at the same location and quarter.
10,000 to 99,000	2 dual sample sets per year; one at the location with the highest TTHM single measurement during the quarter that the highest single TTHM measurement occurred and one at the location with the highest HAA5 single measurement during the quarter that the highest single HAA5 measurement occurred.
100,000 to 1,499,999	2 dual sample sets per quarter; at the locations with the highest TTHM and highest HAA5 LRAAs.
≥1,500,000	4 dual sample sets per quarter; at the locations with the two highest TTHM and two highest HAA5 LRAAs.

Systems may remain on reduced monitoring as long as the TTHM LRAA ≤0.040 mg/L and the HAA5 LRAA ≤0.030 mg/L at each monitoring location for systems with quarterly reduced monitoring. If the LRAA at any location exceeds either 0.040 mg/L for TTHM or 0.030 mg/L for HAA5 or if the source water annual average TOC level, before any treatment, exceeds 4.0 mg/L at any of the system's treatment plants treating surface water or ground water under the direct influence of surface water, the system must resume routine monitoring. For systems with annual or less frequent reduced monitoring, systems may remain on reduced monitoring as long as each TTHM sample ≤0.060 mg/L and each HAA5 sample ≤0.045 mg/L. If the annual sample at any location exceeds either 0.060 mg/L for TTHM or 0.045 mg/L for HAA5, or if the source water annual average TOC level, before any treatment, exceeds 4.0 mg/L at any treatment plant treating surface water or ground water under the direct influence of surface water, the system must resume routine monitoring.

Compliance determination: A PWS is in compliance when the annual sample or LRAA of quarterly samples is less than or equal to the MCLs. If an annual sample exceeds the MCL, the system must conduct increased (quarterly) monitoring but is not immediately in violation of the MCL. The system is out of compliance if the LRAA of the quarterly samples for the past four quarters exceeds the MCL.

2. How Was This Proposal Developed?

The proposed monitoring requirements for the IDSE and Stage 2B primarily follow a plant-based approach that was adopted from the 1979 TTHM Rule and the Stage 1 DBPR. This approach includes differences in monitoring frequency between surface water and ground water sources, and between large and small systems. However, the proposed monitoring requirements differ from Stage 1 DBPR requirements in certain areas, including (a) sampling intervals for quarterly monitoring, (b) reduced monitoring frequency, (c) different sampling locations by disinfectant type (for the IDSE), and (d) population-based monitoring requirements for certain consecutive systems. This subsection

presents the basis for these requirements.

a. *Sampling intervals for quarterly monitoring.* Today's proposal requires systems conducting routine quarterly monitoring to sample approximately every 90 days. This provision modifies the approach used in the 1979 TTHM rule and the Stage 1 DBPR, which requires certain systems to conduct monitoring based on calendar quarters.

When systems are required to monitor based on calendar quarters, systems can choose to cluster samples during times of the year when DBP levels are lower (DBPs tend to form more slowly in colder water temperatures). For example, a system could sample in December (at the end of the fourth quarter) and again in January (at the beginning of the first quarter) when the water is the coldest and sample in April (at the beginning of the second quarter) and September (at the end of the third quarter) at either end of the hot summer months.

To address the concern with systems not sampling during months with the highest DBP levels, EPA is proposing to require systems to monitor during the month of highest historical DBP concentrations and require that systems monitor approximately every 90 days. EPA believes that this new monitoring strategy will improve public health protection because systems will be required to monitor when high DBP levels are expected, and the LRAA will better reflect actual exposure during the year.

b. *Reduced monitoring frequency.* Today's proposal contains provisions allowing reduced routine monitoring when certain criteria are fulfilled (shown in Table V–5 and V–7). EPA believes that more stringent standards are necessary to ensure public health protection when systems reduce the frequency of their DBP monitoring. Under the reduced monitoring provisions, systems must collect samples during the months of highest DBP occurrence. For systems sampling annually under the reduced monitoring provisions, EPA believes that public health protection would likely be ensured throughout the year if the high values are known to be below 0.060 mg/L for TTHM and 0.045 mg/L for HAA5. Systems monitoring every three years must maintain single samples under 0.040 mg/L for TTHM and 0.030 mg/L for HAA5 to ensure adequate public health protection over the course of the three years.

c. *Different IDSE sampling locations by disinfectant type.* Today's proposal contains different requirements for IDSE monitoring locations based on the disinfectant residual used in the distribution system. Systems that use chloramines are required to select more near-entry point monitoring sites for the IDSE than chlorinated systems of similar size and source water type. This is due to differences in DBP formation under chloraminated and chlorinated conditions. Chloramine residuals are more stable than chlorine residuals and do not react as readily with organic compounds in the water. Based on evaluation of Information Collection Rule data, DBP concentrations in chloraminated systems vary less throughout the distribution system than in chlorinated systems. HAA5, in particular, can peak at or near the entry point to the distribution system in a chloraminated system (USEPA 2003o).

d. *Population-based monitoring requirements for certain consecutive systems.* While the Advisory Committee recommended basic principles for how consecutive systems should be regulated, it did not recommend how EPA should explicitly address some of the unique situations that pertain to consecutive systems. In this regard, consecutive systems that purchase all of their finished water year-round are different than other systems in that they do not have a treatment plant. Rather, these systems often receive water from multiple wholesale systems or through multiple consecutive system entry points on a seasonal or intermittent basis. Because a plant-based monitoring approach (which counts treated water distribution system entry points from different entities as plants) would be very difficult to implement for consecutive systems that purchase all of their finished water year-round, EPA is proposing a population-based approach for such systems.

Under a population-based approach, the frequency of monitoring is based on the population served and remains the same regardless of how many entities are providing water to the consecutive system at different times of the year. The population categories and associated monitoring frequencies in Tables V–4 and V–6 for IDSE and Stage 2B routine monitoring reflect EPA's consideration that distribution system complexity generally increases as the population served grows. Increasing distribution system complexity warrants more monitoring to represent DBP occurrence.

EPA developed the proposed population-based monitoring requirements in accordance with certain guidelines. These are stated as follows:

—The sampling frequency for surface water systems should be greater than for ground water systems. The basis for this is that, in general, systems using surface water or mixed source water supplies are likely to experience higher and more variable DBP occurrence over time than systems using ground water exclusively.

—Smaller systems should be allowed to monitor less frequently per location than larger systems because their distribution systems are generally less complex and monitoring costs on a per capita basis are much higher.

—For systems using surface water, the ratio of IDSE sample locations to the number of routine sample locations required for Stage 2B should be approximately 2:1 (consistent with Advisory Committee recommendations for plant-based monitoring). IDSE sampling is intended to identify distribution system locations with high DBP levels and should, therefore, be more thorough than routine monitoring.

—Because ground water systems have much less variable DBP levels within the distribution system than surface water systems (see section IV), a smaller number of additional IDSE monitoring locations is warranted.

—Distribution system sampling locations should be approximately consistent with the proposed plant-based approach as recommended by the Advisory Committee. This will capture the locations with the high TTHM and HAA5 LRAAs identified in the IDSE, but also include Stage 1 compliance locations with high TTHM and HAA5 for historical tracking.

Consistent with the first two guidelines, the proposed population-based monitoring requirements maintain the same monitoring frequency per sample location as proposed under the plant-based approach. The following subsection provides further discussion of the population-based approach as it might apply to all systems.

3. Request For Comment

EPA is requesting comments on the proposed monitoring requirements. This subsection begins with a list of specific questions related to the proposed requirements for IDSE and Stage 2B monitoring. This is followed by a discussion of issues associated with plant-based monitoring requirements and a request for comment on potential approaches to address these issues, including the extension of population-based monitoring requirements to all systems under the Stage 2 DBPR.

a. *Proposed IDSE and Stage 2B monitoring requirements.* EPA is

requesting comment on a number of specific aspects of the proposed monitoring requirements.

—Should EPA require all systems that are on reduced monitoring to revert to routine monitoring during the IDSE monitoring period to allow for more data to be evaluated in the IDSE report to better select Stage 2B monitoring locations? Or should EPA require a system to be on routine monitoring during the IDSE monitoring period in order to be eligible for an IDSE waiver? What limitations, if any, should EPA put on system eligibility for an IDSE waiver?

—Should EPA require different IDSE monitoring locations for subpart H systems based on the residual disinfectant (chlorine or chloramines) in light of the possible difficulties for implementation and data management? Should EPA specify monitoring locations in the rule language for samples intended to represent exposure for people in high-rise buildings? Should monitoring location selection be addressed in guidance? Where should these locations be so that they are truly representative of the levels of DBPs in water actually being consumed in these kinds of structures?

—Is a population-based monitoring approach (instead of a plant-based monitoring approach) for consecutive systems that purchase all of their finished water year-round appropriate and, if so, is the population-based approach proposed today adequate?

EPA solicits comment on the significance of monitoring and implementation issues such as common aquifer determinations, consecutive system entry point determinations, seasonal plants, and monitoring inequities, and whether the proposed monitoring requirements should be modified. EPA also solicits comment on modifying the proposed monitoring requirements to address these issues, in part, with provisions such as the following:

—Should EPA set a limit on the maximum number of IDSE and routine monitoring samples that could be required? Should this limit be different for systems using ground water or surface water or mixed systems? For different system size categories? What rationale should be used to specify maximum sample numbers?

—Should a provision be included that would allow States to reduce the sampling frequency, beyond those currently proposed (*i.e.*, common aquifer determinations and low DBP levels)? If so, should specific criteria for systems to qualify for State approval of reduced monitoring be specified in the rule?

—What, if any, criteria should be set by which systems with very large distribution systems but few plants would be required to conduct additional IDSE or routine monitoring, beyond that currently proposed?

—For subpart H mixed systems, should States be given discretion to reduce routine compliance monitoring samples intended to represent ground water sources, since such sources typically have lower precursor levels and produce lower DBP concentrations?

—Should EPA allow or require systems to reallocate plant-based IDSE monitoring locations from small plants to large plants? From plants with better water quality (based on expected lower DBP formation) to poorer water quality? What criteria should be used?

b. *Plant-based vs. population-based monitoring requirements.* The proposed monitoring requirements incorporate a plant-based approach for all systems other than consecutive systems that purchase all of their finished water year-round. The plant-based approach was adopted from the 1979 TTHM Rule and the Stage 1 DBPR and derives from the assumption that as systems increase in size, they will tend to have more plants (with different sources and treatment) and increased complexity. This warrants increased monitoring to represent DBP occurrence in the distribution system.

EPA has identified a number of issues related to the use of a plant-based monitoring approach under the Stage 2 DBPR. The following discussion presents these issues and solicits comment on approaches to address them, including the use of population-based monitoring requirements.

i. *Issues with plant-based monitoring requirements.* One issue with a plant-based monitoring approach is that it can result in disproportionate monitoring requirements for systems serving the same number of people. This occurs because the required number of sampling sites increases with the number of plants that feed disinfected water into a distribution system. Consequently, some systems, depending upon their size, the number of treatment plants, and the nature of their distribution system, will be required to collect relatively large or small numbers of TTHM and HAA5 samples relative to their population served.

Table V–8 reflects EPA estimates of the number of plants per system by system size category for systems using ground water and subpart H systems. Subpart H systems include systems that use ground water as a source because under the proposal, ground water plants in subpart H systems are treated as surface water plants for purposes of determining monitoring requirements. While the proposed plant-based requirements distinguish sampling requirements by three systems sizes (<500 people, 500–9999 people, and 10,000 or more people), Table V–8 includes additional size categories to reflect the potential inequities in sampling requirements among different-sized systems.

TABLE V–8.—NUMBER OF TREATMENT PLANTS PER SYSTEM (BASED ON DATA FROM 1995 CWSS (1))

Source water type	Population served	No. of systems in database	No. of treatment plants per system					
			10th percentile	Median	Mean	90th percentile	95th percentile	Maximum
Subpart H	0–499	124	1	1	1.4	2	3	5
	500–4,999	146	1	1	1.3	2	3	6
	5,000–9,999	64	1	1	1.7	3	4	6
	10,000–24,999	59	1	1	2.0	3	4	18
	25,000–49,999	46	1	1	2.2	4	6	9
	50,000–99,999	76	1	2	3.4	6	12	34
	100,000–499,999	51	1	2	3.0	5	10	21
	≥500,000	23	2	4	5.8	10	13	56
Ground Water	0–499	181	1	1	1.4	3	4	11
	500–9,999	332	1	1	1.8	3	4	13

TABLE V–8.—NUMBER OF TREATMENT PLANTS PER SYSTEM (BASED ON DATA FROM 1995 CWSS (1))—Continued

Source water type	Population served	No. of systems in database	No. of treatment plants per system					
			10th percentile	Median	Mean	90th percentile	95th percentile	Maximum
	10,000–99,999	128	1	4	4.2	9	11	18
	≥100,000	21	1	3	9.9	31	32	33

(1) Results from analysis of 1995 CWSS data (Question Q18). The analysis uses a statistical bootstrapping approach to generate the number of plants per system. Details of this analysis are described in the 2002 revisions to the Model Systems Report [to be published]. The maximums reflect the maximum number of plants per system among the respondents to the 1995 CWSS. Since the 1995 CWSS database only reflects a fraction of all the systems in the respective size categories, some systems are likely to have a higher number of plants per system than the maximums listed in this table.

Noteworthy in Table V–8 are the wide ranges of number of plants per system in the various size categories for both ground water and surface water systems and, consequently, the wide range of potential monitoring implications. Since the number of treatment plants directly influences the number of samples required, systems serving the same number of people may have more than a 10-fold difference in required sampling, depending on the numbers of plants in their systems. For example, Table V–8 indicates that for ground water systems serving at least 10,000 people, at least 10% of the systems had only one treatment plant, while 10% (90th percentile) had 10 or more treatment plants.

While Table V–8 does not take into account factors that may reduce monitoring requirements, such as common aquifer determinations, EPA believes these data indicate that DBP sampling requirements based on the number of water treatment plants per system may be excessive for many systems. This is particularly the case for those systems with many ground water plants, since their DBP levels are often low and relatively stable.

Conversely, for other systems, such as large surface water systems with one plant, plant-based monitoring requirements may not require enough samples to fairly represent DBP occurrence in the distribution system. For example, under the plant-based approach, a system with only one plant serving 100,000—499,000 people would have the same sampling requirements as a system with one plant serving 11,000 people. The larger of these two systems is likely to have much more pipe length and other complex factors influencing DBP formation (such as number of storage tanks or booster chlorination points in the distribution system). Also, systems with multiple plants must take the same number of samples per plant, even if one plant provides a much higher percentage of the water than another.

Another issue with plant-based monitoring requirements is when plants or consecutive system entry points are operated seasonally or intermittently. A monitoring location that represents a plant or entry point during a monitoring period when it is in operation will not be representative when that plant or entry point it is not in operation.

A third issue is requirements for consecutive systems. For consecutive systems that also treat source water to produce finished water, each consecutive system entry point is considered a treatment plant for the purpose of determining monitoring requirements, except when the State allows multiple entry points to be treated as a single plant (see section V.C. for further discussion). Each entry point is treated as a separate plant to recognize different source waters and treatment (resulting in different DBP levels) from the wholesale system(s) and the treatment plants(s) operated by the consecutive system. However, under this plant-based approach, State determinations of monitoring requirements for consecutive systems will be complicated, especially in large combined distribution systems with many connections between systems.

ii. Approaches to addressing issues with plant-based monitoring. EPA is requesting comment on two approaches to address the issues with plant-based monitoring requirements described in this subsection. One approach is to keep the proposed plant-based monitoring approach and add new provisions to address specific concerns. Another approach is to base monitoring requirements on population served in lieu of the number of water treatment plants per system. The following paragraphs describe each approach.

EPA could maintain a plant-based monitoring approach and try to address the related issues described in this subsection through modifying the proposed monitoring requirements with provisions like the following:

—Set a limit on the maximum number of IDSE and routine monitoring samples that could be required. EPA believes that this limit should be different for systems using ground water or surface water or mixed systems and for different system size categories. However, the Agency has not developed a rationale to specify maximum sample numbers for specific system categories.

—Include a provision that would allow States to reduce the required number of samples for reasons other than those currently proposed (*i.e.*, common aquifer determinations and low DBP levels). EPA would have to develop specific criteria in the rule for systems to qualify for State approval of reduced monitoring. For example, in subpart H mixed systems, States could be given discretion to reduce routine compliance monitoring for ground water sources, since such sources typically have lower DBP concentrations.

—Develop criteria by which systems with very large distribution systems but with few plants would be required to conduct additional IDSE or routine monitoring in order to better characterize DBP exposure throughout the distribution system.

These provisions would allow for some issues to be addressed, but would make implementation complex and could add a significant burden to States.

An alternative approach to addressing the issues with plant-based monitoring requirements is to apply population-based monitoring requirements to all systems. Under a population-based monitoring approach, the total system population served and the source water type would determine the number of IDSE and routine monitoring samples taken. Monitoring requirements would not be based on the number of plants per system or consecutive system entry points. States would not be required to make common aquifer determinations or address whether plants are combined into a single pipe prior to entering the distribution system.

Proposed population-based monitoring requirements for

consecutive systems that purchase all their finished water year-round are shown in Tables V–4, V–6, and V–7. Also, the proposed rule language in subparts U and V contains requirements for population-based monitoring similar to what might be required for all systems. EPA believes that through using a broader array of system size categories than under the plant-based approach, population-based monitoring could result in an equitable proportioning of DBP sampling requirements. Tables V–9 and V–10 compare the proposed numbers of sampling locations per system under a population-based approach with a plant-based approach, using the median and mean number of plants per system given in Table V–8 for each of the size categories. For surface water systems, the median provides a better indicator of the typical number of required sampling locations under the plant-based approach because it is much less sensitive to systems with a very large number of plants.

TABLE V–9.—COMPARISON OF MONITORING LOCATIONS PER SYSTEM UNDER IDSE FOR PLANT-BASED AND POPULATION-BASED APPROACHES

Source water type	Population size category	Number of sampling periods	Plant-based			Population-based
			Number of monitoring locations per plant [1]	Number of monitoring locations per system		Number of monitoring locations per system [3]
				Based on median number of plants per system [2]	Based on mean number of plants per system [2]	
Subpart H	0–499	2	2	2	3	2
	500–4,999	4	2	2	3	2
	5,000–9,999	4	2	2	3	4
	10,000–24,999	6	8	8	16	8
	25,000–49,999	6	8	8	18	12
	50,000–99,999	6	8	16	27	16
	100,000–499,999	6	8	16	24	24
	500,000–1,499,000					32
	1,500,000–4,999,999	6	8	32	46	40
	≥5,000,000					48
Ground Water	0–499	2	2	2	2	2
	500–9,999	2	2	2	4	2
	10,000–99,999	4	2	8	9	6
	100,000–499,999	4	2	6	20	8
	≥500,000					12

[1] From Table V–5.
[2] Calculated from the number of locations per plant multiplied by number of plants per system (Table V–8).
[3] From Table V–4.

TABLE V–10.—COMPARISON OF ROUTINE MONITORING LOCATIONS PER SYSTEM UNDER STAGE 2B FOR PLANT-BASED AND POPULATION-BASED APPROACHES

Source water type	Population size category	Frequency of monitoring	Plant-based			Population-based
			Number of monitoring locations per plant [1]	Number of monitoring locations per system		Number of monitoring locations per system [3]
				Based on median number of plants per system [2]	Based on mean number of plants per system [2]	
Subpart H	0–499	1	1	1	1	2
	500–4,999	4	2	2	3	2
	5,000–9,999	4	2	2	3	2
	10,000–24,999	4	4	4	8	4
	25,000–49,999	4	4	4	9	6
	50,000–99,999	4	4	8	14	8
	100,000–499,999	4	4	8	12	12
	500,000–1,499,000					16
	1,500,000–4,999,999	4	4	16	23	20
	≥5,000,000					24
Ground Water	0–499	1	1	1	1	2
	500–9,999	1	2	2	4	2
	10,000–99,999	4	2	8	9	4
	100,000–499,999	4	2	6	20	6
	≥500,000					8

[1] From Table V–5.
[2] Calculated from the number of locations per plant multiplied by number of plants per system (Table V–8).
[3] From Table V–6.

Under the population-based approach, the number of required sampling locations for systems of different size and source water type approximates the number of sampling locations that would be required for the majority of systems under the plant-based approach. However, systems in the tail ends of the distribution of number of plants per system would be required to take more or fewer samples than under the plant-based approach. EPA used the median number of plants in a given size category as the primary basis for establishing the number of monitoring locations for the population-based approach.

EPA adjusted the number of sampling locations for systems in population sizes 25,000 to 49,999, 100,000–499,999, and greater than 1,500,000 to provide a more even upward trend in proportion to population increase. Consistent with the plant-based approach, ground water systems serving 10,000 people or greater would be required to sample at approximately ⅓ to ½ the frequency required for surface water systems under the population-based approach.

EPA suggests that the monitoring frequencies for the IDSE and Stage 2B compliance proposed for consecutive systems that purchase all of their finished water year-round (as presented in Tables V–4 and V–6) are appropriate for all systems if a population-based approach were used in lieu of a plant-based approach in the final rule. EPA believes that the population-based approach would ensure more equal and rational monitoring requirements among systems serving similar populations than the plant-based approach does, while providing generally improved representation of DBP occurrence throughout the distribution system. Such an approach would simplify implementation and reduce transactional costs to States by facilitating determination of the number of sampling locations.

To further evaluate the potential implications of monitoring under the population-based approach, EPA has prepared an economic analysis addressing monitoring impacts using the population-based approach (*Economic Analysis for the Stage 2 DBPR,* EPA 2003i) and guidance on how plant-based monitoring requirements would be affected if a population-based approach were used instead (*Draft IDSE Guidance Manual,* EPA 2003j).

EPA requests comments on alternative DBP monitoring requirements that are population-based versus plant-based; specifically on the merits of a population-based monitoring approach for all systems for the purpose of addressing the issues raised in this section. Specifically:

—Should alternative system size categories be specified under the suggested population-based approach?

—What potential issues might be unique for a population-based monitoring approach and how might they be addressed?

—Should alternative numbers of monitoring locations or frequencies be required in the IDSE or for Stage 2B monitoring?

—Are reduced monitoring requirements adequate to ensure continued protection relative to the MCL?

—What are the transition costs and issues associated with moving from a plant-based to a population based approach and how might they be addressed?

J. Compliance Schedules

1. What is EPA Proposing?

Today's proposed rule establishes compliance deadlines for public water systems to implement the requirements in this rulemaking. EPA is proposing a phased strategy for MCLs and simultaneous compliance with the LT2ESWTR consistent with the recommendation of the M-DBP Advisory Committee and to comply with SDWA requirements for risk balancing. Central to the determination of these deadlines is the principle of simultaneous compliance between the Stage 2 DBPR and the LT2ESWTR, which will ensure continued microbial protection as systems implement changes to decrease DBP levels and minimize risk-risk tradeoffs.

IDSE schedule. Subpart H and ground water systems covered by today's proposed rule that serve a population of 10,000 or more must submit the results of their IDSE to the primacy agency two years after rule promulgation. In addition, wholesale or consecutive systems serving fewer than 10,000 that are part of a combined distribution system with at least one system serving ≥10,000 must meet this same schedule. These systems must begin IDSE monitoring early enough to collect and analyze 12 months of data and prepare an IDSE report, which includes recommendations for Stage 2B monitoring locations (see section V.H). Subpart H and ground water systems covered by today's proposed rule that serve a population of fewer than 10,000 (except those noted before) must submit the results of their IDSE to the primacy agency four years after rule promulgation. These systems must begin IDSE monitoring early enough to collect and analyze the data and prepare the IDSE report.

Stage 2A schedule. All systems must comply with the Stage 2A MCLs for TTHM and HAA5 three years after rule promulgation.

Stage 2B schedule. Systems required to submit an IDSE report due two years after the rule is promulgated must comply with Stage 2B six years after rule promulgation. Subpart H systems required to submit IDSE reports four years after rule promulgation and required to do *Cryptosporidium* monitoring under the LT2ESWTR must comply with Stage 2B 8.5 years after rule promulgation. Small systems not required to *Cryptosporidium* monitoring must be in compliance with Stage 2B 7.5 years after rule promulgation. Figure V–2 contains several examples of how to determine IDSE and Stage 2B compliance dates.

FIGURE V–2. SCHEDULE EXAMPLES

—Wholesale system (pop. 64,000) with three consecutive systems (pops. 21,000; 15,000; 5,000):
  —IDSE report due for all systems two years after promulgation since wholesale system serves at least 10,000
  —Stage 2B compliance beginning six years after promulgation for all systems
—Wholesale system (pop. 4,000) with three consecutive systems (pops. 21,000; 5,000; 5,000):
  —IDSE report due for all systems two years after promulgation since one consecutive system in combined distribution system serves at least 10,000
  —Stage 2B compliance beginning six years after promulgation for all systems
—Wholesale system (pop. 4,000) with three consecutive systems (pops. 8,000; 5,000; 5,000):
  —IDSE report due for all systems four years after promulgation since no system in combined distribution system exceeds 10,000 (even though total population exceeds 10,000)
  —Stage 2B compliance beginning 7.5 years after promulgation if no *Cryptosporidium* monitoring under the LT2ESWTR is required or beginning 8.5 years after promulgation if *Cryptosporidium* monitoring under the LT2ESWTR is required

2. How Did EPA Develop This Proposal?

EPA is proposing provisions for simultaneous rule compliance with the LT2ESWTR to maintain a balance between DBP and microbial risks. Simultaneous compliance was mandated by the 1996 SDWA Amendments which require that EPA ''minimize the overall risk of adverse health effects by balancing the risk from the contaminant and the risk from other contaminants, the concentrations of which may be affected by the use of a treatment technique or process that would be employed to attain the maximum contaminant level'' (Sec. 1412(b)(5)(B)(i)).

If systems were required to comply with the Stage 2 DBPR prior to the LT2ESWTR, systems could lower their disinfectant dose or switch to a less effective disinfectant in an attempt to decrease DBP levels. This practice could leave segments of the population exposed to greater microbial risks. Therefore, simultaneous compliance was a consensus recommendation of the Stage 2 M-DBP Advisory Committee to ensure that systems would not compromise microbial protection while attempting to meet more stringent DBP requirements.

The Advisory Committee supported the Initial Distribution System Evaluation, as discussed in section V.H, and EPA is proposing an IDSE schedule consistent with the Advisory Committee's recommendations, in which systems are required to submit their IDSE reports to the State either two or to four years following rule promulgation. The Advisory Committee recommended this to allow enough time for the State to review (and revise, if necessary) systems' recommendations for Stage 2B monitoring locations and to allow systems three years after completion of the State review to comply with Stage 2B MCLs as LRAAs at Stage 2B monitoring locations.

This schedule requires systems serving ≥10,000 people and smaller wholesale and consecutive systems that are part of a combined distribution system that includes at least one system serving ≥10,000 to complete IDSE monitoring and prepare and submit the IDSE report two years after the rule is finalized. This requirement for wholesale systems and consecutive systems serving fewer than 10,000 that are part of a combined distribution system with at least one system serving at least 10,000 to conduct an ''early IDSE'' allows the wholesale system to be aware of compliance challenges facing the consecutive system and to implement treatment plant capital and operational improvements as necessary to ensure compliance. The Advisory Committee and EPA both recognized that DBPs, once formed, are difficult to remove and are generally best addressed by treatment plant improvements.

While this schedule allows for systems to have the three years to comply with Stage 2B following State review of the IDSE report, it begins prior to States being required to obtain primacy to implement the IDSE. States have two years from promulgation to adopt and implement new regulations and may request a two year extension. While EPA is preparing to support implementation of those IDSE requirements that must be completed prior to States achieving primacy, several States have expressed concern about EPA providing guidance and reviewing reports from systems that the State has permitted, inspected, and worked with for a long time. These States believe that their familiarity with the systems enables them to make the best decisions to implement the rule and protect public health.

As specific rule requirements were developed and implementation schedules and resource burdens determined, States also expressed concerns about the challenges that early implementation posed. In response to these concerns, EPA has developed several alternatives to the IDSE schedule and provisions that may meet the goals of the IDSE, but allow for greater State involvement, lower implementation burden, and no delay of the public health protection assured by compliance with Stage 2B.

The first, the ''Alternative IDSE'' option, would delay the schedule for each IDSE requirement for two years. Since the compliance date for Stage 2B would not be delayed, systems would need to implement changes necessary for compliance on a much shorter schedule.

The second, the ''Concurrent Compliance Monitoring'' option, would eliminate the IDSE but require compliance monitoring at an increased number of sites during the first year of compliance monitoring as a way to identify sites with high DBP levels. This option would reduce government oversight and management and, as with other rules, leave compliance determinations and preparations to individual systems (with guidance available from States). In addition to compliance monitoring at Stage 1 DBPR compliance monitoring sites during the first year under Stage 2B, systems would also monitor at additional compliance monitoring sites equal in number to the IDSE requirement and selected using the same criteria that systems use to select IDSE monitoring sites. Following one year of concurrent compliance monitoring, the system would select routine Stage 2B compliance monitoring locations using a protocol similar to the one used to recommend Stage 2B compliance monitoring locations in the IDSE report.

Neither alternative would extend the compliance dates for either Stage 2A or Stage 2B. As with the proposed IDSE, systems would be eligible for the 40/30 certification approach if all TTHM and HAA5 compliance monitoring results in the two years prior to the effective date were below 0.040 mg/L and 0.030 mg/L, respectively. States would be able to grant very small system waivers to systems serving <500 with a State finding that Stage 1 DBPR compliance monitoring locations sites are adequate to represent both high TTHM and high HAA5 concentrations. Table V–11 contains a comparison of the proposed IDSE schedule and the schedules for the alternatives.

TABLE V–11.—COMPARISON OF IDSE AND IDSE ALTERNATIVE SCHEDULES

[Dates in italics are not in today's proposed rule, but reflect EPA's recommendation and guidance]

Requirement [1]	Today's proposal	"Alternative IDSE" option	"Concurrent compliance monitoring" option
IDSE start date for systems ≥10,000	0.5 years after publication.	2.5 years after publication	Requirement is for system to conduct concurrent compliance monitoring (generally equal to number of samples required under Stage 1 plus number under IDSE) during first year of compliance monitoring. Based on results in first year, system would identify routine compliance monitoring locations using a procedure similar to that in IDSE report and begin routine monitoring.
IDSE start date for systems <10,000	2.5 years after publication.	4.5 years after publication	
IDSE report due for systems ≥10,000	2 years after publication.	4 years after publication	
IDSE report due for systems <10,000	4 years after publication.	6 years after publication	
State review of IDSE report complete for systems ≥10,000.	3 years after publication.	5 years after publication	
State review of IDSE report complete for systems <10,000.	4.5 years after publication.	6.5 years after publication	
Stage 2B compliance for systems ≥10,000	6 years after publication [2]		
Stage 2B compliance for systems <10,000	7.5 years after publication if system is not required to conduct Cryptosporidium monitoring; 8.5 years after publication if system required to conduct Cryptosporidium monitoring [2]		

[1] Systems serving ≥10,000 also include wholesale systems and consecutive systems serving <10,000 that are part of a combined distribution system in which at least one system serves ≥10,000.

[2] State may grant up to two additional years for capital improvements necessary to comply.

3. Request for Comments

EPA requests comments on today's proposed compliance schedules. Specifically:

—Should EPA promulgate an alternative approach to the IDSE recommended in section V.H. that achieves the same goal of identifying Stage 2B compliance monitoring locations and does not delay compliance with Stage 2B MCLs, but allows for the States to receive primacy and be more involved in IDSE implementation? Do either the "Alternative IDSE" option or the "Concurrent Compliance Monitoring" option achieve this goal? Does one achieve the goal better than the other? Why? Are there either changes to these alternatives or other alternatives not presented that achieve this goal?

—Should EPA allow small consecutive systems to meet Stage 2B compliance deadlines corresponding to their size (and later than the deadlines for their wholesale system) provided they complete their IDSE on the same schedule as the wholesale system and provided their water quality does not affect the water quality of any other system?

K. Public Notice Requirements

1. What is EPA Proposing?

SDWA section 1414(c) requires PWSs to provide notice to their customers for certain violations or in other circumstances. EPA's public notification rule was published on May 4, 2000 (65 FR 25982), and is codified at 40 CFR 141.201–141.210 (Subpart Q). Today's proposal does not alter the existing TTHM and HAA5 health effects language that is required in most public notices under Subpart Q. Because of the uncertainties in the health data discussed in section III of today's document, EPA is not proposing to include information about reproductive and developmental health effects in public notices at this time.

2. Request for Comments

EPA requests comment on the proposed public notification requirements, including whether information about the possible reproductive or fetal development effects that may be associated with high levels of DBPs should be provided.

L. Variances and Exemptions

States may grant variances in accordance with sections 1415(a) and 1415(e) of the SDWA and EPA's regulations. States may grant exemptions in accordance with section 1416 of the SDWA and EPA's regulations.

1. 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 that has primary enforcement responsibility (primacy), or EPA as the primacy agency, may grant general variances from MCLs to those public water systems of any size that cannot comply with the MCLs because of characteristics of the water sources. A variance may be issued to a system on condition that the system install the best technology, treatment techniques, or other means that EPA finds available and based upon an evaluation satisfactory to the State that indicates 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 to the public served by the public water system. In this proposed rule, EPA is specifying BATs for general variances under section 1415(a) (see section V.F).

Section 1415(e) authorizes the primacy agency to issue variances to small public water systems (those serving fewer than 10,000 people) where the primacy agent determines (1) that the system cannot afford to comply with an MCL or treatment technique and (2) that the terms of the variances will ensure adequate protection of human health (63 FR 1943–57; USEPA 1998d). These variances may only be granted where EPA has determined that there is no affordable compliance technology and has identified a small system variance technology under section 1412(b)(15) for the contaminant, system size and source water quality in question. As discussed below, small system variances under section 1415(e) are not available because EPA has determined that affordable compliance technologies are available.

The 1996 Amendments to the SDWA identify three categories of small public water systems that need to be addressed: (1) Those serving a population of 3301–10,000; (2) those serving a population of 500–3300; and (3) those serving a population of 25–499. 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. Based on this analysis, multiple affordable compliance technologies were found for each of the three system sizes (USEPA 2003i) 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'' (USEPA 1998g) and the ''Variance Technology Findings for Contaminants Regulated Before 1996'' (USEPA 1998h).

2. What Are the Affordable Treatment Technologies for Small Systems?

The treatment trains considered and predicted to be used in EPA's compliance forecast for systems serving under 10,000 people, are listed in Table V–12.

TABLE V–12.—TECHNOLOGIES CONSIDERED AND PREDICTED TO BE USED IN COMPLIANCE TECHNOLOGY FORECAST FOR SMALL SYSTEMS [1]

SW water plants	GW water plants
• Switching to chloramines as a residual disinfectant	• Switching to chloramines as a residual disinfectant
• Chlorine dioxide (Not for systems serving fewer than 100 people)	• UV
• UV	• *Ozone (not for systems serving fewer than 100 people)* [2]
• *Ozone (not for systems serving fewer than 100 people)*	• *GAC20* [2]
• *Micro-filtration/Ultra-Filtration* [2]	• *Nanofiltration* [2]
• *GAC20* [2]	
• GAC20 + Advanced disinfectants	
• Membranes (Micro-Filtration/Ultra-Filtration + Nanofiltration)	

[1] Based on exhibits 6.8a and 6.8b in Economic Analysis for the proposed Stage 2 DBPR (USEPA 2003i)
[2] Italicized technologies are those predicted to be used in the compliance forecast.

The household costs for these technologies were compared against the national-level affordability criteria to determine the affordable treatment technologies. The Agency's national-level affordability criteria were published in the August 6, 1998 **Federal Register** (USEPA 1998g). In this document, EPA discussed the procedure for affordable treatment technology determinations for the contaminants regulated before 1996.

The following section provides a description of how EPA derived the national-level affordability criteria pertinent to this rule. First, EPA calculated an ''affordability threshold'' (*i.e.*, the total annual household water bill that would be considered affordable). The total annual water bill includes costs associated with water treatment, water distribution, and operation of the water system. In developing the threshold of 2.5% median household income, EPA considered the percentage of median household income spent by an average household on comparable goods and services and on cost comparisons with other risk reduction activities for drinking water such as households purchasing bottled water or a home treatment device. The complete rationale for EPA's selection of 2.5% as the affordability threshold is described in ''Variance Technology Findings for Contaminants Regulated Before 1996'' (USEPA 1998h).

The Variance Technology Findings document also describes the derivation of the baselines for median household income, annual water bills, and annual household consumption. Data from the Community Water System Survey (CWSS) were used to derive the annual water bills and annual water usage values for each of the three small system size categories. The data on zip codes were used with the 1990 Census data on median household income to develop the median household income values for each of the three small-system size categories. The median household-income values used for the affordable technology determinations are not based on the national median income. The value for each size category is a national median income for communities served by small water systems within that range. Table V–13 presents the baseline values for each of the three small-system size categories. Annual water bills are based on 1995 estimates (USEPA 1998h) and adjusted upward for anticipated costs attributed to new drinking water regulations since 1995, *i.e.*, the IESWTR, Stage 1 DBPR, Filter Backwash Recycling Rule, Arsenic Rule, LT1ESWTR, Public Notification Rule, and Consumer Confidence Rule.[1] Median household income estimates are based on estimates made in 1995 (USEPA 1998h) and adjusted upward for inflation to represent 2000 incomes (USEPA 2003i).

[1] EPA is currently receiving input from a National Drinking Water Advisory Council (NDWAC). This process is expected to conclude in the fall of 2003 with a report that will be sent by the NDWAC. EPA has also received a report from the Science Advisory Board's Environmental Economics Advisory Committee on its review of the national-level affordability criteria (USEPA 2002c). One of the charges given to both groups was to evaluate the process used by EPA to adjust the baseline water bills to account for costs attributable to regulations promulgated after 1996. Because the Stage 2 DBPR affordability analysis is being conducted before EPA can complete a comprehensive reassessment of affordability, today's estimate for the increase to the average water bill to account for regulations after 1996 reflects existing Agency affordability criteria and methodology. This estimate may change in the future.

TABLE V–13.—BASELINE VALUES FOR SMALL SYSTEMS CATEGORIES AND AVAILABLE EXPENDITURE MARGIN FOR AFFORDABLE TECHNOLOGY DETERMINATIONS

System size category (pop. served)	Annual HH consumption (1000 gallons/yr)	Median HH income ($)	2.5% median HH income(s)	Current annual water bills ($/yr)	Available expenditure margin ($/hh/year)
25–500	72	35,148	878	290	588
501–3,300	74	30,893	772	230	542
3,301–10,000	77	31,559	789	219	570

For each size category, the threshold value was determined by multiplying the median household income by 2.5 percent. The annual household water bills were subtracted from this value to obtain the available expenditure margin. Projected treatment costs were compared against the available expenditure margin to determine if there were affordable compliance technologies for each size category. The available expenditure margin for the three size categories is presented in Table V–13.

The size categories specified in SDWA for affordable technology determinations are different from the size categories typically used by EPA in the Economic Analysis. A weighted average procedure was used to derive design and average flows for the 25–500 category using design and average flows from the 25–100 and 101–500 categories. A similar approach was used to derive design and average flows from the 501–1000 and 1001–3300 categories for the 501–3300 category. The Variance Technology Findings document (USEPA 1998h) describes this procedure in more detail. Table V–14a lists the design and average flows for the three size categories.

TABLE V–14A.—DESIGN AND AVERAGE DAILY FLOWS USED FOR AFFORDABLE TECHNOLOGY DETERMINATIONS

System size category (population served)	Design flow (mgd)	Average flow (mgd)
25–500	0.058	0.015
501–3,300	0.50	0.17
3,301–10,000	1.8	0.70

Capital and operating and maintenance costs were derived for each treatment technology used in the compliance forecast for small systems using the flows listed previously and the cost equations in the Technology and Cost Document (USEPA 2003k). Capital costs were amortized using the 7 percent interest rate preferred by Office of Management and Budget (OMB) for benefit-cost analyses of government programs and regulations rather than a 3 percent interest rate.

The annual system treatment cost in dollars per year was converted into a rate increase using the average daily flow. The annual water consumption values listed in Table V–13 were multiplied by 1.15 to account for water lost due to leaks. Since the water lost to leaks is not billed, the water bills for the actual water used were adjusted to cover this lost water by increasing the household consumption. The rate increase in dollars per thousand gallons used was multiplied by the adjusted annual consumption to determine the annual cost increase for the household for each treatment technology.

With very few exceptions, the household costs for all predicted compliance technologies in Table V–12 are below the available expenditure margin. The only technology that was predicted to be used in the compliance forecast for the Stage 2 DBPR and that costs slightly more than the available expenditure margin is GAC20 (240 day carbon replacement) with advanced disinfectants for systems serving 500 people or fewer. As shown in the Economic Analysis (USEPA 2003i), 13 systems (less than 1 percent) among systems serving fewer than 500 people are predicted to use GAC20 with advanced disinfection to comply with the proposed Stage 2 DBPR. However, alternate affordable technologies are available. Thus, EPA believes that compliance by these systems will be affordable. In some cases, the compliance data for these systems under the Stage 2 DBPR is the same as under the Stage 1 DBPR (because many systems serving fewer than 500 people will have the same single sampling site under both rules); these systems will have already installed the necessary compliance technology to comply with the Stage 1 DBPR. It is also possible that less costly technologies such as those for which percentage use caps were set in the decision tree may actually be used to achieve compliance (*e.g.*, chloramines, UV).

As shown in Table V–14b, the cost model (USEPA 2003i) predicts that households served by very small systems will experience household cost increases greater than the available expenditure margins as a result of adding advanced technology for the Stage 2 DBPR. This prediction is probably overestimated because small systems have other compliance alternatives available to them besides adding treatment. For example, some of these systems currently may be operated on a part-time basis; therefore, they may be able to modify the current operational schedule or use excessive capacity to avoid installing a costly technology to comply with the Stage 2 DBPR. The system also may identify another water source that has lower TTHM and HAA5 precursor levels. Systems that can identify such an alternate water source may not have to treat that new source water as intensely as their current source, resulting in lower treatment costs. Systems may elect to connect to a neighboring water system. While connecting to another system may not be feasible for some remote systems, EPA estimates that more than 22 percent of all small water systems are located within metropolitan regions (USEPA 2000c) where distances between neighboring systems will not present a prohibitive barrier. More discussion of household cost increases is presented in a later section (Section VII) and the Economic Analysis (USEPA 2003i).

Table V-14b: Annual Household Cost Increases versus Available Expenditure Margin for Households Served by Small Systems Adding Treatment

Systems Size (population served)	Number of Households Served by Plants Adding Treatment (Percent of all Households Subject	Mean Annual Household Cost Increase	Median Annual Household Cost Increase	90th Percentile Annual Household Cost Increase	95th Percentile Annual Household Cost Increase	Available Expenditure Margin ($/hh/yr)	Number of Housholds with Annual Cost Increases Greater then the Available Expenditure Margin	Number of Plants with Annual Cost Increases Greater than the Available Expenditure Margin
0 - 500	42,355 (3.0%)	$184.55	$189.59	$189.59	$409.40	$588	1,325	22
501 - 3,300	158,044 (2.8%)	$47.74	$38.48	$152.41	$215.85	$542	0	0
3,301 - 10,000	221,110 (3.0%)	$33.21	$13.30	$98.18	$186.72	$570	0	0

[1]Detail may not to total add due to independent rounding. Households served by all plants will be higher than households served by plants adding treatment because an entire system will incur costs even if less than the total number of plants for that system

[2]The affordability criteria for systems serving 25 - 500 people is $588, for systems serving 501 - 3,300 is $542, and for systems serving 3,301 - 10,000 is $570

Source: Economic Analysis (USEPA 2003i) exhibit 8.4c

EPA is currently reviewing its national-level affordability criteria, and has solicited recommendations from both the NDWAC and the SAB as part of this review. If the national-level affordability criteria are revised prior to promulgation of the final Stage 2 DBPR, EPA may reevaluate the affordability of the identified small system compliance technologies based on the revised criteria and may revise its determination of whether to list any variance technologies as a result. EPA requests comment on the application of its affordability criteria in this rulemaking and on its determination that there are affordable small system compliance technologies for all three statutory small system size categories.

M. Requirements for Systems To Use Qualified Operators

EPA believes that systems that must make treatment changes to comply with requirements to reduce microbiological risks and risks from disinfectants and disinfection byproducts should be operated by personnel who are qualified to recognize and respond to problems. Subpart H systems were required to be operated by qualified operators under the SWTR (40 CFR 141.70). The Stage 1 DBPR added requirements for all disinfected systems to be operated by qualified personnel who meet the requirements specified by the State, which may differ based on system size and type. The rule also required that States maintain a register of qualified operators (40 CFR 141.130(c)). While the proposed Stage 2 DBPR requirements do not supercede or modify the requirement that disinfected systems be operated by qualified personnel, the Stage 2 DBPR re-emphasizes the important role that qualified operators play in delivering safe drinking water to the public. States should also review and modify, as required, their qualification standards to take into account new technologies (*e.g.*, ultraviolet (UV) disinfection) and new compliance requirements (including simultaneous compliance and consecutive system requirements).

N. System Reporting and Recordkeeping Requirements

1. Confirmation of Applicable Existing Requirements

Today's proposed Stage 2 DBPR, consistent with the current system reporting regulations under 40 CFR 141.131, requires public water systems 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 ten days of the end of the monitoring period for less frequent monitoring.

2. Summary of Additional Reporting Requirements

EPA proposes that two years after rule promulgation, systems serving 10,000 or more people (plus consecutive systems that are part of a combined distribution system with a system serving at least 10,000) be required to report the results of their IDSE to their State, unless the State has waived this requirement for systems serving fewer than 500. Systems are also required to report to the State recommended long-term (Stage 2B) compliance monitoring sites as part of the IDSE report. While the IDSE options discussed in section V.J. would delay the timing of this requirement, EPA believes that the burden would not change.

Beginning three years after rule promulgation, systems must report compliance with Stage 2A MCLs based on LRAAs (0.120 mg/L TTHM and 0.100 mg/HAA5), as well as continue to report compliance with 0.080 mg/L TTHM and 0.060 mg/L HAA5 as RAAs. Systems must report compliance with the Stage 2B TTHM and HAA5 MCLs (0.080 mg/L TTHM and 0.060 mg/L HAA5 as LRAAs) according to the compliance schedules outlined in section V.J. of today's proposal. Reporting for DBP monitoring, as described previously, will remain generally consistent with current public water system reporting requirements (§ 141.31 and § 141.134); systems will be required to calculate and report each LRAA (instead of the system's RAA) and each individual monitoring result (as required under the Stage 1 DBPR). Systems will also be required to consult with the State about each peak excursion event no later than the next sanitary survey for the system, as discussed in section V.E.

3. Request for Comment

EPA requests comment on all system reporting and recordkeeping requirements.

O. Analytical Method Requirements

1. What Is EPA Proposing Today?

The Stage 2 DBPR proposed today does not add any new disinfectants or disinfection byproducts to the list of contaminants currently covered by MRDLs or MCLs. However, additional methods have become available since the analytical methods in the Stage 1 DBPR were promulgated (USEPA 1998c). EPA is proposing to add to 40 CFR 141.131 one method for chlorine dioxide and chlorite, one method for HAA5 which can also be used to analyze for the regulated contaminant dalapon, three methods for bromate, chlorite, and bromide, one method for bromate only, and one method for total

organic carbon (TOC) and specific ultraviolet absorbance (SUVA). One of the methods that is currently approved for bromate, chlorite, and bromide can be used to determine chloride, fluoride, nitrate, nitrite, orthophosphate, and sulfate, so EPA is proposing to add it as an approved method for those contaminants in 40 CFR 141.23 and 40 CFR 143.4. EPA is also proposing to add the HAA5 method that includes dalapon to 40 CFR 141.24 for dalapon compliance monitoring.

Several of the methods that were promulgated with the Stage 1 DBPR have been included in publications that were issued after December 1998. EPA is proposing to approve the use of the recently published versions of three methods for determining free, combined, and total chlorine residuals, two methods for total chlorine only, one method for free chlorine only, one method for chlorite and chlorine dioxide, one method for chlorine dioxide only, one method for HAA5, three methods for TOC and dissolved organic carbon (DOC), and one method for ultraviolet absorption at 254nm (UV_{254}). EPA is proposing to update the citation for one method for bromate, chlorite, and bromide.

EPA is also proposing to standardize the HAA5 sample holding times and the bromate sample preservation procedure and holding time. EPA is clarifying which methods are approved for magnesium hardness determinations in 40 CFR 141.131 and 40 CFR 141.135.

Analytical methods that are proposed for approval or for which changes are proposed in today's rule are summarized in Table V–15 and are described in more detail later in this section.

TABLE V–15.—ANALYTICAL METHODS ADDRESSED IN TODAY'S PROPOSED RULE

Analyte	EPA method	Standard method [1]	Other
§ 141.23			
Fluoride	300.1		
Nitrate	300.1		
Nitrite	300.1		
Orthophosphate	300.1		
§ 141.24			
Dalapon	552.3		
§ 141.131—Disinfectants			
Chlorine (*free, combined, total*)		4500–Cl D	
		4500–Cl F	
		4500–Cl G	
(*total*)		4500–Cl E	
		4500–Cl I	
(*free*)		4500–Cl H	
Chlorine Dioxide	327.0	4500–ClO_2 D	
		4500–ClO_2 E	
§ 141.131—Disinfection Byproducts			
HAA5	552.1 [2]	6251 B [2]	
	552.3		
Bromate	300.1 [3]		ASTM D 6581–00
	317.0 Revision 2		
	321,8 [4]		
	326.0		
Chlorite (*monthly or daily*)	300.1 [3]		ASTM D 6581–00
	317.0 Revision 2		
	326.0		
(*daily*)	327.0	4500–ClO_2 E	
§ 141.131—Other parameters			
Bromide	300.1 [3]		ASTM D 6581–00
	317.0 Revision 2		
	326.0		
TOC/DOC	415.3	5310 B	
		5310 C	
		5310 D	
UV_{254}	415.3	5910 B	
SUVA	415.3		
§ 143.4			
Chloride	300.1		
Sulfate	300.1		

[1] EPA is proposing to cite both the 20th edition and the 2003 On-Line Version of *Standard Methods for the Examination of Water and Waste Water* in addition to the currently cited 19th editions for all methods listed in this column with the exception of 4500–ClO_2 D for chlorine dioxide which is not available in the 2003 On-Line Version.
[2] EPA is proposing to change the sample holding time to 14 days.
[3] EPA is proposing to update the citation.
[4] EPA is proposing that samples be preserved with 50 mg ethylenediamine/L and analyzed within 28 days.

2. How Was This Proposal Developed?

EPA evaluated the performance of the new methods for their applicability to compliance monitoring. The primary purpose of this evaluation was to determine if the new methods provide data of comparable or better quality than the methods that are currently approved. Methods currently approved for DBPs were also examined to determine applicability to other regulated contaminants.

EPA reviewed the new publications of methods from consensus organizations such as Standard Methods and American Society for Testing and Materials (ASTM). As a result, EPA identified one new method from ASTM

which is suitable for compliance monitoring. EPA also determined that the newer editions of Standard Methods did not change the individual methods approved under the Stage 1 DBPR.

3. Which New Methods Are Proposed for Approval?

a. *EPA Method 327.0 for chlorine dioxide and chlorite.* EPA is proposing to add a new method for the measurement of chlorine dioxide residuals and daily chlorite concentrations. EPA Method 327.0 (USEPA 2003q) is an enzymatic/spectrophotometric method in which a total chlorine dioxide plus chlorite concentration is determined in an unsparged sample and the chlorite concentration is determined in a sparged sample. The chlorine dioxide concentration is then calculated by subtracting the chlorite concentration from the total.

The pH of the samples (sparged and unsparged) and blank are adjusted to 6.0 with a citric acid/glycine buffer. The chromophore Lissamine Green B (LGB) and the enzyme horseradish peroxidase are added. The enzyme reacts with the chlorite in the sample to form chlorine dioxide which then reacts with the chromophore LGB to reduce the absorbance at 633nm of the sample. The absorbance of the samples and blank are determined spectrophotometrically. The difference in absorbance between the samples and the blank is proportional to the chlorite and total chlorine dioxide/chlorite concentrations in the samples.

EPA Method 327.0 offers advantages over the currently approved methods in that it is not subject to positive interferences from other chlorine species and it is easier to use.

The single laboratory detection limits presented in the method are 0.08–0.11 mg/L for chlorite and 0.04–0.16 mg/L for chlorine dioxide. The detection limits are based on the analyses of sets of seven replicates of reagent water that were fortified with low concentrations of chlorite with and without the presence of chlorine dioxide and low concentrations of chlorine dioxide with and without the presence of chlorite. The standard deviation of the mean concentration for each set of samples was calculated and multiplied by the student's t-value at 99% confidence and n–1 degrees of freedom (3.143 for 7 replicates) to determine the detection limit. The accuracy reported in the method for laboratory fortified blanks at concentrations of 0.2–1.0 mg/L is 103–118 % for chlorite and 102–124 % for chlorine dioxide with relative standard deviations between 2.9 and 16 %. Replicate analyses of drinking water samples from surface and ground water sources fortified at concentrations of approximately 1 and 2 mg/L chlorite and chlorine dioxide showed average recoveries of 91–110 % with relative standard deviations of 1–9 %.

EPA is proposing to approve EPA Method 327.0 as an additional method for monitoring chlorine dioxide and for making the daily determination of chlorite at the entry point to the distribution system. It will provide water systems with additional flexibility in monitoring the application of chlorine dioxide. EPA believes that many water plant operators will prefer the new method over the currently approved methods due to its ease of use.

b. *EPA Method 552.3 for HAA5 and dalapon.* EPA is proposing to add a new method (EPA Method 552.3) for HAA5 that provides comparable sensitivity, accuracy, and precision to the previously approved methods. EPA Method 552.3 (USEPA 2003p) has the added benefit of allowing laboratories to more easily measure four additional haloacetic acids (bromochloroacetic acid, bromodichloroacetic acid, chlorodibromoacetic acid, and tribromoacetic acid) at the same time the HAA5 compounds are being measured, without compromising the quality of data for the HAA5 compounds. Of the currently approved methods for HAA5, only EPA Method 552.2 (USEPA 1995) provides method performance data for all of these additional compounds, but the reaction conditions must be carefully controlled. EPA believes that analyses for these additional HAAs can be accomplished more easily without compromising the quality of data for the HAA5 compounds by using EPA Method 552.3.

EPA Method 552.3 for HAA5, other haloacetic acids, and the regulated contaminant dalapon allows two extraction options. The first option involves an acidic extraction with methyl tertiary butyl ether (MTBE) which is the same solvent used in the currently approved HAA5 methods. The analytes (HAA5, other HAAs, and dalapon) are then converted to their methyl esters by the addition of acidic methanol to the extract followed by heating. The amount of acidic methanol that is added to the extract is increased in the new method resulting in increased methylation efficiency for some of the analytes. The increased methylation efficiency is significant for the additional HAAs and thus provides greater sensitivity, precision, and accuracy for them when compared to EPA Method 552.2. The acidic extract is neutralized with a saturated solution of sodium bicarbonate and the target analytes are identified and measured by gas chromatography using electron capture detection (GC/ECD).

The second option in the new EPA Method 552.3 involves an acidic extraction with tertiary amyl methyl ether (TAME). The HAAs are then converted to their methyl esters by the addition of acidic methanol to the extract followed by heating. The use of TAME instead of MTBE as the extraction solvent allows the use of a higher temperature during the methylation process. This increases the methylation efficiency and thus provides significant increases in sensitivity, precision, and accuracy for the additional HAAs. The acidic extract is neutralized with a saturated solution of sodium bicarbonate and the target analytes are identified and measured by gas chromatography using electron capture detection (GC/ECD).

The performance of EPA Method 552.3 is comparable to the currently approved methods for determining the HAA5 analytes. A comparison of the performance of EPA Method 552.3 to the currently approved HAA5 methods is shown in Table V–16. The data are taken from the individual methods, so the precision, accuracy, and detection data were not generated using the same samples or by the same laboratory.

TABLE V–16.—PERFORMANCE OF HALOACETIC ACID METHODS

QC Parameter	MCAA	DCAA	TCAA	MBAA	DBAA
Precision (Max %RSD in fortified drinking water samples) [1]					
EPA 552.1	15	14	28	11	7
EPA 552.2	13	6	15	6	5
EPA 552.3 (MTBE option)	6	4	1	4	5
EPA 552.3 (TAME option)	10	4	2	4	5
SM 6251 B	8	7	6	8	7

TABLE V–16.—PERFORMANCE OF HALOACETIC ACID METHODS—Continued

QC Parameter	MCAA	DCAA	TCAA	MBAA	DBAA
Accuracy (Range of % Recoveries in fortified drinking water samples) [2]					
EPA 552.1	76–100	75–126	56–106	86–97	94–103
EPA 552.2	84–97	96–105	62–82	86–100	72–112
EPA 552.3 (MTBE option)	98–126	96–103	89–100	99–113	101–111
EPA 552.3 (TAME option)	97–131	97–107	89–103	99	101–105
SM 6251 B	99–103	96–103	100–103	97–101	102
Detection Limit (μg/L) [3]					
EPA 552.1	0.21	0.45	0.07	0.24	0.09
EPA 552.2	0.27	0.24	0.08	0.20	0.07
EPA 552.3 (MTBE option)	0.17	0.02	0.02	0.03	0.01
EPA 552.3 (TAME option)	0.20	0.08	0.02	0.13	0.02
SM 6251 B	0.08	0.05	0.05	0.09	0.06

[1] The highest relative standard deviation (%RSD) for replicate analyses of fortified drinking water samples as shown in each method.
[2] The range of recoveries reported for replicate analyses of fortified drinking water samples as shown in each method.
[3] The detection limit as determined by analyzing seven or more replicates of reagent water that is fortified with low concentrations of the haloacetic acids. The standard deviation of the mean concentration for each analyte is calculated and multiplied by the student's t-value at 99% confidence and n-1 degrees of freedom (3.143 for 7 replicates).

Two of the currently approved HAA5 methods (EPA Methods 552.1 (USEPA 1992) and 552.2 (USEPA 1995)) are also approved for analyses of water samples for the regulated contaminant dalapon, a synthetic organic chemical. The new HAA5 method can also be used to determine dalapon in drinking water. As shown in Table V–17, both solvent options in EPA Method 552.3 provide comparable or better method performance than the approved methods.

TABLE V–17.—PERFORMANCE OF DALAPON METHODS

Dalapon performance characteristic	EPA 552.1	EPA 552.2	EPA 552.3	
			MTBE	TAME
Precision[1] (% RSD)	14	11	2	4
Accuracy[2] (% Recovery)	88–102	86–100	98–112	87–103
Detection Limit[3] (μg/L)	0.32	0.12	0.02	0.14

[1] The highest relative standard deviation (%RSD) for replicate analyses of fortified drinking water samples as shown in each method.
[2] The range of recoveries reported for replicate analyses of fortified drinking water samples as shown in each method.
[3] The detection limit as determined by analyzing seven or more replicates of reagent water that is fortified with low concentrations of dalapon. The standard deviation of the mean dalapon concentration is calculated and multiplied by the student's t-value at 99% confidence and n-1 degrees of freedom (3.143 for 7 replicates).

EPA is proposing to approve EPA Method 552.3 for dalapon (§ 141.24(e)(1)) in addition to HAA5 even though dalapon is not a contaminant that is addressed in this proposed rule. EPA believes that extending approval to all the regulated contaminants covered by the method provides more flexibility to laboratories. It allows the laboratories the option of reducing the number of methods that they need to keep in operation for their clients, because the new method can be used for dalapon and HAA5 compliance monitoring samples and for determining the additional HAAs for non-regulatory purposes. EPA recognizes that laboratories will probably not be determining dalapon concentrations for compliance purposes in the same samples as used for HAA5 compliance monitoring. However, EPA believes allowing the same method to be used even if the samples are not the same is more cost effective for laboratories, because switching between methods results in increased analyst and instrument time. EPA is not proposing to withdraw the other dalapon methods, because that would reduce flexibility for the laboratories and place an unnecessary burden on laboratories that do not need to use EPA Method 552.3.

c. *ASTM D 6581–00 for bromate, chlorite, and bromide.* ASTM Method D 6581–00 (ASTM 2002) for the determination of bromate, chlorite, and bromide was adopted by ASTM in 2000. This method uses the same procedures as EPA Method 300.1 (USEPA 2000l) (the method promulgated in the Stage 1 DBPR) and thus is considered equivalent to the approved method (Hautman *et al.* 2001). The ASTM method includes interlaboratory study data that were not available when EPA Method 300.1 was published. The study data demonstrate good precision and low bias for all analytes.

Under section 12(d) of the National Technology Transfer and Advancement Act, the Agency is directed to consider whether to use voluntary consensus standards in its regulatory activities. ASTM Method D 6581–00 is an acceptable consensus standard and it is published in the 2001, 2002, and 2003 editions of *The ASTM Annual Book of Standards.* EPA is proposing to approve ASTM Method D 6581–00 in order to provide additional flexibility to laboratories. Any edition containing the cited version may be used.

d. *EPA Method 317.0 revision 2 for bromate, chlorite, and bromide.* EPA Method 317.0 Revision 2 (USEPA 2001d) is an extension of the currently approved EPA Method 300.1 for bromate, chlorite, and bromide. It uses the EPA Method 300.1 technology, but it adds a postcolumn reactor that provides a more sensitive and specific analysis for bromate than is obtained using EPA Method 300.1. As with EPA Method 300.1, the anions are separated by ion chromatography and detected using a conductivity detector. (Bromate, chlorite, and bromide concentrations determined by the conductivity detector are equivalent to those measured using EPA Method 300.1.) After the sample

passes through the conductivity detector, it enters a postcolumn reactor chamber in which *o*-dianisidine dihydrochloride (ODA) is added to the sample. This compound forms a chromophore with the bromate that is present in the sample and the chromophore concentration is determined using a ultraviolet/visible (UV/Vis) absorbance detector. There are several advantages of this method:

(1) Very few ions react with ODA to form compounds that are detected by the UV/Vis detector. This makes the method less susceptible to interferences for bromate.

(2) The UV/Vis detector is very sensitive to the chromophore, so lower concentrations of bromate can be detected and quantitated. (Bromate concentrations can be reliably quantitated as low as 1 μg/L using this detector versus 5 μg/L for EPA Method 300.1.)

(3) Since the front part of the analysis is the same as EPA Method 300.1, bromate, chlorite, and bromide can be determined in the same analysis.

The first version of this method, EPA Method 317.0 has been evaluated in a multiple laboratory study (Wagner *et al.* 2001; Hautman *et al.* 2001). The results from the study indicate high precision and very low bias in data generated using this method. The interlaboratory precision for bromate, chlorite, and bromide using the conductivity detector and bromate using the UV/Vis detector are 12%, 4.2%, 6.9%, and 9.6% relative standard deviation (RSD), respectively. The interlaboratory bias for bromate, chlorite, and bromide using the conductivity detector and bromate using the UV/Vis detector are 0.35%, −0.98%, −0.87%, and 4.8%, respectively. The average detection levels for bromate, chlorite, and bromide using the conductivity detector and bromate using the UV/Vis detector are 2.2, 1.6, 2.8, and 0.24 μg/L, respectively.

Subsequent to the interlaboratory study of EPA Method 317.0, a problem with ODA was discovered. The purity of the reagent can vary from lot to lot and this affects the performance of the method. EPA has evaluated the method performance using ODA obtained from several commercial sources and from different lots from the same supplier. Based on that new information, EPA revised Method 317.0 to document how to detect and correct problems that can result from a contaminated ODA supply. The revised method is designated EPA Method 317.0 Revision 2.0 and this is the version that is being proposed today. The performance of the revised method is identical to the original version.

EPA believes EPA Method 317.0 Revision 2.0 should be approved as an additional method for bromate, chlorite, and bromide compliance monitoring. EPA anticipates that water systems will prefer to have their bromate samples analyzed by this new method, because it provides higher quality data than the currently approved method when bromate concentrations are below the MCL of 0.010 mg/L (10 μg/L). Only a few laboratories are currently performing analyses using the postcolumn reactor technology included in the method, but the number is increasing as more laboratories become aware of the advantages.

e. *EPA Method 326.0 for bromate, chlorite, and bromide*. EPA Method 326.0 (USEPA 2002a) is based on the procedure reported by Salhi and von Gunten (1999) and uses an approach that is similar to EPA Method 317.0 Revision 2.0. The method involves the separation of the anions (bromate, chlorite, and bromide) following the scheme outlined in EPA Methods 300.1 and 317.0 Revision 2.0. (Bromate, chlorite, and bromide data from the conductivity detector are equivalent to data generated using EPA Method 300.1.) The eluent stream exiting the conductivity detector is mixed with a postcolumn reagent consisting of an acidic solution of potassium iodide with a catalytic concentration of molybdenum (VI). Bromate reacts with the iodide to form triiodide which is measured by its UV absorption at 352 nm.

EPA Method 326.0 has similar accuracy, precision, and sensitivity for bromate compared to EPA Method 317.0 Revision 2.0. Thirty drinking water samples fortified with 1–7 μg bromate/L were analyzed using both methods. Accuracy, expressed as % recovery, ranged from 78.0 to 129% for both methods and precision, expressed as % RSD ranged from 3.7 to 13.5% (Wagner *et al.* 2002). The detection limit of EPA Method 326.0 is 0.17 μg/L as determined by analyzing seven or more replicates of reagent water that is fortified with low concentrations of bromate. The standard deviation of the mean bromate concentration is calculated and multiplied by the student's t-value at 99% confidence and n-1 degrees of freedom (3.143 for 7 replicates).

EPA is proposing EPA Method 326.0 as an additional method for bromate, chlorite, and bromide compliance monitoring. It provides higher quality bromate data than the currently approved EPA Method 300.1 when bromate concentrations are below 10 μg/L. EPA anticipates the number of laboratories using this method will increase as utilities become aware of the method's sensitivity and begin to request it be used for their samples.

f. *EPA Method 321.8 for bromate*. EPA is proposing to add EPA Method 321.8 (USEPA 2000d) specifically for bromate compliance monitoring. It involves an ion chromatograph coupled to an inductively coupled plasma mass spectrometer (IC/ICP–MS). The ion chromatograph separates bromate from other ions present in the sample and then bromate is detected and quantitated by the ICP–MS. Mass 79 is used for quantitation while mass 81 provides isotope ratio information that can be used to screen for potential polyatomic interferences. The advantage of this method is that it is very specific and sensitive to bromate. The single laboratory detection limit presented in the method is 0.3 μg/L. The average accuracy reported in the method for laboratory fortified blanks is 99.8% recovery with a three sigma control limit of 10.2%. Average accuracy and precision in fortified drinking water samples are reported as 97.8% recovery and 2.9% relative standard deviation, respectively.

During the Information Collection Rule, thirty-three samples were analyzed by this method in addition to the selective anion concentration (SAC) method used by EPA for the low-level bromate analyses. EPA Method 321.8 provided comparable data to that generated by the SAC method (Fair 2002).

EPA Method 321.8 has undergone second laboratory validation (Day *et al.* 2001) and the results indicate the method can be successfully performed in non-EPA laboratories. The calculated detection limit determined by the second laboratory is 0.4 μg/L. The average accuracy achieved for laboratory fortified blanks at 5 μg/L is 93% recovery with a relative standard deviation of 8.9%. Average accuracy and precision in fortified drinking water samples are reported as 101% recovery and 9% relative standard deviation, respectively.

The IC/ICP–MS instrumentation used in EPA Method 321.8 is a new technology in the drinking water laboratory community. Even though the technology is not yet widely used, EPA believes that approving this new method will provide laboratories with the flexibility to adopt the new technology if they have additional applications for it. The instrumentation is especially promising in the area of trace metal speciation. Laboratories that are performing that type of analysis would find it very useful to also be able

to perform bromate compliance monitoring analyses by EPA Method 321.8. EPA believes that advances in analytical technology should be encouraged when they provide additional options for obtaining accurate and precise data for compliance monitoring. Approval of this method would not require laboratories to adopt the new technology; it strictly offers the choice for laboratories that would like to use the latest technology.

EPA is proposing to add sample collection and holding time requirement to EPA Method 321.8. The current method does not address the potential for changes in bromate concentrations after the sample is collected as a result of reactions with hypobromous acid/hypobromite ion. Hypobromous acid/hypobromite ion are intermediates formed as byproducts of the reaction of either ozone or hypochlorous acid/hypochlorite ion with bromide ion. If not removed from the sample matrix, further reactions may form bromate ion. The reactions can be prevented by adding 50 mg of ethylenediamine (EDA)/L of sample. This is the preservation technique specified in the other methods both approved and proposed for bromate compliance analyses. The fortified drinking water samples analyzed in the second laboratory validation study of EPA Method 321.8 (Day *et al.* 2001) and the Information Collection Rule samples that were analyzed using the SAC method and EPA Method 321.8 were preserved with EDA, thus demonstrating that EDA can be used in samples analyzed by IC/ICP–MS. EPA believes that adding this sample preservation requirement to EPA Method 321.8 will help ensure sample integrity. It will also simplify the sampling protocols that water systems must follow, because all sampling for bromate, regardless of the method employed to analyze the sample, will require the same sample preservation technique.

EPA Method 321.8 does not include information concerning how long a sample may be stored prior to analysis. EPA is proposing to specify a maximum of 28 days for the sample holding time. This would make the method consistent with the other bromate methods proposed today and the method that is currently approved.

g. *EPA 415.3 for TOC and SUVA (DOC and UV_{254})*. Today's rule proposes to add EPA Method 415.3 (USEPA 2003r) as an approved method for TOC and SUVA. The Stage 1 DBPR included three Standard Methods for TOC and one method for UV_{254}. Additional quality control (QC) requirements were included for these measurements, because the methods did not contain the necessary criteria. The rule included instructions for calculating SUVA based on UV_{254} and DOC analyses. The new EPA Method 415.3 includes the additional QC necessary to achieve reliable determinations for TOC, DOC, and UV_{254}. It describes a procedure for removing inorganic carbon from the sample prior to the organic carbon analysis. The method uses the same technologies as already approved. The advantage of this new method is that it documents the precision and accuracy that can be expected when proper QC procedures are implemented and it places all the necessary information for SUVA in one place.

EPA Method 415.3 provides sensitivity, precision and accuracy data for TOC and DOC measured using five different technologies:

(1) Catalyzed 680°C combustion oxidation of organic carbon to carbon dioxide (CO_2) followed by nondispersive infrared detection (NDIR).

(2) High temperature (700 to 1100°C) combustion oxidation followed by NDIR.

(3) Elevated temperature (95–100°C) catalyzed persulfate digestion of organic carbon to CO_2 followed by NDIR.

(4) UV catalyzed persulfate digestion followed by NDIR.

(5) UV catalyzed persulfate digestion followed by membrane permeation into a conductivity detector.

These technologies are included in the currently approved Standard Methods 5310 B and 5310 C (APHA, 1996). The new method indicates these technologies can provide detection limits between 0.02 mg/L and 0.12 mg/L. Accuracy and precision data from analyses of fortified reagent water and natural waters indicate the technologies can produce acceptable data for determining compliance with the treatment technique for control of disinfection byproduct precursors specified in § 141.135. Seven natural waters were fortified with organic carbon from potassium hydrogen phthalate and analyzed by each of the five technologies. The average recoveries ranged from 97% to 103% for TOC and 98% to 106% for DOC.

The method presents data from the analyses of seven different waters and demonstrates that comparable analytical results are obtained regardless of the technology used as long as all inorganic carbon is removed from the sample prior to the analysis. The samples ranged in concentration from 0.4 to 3.6 mg/L and the relative standard deviations across the analyses ranged from 35% RSD (for the lowest concentration sample) to ≤13% RSD for the remainder of the samples.

EPA Method 415.3 includes a procedure to ensure that inorganic carbon does not interfere with the organic carbon analyses. Since this is critical to obtaining accurate organic carbon determinations, EPA is proposing to add a requirement at §§ 141.131(d)(3) and (4)(i) to remove inorganic carbon prior to performing TOC or DOC analyses. Laboratories will have the option of using the procedure described in EPA Method 415.3 or verifying that the process used by their TOC instrument adequately removes the inorganic carbon prior to the organic carbon measurement. Determination of organic carbon by subtracting the inorganic carbon from the total carbon is not acceptable for compliance purposes, because the percentage of inorganic carbon is usually large in relation to the organic carbon of the sample and the subtraction process introduces a large potential for error.

The manufacturer of one of the instruments that was used during the development of EPA Method 415.3 recommends that hydrochloric acid be used to acidify TOC and DOC samples prior to analysis. EPA confirmed that use of this acid is critical for proper operation of the instrument. However, use of hydrochloric acid is in conflict with the current regulation at §§ 141.131(d)(3) and (4)(i) which specify phosphoric or sulfuric acid. The type of acid used to preserve samples and to treat the samples to remove inorganic carbon prior to the organic carbon analysis should be based on the analytical method or the instrument manufacturer's specification. Therefore, EPA is proposing to remove the specification of acid type from §§ 141.131(d)(3) and (4)(i).

EPA Method 415.3 specifies that TOC samples be acid preserved at the time of collection in order to prevent microbial degradation of the organic carbon. This is consistent with the sampling instructions in the currently approved methods (Standard Methods 5310 B, 5310 C, and 5310 D). EPA proposes to amend § 141.131(d)(3) by removing the phrase ''not to exceed 24 hours'' in the description of when samples must be preserved, so that the rule is consistent with the method specifications.

Analyses for both DOC and UV_{254} are required for a SUVA determination. The DOC measurement is identical to the TOC measurement after the sample is filtered through a 0.45 μm pore size filter. The filtration step must be

performed using a prewashed filter in order to eliminate positive interferences from material that can leach from improperly cleaned filters. EPA Method 415.3 contains a description of how to properly rinse the filters and how to verify that the filter blank is acceptable. The method demonstrates that it is feasible to have a filter blank with a DOC concentration <0.2 mg/L. The method also provides performance data for DOC.

The UV_{254} analysis that is part of the SUVA determination is also described in EPA Method 415.3. As with the DOC measurement, the UV_{254} analysis is performed on a sample that has been filtered through a prewashed 0.45 µm pore size filter. In addition to verifying that the filter blank is low enough, the method also includes a spectrophotometer check procedure to ensure that the spectrophotometer is operating properly.

4. What Additional Regulated Contaminants Can Be Monitored by Extending Approval of EPA Method 300.1?

In addition to bromate, chlorite, and bromide, EPA Method 300.1 (USEPA 2000l) can also be used to determine chloride, fluoride, nitrate, nitrite, orthophosphate, and sulfate in drinking water. A comparison of the performance of EPA Method 300.1 to the currently approved EPA Method 300.0 (USEPA 1993) is shown in Table V–18 and demonstrates that EPA Method 300.1 provides comparable or better precision, accuracy, and sensitivity for these contaminants based on the single laboratory data presented in each method.

TABLE V–18.—COMPARISON OF EPA METHODS 300.0 AND 300.1

QC parameter	Chloride	Fluoride	Nitrate	Nitrite	Phosphate-P	Sulfate
Precision (Max % RSD in fortified water samples) [1]						
EPA 300.0	5.7	18	4.8	3.6	3.5	7.1
EPA 300.1	0.22	0.85	0.41	0.77	4.7	0.39
Accuracy (Range of % Recoveries in fortified water samples) [2]						
EPA 300.0	86–114	73–95	93–104	92–121	95–99	95–112
EPA 300.1	93–98	80–89	88–96	72–87	61–92	89
Detection Limit (mg/L) [3]						
EPA 300.0	0.02	0.01	0.002	0.004	0.003	0.02
EPA 300.1	0.004	0.009	0.008	0.001	0.019	0.019

[1] The highest relative standard deviation (%RSD) reported in the method for replicate analyses of fortified water samples in a single laboratory.
[2] The range of recoveries reported for replicate analyses of fortified water samples in a single laboratory as shown in the method.
[3] The detection limit as determined by analyzing seven or more replicates of reagent water that is fortified with low concentrations of the anions. The standard deviation of the mean concentration for each analyte is calculated and multiplied by the student's t-value at 99% confidence and n-1 degrees of freedom (3.143 for 7 replicates).

EPA is proposing to extend approval of EPA Method 300.1 for fluoride, nitrate, nitrite, and orthophosphate (§ 141.23(k)(1)) and for chloride and sulfate (§ 143.4(b)) even though these contaminants are not addressed in today's proposed rule. As discussed before for dalapon, EPA believes that extending approval to all the regulated contaminants covered in a method provides greater flexibility to laboratories and allows them to reduce analytical costs. EPA recognizes that laboratories will probably not be determining concentrations of these non-DBP anions for compliance purposes in the same samples as used for chlorite or bromate compliance monitoring. However, EPA believes allowing the same method to be used even if the samples are not the same is more cost effective for laboratories. EPA is not proposing to withdraw any methods for the non-DBP anions, because that would place an unnecessary burden on laboratories that do not need to use EPA Method 300.1.

5. Which Methods in the 20th Edition and 2003 On-Line Version of Standard Methods Are Proposed for Approval?

The Stage 1 DBPR approved eight methods (4500–Cl D, 4500–Cl F, 4500–Cl G, 4500–Cl E, 4500–Cl I, 4500–Cl H, 4500–ClO_2 D, and 4500–ClO_2 E) for determining disinfection residuals from the 19th edition of Standard Methods (APHA, 1995). *Standard Methods* 6251 B and 4500–ClO_2 E in the 19th edition of *Standard Methods* (APHA, 1995) were approved for HAA5 and daily chlorite analyses, respectively. Three TOC methods (5310 B, 5310 C, and 5310 D) from the Supplement to the 19th edition of *Standard Methods* (APHA, 1996) and one UV_{254} method (5910 B) from the 19th edition of *Standard Methods* (APHA, 1995) were also approved in the Stage 1 DBPR.

These thirteen methods are unchanged in the 20th edition of *Standard Methods* (APHA, 1998), so EPA proposes to cite the 20th edition for these analyses in addition to the 19th editions.

The On–Line Version of *Standard Methods* is an effort to provide the consensus methods to the public prior to the release of the next full publication. Standard Methods is making sections of the next version available for purchase in both electronic or printed format. EPA has reviewed the applicable sections and determined that ten of the methods are identical to the currently approved versions from the 19th editions. Section 4500–Cl contains the methods for determining chlorine residuals and it includes the 4500–Cl D, 4500–Cl F, 4500–Cl G, 4500–Cl E, 4500–Cl I, and 4500–Cl H. Section 4500–ClO_2 contains the methods for determining chlorine dioxide residuals and chlorite and it includes method 4500–ClO_2 E. Section 5310 contains the methods for determining TOC and it includes methods 5310 B, 5310 C, and 5310 D. Because the ten listed methods in these sections are unchanged from the versions that were published in the 19th editions, EPA is proposing to cite the On–Line Version for these analyses in

addition to the currently approved 19th editions and the proposed 20th edition.

Section 6251 includes method 6251 B for HAA5. The method has been updated for the On–Line Version to include precision and accuracy data from the Information Collection Rule and the sample holding time has been extended from 9 days to 14 days. The additional quality control data does not technically change the method from the previously approved version in the 19th edition; it simply demonstrates the performance that can be expected when the method is used. The change in sample holding time is consistent with EPA's proposal to standardize the HAA5 sample holding time at 14 days (*See* discussion in section V.O.7). Thus EPA is proposing to cite the On–Line Version for this analysis in addition to the currently approved 19th edition and the proposed 20th edition.

Section 5910 includes method 5910 B for determining UV_{254}. The method has been updated for the On–Line Version to include precision data from the Information Collection Rule. Because the additional quality control data does not technically change the method from the previously approved version in the 19th edition, EPA is proposing to cite the On–Line Version for this analysis in addition to the currently approved 19th edition and the proposed 20th edition.

The On–Line Version of *Standard Methods* will not include method 4500–ClO_2 D, so it is not being proposed with the other twelve methods cited in the On–Line Version.

EPA is proposing to add a citation to the 20th edition and the On–Line Version of *Standard Methods* for thirteen and twelve methods, respectively. EPA believes these should be cited in addition to the 19th editions in order to allow flexibility for the water systems performing the analyses. Withdrawal of the older editions would require all systems to purchase one of the newer editions, which could impose an unnecessary burden on systems that use the reference for only a few methods.

6. What Is the Updated Citation for EPA Method 300.1?

EPA Method 300.1 (USEPA 2000l) for bromate, chlorite and bromide is now included in an EPA methods manual that was published August 2000. The manual titled ''Methods for the Determination of Organic and Inorganic Compounds in Drinking Water'' is a compilation of methods developed by EPA for drinking water analyses. EPA Method 300.1 was previously only available as an individual method. EPA proposes to update the bromate, chlorite, and bromide citation for this method to the August 2000 methods manual in today's rule so that the users are directed to the correct source of the method.

7. How Is the HAA5 Sample Holding Time Being Standardized?

The analytical methods approved for HAA5 compliance monitoring (EPA 552.1, EPA 552.2, and Standard Method 6251 B) all specify the use of ammonium chloride to eliminate the free chlorine residual in samples and they require samples be iced/refrigerated after collection. Even though the sampling parameters agree in the three methods, the methods specify different sample holding times (time between sample collection and extraction). EPA Methods 552.1 (USEPA 1992) and 552.2 (USEPA 1995) allow at least 14 days while Standard Method 6251 B (APHA 1995 and 1998) specifies that samples must be extracted within nine days of sample collection. The holding time for the Standard Method is based on data which indicated an increase in DCAA concentration to slightly greater than 120% of the initial concentration after the sample was stored for 14 days (Krasner *et al.* 1989). All other HAA5 compounds were well within the 80–120% criteria set by the researchers. The decision was made to use a conservative approach to be sure that the concentrations of all HAAs were stable, and nine days was the closest data point to the 14 day–data point in question. Subsequent to Krasner's study, EPA conducted additional sample holding time studies as part of the EPA methods development process. EPA has published data to support the 14–day sample holding time for the HAA5 compounds (Pawlecki–Vonderheide *et al.* 1997; USEPA 2003p). Since there is no technical reason for the holding times to be different between the HAA5 methods addressed in this rule, EPA proposes to allow a 14–day sample holding time for samples being analyzed by Standard Method 6251 B. This would provide consistency across methods and it would simplify sampling considerations for water systems. EPA is only proposing to standardize the holding time allowed for the samples. Due to differences in the sample preparation (*i.e.*, extraction) procedures in the various methods, the extract holding times cannot be standardized. Laboratories must follow the individual method requirements when determining storage conditions and holding times for the extracts.

EPA Method 552.1 specifies a 28–day holding time for HAA samples. This was based on studies conducted on fortified reagent water samples rather than drinking water samples. Because HAAs have been shown to biodegrade in some distribution systems (Williams *et al.* 1995), EPA believes that some samples may not be stable for 28 days. Today's rule proposes reducing the holding time to 14 days when EPA Method 552.1 is used in order to better ensure sample stability. During the Information Collection Rule, EPA only allowed the 14–day sample holding time for all HAA samples (regardless of the method used to analyze the samples), so laboratories and water systems have demonstrated their capability to implement this method change.

EPA believes that by standardizing the sample holding times allowed in the various HAA5 methods, the burden for laboratories and water systems will be reduced. Sampling considerations will be simplified, because all HAA5 samples will be collected and stored the same way.

8. How Is EPA Clarifying Which Methods Are Approved for Magnesium Determinations?

The Stage 1 DBPR allows systems practicing enhanced softening that cannot achieve the specified level of TOC removal, to meet instead one of several alternative performance criteria, including the removal of 10 mg/L magnesium hardness (as CaCO3) from the source water. Analytical methods for measuring magnesium hardness were not included in the rule, but they were later promulgated in a Methods Update Rule (USEPA 1999b). The December 1999 Methods Rule cited the magnesium methods at § 141.23(k)(1), but it did not identify that these methods were to be used to demonstrate compliance with the alternative performance criteria specified in § 141.135(a)(3)(ii). EPA is proposing to clarify this today by referencing the approved magnesium methods at § 141.131(d)(6) and § 141.135(a)(3)(ii).

9. Which Methods Can Be Used To Demonstrate Eligibility for Reduced Bromate Monitoring?

Today's rule proposes to change the monitoring requirements for demonstrating eligibility to reduce bromate monitoring from monthly to quarterly. The Stage 1 DBPR allows the monitoring to be reduced if the system demonstrates that the average source water bromide concentration is less than 0.05 mg/L based upon monthly bromide measurements for one year. Today's rule proposes to change that requirement to a demonstration that the finished water

bromate concentration is <0.0025 mg/L as a running annual average. If this change is implemented, there will no longer be a need for bromide compliance monitoring methods. EPA is proposing additional bromide methods today in order to provide flexibility to the laboratories and water systems in the interim period before the Stage 2 DBPR compliance monitoring requirements becomes effective.

In order to qualify for reduced bromate monitoring, EPA is proposing that the samples must be analyzed for bromate using either EPA Method 317.0 Revision 2.0 (UV/Vis detector), EPA Method 326.0 (UV/Vis detector), or EPA Method 321.8. These three methods can provide quantitative data for bromate concentrations as low as 0.001 mg/L, thus ensuring that a bromate running annual average of <0.0025 mg/L can be reliably demonstrated. Laboratories that analyze samples by these three methods must report quantitative data for bromate concentrations as low as 0.001 mg/L.

Since EPA Methods 317.0 Revision 2.0, 326.0, and 321.8 offer significantly greater sensitivity for bromate analyses, EPA considered whether these should be the only methods approved for bromate compliance monitoring. However, the new methods using postcolumn reactions with UV/Vis detection (EPA Methods 317.0 Revision 2.0 and 326.0) or IC/ICP–MS (EPA Method 321.8) require greater analyst skill than is necessary for the standard ion chromatographic (IC) methodology (EPA Method 300.1 and ASTM Method D 6581–00). They also require instrumentation that may not be currently owned by many laboratories that perform bromate analyses. As a result of these factors and because the standard IC methods are adequate for determining compliance with the bromate MCL that was promulgated as part of the Stage 1 DBPR, EPA decided not to propose withdrawal of the currently approved method (EPA Method 300.1). In addition, EPA decided to propose ASTM Method D 6581–00, because it is equivalent to EPA Method 300.1. EPA strongly encourages laboratories to expand their services by adding the capability to perform analyses using one of the more sensitive methods for bromate. EPA believes that there will be a shift to the more sensitive methods as water systems realize that the analytical capabilities are available for a slightly increased analytical cost. (The ability to determine bromate concentrations as low as 1 μg/L will provide water systems more information concerning the optimization of ozone application to control for bromate formation.)

10. Request for Comments

EPA requests comments on whether the methods proposed today should be approved for compliance monitoring.

EPA solicits comments as to whether standardizing the sample holding times for the HAA5 methods is appropriate. Specifically, should the sample holding time for Standard Method 6251 B be extended from 9 days to 14 days and should the sample holding time for EPA Method 552.1 be shortened from 28 days to 14 days?

EPA requests comments as to whether laboratories should be required to switch to one of the more sensitive bromate methods for compliance monitoring sample analyses. Should EPA Method 300.1 be withdrawn as a compliance monitoring method for bromate and be replaced by EPA Methods 317.0 Revision 2.0, 326.0, and 321.8 which provide reliable data for bromate concentrations as low as 1μg/L?

P. Laboratory Certification and Approval

1. What Is EPA Proposing Today?

EPA recognizes that the effectiveness of today's proposed regulation depends on the ability of laboratories to reliably analyze the regulated disinfection byproducts at the proposed MCLs. EPA has established a drinking water laboratory certification program that States must adopt as part of primacy. Laboratories must be certified in order to analyze samples for compliance with the MCLs. EPA has also specified laboratory requirements for analyses, such as alkalinity, bromide, disinfectant residuals, magnesium, TOC, and SUVA, that must be conducted by parties approved by EPA or the State. EPA's ''Manual for the Certification of Laboratories Analyzing Drinking Water'' (USEPA 1997b) specifies the criteria that EPA uses to implement the drinking water laboratory certification program. Today's proposed rule maintains the requirements of laboratory certification for laboratories performing analyses to demonstrate compliance with MCLs and all other analyses to be conducted by approved parties. It revises the acceptance criteria for performance evaluation (PE) studies and proposes reporting limits for the DBPs as part of the certification program. Today's rule also proposes that TTHM and HAA5 analyses that are performed for the IDSE or system-specific study be conducted by laboratories certified for those analyses.

2. What Changes Are Proposed for the PE Acceptance Criteria?

The Stage 1 DBPR specified that in order to be certified the laboratory must pass an annual performance evaluation (PE) sample approved by EPA or the State using each method for which the laboratory wishes to maintain certification. The acceptance criteria for the DBP PE samples were set as statistical limits based on the performance of the laboratories in each study. This was done because EPA did not have enough data to specify fixed acceptance limits.

Subsequent to the 1998 promulgation, EPA evaluated the results for the EPA Water Supply (WS) PE studies and the Information Collection Rule PE studies to determine if fixed acceptance limits could now be applied. (Fixed limits were used during the Information Collection Rule).

Four different fixed limits (±20%, ±30%, ±40%, and ±50% of the true value) were applied to each analyte in the WS PE study TTHM, HAA5, bromate, and chlorite samples. Successful analysis of the sample was defined as passing all four THMs individually in the TTHM PE sample; passing four of the five HAAs in the HAA5 PE sample; and passing bromate and chlorite individually. The number and percentage of laboratories that successfully passed each study sample were determined for the four fixed limits. These results were then evaluated to determine how narrow the criteria could be set in order to achieve accurate data and also provide enough certified laboratories to meet the capacity needs. Only the last six WS PE Studies administered by EPA (WS36–WS41 conducted between 1996–1998) were used in the final recommendation, because they provided a better estimate of current laboratory capabilities. Table V–19 summarizes the results of this WS PE Study evaluation.

The number of laboratories that analyzed WS TTHM PE samples was significantly larger than for the other DBPs, because a laboratory certification program for TTHM has been in effect since the promulgation of the THM rule in 1979 (USEPA 1979). Most of the analytical methods for TTHM have been in use for many years, and the laboratories are experienced in their use. The Stage 1 DBPR established the first requirements to monitor for the other DBPs and certification was not required until December 2001. Therefore, the WS PE results for HAA5, chlorite, and bromate were from laboratories that were not part of a certification process and the laboratories

were using methods that were relatively new. In addition, the method used for bromate during the WS studies was EPA Method 300.0 which was replaced by EPA Method 300.1 in the Stage 1 DBPR, because Method 300.1 is more sensitive. Laboratories would be expected to have greater success in passing the bromate PE samples using Method 300.1 and the bromate methods that are being proposed in today's rule.

TABLE V–19.—FIXED LIMIT EVALUATION OF WS PE STUDIES 36—41

[Average # and % of labs successfully completing studies]

DBP Sample	±20% of TV		±30% of TV		±40% of TV		±50% of TV	
	#Labs	%Labs	#Labs	%Labs	#Labs	%Labs	#Labs	%Labs
TTHM	609	73	731	88	773	93	788	94
HAA5 [1]	50	37	83	61	103	75	115	84
chlorite	55	63	68	78	72	82	74	85
bromate	45	50	52	57	57	64	60	68

[1] Study 38 was excluded from this analysis, because a valid DCAA true value was not available for the HAA sample.

Based on the results from the analyses described previously, EPA believes it is reasonable to set the TTHM acceptance criteria at ±20% around the study true values. The number of laboratories capable of performing TTHM analyses is large and the results described previously show that in the time frame of 1996–1998, over 70% of the laboratories could successfully meet the ±20% criteria. The PE studies conducted during the Information Collection Rule used the same acceptance criteria (USEPA 1996b).

The data indicate that ±40% are probably the tightest criteria that could be used to evaluate HAA5 PE samples. Setting this criteria balances the need for approval of enough labs to meet monitoring capacity and the need to provide data of acceptable accuracy. The ±40% criteria is consistent with the Information Collection Rule PE study acceptance criteria and it is tighter than the criteria established in the Stage 1 DBPR. During the Information Collection Rule, laboratories that were approved using the ±40% criteria were able to provide accurate and precise data as evidenced by the quality control data collected when the Information Collection Rule samples were analyzed (Fair *et al.* 2002). Of the 1,250 Information Collection Rule samples that were fortified with known amounts of HAAs, the median recovery was 103% and the recoveries ranged between 89% and 120% in 80% of the fortified samples. There were 1,211 Information Collection Rule samples that were analyzed in duplicate and the median relative percent difference for those HAA5 analyses was 4%. Ninety percent of the analyses had RPDs less than 21%. EPA believes laboratories that are certified using the ±40% criteria in PE studies should be capable of performing at a level comparable to the Information Collection Rule laboratories.

EPA believes chlorite PE samples should be evaluated using a ±30% criteria. Over 70% of the laboratories could meet this requirement for chlorite in the WS studies.

The percentage of passing labs for bromate is almost 60% when a ±30% criteria is applied to the WS study data. Since the data do not accurately reflect the bromate methods that are now being used by laboratories, EPA believes a greater percentage of laboratories would pass the bromate PE study using today's technology. Unfortunately, EPA does not have the data to verify this assumption, because EPA no longer conducts PE studies. Even if the assumption is flawed, a 57% acceptance rate would still provide enough certified laboratories to handle the number of bromate samples required for compliance monitoring under the Stage 1 DBPR.

The proposed acceptance criteria are listed in Table V–20.

TABLE V–20.—PROPOSED PERFORMANCE EVALUATION (PE) ACCEPTANCE CRITERIA

DBP	Acceptance limits (percent)	Comments
TTHM		
Chloroform	±20	Laboratory must meet all 4 individual THM acceptance limits in order to successfully pass a PE sample for THMs.
Bromodichloromethane	±20	
Dibromochloromethane	±20	
Bromoform	±20	
HAA5		
Monochloroacetic Acid	±40	Laboratory must meet the acceptance limits for 4 out of 5 of the HAA5 compounds in order to successfully pass a PE sample for HAA5.
Dichloroacetic Acid	±40	
Trichloroacetic Acid	±40	
Monobromoacetic Acid	±40	
Dibromoacetic Acid	±40	
Chlorite	±30	
Bromate	±30	

EPA is also proposing that the PE acceptance limits described previously become effective within 60 days of promulgation of the final rule. This will allow the laboratory certification program to implement the fixed limits as soon as possible. Laboratories that were certified under the Stage 1 PE acceptance criteria would be subject to the new criteria when it is time for them to analyze their annual DBP PE samples(s).

3. What minimum reporting limits are being proposed?

The Consumer Confidence Reports Rule (USEPA 1998i) requires that all detected regulated contaminants be reported in the annual reports, but detection is not defined for the DBP contaminants. This rule addresses the deficiency by proposing reporting limits for the regulated DBPs.

Laboratories that analyze compliance samples must be able to reliably measure the DBPs at concentrations below the MCL. Laboratories must also be able to measure the individual TTHM and HAA5 compounds at levels that are much lower than the MCLs for these compound classes, because the MCLs are based on the sum of the individual compound concentrations.

Historically, EPA has used practical quantitation levels to estimate the lowest concentration at which laboratories can be expected to provide data within specified limits of precision and accuracy during routine operating conditions (USEPA 1985). The estimates are based on PE data, if available, or are set at five or ten times the method detection level.

In today's rule, EPA is proposing an alternate approach for establishing the lowest concentration for which laboratories are expected to report quantitative data for DBPs. The approach is based on a unique data set from the Information Collection Rule. Laboratories were required to meet specific quality control criteria when they analyzed samples for the Information Collection Rule. The rule established a regulatory minimum reporting level (MRL) for each analyte and laboratories were required to demonstrate they could accurately measure at these concentrations each time a set of samples was analyzed. The regulatory MRLs were based on recommendations from experts who were experienced in DBP analyses and were set at concentrations for which most laboratories were expected to be able to meet the precision and accuracy criteria under normal operating conditions. Most samples were also expected to contain concentrations greater than the specified MRLs.

EPA evaluated the data from the Information Collection Rule to determine if the laboratories were able to reliably measure down to the required MRL concentrations. Precision and accuracy data from the calibration check standards prepared at the MRL concentrations (listed in Table V–21) were examined. The data indicated most laboratories were able to provide quantitative data for samples with these concentrations.

Because laboratories demonstrated the capability to meet the Information Collection Rule MRLs, EPA believes it is reasonable to expect similar performance during the analyses of DBP compliance monitoring samples. In today's rule, EPA is proposing to incorporate MRL requirements into the laboratory certification program for DBPs and to use regulatory MRLs as the minimum concentrations that must be reported as part of the Consumer Confidence Reports (§ 141.151(d)).

TABLE V–21.—PROPOSED MINIMUM REPORTING LEVEL (MRL) REQUIREMENTS

DBP	MRL (μg/L)		Comments
	Information collection rule	Proposed stage 2 DBPR	
TTHM			
Chloroform	1.0	1.0	
Bromodichloromethane	1.0	1.0	
Dibromochloromethane	1.0	1.0	
Bromoform	1.0	1.0	
HAA5			
Monochloroacetic Acid	2.0	2.0	
Dichloroacetic Acid	1.0	1.0	
Trichloroacetic Acid	1.0	1.0	
Monobromoacetic Acid	1.0	1.0	
Dibromoacetic Acid	1.0	1.0	
Chlorite	20.0	200.0	
Bromate	5.0	5.0 or 1.0	Laboratories that use EPA Methods 317.0 Revision 2.0, 326.0, or 321.8 must meet a 1.0 μg/L MRL for bromate.

As part of the request for certification, EPA is proposing to require laboratories to demonstrate they can reliably measure concentrations at least as low as the ones listed in Table V–21 in order to be certified for those parameters. This would mean that the calibration curve must encompass the proposed regulatory MRL concentration and that the laboratory must verify the accuracy of the calibration curve at the lowest concentration for which quantitative data are reported by analyzing a calibration check standard at that concentration prior to analyzing each batch of samples. (Laboratories would analyze a check standard at the specified MRL concentration daily or each time samples are analyzed.) The measured concentration for this check standard must be within ±50% of the expected value. Laboratories may choose to report quantitative data at concentrations lower than the proposed regulatory MRLs as long as the required accuracy criteria (±50% of the expected value) is met by daily analyzing standards at the lowest reporting limit chosen by the laboratory.

Laboratories were not given the opportunity to report concentrations lower than the specified MRLs during the Information Collection Rule. Some laboratories indicated they have met the precision and accuracy criteria at lower concentrations, so EPA believes that each laboratory should have the flexibility to continue using its own reporting limits as long as the laboratory MRLs are not higher than the regulatory ones proposed in this rule. This flexibility would minimize the cost of implementing the regulatory MRL requirements, because the laboratory would not have to make changes in its established quality control procedures unless its procedures are less stringent than those being proposed today. Requiring a laboratory to adopt regulatory MRLs that are higher than the laboratory reporting limits currently in

use offers no advantage and could increase analytical costs. The capability to provide quantitative data at the laboratory's MRL or the regulatory MRL would need to be demonstrated on a daily basis by analyzing a check standard at that concentration and by achieving a recovery in the range of 50 to 150%.

The proposed regulatory MRL for MCAA is 2.0 μg/L based on the Information Collection Rule performance data. However, MCAA was not present at concentrations higher than this in more than half of the samples analyzed for HAAs during the Information Collection Rule (USEPA 2003o). Some laboratories reported that they could have provided quantitative data for MCAA down to concentrations as low as 1.0 μg/L.

EPA is proposing a regulatory MRL for chlorite that is much higher than can easily be achieved using the approved or proposed methods. The MRL specified during the Information Collection Rule was 20. μg/L and laboratories were able to successfully obtain quantitative data at that level. However, in the context of this rule, EPA believes that requiring laboratories to verify their calibration curves down to 20. μg/L each time samples are analyzed is unnecessary. This is because chlorite analyses are only performed on samples from water plants that use chlorine dioxide and most of the applied chlorine dioxide is converted to chlorite, so the concentrations that are expected in most compliance monitoring samples will be much higher than 20. μg/L. (The Information Collection Rule data showed a median chlorite concentration of 380 μg/L in the finished water and 333 μg/L as the distribution system average in systems using chlorine dioxide (USEPA 2003o).) EPA is proposing a regulatory MRL of 200. μg/L for chlorite, because most of the samples are expected to contain concentrations higher than 200. μg/L. The MCL for chlorite is 1.0 mg/L (1,000 μg/L). EPA recognizes that setting the regulatory MRL for chlorite based on the concentrations expected to be found in the samples rather than the sensitivity of the analytical method is inconsistent with the approach taken for other compounds in this rule. Nevertheless, EPA believes setting the MRL based on occurrence information is appropriate because it will not compromise the compliance data. Water systems would have the option of requiring that laboratories establish a lower reporting limit when their samples are analyzed and EPA would encourage this in cases in which the samples consistently contain chlorite concentrations that are <200. μg/L. If a lower reporting limit is used, then the laboratory will be required to meet the precision and accuracy requirements at that lower concentration by daily successfully analyzing a check standard at the laboratory reporting limit concentration prior to analyzing compliance samples. EPA believes very few water systems will request more sensitive chlorite analyses, because their samples won't have low enough concentrations to require it.

EPA is proposing two regulatory MRLs for bromate analyses in today's rule. This is because the traditional ion chromatographic (IC) methods using conductivity detection (EPA Method 300.1 and ASTM Method 6581–00) are only capable of quantitating down to 5.0 μg/L while the new IC methods using either post column reactions with UV/Vis detection (EPA Methods 317.0 Revision 2.0 and 326.0) or IC followed by ICP–MS detection (EPA Method 321.8) can reliably quantitate bromate concentrations as low as 1.0 μg/L. EPA believes it is appropriate to set the regulatory MRL based on the capability of the method. (EPA has published detection limits for inorganic contaminants based on method capability (§ 141.23(a)(4)(i)), so the approach proposed today is consistent with previous regulations.) If the regulatory MRL is based on the most sensitive method, then the routine IC methods could no longer be used even though they are adequate for demonstrating compliance with the bromate MCL. If the regulatory MRL is set using the least sensitive method, then the feasibility for reduced bromate monitoring based on a running annual average of <0.0025 μg/L (<2.5 μg/L) would not be adequately demonstrated based on data reported with a reporting limit of 5.0 μg/L.

EPA is proposing MRLs as part of the certification process. Laboratories would be required to demonstrate they can reliably quantitate at the specified MRL concentration when their current DBP certification is subject to renewal or if they are applying for certification for DBP methods for the first time. (Demonstration would be accomplished by providing precision and accuracy data from the analyses of check standards at or below the regulatory MRL concentration over a several day period. The laboratory's standard operating procedure for HAA5 analyses would include a requirement to daily meet the MRL accuracy criteria for a check standard at or below the regulatory MRL concentration.) Although ensuring laboratories can meet the regulatory MRLs is a new certification requirement, EPA does not believe this significantly increases the time required to review a laboratory prior to certification. Each DBP method requires the laboratory to generate a similar set of data at a higher concentration and to meet specific accuracy and precision criteria as part of the initial demonstration of laboratory capability to perform the method; review of the MRL data set will be comparable to what is already being done. This new requirement will ensure that laboratories can reliably analyze samples that contain low concentrations of DBPs on an on-going basis.

EPA is also proposing to require the regulatory MRLs be used for compliance reporting by the Public Water Systems. Finally, the regulatory MRLs would be used when Public Water Systems inform customers of their water quality relative to DBP concentrations in the annual Consumer Confidence Reports.

4. What Are the Requirements for Analyzing IDSE Samples?

EPA is proposing that the TTHM and HAA5 samples collected for the Initial Distribution System Evaluations (IDSE) and the system specific studies conducted in lieu of IDSEs be analyzed by certified laboratories. EPA recognizes that this will require additional laboratory capacity during the time period in which these studies are conducted. The largest challenge will be in developing the capacity to analyze the samples for the water systems that must complete the studies, analyze the data, and recommend Stage 2 DBP sampling sites within two years of the promulgation date of the rule. However, EPA believes commercial laboratories, in particular, will be able to expand their capacity to meet the demand based in the information presented below.

Assuming no waivers or system-specific studies, the number of IDSE samples is estimated to be between 14,000 and 21,000 per month in the first round of IDSE monitoring, depending on whether the monitoring requirements are based on population or number of treatment plants, respectively. Laboratories should easily be able to accommodate this increase in TTHM samples, because experience performing TTHM analyses is spread across a large number of laboratories. Hundreds of laboratories have been certified for TTHM analyses, since certification was first required in 1979. There were close to 600 laboratories certified to perform TTHM analyses in 1991. In the 1996–1998 period, there were over 800 laboratories participating in the PE studies for TTHMs and 600 of those laboratories were capable of meeting the

TTHM PE acceptance criteria proposed in today's rule. Many water system laboratories are certified to perform TTHM analyses and will be able to incorporate the IDSE TTHM samples from their systems into the laboratory schedule. It is reasonable to expect that commercial laboratories will be able to handle the remainder of the TTHM samples. (EPA does not have a current estimate of the number of laboratories certified to perform TTHM analyses. However, if the number of IDSE samples from large systems was evenly spread over the 600 laboratories that were certified in 1991, this would be less than 40 additional samples per month for each laboratory. Analysis of 40 TTHM samples would involve less than two days of analyst and instrument time which does not seem unreasonable for commercial laboratories to accommodate.)

Analyses of the HAA5 samples will present a greater challenge, because certification is relatively new for this measurement. EPA anticipates that most of the HAA5 samples will be analyzed by commercial and State laboratories, because the methods are more complex than the TTHM analyses and monitoring was not widely required until January 2002. Laboratories were not required to be certified to perform HAA5 analyses until January 2002. However, the PE Study results from 1996–1998 indicate that over 130 laboratories were performing HAA5 analyses during that time frame and approximately 100 of those laboratories were capable of meeting the HAA5 PE acceptance criteria proposed in today's rule. Ninety-four laboratories were approved to perform HAA analyses during the Information Collection Rule; twenty-seven of them were commercial laboratories and nine were State laboratories. EPA anticipates that large commercial laboratories already certified to perform HAA5 analyses will recognize this market potential and add staff and instrumentation to accommodate the increased demand.

Most systems serving <10,000 people will not begin their IDSE studies until after the large systems have completed their studies. Even though the potential number of samples is greater, the small systems have two additional years in which to complete their studies, so there is more opportunity to schedule the sampling in such a manner that laboratory capacity is maintained. The laboratory capacity should be readily available by the time analyses of these samples are required.

5. Request for Comments

EPA requests comments concerning the appropriateness of the proposed PE acceptance criteria.

EPA solicits comments as to whether an MRL lower than 2 μg/L is feasible for MCAA and if so, what should that MRL concentration be?

EPA requests comments concerning whether the MRL for chlorite should be based on the sensitivity of the method (*i.e.*, 20. μg/L) or on the expected concentration range of the samples (*i.e.*, 200. μg/L).

EPA solicits comments concerning which MRL approach should be considered for bromate. Specifically, should EPA set the MRL based on the capability of the method which would mean that two different MRLs are defined or should one MRL be established based on either the least or most sensitive method?

EPA requests comments concerning the appropriateness of the MRL certification requirements and whether additional certification requirements should be considered.

EPA solicits comments on the availability of laboratory capacity to perform TTHM and HAA5 analyses for IDSE studies.

VI. State Implementation

This section describes the regulations and other procedures and policies States would have to adopt to implement the Stage 2 DBPR, if finalized as proposed today. States must continue to meet all other conditions of primacy in 40 CFR part 142.

The SDWA establishes requirements that a State or eligible Indian Tribe must meet to assume and maintain primary enforcement responsibility (primacy) for its public water systems. These SDWA requirements include: (1) adopting drinking water regulations that are no less stringent than Federal drinking water regulations, (2) adopting and implementing adequate procedures for enforcement, (3) keeping records and making reports available on activities that EPA requires by regulation, (4) issuing variances and exemptions (if allowed by the State), under conditions no less stringent than allowed under the SDWA, and (5) adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations. General rule implementation activities include notifying systems of rule requirements, updating internal and external databases, providing training and technical assistance, and reviewing (and, if necessary, approving) monitoring and other reports and plans.

To receive primacy for the Stage 2 DBPR, when final, States will be required to adopt the following new or revised requirements under their own regulations:

—Section 141.33(a) and (f), Record maintenance;
—Section 141.64, MCLs for disinfection byproducts;
—Subpart L, Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors;
—Subpart O, Consumer Confidence Reports;
—Subpart Q, Public Notification of Drinking Water Violations;
—Subpart U, Initial Distribution System Evaluation; and
—Subpart V, Stage 2B Disinfection Byproducts Requirements.

In addition to adopting basic primacy requirements specified in 40 CFR part 142, States are required to address applicable special primacy conditions. Special primacy conditions pertain to specific regulations where implementation of the rule involves activities beyond general primacy provisions. The purpose of these special primacy requirements in today's proposal is to ensure State flexibility in implementing a regulation that: (1) Applies to specific system configurations within the particular State and (2) can be integrated with a State's existing Public Water Supply Supervision Program. States must include these rule-distinct provisions in an application for approval or revision of their program. These primacy requirements for implementation flexibility are discussed in the following section.

A. State Primacy Requirements for Implementation Flexibility

To ensure that a State program includes all the elements necessary for an effective and enforceable program within that State under today's rule, a State primacy application must include a description of how the State will review IDSE reports and approve new or revised monitoring sites for long-term DBP compliance monitoring. If a State will use the authority to grant blanket waivers for IDSE requirements to very small systems, it must comply with the special primacy provision for granting such waivers. A State that intends to use the authority for addressing consecutive system monitoring requirements must include a description of how it intends to implement that authority. A State primacy application must also include a description of how the State will require systems to identify significant excursions.

B. State Recordkeeping Requirements

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 proposed Stage 2 DBPR requires that the State keep records related to any decisions made pursuant to the requirements in subparts U and V, plus copies of IDSE reports submitted by systems until those reports are reversed or revised in their entirety. Today's proposal also includes a revision to the State recordkeeping requirements that requires States to maintain records of DBP monitoring plans submitted by public water systems until superceded by a new system monitoring plan.

C. State Reporting Requirements

EPA currently requires in § 142.15 that States report information such as violations, variance and exemption status, and enforcement actions to EPA. The proposed Stage 2 DBPR will not add any additional reporting requirements.

D. Interim Primacy

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) (USEPA 1998j). 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 complete 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 NPDWR 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 the 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.

E. IDSE Implementation

As discussed in section V.J., many systems will be performing certain IDSE activities prior to their State receiving primacy. During that period, EPA will act as the primacy agency, but will consult and coordinate with individual States to the extent practicable and to the extent that States are willing and able to do so. In addition, prior to primacy, States may be asked to assist EPA in identifying and confirming systems that are required to comply with certain IDSE activities. Once the State has received primacy, it will become responsible for IDSE implementation activities.

F. State Burden

Section VII of today's document contains an analysis of the burden that this rule will place on States in receiving primacy and implementing this rule.

G. Request for Comment

EPA requests comment on the State implementation requirements including the special primacy requirements.

VII. Economic Analysis

This section summarizes the Health Risk Reduction and Cost Analysis (HRRCA) in support of the Stage 2 DBPR as required by section 1412(b)(3)(C) of the 1996 SDWA. In addition, under Executive Order 12866, Regulatory Planning and Review, EPA must estimate the costs and benefits of the Stage 2 DBPR in an Economic Analysis (EA). EPA has prepared an EA to comply with the requirements of this order and the SDWA Health Risk Reduction and Cost Analysis (HRRCA) (USEPA 2003i). SDWA (Section 1412 (b)(4)(C)) also requires the Agency to determine that the benefits of the promulgated rule would justify the costs of compliance. The proposed EA is available in the docket and is also published on the Agency's web site: *http://www.epa.gov/edocket.*

It is important to note that the regulatory options considered by the Agency are the direct result of an Advisory Committee process that involved various drinking water stakeholders. More information on this process is discussed in sections II and V of today's preamble.

In order to analyze both benefits and costs of the proposed rule and other regulatory alternatives considered by the Agency, EPA relied on several data sources to understand DBP occurrence, an analytical model to predict treatment changes and changes in DBP occurrence, and input and analysis from expert technical review panels to assist with model validation and technology selection. A brief description of the process is outlined in section VII.E. but a more detailed explanation of the analytical process is in the EA for the proposed Stage 2 DBPR (USEPA 2003i).

The Stage 2 DBPR economic impact analysis uses a model, (referred to as the Surface Water Analytical Tool or SWAT) and information collected under the Information Collection Rule to make predictions about finished water and delivered water DBP levels, as well as predicting technology changes necessary for systems to comply with rule alternatives. Specifically, SWAT estimates post-Stage 1 DBPR (pre-Stage 2) and post-Stage 2 DBPR DBP levels and likely technology choices by the industry to achieve compliance. For smaller systems and for all ground water systems, expert panels considered occurrence data and current treatment technology specific to these systems and used this information to predict technology treatment changes that may result from this proposed rule.

Both benefits and costs are presented as annualized values. The process allows comparison of cost and benefit streams that are variable over a given time period. The time frame used for both benefit and cost comparisons is 25 years; approximately five years account for rule implementation and 20 years for the average useful life of the equipment. The Agency uses social discount rates of both three percent and seven percent to calculate present values from the stream of benefits and costs and also to annualize the present value estimates. The EA for the proposed rule (USEPA 2003i) also shows the undiscounted stream of both benefits and costs over the 25 year analysis period.

A. Regulatory Alternatives Considered by the Agency

Today's proposed Stage 2 DBPR represents the second of a set of rules that address public health risks from DBPs. The Stage 1 DBPR was promulgated to decrease average exposure to DBPs and associated health risks by focusing compliance on MCLs based on average concentrations of TTHM and HAA5 within the distribution system. Today's proposed Stage 2 DBPR further reduces exposure to chlorinated DBPs by basing compliance on the LRAA of TTHM and HAA5 concentrations at each sampling point within the distribution system. Section V illustrated the LRAA concept and differences in the two compliance calculation methodologies. In addition,

section V provided a comparison of the regulatory options considered. This subsection will summarize the comparison of options and subsection VII.B. will outline the exposure analyses that led EPA to propose the preferred option and will present the predicted national occurrence distributions that were used to quantify predicted exposure reductions from today's proposed rule. A detailed discussion of EPA's exposure analyses can be found in the *Economic Analysis for the Stage 2 DBPR* (USEPA 2003i).

There are two components in the Agency's M–DBP regulatory development process that are particularly relevant to evaluation of options discussed in today's proposal: (1) the data synthesis and evaluation resulting from the Information Collection Rule; and (2) the analysis and recommendations of the M–DBP Advisory Committee. Data from the Information Collection Rule were used with the SWAT model to estimate the national distributions of DBP occurrence. The Advisory Committee considered several questions during the negotiation process, including:

—What are the remaining health risks after implementation of the Stage 1 DBPR?

—What are approaches to addressing these risks?

—What are the risk tradeoffs that need to be considered in evaluating these approaches?

—How do the estimated costs of the approach compare to reductions in peak occurrences and overall exposure for that approach? How does this measure (ratio of costs to exposure reduction) compare among the approaches?

The Advisory Committee considered the DBP occurrence estimates and characteristics of these distributions to be important in understanding the nature of public health risks. Although the Information Collection Rule data were collected prior to promulgation of the Stage 1 DBPR, the data support the concept that a system could be in compliance with the Stage 1 DBPR MCLs of 0.080 mg/L and 0.060 mg/L for TTHM and HAA5, respectively, and yet have points in the distribution system with either periodically or consistently higher DBP levels (see section IV).

Based on these findings, and in order to address disproportionate risk within distribution systems, the Advisory Committee discussed an array of options that would base compliance on exposure at specific sampling locations rather than on average exposures for the entire distribution system. These included options for determining compliance as an LRAA (requiring systems to meet the MCL at individual sampling locations as a running annual average) or as absolute maximums (requiring that no samples taken exceed the MCL concentration), in addition to a combination of these approaches. For example, the Advisory Committee reviewed the exposure reductions for a number of approaches based on different LRAA and absolute maximum incremental MCL levels, and combinations of an LRAA approach with a companion absolute maximum for a variety of different concentration levels. The Advisory Committee also evaluated the associated technology changes and costs for these alternatives. In the process of narrowing down alternatives based on this vast amount of information, the Advisory Committee primarily focused on four types of alternative rule scenarios illustrated next.

Preferred Alternative

—Long-term MCLs of 0.080 mg/L for TTHM and 0.060 mg/L for HAA5 as LRAAs.

—Bromate MCL remaining at 0.010 mg/L.

Alternative 1

—Long-term MCLs of 0.080 mg/L for TTHM and 0.060 mg/L for HAA5 as LRAAs.

—Bromate MCL of 0.005 mg/L.

Alternative 2

—Long-term MCLs of 0.080 mg/L for TTHM and 0.060 mg/L for HAA5 as absolute maximums for individual measurements.

—Bromate MCL remaining at 0.010 mg/L.

Alternative 3

—Long-term MCLs of 0.040 mg/L for TTHM and 0.030 mg/L for HAA5 as an RAA.

—Bromate MCL remaining at 0.010 mg/L.

Figure VII–1 shows how compliance would be determined under each of the TTHM/HAA5 alternatives described and the Stage 1 DBPR for a hypothetical large surface water system. This hypothetical system has one treatment plant and measures TTHM in the distribution system in four locations per quarter (the calculation methodology shown would be the same for HAA5). Ultimately, the Advisory Committee recommended the Preferred Alternative in combination with an IDSE requirement.

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Figure VII-1. Calculations of Compliance for the Regulatory Alternatives Considered

Basis of Compliance

Violation of MCL

Stage 1 DBPR
TTHM MCL = 80 µg/L measured as an RAA
No exceedance of MCL

	Loc. 1	Loc. 2	Loc. 3	Loc. 4	Qtrly Avg.
Q1	100	40	50	50	60
Q2	75	50	40	100	66
Q3	55	45	55	110	66
Q4	60	55	40	75	58
				RAA	63

Preferred Stage 2 DBPR Alternative and Alternative 1*
TTHM MCL = 80 µg/L measured as an LRAA
LRAA at Location 4 exceeds MCL

	Loc. 1	Loc. 2	Loc. 3	Loc. 4
Q1	100	40	50	50
Q2	75	50	40	100
Q3	55	45	55	110
Q4	60	55	40	75
LRAA	73	48	46	84

*The Preferred Alternative and Alternative 1 have the same TTHM MCL; they differ only in regard to the bromate MCL.

Alternative 2
TTHM MCL = 80 µg/L measured as a single highest value
Three samples at Locations 1 and 4 exceed MCL

	Loc. 1	Loc. 2	Loc. 3	Loc. 4
Q1	100	40	50	50
Q2	75	50	40	100
Q3	55	45	55	110
Q4	60	55	40	75

Alternative 3
TTHM MCL = 40 µg/L measured as an RAA
RAA exceeds MCL

	Loc. 1	Loc. 2	Loc. 3	Loc. 4	Qtrly Avg.
Q1	100	40	50	50	60
Q2	75	50	40	100	66
Q3	55	45	55	110	66
Q4	60	55	40	75	58
				RAA	63

The Preferred Alternative, coupled with the IDSE's refocused sampling (see section V), was recommended by the Advisory Committee because this approach addresses the objective of reducing potential adverse reproductive and developmental health risks. It achieves this objective by controlling peak TTHM and HAA5 concentrations at sites throughout the distribution system without compromising microbial protection. At the same time, it will only require a few higher risk systems to face the cost of employing additional advanced technologies. While this alternative controls the occurrence of consistently high DBP levels, it is still possible that individual samples could exceed the MCL, and consumers could thus be exposed to higher DBP concentrations for some portion of the year. In addition, this alternative will further reduce average DBP levels as systems make changes to reduce these peak concentrations. Subsection VII.B. will show how today's proposed requirements are predicted to decrease exposure risks. The benefits and costs of each alternative are presented in subsections VII.C. through VII.E.

B. Rationale for the Proposed Rule Option

DBP concentrations can be highly variable throughout a distribution system and over time at the same location in a distribution system (USEPA 2003o). The determination of compliance with an RAA under the Stage 1 DBPR requires a system to average all of their spatially-distributed samples collected in one quarter of the year and to combine this average concentration with the three prior quarterly averages determined by the system. Thus, the RAA-based standard allows utilities to average spatial and temporal variability in TTHM and HAA5 samples to determine compliance, as shown in figure VII–1. This allows lower results found, perhaps, nearer a water treatment plant to offset higher results that might be found at the ends of the distribution system. In addition, systems with multiple plants of differing water quality (either multiple surface water plants or surface and ground water plants) may have particular plant distribution system sampling locations with high DBPs that are offset by lower measurements observed in the portion of the distribution network served by other plants.

Under the Stage 2 DBPR proposed today, TTHM and HAA5 MCLs will remain the same, but compliance will be based on a locational running annual average (LRAA) for each of the sampling sites in the distribution system. In addition, the IDSE requirement will increase the probability that the compliance sampling sites will capture the highest DBP levels in the distribution system. Thus, the reduction in DBP exposure from the Stage 1 DBPR to the proposed Stage 2 DBPR results from the revised requirements for compliance calculations combined with new compliance monitoring sites.

EPA expects the Stage 2 DBPR, as proposed, will result in health benefits by reducing the estimated health risks associated with the following exposures:

—Individual TTHM/HAA5 occurrences significantly exceeding 0.080 mg/L and 0.060 mg/L;
—Chronic exposures at individual distribution system locations that average more than 0.080 mg/L and 0.060 mg/L;
—Chronic exposures at all locations in the distribution system by reducing overall system average DBP concentrations; and
—Chronic and peak exposures in consecutive systems (systems that purchase treated water from another system).

Under the Stage 1 DBPR, high DBP concentrations at specific locations in the distribution system could be masked by spatial and temporal averaging. As discussed in subsection VII.C, short term exposures resulting from these high concentrations may be of concern in regard to potential adverse reproductive and developmental health effects. Chronic exposures at locations having repeated high DBP concentrations may be of concern for cancer endpoints as well. The remainder of this subsection will illustrate how today's proposed rule is expected to reduce ''peak'' and average exposures to address these health concerns.

1. Reducing Peak Exposure

EPA used Information Collection Rule data to estimate the reduction in exposure to DBP peaks resulting from the Stage 2 DBPR. Because the Information Collection Rule data represent pre-Stage 1 DBPR conditions, subsets of those plants already in compliance with the Stage 1 DBPR and Stage 2 DBPR were used to estimate pre-Stage 2 and post-Stage 2 occurrence respectively. By comparing these subsets of data, EPA estimated that approximately 69% of plant locations having TTHM peaks greater than 0.080 mg/L remaining after the Stage 1 DBPR could be reduced through implementation of the Stage 2 DBPR. EPA conducted this additional peak reduction analysis only for TTHMs and not HAA5s because current epidemiological data only considers the association between TTHM exposure and adverse health impacts (see subsection VII.C). Additional information on reduction of peak exposures can be found in section 5.4.1 of the Economic Analysis (USEPA 2003i). EPA recognizes that temporal and spatial variability in systems that need to install treatment to comply with the Stage 1 DBPR may be different than in those that do not, perhaps due to low source water TOC concentrations. However, EPA does not have data representing DBP levels post-Stage 1. EPA requests comment on its approach of using data from plants in compliance with Stage 1 DBPR requirements without implementing additional treatment as a proxy for post-Stage 1 DBP levels.

2. Reducing Average Exposure

To quantify the benefits of today's proposed rule, EPA compared predicted post-Stage 2 DBPR occurrence and compared this to the predicted baseline concentrations after the Stage 1 DBPR to determine reductions in exposure resulting from the Stage 2 DBPR. The SWAT model was the main tool used in this analysis. SWAT results were used directly for medium and large surface water systems. For small surface water systems and all ground water systems. Adjustments were made to the SWAT results to account for different percentages of plants changing technology to meet Stage 2 DBPR requirements. The Economic Analysis for today's proposed rule (USEPA 2003i) provides an in-depth discussion of this analysis.

Table VII–2 shows the reduction in average plant-level TTHM and HAA5 concentrations estimated to result from the Stage 2 DBPR. EPA expects average DBP levels to decline by 4.7 percent for all surface water systems. DBP averages are expected to decline by 2.2 percent for all large ground water systems and 1.7 percent for all small ground water systems. These estimates include both systems already in compliance with the Stage 2 DBPR and systems making treatment changes to comply with the rule. The Agency uses these national average reductions to quantify the primary benefit of this rule which is the estimated range of reduction in bladder cancer cases nationally. Systems making treatment changes to comply with the rule will experience significantly greater estimated average reductions than the national average for all systems. Chapter 5 of the EA (USEPA 2003i) includes a more detailed discussion of this analysis.

TABLE VII–2.—REDUCTION IN AVERAGE DBP LEVELS FROM PRE-STAGE 2 TO POST-STAGE 2 (ALL PLANTS)

Source water	System size (population served)	Average plant-level TTHM concentrations (μg/L)			Average plant-level HAA5 concentrations (μg/L)		
		Pre-stage 2	Post-stage 2	Percent reduction	Pre-stage 2	Post-stage 2	Percent reduction
SW	≤ 10,000	35.5	33.8	4.7	25.0	23.8	4.7

TABLE VII–2.—REDUCTION IN AVERAGE DBP LEVELS FROM PRE-STAGE 2 TO POST-STAGE 2 (ALL PLANTS)—Continued

Source water	System size (population served)	Average plant-level TTHM concentrations (μg/L)			Average plant-level HAA5 concentrations (μg/L)		
		Pre-stage 2	Post-stage 2	Percent reduction	Pre-stage 2	Post-stage 2	Percent reduction
	> 10,000	35.5	33.8	4.7	25.0	23.8	4.7
GW	≤ 10,000	16.0	15.6	2.2	8.5	8.3	2.2
	10,000	16.2	16.0	1.7	8.6	8.5	1.7

Note: Due to rounding, percent reductions calculated from data in the tables may differ from the actual values presented here
Source: Economic Analysis (USEPA 2003i) Exhibit 5.22b

C. Benefits of the Proposed Stage 2 DBPR

As described previously, the Stage 2 DBPR is expected to reduce both peak and long-term exposure to DBPs, thereby reducing the potential risk of both adverse reproductive and developmental health effects and bladder cancer. As discussed in section III of this preamble, both epidemiological and toxicological evidence suggest a possible increased risk for pregnant women and their fetuses who are exposed to DBPs in drinking water. The Agency believes and the Advisory Committee concluded that the weight of evidence is enough to take regulatory action to help address the potential reproductive and developmental endpoints in the Stage 2 DBPR. However, data are not available at this time to conduct a traditional quantitative risk assessment. Instead, the benefits from reducing most reproductive and developmental risks are discussed qualitatively in this preamble. For one endpoint, fetal loss, the Agency provides an illustrative calculation to explore the implications of some published results for potential benefits associated with reducing fetal losses that may be attributable to certain DBP exposures.

In addition to achieving greater protection from possible adverse reproductive and developmental health effects, the rule may provide additional reduction in bladder cancer cases as the overall level of DBPs in distribution systems nation-wide decreases. The Agency estimated and monetized the potential benefits from reduction in bladder cancers resulting from this rule. Reductions in bladder cancer (including both fatal and non-fatal cases) provide a range of annualized present value benefits from $0 to $986 million using a three percent discount rate ($0 to $854 million using a seven percent discount rate) depending on the risk level assumed. These estimates are based on the assumption that the percent reductions in TTHM and HAAs will correspond to the percent reductions in bladder cancer risk attributed to populations receiving chlorinated drinking water as indicated by various epidemiology studies (USEPA 1998a). Zero is included in this range because of the inconsistent evidence regarding the association between exposure from DBPs and cancer.

Other regulatory alternatives considered by the FACA committee and the Agency could provide greater benefits but with greater technology cost implications. Table VII–3 presents benefits estimates of the proposed Stage 2 DBPR using two population attributable risks derived from published studies (2% and 17%) and assuming there is a causal link between DBP exposure and bladder cancer. In subsection VII.G., Table VII–14 shows potential benefits of all regulatory alternatives considered by the Agency.

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Table VII-3. Benefits Summary for the Stage 2 DBPR, Preferred Regulatory Alternative (Millions, 2000$)

Adverse Reproductive and Developmental Health Effects Avoided					
Causality has not been established, and numbers and types of cases avoided, as well as the value of such cases, were not quantified in the primary benefits analysis. Given the numbers of women of child bearing age exposed (58 million), the evidence indicates that the number of cases and the value of preventing those cases could be significant. See results of the illustrative calculation in VII.C.1.					
Number and Value of Estimated Bladder Cancer Cases Avoided [1]					
Causality has not been established; however, the weight of evidence supports PAR estimates of potential benefits. Zero is within the range of potential benefits, but evidence indicates that both the number of cases and the value of preventing those cases could be significant (see below).					
PAR	Annual Average Cases Avoided	Discount Rate, WTP for Non-Fatal Cases	Annualized Benefits of Cases Avoided (90 % Confidence Bounds [2])		
			Value of Fatal Cases Avoided	Value of Non-Fatal Cases Avoided	Value of Total Cases Avoided
2 %	20.9	3 %, Lymphoma	$42.8 ($7.1 - 97.4)	$70.2 ($10.9 - 160.7)	$113.0 ($17.9 - 258.2)
		7 % Lymphoma	$37.1 ($6.1 - 84.4)	$60.8 ($9.4 - 139.3)	$97.9 ($15.6 - 223.7)
		3 % Bronchitis	$42.8 ($7.1 - 97.4)	$12.1 ($5.4 - 22.2)	$54.9 ($12.5 - 119.6)
		7 % Bronchitis	$37.1 ($6.1 - 84.4)	$10.5 ($4.7 - 19.2)	$47.6 ($10.9 - 103.7)
17 %	182.2	3 %, Lymphoma	$373.8 ($61.8 - 850.3)	$612.4 ($94.8 - 1,403.1)	$986.2 ($156.6 - 2,253.4)
		7 % Lymphoma	$323.9 ($53.6 - 736.7)	$530.6 ($82.1 - 1,215.6)	$854.4 ($135.8 - 1.952.3)
		3 % Bronchitis	$373.8 ($61.8 - 850.3)	$105.5 ($47.5 - 193.5)	$479.3 ($109.3 - 1.043.7)
		7 % Bronchitis	$323.9 ($53.6 - 736.7)	$91.6 ($41.2 - 167.9)	$415.5 ($94.9 - 904.6)
Other Health Benefits					
Qualitative assessment indicates that the value of other health benefits could be positive and significant.					
Non-Health Benefits					
Qualitative assessment indicates that the value of non-health benefits could be positive.					

1. Based on TTHM as indicator. EPA recognizes that the lower bound estimate may be as low as zero since causality has not yet been established between exposure to chlorinated water and bladder cancer.
2. The 90 percent confidence bounds shown in the exhibit reflect uncertainty in the VSL, WTP, and income elasticity adjustment.

Source: Economic Analysis (USEPA 2003i) Exhibit 5.27. Detail may not add to totals due to independent rounding.

It is important to note that the monetized benefits only reflect estimated benefits from reductions in bladder cancer. As shown in subsection VII.C.1.and in Table VII–3, there may be significant nonquantifiable benefits associated with regulating DBPs in drinking water. Were EPA able to quantify some of the currently nonquantifiable health effects and other benefits potentially associated with DBP regulation, monetized benefits estimates could be significantly higher than what is shown in the table. A complete discussion of how EPA calculated the risks and the corresponding health benefits potentially associated with exposure to DBPs in drinking water can be found in the Stage 2 DBPR EA (USEPA 2003i).

For additional perspective EPA used updated cancer risk factors for four DBPs for which we have toxicological data. Table III–3 (*see* section III of this preamble) shows the estimated pre-Stage 2 concentrations of these four compounds and the estimated number

of people exposed to them. The Agency used these four DBPs to calculate an alternative baseline number of annual pre-Stage 2 cancer cases. The calculations use the linearized multistage model and predict 37 cases for the ED_{10} risk factors and 87 cases for the LED_{10} risk factors. The ED_{10} risk factors (also known as the maximum likelihood estimate) are based on the estimated dose that the model predicts will result in a carcinogenic response in 10 percent of the subjects, while LED_{10} risk factors correspond to the lower 95% confidence bound on the dose that the model predicts will result in a carcinogenic response in 10% of the subjects (LED_{10} is EPA's more conservative and more commonly used expression of toxicologically based cancer risk). Assuming that DBP risk reductions for Stage 2 for the entire population average 4.2% (corresponding to the reduction in average TTHM levels), Stage 2 cancer cases avoided based on the toxicological data range from 1.7 to 4.0 cases per year. Section 5.2.2.2 of the Economic Analysis (USEPA 2003i) presents a more detailed basis for the derivation of these estimates. It is important to note that these estimates do not include risks from dermal or inhalation exposure nor do they account for many other DBPs (or the mixture of DBPs seen in actual PWSs) for which occurrence or toxicological risk data do not exist.

1. Non-Quantifiable Health and Non-Health Related Benefits

Although there are significant monetized benefits that may result from this rule from the reduction in bladder cancer, other important potential benefits of this rule are not quantified including potential reductions in adverse reproductive and developmental effects and other cancers.

The primary purpose of the Stage 2 DBPR is to address potential adverse reproductive and developmental health effects that might be associated with DBP exposure. EPA concludes that, ''the epidemiologic data, although not conclusive, are suggestive of potential developmental, reproductive, or carcinogenic health effects in humans exposed to DBPs'' (Simmons et al 2002). EPA does not believe the available evidence provides an adequate basis for quantifying potential reproductive/developmental risks. Nevertheless, given the widespread nature of exposure to DBPs and the priority our society places on reproductive/developmental health, and the large number of fetal losses experienced each year in the U.S. (nearly 1 million (Ventura *et al.* 2000)), we believe it is important to provide some quantitative indication of the potential risk suggested by some of the published results on reproductive/developmental endpoints, despite the absence of certainty regarding a causal link between disinfection byproducts and these risks. To do this, we have adapted illustrative PAR calculations from several studies on the relationship between chlorinated water exposure and fetal loss and applied these to national statistics on annual incidence of fetal loss.

Specifically, we calculate the unadjusted population attributable risk associated with each of the three distinct population-based epidemiological studies of fetal loss published: Waller et al. 2001, King et al. 2000a, and Savitz et al. 1995. All three are high quality studies that have sufficient sample sizes and high response rates, adjust for known confounders [2], and have exposure assessment information from water treatment data, residential histories, and THM measurements. Because the populations in these three studies appear to have TTHM exposures significantly greater than those of the general U.S. population, we have chosen to scale the results using Information Collection Rule data to allow us to derive population attributable risks that may be more relevant to the general U.S. population (USEPA 2003i).

These three studies (using unadjusted data to allow for comparability, and scaled to the TTHM levels reported in the Information Collection Rule data base) yield median PARs of 0.4%, 1.7%, and 1.7% (with 95% confidence intervals for each of the studies of 0 to 4%) [3]. Using the prevalence of fetal loss reported by CDC, the median PARs for these three studies suggest that the incidence of fetal loss attributable to exposure to chlorinated drinking water could range from 3,900 to 16,700 annually. As part of the analysis to evaluate potential reduction in fetal loss for the Stage 2 DBPR, EPA assumed that reductions in risk are proportional to the 28 percent reductions in the number of locations having one or more quarterly TTHM measurements that exceed the study population cut-offs (>75 to >81 ug/l, depending on study). This analysis implies that a range of 1,100 to 4,700 fetal losses could be avoided per year as a result of the Stage 2 rule.

Caution is required in interpreting the numbers because many experts recommend that population attributable risk analysis should not be conducted unless causality has been established. Causality has not been established between exposure to disinfection byproducts and fetal loss. The estimates presented here are not part of EPA's quantitative benefits analysis, and the ranges are not meant to suggest upper and lower bounds. Rather, they are intended to illustrate quantitatively the potential risk implications of some of the published results.

EPA has not monetized the value of potential reductions in fetal loss, but recognizes that there is a significant value associated with improvements in reproductive and developmental health. In the absence of valuation studies specific to the health endpoints of concern, the Agency typically draws upon existing studies of similar health endpoints to estimate benefits. The ''transfer'' of the results of these studies to value similar health endpoints must be done carefully and methodically, controlling for differences in the health endpoints and in the relevant populations. Some researchers have attempted to transfer values using sophisticated analytical techniques such as preference calibration methods (e.g., Smith et al. 2002). Regardless of the approach used, ''benefit transfer'' requires systematic comparison of the differences in the health effects in the studies and those resulting from the regulation. Application of benefit transfer leads to a detailed qualitative examination of the implications of using those studies and potentially to empirical adjustments to the results of the existing studies.

The Agency is investigating further work specific to the case of fetal loss valuation. One possible area of further research is the value that prospective parents attach to reducing risks during pregnancy. In this regard, the substantial lifestyle changes that prospective parents often undertake during pregnancy suggests that reducing these kinds of risks is of value. A second possible area of further investigation would be work on benefit transfer methodologies that address how existing studies can inform the estimation of the benefits of reduced fetal loss.

EPA has not monetized the potential reductions in fetal loss. Without more information and discussion on these subjects the Agency cannot fully consider and describe the implications of relying upon existing studies.

[2] Use of unadjusted PAR estimates has the effect of removing the adjustments for known confounders, however, EPA believes the unadjusted estimates are adequate for purposes of the illustrative calculations presented here.

[3] The negative lower 95% confidence intervals for all three studies was truncated at zero.

However, research on valuation and benefit transfer continues to progress and the Agency anticipates new research and future efforts to value reproductive and developmental endpoints.

EPA was also unable to quantify or monetize the benefit from potential reductions in other cancers, such as colon and rectal, that may result from this rule. Both toxicology and epidemiology studies indicate that other cancers may be associated with DBP exposure but currently there is not enough data to quantify or monetize these cancer risks.

Other potential non-health related benefits not quantified or monetized in today's proposed rule include reduced uncertainty about becoming ill from consumption of DBPs in drinking water, the ability for some treatment technologies to eliminate or reduce multiple contaminants, and monitoring changes that will ensure that systems can effectively measure their DBP levels resulting in greater equity in protection from DBPs. First, the reduced uncertainty concept depends on several factors including consumer's degree of risk aversion, their perceptions about drinking water quality (degree to which they will be affected by the regulatory action), and the expected probability and severity of human health effects associated with DBPs in drinking water. This effect could be positive or negative depending on whether knowledge of the rule decreases or increases their concern about DBPs in drinking water and potentially associated health effects.

Another nonquantified potential benefit is the impact of technology selection to address DBPs on a system's ability to address other contaminants. For example, membrane technology (depending on pore size), can be used to lower DBP formation but it can also remove other contaminants that EPA is in the process of regulating or considering regulating. Therefore, by installing membrane technology, a system may not have to make new capital improvement to comply with future regulations.

Last, today's proposed rule makes changes to Stage 1 monitoring requirements. The IDSE monitoring provision of the proposed Stage 2 DBPR will help systems identify locations to conduct their routine monitoring to capture high DBP occurrence levels. Also, the proposed Stage 2 DBPR will prevent a system from conducting sampling designed to avoid monitoring when DBP formation is generally higher. For example, the Stage 1 DBPR required systems to take quarterly samples but samples could conceivably be taken in December (4th quarter) and January (1st quarter) when the waters in the distribution system are colder and DBP formation generally lower. The proposed Stage 2 DBPR addresses this issue by requiring that the samples must be taken about 90 days apart. The benefits of these provisions include the greater certainty that health protection is actually achieved because it is more likely that a system's high DBP levels will be identified. In addition, the rule will reduce variability in the DBP levels throughout the distribution system, ensuring greater equity in public health protection.

2. Quantifiable Health Benefits

Although DBPs in drinking water have been associated with non-cancerous health effects discussed previously, the quantified benefits that result from today's rule are associated only with estimated reductions in DBP-related bladder cancer. A complete discussion of risk assessment methodology and assumptions can be found in Chapter 5 of the Stage 2 DBPR Economic Analysis (USEPA 2003i). Section III of this preamble also discusses the health effects that have been associated with DBP exposure.

The annualized present value benefits for reductions in bladder cancer that are the result of today's rule for both community water system (CWS) and non-transient non-community water systems (NTNCWSs) range from $0 to $986 million using a three percent discount rate ($0 to $854 million using a seven percent discount rate). Overall, the Stage 2 DBPR may reduce on average 0 to 182 bladder cancer cases per year.

The lower estimate of zero is included because of inconsistent evidence regarding the association between exposure to DBPs and cancer. The upper estimate of monetized benefits and cases avoided is based on a population attributable risk (PAR) of 17 percent. Table VII–3 also presents monetized benefits based on a PAR value of 2%. The PAR estimates are derived from an analysis of five epidemiological studies which indicate that perhaps 2 to 17 percent of bladder cancers may be attributable to DBP exposure. These PAR estimates are described in more detail in section III of today's document. These are the same PAR values that EPA used in the Stage 1 DBPR benefits analysis, as discussed in the Regulatory Impact Analysis for the Stage 1 DBPR (USEPA 1998f). Table VII–3 shows the estimated benefits associated with bladder cancer reduction as a result of the proposed rule. Table VII–4 summarizes the mean, median and confidence intervals used to value reductions in bladder cancer.

To calculate the total value of benefits derived from reductions in bladder cancer cases as a result of the Stage 2 DBPR, a stream of estimated monetary benefits is calculated by combining the annual cases avoided with valuation inputs using Monte Carlo simulation. Use of a Monte Carlo simulation allows the characterization of uncertainty around final modeling outputs based on the uncertainty underlying the various valuation inputs. The Stage 2 DBPR benefits model uses distributions of value of statistical life (VSL), willingness-to-pay (WTP), and income elasticity values to attribute monetary values (with uncertainty bounds) to the number of bladder cancer cases avoided.

Several of the inputs needed in the benefit analysis, such as the VSL and WTP estimates, are based on older studies that were updated to current dollar values. In addition, both the VSL and WTP values are dependent on income levels. Therefore, these values also have to be adjusted for increases in real income growth from when the studies were conducted. The valuation inputs and an explanation of the update factors used to bring these values to current price levels and discussed in the following two sections.

Valuation inputs. In order to monetize the benefit from the bladder cancer fatalities, EPA applied a VSL estimate to the cancer cases that result in mortality. EPA assumed a 26 percent mortality rate for bladder cancer (USEPA 1999d). The Agency uses a distribution of VSL values which are based on 26 wage-risk studies. The mean VSL value from these studies is $4.8 million in 1990 dollars. The mean value reflects the best estimate in the range of plausible values reflected by the 26 studies. A more detailed discussion of these studies and the VSL estimate can be found in EPA's *Guidelines for Preparing Economic Analyses* (USEPA 2000b).

The VSL represents the value of reducing the risk of a premature death. This valuation, however, does not take into account the medical costs associated with the period of illness (morbidity increment) leading up to a death. In its review of the Arsenic Rule, the Science Advisory Board (SAB) suggested that the appropriate measure to use in valuing the avoidance of the morbidity increment is the medical cost attributable to a cancer case (USEPA 2001e). Based on available medical data, EPA estimates the medical costs for a fatal bladder cancer case to be $93,927 at a 1996 price level (USEPA 1999d). This medical cost value (updated to 2000 price levels) is applied as a point

estimate to each fatal case of bladder cancer in the benefits model.

A review of the available literature did not reveal any studies that specifically measured the WTP to avoid risks of contracting nonfatal cases of bladder cancer. Instead, two alternates were used, the WTP to avoid the risk of contracting a case of curable lymph cancer (lymphoma) and the WTP to avoid a case of chronic bronchitis. The SAB suggested this approach in their review of the Arsenic Rule (USEPA 2001e). The median risk-risk trade-off for a curable case of lymphoma was equivalent to 58.3 percent of the risk attributed to reducing the chances of facing a sudden death and are derived from the Magat *et al.* study (1996). Therefore, the Agency applies the 58.3 percent to the VSL distribution to derive a range of value for non-fatal cancers with a mean WTP value of $2.8 million ($4.8 million * 58.3 percent) at a 1990 price level. The WTP for avoiding a case of chronic bronchitis is based on the same methodology used for the Stage 1 DBPR (see Stage 2 DBPR EA (USEPA 2003i) for a complete discussion). The estimate is based on a lognormal distribution that uses the risk-dollar tradeoff estimate and has a mean of $587,500, standard deviation of $264,826, and a maximum value of $1.5 million at 1998 price values.

Update factors. All valuation parameters must be updated to the same price level so comparisons can be made in real terms. Values for VSL, WTP, and the morbidity increment used in the model are updated based on adjustment factors derived from Bureau of Labor Statistics (BLS) consumer price index (CPI) data so that each represents a year 2000 price level. Table VII–4 summarizes these updates.

Table VII-4. VSL, WTP, and Morbidity Increment Price Level Updates

Valuation Parameter	Base Year	Mean Value in Base Year (Millions)	CPI Update Factor	Values at Year 2000 Price Level (Millions)			
				Mean	Median	Lower (5th %tile)	Upper (95th %tile)
Morbidity Increment	1996	$ 0.1	1.14	$ 0.1	N/A	N/A	N/A
VSL	1990	$ 4.8	1.32	$ 6.3	$ 5.5	$ 1.0	$ 14.5
WTP - Non-Fatal Lymphoma	1990	$ 2.8	1.32	$ 3.7	$ 3.2	$ 0.6	$ 8.5
WTP - Chronic Bronchitis	1998	$ 0.6	1.06	$ 0.6	$ 0.6	$ 0.3	$ 1.1

Notes: Morbidity increment value is presented as a point estimate.

Source: Economic Analysis (USEPA 2003i) Exhibit 5.29

Although the price level (year 2000) is held constant throughout the benefits model, projections of benefits in future years are subject to income elasticity adjustments. Income elasticity adjustments represent changes in valuation in relation to changes in real income. For fatal cancers, the Agency used a triangular distribution with a central estimate of 0.40 (low end: 0.08; high end:1.00) to represent the uncertainty of the income elasticity value. For non-fatal cancers, the Agency uses a triangular distribution with a central estimate of 0.45 (low end: 0.25; high end: 0.60). These distributions are used as assumptions in the Monte Carlo simulation to further characterize uncertainty in benefits estimates.

In order to apply the income elasticity values in the model, they are combined with projections of real income growth over the time frame for analysis. Population and real gross domestic product (GDP) projections are combined to calculate per-capita real GDP values. A more detailed discussion of these adjustments is in Chapter 5 of the EA (USEPA 2003i).

The development of cancer due to exposure to environmental carcinogens involves a complex set of processes that are not well-understood for most specific substances. In general, however, the development of cancer involves some time period, usually referred to as the latency period, between the initial exposure and the manifestation of disease. Defining a latency period is highly uncertain because the mode of action for most chemical contaminants are poorly understood. Latency periods in humans often involve many years, even decades.

EPA recognizes that despite uncertainties in the latency period associated with different types of carcinogens, it is unlikely that all cancer reduction benefits would be realized immediately upon exposure reduction. If it is assumed that lower risk is attained immediately upon reduction in exposure, this would tend to overestimate the benefits. On the other hand, assuming that no risk reduction occurs for some period of time following exposure reduction may lead to an underestimation of the benefits. There will likely be some transition period as individual risks become more reflective of the new lower exposures than the past higher exposures.

Recently, the Arsenic Rule Benefits Review Panel of the EPA Science Advisory Board (SAB) addressed this issue in detail and provided some guidance for computing benefits to account for this transition period between higher and lower steady-state risks (USEPA 2003s). The Arsenic Rule Benefits Review Panel coined the term ''cessation-lag'' to emphasize the focus on the timing of the attenuation of risk after reduction in exposures to avoid confusion with the more traditional term of ''latency'' that reflects the increased risk [4] from the time of initial exposure.

[4] SAB included the following in its report on arsenic to emphasize this difference: ''An important point is that the time to benefits from reducing arsenic in drinking water may not equal the estimated time since first exposure to an adverse effect. A good example is cigarette smoking: the latency between initiation of exposure and an increase in lung cancer risk is approximately 20 years. However, after cessation of exposure, risk for lung cancer begins to decline rather quickly. A benefits analysis of smoking cessation programs

Continued

Although the focus of the cessation lag discussion in the SAB review was on reducing levels of arsenic in drinking water, much of their consideration of this issue has more general applications beyond just the arsenic issue at hand. In particular, SAB noted the following:

- The same model should be used to estimate the time pattern of exposure and response as is used to estimate the potency of the carcinogen.
- If possible, information about the mechanism by which cancer occurs should be used in estimating the cessation lag (noting that late-stage mechanisms in cancer formation imply a shorter cessation lag than early stage mechanisms).
- If specific data are not available for characterizing the cessation lag, an upper bound for benefits can be provided based on the assumption of immediately attaining steady-state results.
- In the absence of specific cessation lag data, other models should be considered to examine the influence of the lag.

Following the release of the SAB report on arsenic, EPA initiated an effort to explore approaches to including the cessation lag in modeling risk reduction and calculating benefits for the arsenic regulation. EPA recognized, however, that the concept of cessation lag is not only applicable to arsenic but to other drinking water contaminants having a cancer end-point as well.

In response to the SAB cessation lag recommendations, EPA has:

- Conducted a study using data on lung cancer risk reductions following cessation of smoking that resulted in the January 2003 report Arsenic in Drinking Water: Cessation Lag Model (USEPA 2003s).
- Conducted an expert scientific peer review of that draft report.
- Initiated development of general criteria for incorporating cessation lag modeling in benefits analyses for other drinking water regulations.

In the effort to develop a cessation lag model specific to DBPs, EPA reviewed the available epidemiological literature for information relating to the timing of exposure and response, but could not identify any studies that were adequate, alone or in combination, to support a specific cessation lag model for DBPs in drinking water. Thus, in keeping with the SAB recommendation to consider other models in the absence of specific cessation lag information, EPA explored the use of information on other carcinogens that could be used as a indicator to characterize the influence of cessation lag in calculating benefits. The carcinogen for which the most extensive database was available for characterizing cessation lag was for cigarette smoking. EPA examined several extensive epidemiological studies on the comparison of the risks of adverse health effects, including lung cancer, for smokers and former smokers. EPA selected the Hrubek and McLaughlin (1997) study as the most appropriate study for development of a statistical model of disease response to smoking cessation. This was a comprehensive study involving a 26-year follow-up of almost 300,000 U.S. male military veterans. More detail about this study and how it is applied to estimate the cessation lag can be found in Chapter 5 of the EA (USEPA 2003i) and the cessation lag document (USEPA 2003s).

The smoking cessation lag data imply that the majority of the potential steady state cases avoided occur within the first several years, but with diminishing incremental increases in later years. For example, the cessation lag model indicates that approximately 40 percent of the steady-state cases avoided are achieved by the end of the second year, with 70 percent achieved by the end of the fifth year, and approximately 80 percent by the tenth year. By the twentieth year, 90 percent of the steady state cases are avoided.

EPA recognizes that there are several factors that contribute to the uncertainty in the application of the specific cessation lag model used in the estimation of the benefits of the proposed Stage 2 regulation. A key factor to consider in assessing this impact is the likely mode of action of DBPs in eliciting bladder cancer versus the mode of action of tobacco smoke in producing lung cancer, and in particular whether they behave as initiators or promoters of the carcinogenic process. As discussed in the SAB report and the EPA Cessation Lag report (USEPA 2001e, USEPA 2003s), carcinogens that act solely or primarily as initiators would tend to show a longer cessation lag (lower rate of risk reduction following reductions in exposure) than carcinogens that act solely or primarily as promoters. The available information on tobacco smoke and lung cancer suggests that it involves a mixture of both initiators and promoters, and therefore the cessation lag derived from smoking data is expected to reflect the combined influence of these divergent mechanisms. There are no data available on the mechanism of action for DBPs and bladder cancer; indeed the specific carcinogenic agent(s) present in disinfected water responsible for the observed effect have not been identified. The use of the tobacco smoke cessation lag model reflecting a mixture of initiators and promoters would be expected to attenuate a possible bias in either direction if the DBPs responsible for bladder cancer are acting predominately as either initiators or promoters.

Another factor to consider is that the cessation lag model used is based upon exposure to tobacco smoke where lung cancer is the end-point but is being applied to exposure to disinfection by-products where the end-point is bladder cancer. Of concern here is that there is a more direct correlation between inhalation and the site of cancer for smoking than there is for ingestion and inhalation of drinking water and the sites of cancer for DBP exposure. Unfortunately, EPA does not have data on which to develop a cessation lag model using data specific to how changes in DBP exposures affect the risks of developing bladder cancer.

Another divergence, and perhaps the most important, between the smoking model and the DBP application is that the smoking model is based on complete cessation of exposure, whereas in the case of DBP exposure is only being reduced. In some water systems the reduction is only 10 percent, whereas in others it may be as high as 60 percent, with an average of approximately 30%. This moderate reduction in exposure may prevent full DNA repair, which some scientists interpret as the basis for the short cessation lag associated with smoking.

Currently, smoking is the only contaminant for which enough data exist to estimate a cessation lag. In the absence of a reliable cessation lag model based specifically on DBPs and bladder cancer, EPA used the cessation lag model based on smoking to provide a means of estimating the rate at which bladder cancer risk in the exposed population falls from the pre-Stage 2 levels to the post-Stage 2 levels. However, this model is derived from data involving notable differences from DBPs in drinking water, including different cancer sites (lung versus bladder), different exposure pathways (inhalation versus a combination of ingestion, inhalation and dermal), different risk levels, and, perhaps most importantly, complete cessation for smoking versus small exposure decreases for DBPs. For these reasons, the extent to which the smoking / lung cancer model is directly transferable to DBP / bladder cancer is uncertain. It is not possible to know, however, whether and to what degree the tobacco smoke

based on the observed latency would greatly underestimate the actual benefits.''

cessation lag model either over-states or under-states the rate at which population risk reduction for bladder cancer occurs following DBP exposure reductions.

EPA is currently examining the recently published meta-analysis by Villanueva *et al.* (2003) to determine if the information provided on increases in risk as a function of duration of exposure can provide any insight on how reductions in risk over time might occur following reductions in exposure. Villanueva *et al.* (2003) demonstrated that the risk associated with chlorinated drinking water and bladder cancer are related to exposure duration. Specifically, they estimated a unit increase in the odds ratio of 1.006 per year (95% CI of 1.004 to 1.009). The model suggests a cumulative odds ratio of 1.13 after 20 years of exposure (95% CI of 1.08 to 1.20), and 1.27 (95% CI of 1.17 to 1.43) after 40 years. This result is consistent with most of the individual studies which do not show statistically significant risk increases until at least 30–40 years of exposure. However, these studies provide indirect evidence only about the latency of potential effects. For perspective, it is important to note that the latency between initiation of exposure and an increase in lung cancer risk is approximately 20 years. As noted above, latency is not the same as the cessation lag. EPA is requesting comment on (a) the potential application of the Villanueva *et al.* (2003) model to estimate reductions in bladder cancer risk that might accompany decreased exposure to DBPs as a result of the Stage 2 Rule; (b) the advantages and disadvantages of using the current approach—*i.e.*, application of the smoking cessation lag model; and (c) suggestions for alternative data sets or approaches to characterize cessation lag.

In addition to the delay in reaching a new steady-state level of risk reduction as a result of cessation lag effects, there is a delay in exposure reduction resulting from the Stage 2 DBPR implementation. In general, EPA assumes that a fairly uniform increment of systems will complete installation of new treatment technologies each year, with the last systems installing treatment by 2013. EPA recognizes that more systems may start in early or later years, but believes that a uniform schedule is a reasonable assumption. Appendix D of the EA presents detailed information regarding the rule activity schedule assumptions (USEPA 2003i).

The delay in exposure reduction resulting from the rule implementation schedule is incorporated into the benefits model by adjusting the cessation lag weighting factor. For example, if ten percent of systems install treatment equipment (and start realizing reductions in cancer cases) in year one, only that portion of the cases are modeled to begin the cessation lag equilibrium process in that year. Thus, the resulting ''weighted weighting factor'' is higher relative to the base factor. Appendix E in the EA (USEPA 2003i) presents detailed breakdowns of all weighting factor adjustments and resulting cancer cases avoided, by year, for each rule alternative based on the application of the cessation lag methodology.

3. Benefit Sensitivity Analyses

The Agency performed one other benefit sensitivity analysis which is included in the EA to allow for comparison with the benefit estimates calculated for the Stage 1 DBPR. This analysis assumes that there is not a cessation lag or latency adjustment associated with bladder cancer reductions that result from the rule. In this case, the analysis assumes that the steady state reduction in bladder cancer occurs immediately with rule implementation. This is the same methodology used to estimate the quantified benefits of the Stage 1 DBPR.

D. Costs of the Proposed Stage 2 DBPR

In estimating the costs of today's proposed rule, the Agency considered impacts on water systems (CWSs and NTNCWSs) and on States (including territories and EPA implementation in non-primacy States). EPA assumed that systems would be in compliance with the Stage 1 DBPR, which has a compliance date of January 2004 for ground water systems and small surface water systems and January 2002 for large surface water systems. Therefore, the cost estimate only considers the additional requirements that are a direct result of the Stage 2 DBPR. More detailed information on cost estimates are described later and a complete discussion can be found in Chapter 6 of the Stage 2 DBPR EA (USEPA 2003i)

1. National cost estimates

EPA estimates that the mean annualized cost of the proposed rule ranges from approximately $59.1 million using a three percent discount rate to $64.6 million using a seven percent discount rate. Drinking water utilities will incur approximately 98 percent of the rule's costs. States will incur the remaining rule cost. Tables VII–5 a and b summarize the total annualized cost estimates for the proposed Stage 2 DBPR. In addition to mean estimates of costs, the Agency calculated 90 percent confidence bounds by considering the uncertainty around the mean unit technology costs. Table VII–6 shows the undiscounted capital cost and all one-time costs broken out by rule component. A table comparing total annualized costs among the regulatory alternatives considered by the Agency is located in subsection VII.G.

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Table VII-5a Total Annualized Costs ($ millions, 2000$), 3 Percent Discount Rate

System Size (Population Served)	System Costs													State Costs	Total Costs of the Rule		
	Capital Costs			O&M Costs			Non-Treatment Costs (Point Estimate)				Total System Costs						
	Mean Value	90 Percent Confidence Bound		Mean Value	90 Percent Confidence Bound		Implement-ation	IDSE	Moni-toring	Significant Excursion	Mean Value	90 Percent Confidence Bound			Mean Value	90 Percent Confidence Bound	
		Lower (5th %tile)	Upper (95th %tile)		Lower (5th %tile)	Upper (95th %tile)						Lower (5th %tile)	Upper (95th %tile)			Lower (5th %tile)	Upper (95th %tile)
Surface Water CWSs																	
≤ 10,000	$2.23	$1.92	$2.54	$3.94	$3.66	$4.22	$0.08	$0.84	$1.20	$0.00	$8.30	$7.71	$8.89				
> 10,000	$10.76	$9.44	$12.08	$10.08	$9.50	$10.67	$0.02	$2.68	-$2.14	$0.01	$21.42	$19.51	$23.33				
Surface Water NTNCWSs																	
≤ 10,000	$0.18	$0.15	$0.21	$0.43	$0.40	$0.46	$0.01	$0.00	$0.00	$0.00	$0.62	$0.56	$0.68				
> 10,000	$0.04	$0.04	$0.05	$0.04	$0.04	$0.04	$0.00	$0.01	$0.01	$0.00	$0.10	$0.10	$0.11				
Ground Water CWSs																	
≤ 10,000	$4.68	$3.94	$5.41	$5.60	$5.19	$6.00	$0.21	$0.21	$1.16	$0.00	$11.85	$10.71	$12.99				
> 10,000	$5.04	$4.52	$5.56	$7.31	$6.87	$7.77	$0.01	$0.14	$1.68	$0.00	$14.19	$13.23	$15.17				
Ground Water NTNCWSs																	
≤ 10,000	$0.55	$0.47	$0.63	$0.81	$0.74	$0.88	$0.05	$0.00	$0.00	$0.00	$1.41	$1.26	$1.56				
> 10,000	$0.01	$0.01	$0.01	$0.02	$0.02	$0.02	$0.00	$0.00	$0.00	$0.00	$0.04	$0.03	$0.04				
TOTAL	**$23.49**	**$20.49**	**$26.49**	**$28.23**	**$26.41**	**$30.07**	**$0.38**	**$3.89**	**$1.92**	**$0.01**	**$57.93**	**$53.12**	**$62.77**	**$1.14**	**$59.08**	**$54.26**	**$63.91**

Note: Detail may not add due to independent rounding

Present value in millions of $2000 dollars. Estimates are discounted to 2003.

Source: Economic Analysis (USEPA 2003i) Exhibit 6.6a

Table VII-5b Total Annualized Costs ($ millions, 2000$), 7 Percent Discount Rate

System Size (Population Served)	System Costs													State Costs	Total Costs of the Rule		
	Capital Costs			O&M Costs			Non-Treatment Costs (Point Estimate)				Total System Costs						
	Mean Value	90 Percent Confidence Bound		Mean Value	90 Percent Confidence Bound						Mean Value	90 Percent Confidence Bound			Mean Value	90 Percent Confidence Bound	
		Lower (5th %tile)	Upper (95th %tile)		Lower (5th %tile)	Upper (95th %tile)	Implement-ation	IDSE	Moni-toring	Significant Excursion		Lower (5th %tile)	Upper (95th %tile)			Lower (5th %tile)	Upper (95th %tile)
Surface Water CWSs																	
≤ 10,000	$2.69	$2.31	$3.06	$3.56	$3.31	$3.81	$0.11	$1.21	$1.03	$0.00	$8.61	$7.98	$9.24				
> 10,000	$13.62	$11.94	$15.29	$9.38	$8.85	$9.93	$0.03	$3.94	-$1.89	$0.01	$25.09	$22.88	$27.31				
Surface Water NTNCWSs																	
≤ 10,000	$0.22	$0.19	$0.25	$0.39	$0.36	$0.41	$0.01	$0.00	$0.00	$0.00	$0.62	$0.55	$0.68				
> 10,000	$0.05	$0.05	$0.06	$0.03	$0.03	$0.04	$0.00	$0.01	$0.01	$0.00	$0.12	$0.11	$0.12				
Ground Water CWSs																	
≤ 10,000	$5.63	$4.74	$6.51	$5.06	$4.69	$5.43	$0.28	$0.28	$0.99	$0.00	$12.24	$10.98	$13.49				
> 10,000	$6.38	$5.72	$7.04	$6.81	$6.40	$7.23	$0.02	$0.21	$1.48	$0.00	$14.89	$13.83	$15.97				
Ground Water NTNCWSs																	
≤ 10,000	$0.66	$0.57	$0.75	$0.74	$0.67	$0.80	$0.06	$0.00	$0.00	$0.00	$1.46	$1.30	$1.62				
> 10,000	$0.02	$0.01	$0.02	$0.02	$0.02	$0.02	$0.00	$0.00	$0.00	$0.00	$0.04	$0.03	$0.04				
TOTAL	**$29.26**	**$25.54**	**$32.98**	**$25.99**	**$24.32**	**$27.68**	**$0.51**	**$5.66**	**$1.64**	**$0.01**	**$63.07**	**$57.67**	**$68.48**	**$1.48**	**$64.55**	**$59.16**	**$69.96**

Note: Detail may not add due to independent rounding
Present value in millions of $2000 dollars. Estimates are discounted to 2003.
Source: Economic Analysis (USEPA 2003i) Exhibit 6.6b

Table VII-6 Initial Capital and One-time Costs for the Stage 2 DBPR ($million, 2000$)

	Surface Water		Disinfecting Ground Water		
	Serving ≤ 10,000	Serving > 10,000	Serving ≤ 10,000	Serving > 10,000	Total
Total Initial Capital Costs for the Rule	**$ 50.0**	**$ 214.64**	**$ 108.3**	**$ 100.3**	**$ 473.3**
(90% Confidence Bounds)	($43.1 - 57.1)	($188.2 - 240.9)	($91.5 - 125.1)	($90.0 - 110.7)	
CWS Total Initial Capital	$ 46.26	$ 213.8	$ 96.9	$ 100.1	$ 457.0
(90% Confidence Bounds)	($39.8 - 52.7)	($187.4 - 239.9)	($81.6 - 112.1)	($89.8 - 110.4)	
NTNCWS Total Initial Capital	$ 3.79	$ 0.9	$ 11.4	$ 0.3	$ 16.3
(90% Confidence Bounds)	($3.2 - 4.4)	($0.7 - 1.0)	($9.8 - 13.0)	($0.2 - 0.3)	
CWS One-Time Costs	$ 16.7	$ 47.9	$ 8.1	$ 2.7	$ 75.4
Implementation	$ 1.5	$ 0.4	$ 4.1	$ 0.2	$ 6.2
IDSE	$ 15.2	$ 47.4	$ 4.0	$ 2.5	$ 69.2
NTNCWS One-Time Costs	$ 0.1	$ 0.2	$ 0.9	$ 0.0	$ 1.2
Implementation	$ 0.1	$ 0.0	$ 0.9	$ 0.0	$ 1.0
IDSE	$ -	$ 0.2	$ 0.0	$ 0.0	$ 0.2
State/Primacy Agency One-Time Costs					$ 14.4
Implementation					$ 6.7
IDSE					$ 7.7

Notes: 1) Detail may not add due to independent rounding (Some data are rounded to zero if less than $0.05 million).
Source: Economic Analysis (USEPA 2003i) Exhibit 6.5

2. Water system costs

The proposed Stage 2 DBPR applies to all community or nontransient noncommunity water systems that add a chemical disinfectant other than UV or distribute water that has been treated with a disinfectant other than UV. EPA has estimated the cost impacts for both types of public water systems. As shown in Tables VII–5 a and b, the total annualized present value costs for CWSs is approximately $55.8 million and for NTNCWSs, $2.2 million, using a three percent discount rate ($60.8 million and $2.2 million using a seven percent discount rate).

Although the number of systems adding treatment is small, treatment costs make up a significant portion of the total costs of the rule (more than 75 percent of total rule costs). Table VII–7 shows the baseline number of plants and the estimated percent of those plants adding treatment. The estimated percent of plants adding advanced treatment or converting to chloramines is 2.8 percent of all systems. A higher percentage of surface water plants are predicted to add treatment compared to ground water plants. However, the baseline number of ground water plants is larger than that of surface water plants, so there is a larger number of ground water plants adding treatment. Subsection VII.F. provides a more detailed explanation of treatment changes that may occur as a result of the proposed rule.

All systems will incur costs for rule implementation. Some will need to conduct a one-time Initial Distribution System Evaluation (IDSE) and others (a different subgroup depending on the system size) may incur additional costs for routine DBP monitoring. Some systems may also have to conduct a peak excursion evaluation if single samples indicate high DBP levels.

Sixty-nine percent of surface water and 7 percent of ground water CWSs are predicted to conduct the IDSE monitoring. EPA estimates that a very small portion of systems (approximately 16 percent overall) will conduct additional routine monitoring beyond the Stage 1 DBPR requirements. However, fewer samples overall would be required if a population-based approach is implemented instead of the plant-based approach that is currently being used to estimate monitoring costs. Section V describes the population-based approach in more detail and a discussion of how this approach may influence costs is provided in Appendix H of the EA (USEPA 2003i). A small percentage of systems (approximately 3.0 percent of surface water CWSs and 0 percent of ground water systems) are expected to experience significant excursions.

A complete discussion of the rule provisions is located in section V of this preamble; the *Stage 2 DBPR Economic Analysis* includes a complete analysis of rule impacts (USEPA 2003i). Table VII–8 summarizes the number of systems subject to non-treatment related rule activities. Column D indicates the number of systems expected to use the standard monitoring program to implement the IDSE. Column F indicates the number of systems expected to increase monitoring sites beyond that required by Stage 1. The last two columns show the number and percent of plants estimated to experience significant excursions each year.

Table VII-7. Number of Plants Adding Treatment

System Size (Population Served)	Stage 2 DBPR Plant Baseline	Number and Percentage of Plants Adding Treatment	
Primarily Surface Water CWSs			
≤ 100	470	21	4.4%
101-500	799	26	3.3%
501-1,000	505	17	3.3%
1,001-3,300	1,103	41	3.7%
3,301-10,000	1,213	45	3.7%
10,001-50,000	1,287	75	5.8%
50,001-100,000	538	31	5.8%
100,001-1 Million	572	33	5.8%
> 1 Million	74	4	5.8%
National Totals	**6,560**	**293**	**4.5%**
Primarily Ground Water CWSs			
≤ 100	7,772	211	2.7%
101-500	15,725	461	2.9%
501-1,000	6,133	180	2.9%
1,001-3,300	7,890	184	2.3%
3,301-10,000	4,975	116	2.3%
10,001-50,000	5,367	112	2.1%
50,001-100,000	738	15	2.1%
100,001-1 Million	875	17	1.9%
> 1 Million	18	0	1.9%
National Totals	**49,495**	**1,296**	**2.6%**
Primarily Suface Water NTNCWSs			
≤ 100	298	13	4.4%
101-500	301	10	3.3%
501-1,000	108	4	3.3%
1,001-3,300	72	3	3.7%
3,301-10,000	23	1	3.7%
10,001-50,000	9	1	5.8%
50,001-100,000	1	0	5.8%
100,001-1 Million	1	0	5.8%
> 1 Million	0	0	0.0%
National Totals	**813**	**31**	**3.8%**
Primarily Ground Water NTNCWSs			
≤ 100	3,662	99	2.7%
101-500	2,624	77	2.9%
501-1,000	717	21	2.9%
1,001-3,300	267	6	2.3%
3,301-10,000	27	1	2.3%
10,001-50,000	4	0	2.1%
50,001-100,000	0	0	2.1%
100,001-1 Million	1	0	1.9%
> 1 Million	0	0	0.0%
National Totals	**7,303**	**204**	**2.8%**
Grand Total All Plants	**64,171**	**1,824**	**2.8%**

Source : Economic Analysis (USEPA 2003i) Exhibit 6.16a, 6.16.b,6.17a, 6.17b

Table VII-8 Number of Systems Subject to Non-Treatment Related Rule Activities

System Size (Population Served)	Stage 2 DBPR System Baseline	Number and Percent of Systems Performing Various Rule Activities							
		Implementation		IDSE Monitoring		Additional Routine Monitoring		Significant Excursion Evaluations	
	A	B	C=B/A*100	D	E=D/A*100	F	G=F/A*100	H	I=H/A*100
Surface Water and Mixed CWSs									
≤ 100	1,283	1,283	100%	289.2	23%	0.0	0%	0.0	0%
101-500	2,120	2,120	100%	546.4	26%	42.5	2%	2.0	0%
501-1,000	1,313	1,313	100%	1,179.3	90%	546.6	42%	26.2	2%
1,001-3,300	2,467	2,467	100%	2,215.8	90%	1,027.0	42%	49.3	2%
3,301-10,000	1,928	1,928	100%	1,722.8	89%	1,084.3	56%	42.3	2%
10,001-50,000	1,690	1,690	100%	1,454.0	86%	0.0	0%	133.2	8%
50,001-100,000	313	313	100%	255.3	82%	0.0	0%	40.6	13%
100,001-1 Million	276	276	100%	213.3	77%	0.0	0%	41.1	15%
> 1 Million	13	13	100%	9.9	76%	0.0	0%	3.3	25%
National Totals	11,403	11,403	100%	7,886	69%	2,700	24%	338	3%
Ground Water Only CWSs									
≤ 100	7,601	7,601	100%	236.2	3%	0.0	0%	0.0	0%
101-500	11,836	11,836	100%	392.6	3%	118.6	1%	0.0	0%
501-1,000	4,089	4,089	100%	482.0	12%	1,691.9	41%	0.0	0%
1,001-3,300	4,869	4,869	100%	573.9	12%	2,014.5	41%	0.0	0%
3,301-10,000	2,288	2,288	100%	270.5	12%	946.6	41%	0.0	0%
10,001-50,000	1,232	1,232	100%	218.0	18%	493.7	40%	0.0	0%
50,001-100,000	129	129	100%	22.8	18%	51.6	40%	0.0	0%
100,001-1 Million	60	60	100%	16.0	27%	22.8	38%	0.0	0%
> 1 Million	2	2	100%	1.0	50%	0.9	44%	0.0	0%
National Totals	32,105	32,105	100%	2,213	7%	5,341	17%	0	0%
Surface Water and Mixed NTNCWSs									
≤ 100	303	303	100%	0.0	0%	0.0	0%	0.0	0%
101-500	302	302	100%	0.0	0%	0.0	0%	0.0	0%
501-1,000	109	109	100%	0.0	0%	0.0	0%	0.0	0%
1,001-3,300	74	74	100%	0.0	0%	0.0	0%	0.0	0%
3,301-10,000	22	22	100%	0.0	0%	6.0	27%	0.0	0%
10,001-50,000	9	9	100%	8.0	89%	4.0	44%	0.0	0%
50,001-100,000	1	1	100%	1.0	100%	1.0	100%	0.0	0%
100,001-1 Million	1	1	100%	1.0	100%	1.0	100%	0.0	0%
> 1 Million	0	0	-	0.0	-	0.0	-	0.0	-
National Totals	821	821	100%	10	1%	12	1%	0	0%
Ground Water Only NTNCWSs									
≤ 100	3,662	3,662	100%	0.0	0%	0.0	0%	0.0	0%
101-500	2,624	2,624	100%	0.0	0%	0.8	0%	0.0	0%
501-1,000	717	717	100%	0.0	0%	5.1	1%	0.0	0%
1,001-3,300	267	267	100%	0.0	0%	1.9	1%	0.0	0%
3,301-10,000	27	27	100%	0.1	0%	0.3	1%	0.0	0%
10,001-50,000	4	4	100%	0.9	19%	0.9	19%	0.0	0%
50,001-100,000	0	0	100%	0.1	19%	0.1	19%	0.0	0%
100,001-1 Million	1	1	100%	0.0	0%	0.0	0%	0.0	0%
> 1 Million	0	0	-	0.0	-	0.0	-	0.0	-
National Totals	7,303	7,303	100%	1	0%	9	0%	0	0%
GRAND TOTAL	51,632	51,632	100%	10,110	20%	8,062	16%	338	1%

Source: Economic Analysis (USEPA 2003i) Exhibit 6.3

In addition to using distributions to develop unit cost estimates, the Agency conducted sensitivity analyses to further explore uncertainty regarding system compliance estimates. The first two sensitivity analyses were prepared to evaluate the possibility that the IDSE monitoring requirement will result in more systems needing to install treatment beyond what is predicted in the current cost model (see chapter 7 of the EA, USEPA 2003i, for details of this analysis). Table VII–9 lists the high-end estimates of the number of systems adding treatment in IDSE sensitivity analyses No. 1 and No. 2. For both IDSE sensitivity analyses, only small additional impacts were assumed possible for systems serving 10,000 people or fewer because such systems generally have much less complicated distribution systems than larger systems. EPA estimated that the mean annualized costs at the 3% discount rate could be as high as $77.5 million (IDSE Sensitivity Analysis No. 1) or $108.8 million (IDSE Sensitivity Analysis No. 2) versus the Preferred Alternative analysis estimate of $57.4 million. At the 7% discount rate these estimates would respectively correspond to $86.1 million, $120.7 million, and $63.3 million.

Table VII-9 Sensitivity Analysis on Potential Treatment Impacts of IDSE From Stage 1 to Stage 2 (Community Water Systems)

	Percent Adding Treatment		
	Preferred Alternative	IDSE No. 1	IDSE No. 2
SW ≤ 10,000	3.7%	4.6%	4.8%
SW > 10,000	5.8%	9.9%	15.1%
GW ≤ 10,000	2.7%	2.8%	2.9%
GW > 10,000	2.1%	3.2%	3.6%

Source: Economic Analysis, Exhibit 7.1 Chapter 7 (USEPA 2003i).

EPA believes that the percentage of systems estimated to add treatment under IDSE sensitivity analyses No. 1 and No. 2 are overestimates and that the estimate for the Preferred Alternative is likely to already capture the influence of the IDSE because of the conservative assumptions used in the analysis. For example, the compliance forecast analysis assumes that systems will try to meet the LRAA MCLs with a 20% margin of safety. Systems complying by switching to chloramines may choose to meet the new MCLs with a much smaller margin of safety since chloramines dampen the variability of DBP concentrations within the distribution system. Furthermore, EPA believes that the number of ground water and small surface water systems adding chloramines or changing technology in the baseline analysis may be overestimated because their monitoring requirements are expected to be very similar from Stage 1 to Stage 2. The Stage 1 DBPR required only one compliance monitoring location (at the point of maximum residence time) for producing surface water systems serving between 500 and 10,000 people and for all ground water systems. The Stage 2 DBPR requires that these systems add an additional site if they determine that their high TTHM and high HAA5 concentrations do not occur at the same location. If systems maintain a single monitoring location for the Stage 2 DBPR, as many are expected to do, calculation of compliance will produce the same results for the running annual average (RAA) and locational running annual average (LRAA) measure, implying that they are not likely to add treatment for the Stage 2 DBPR if they comply with the Stage 1 DBPR.

EPA conducted a third sensitivity analysis to evaluate the possibility that small systems will continue to monitor at one point in their distribution system. In this sensitivity analysis, EPA assumed that no surface water plants serving fewer than 10,000 people and no ground water plants would add treatment to meet Stage 2 DBPR requirements (*i.e.*, only costs are associated for large surface water systems). Under this analysis, the average cost figures are reduced dramatically from $57.4 million or $63.3 million to $22.9 million or $25.7 million using a 3 percent or 7 percent discount rate, respectively, for the Preferred Regulatory Alternative. Chapter 7 of the Economic Analysis (USEPA 2003i) contains a detailed explanation of the aforementioned sensitivity analysis.

3. State Costs

The Agency estimates that the States and primacy agencies will incur an annualized present value cost of $1.1 million to $1.5 million (using a three percent and seven percent discount rate, respectively). In order to estimate the cost impact to States, EPA considered initial implementation costs, costs for assisting systems in evaluating IDSE information, and for annual rule implementation activities. EPA considered the incremental change in activities that result from the Stage 2 DBPR. For example, States may have to update their databases to track the new Stage 2 DBPR monitoring strategy but could modify the system they developed for the Stage 1 DBPR. EPA accounted for the cost of a Stage 1 DBPR database in the Stage 1 Regulatory Impact Analysis (USEPA 1998f). State costs are not expected to change dramatically between alternatives.

4. Non-quantifiable

EPA has identified and quantified costs that it believes are likely to be significant. In some instances, EPA did not include a potential cost element because it believes the effects are relatively minor and difficult to estimate. For example, the Stage 2 DBPR may be the determining factor in the decision by some small water systems to merge with neighboring systems. Such changes have both costs (legal fees and connecting infrastructure) and benefits (economies of scale). Likewise, costs for procuring a new source of water would have costs for new infrastructure but could result in lower treatment costs.

Also, EPA was unable to quantify several distribution system-related

changes that can reduce TTHM and HAA5 levels. Activities such as looping distribution systems and optimizing storage can minimize retention times and help to control DBP formation. Costs for these activities range from almost zero (modifying retention time) to more substantial costs for modifying distribution systems. In the absence of detailed information needed to make cost evaluations for situations such as these, EPA has included a discussion of possible effects where appropriate.

E. Expected System Treatment Changes

In order to quantify the effects of the Stage 2 DBPR, it is necessary to predict how plants will modify their treatment processes to meet the proposed requirements. To estimate the incremental impacts of the Stage 2 DBPR, relative to the Stage 1 DBPR, EPA compared predicted ''ending technologies'' (types of treatment in use after implementation of the Stage 2 DBPR) to the distribution of baseline technologies predicted to be in place after the implementation of the Stage 1 DBPR. This subsection outlines the process for deriving baseline and ending Stage 2 technology distributions that are the basis for the national cost estimates of today's proposed rule.

1. Pre-Stage 2 DBPR Baseline Conditions

Development of the Pre-Stage 2 baseline (*i.e.*, conditions following the Stage 1 DBPR) consists of the following processes:

- Compiling an industry profile—identifying and collecting information on the segment(s) of the water supply industry subject to the Stage 2 DBPR;
- Characterizing influent water quality—summarizing the relevant characteristics of the raw water treated by the industry; and
- Characterizing treatment for the Stage 1 DBPR—predicting what the industry will do to comply with the provisions of the Stage 1 DBPR.

Section IV of this document details the data sources EPA used to characterize water quality and treatment practices for the nation's public water systems. EPA also used information in the *Water Industry Baseline Handbook* (USEPA 2000j) to develop the industry profile. The Baseline Handbook uses data derived from the 1995 Community Water Systems Survey and the Safe Drinking Water Information System to characterize the U.S. drinking water systems. Another EPA study, *Geometries and Characteristics of Water Systems Report* (USEPA 2000k), also provided information for the industry profile.

EPA developed and used a model (SWAT) to characterize treatment following the Stage 1 DBPR and Stage 2 DBPR options considered. SWAT served as the primary tool to predict changes in treatment and DBP occurrence. The model used a series of algorithms and decision rules to predict the type of treatment a large surface water plant will use given a specific regulatory alternative and source water quality. Other tools were used to estimate practices at large ground water systems or any medium or small systems. A Delphi process (a detailed technical treatment characterization and DBP occurrence review by drinking water experts) was used to predict treatment changes for large ground water systems (those serving 10,000 or more people). The results of the SWAT analyses and the Delphi process were extrapolated to the medium surface water and ground water systems based on analysis of source water treatment characteristics and treatment decision trees. For the small surface and ground water systems analyses, a group of experts provided predictions for a pre-Stage 2 baseline and resulting treatment and water quality conditions under the Stage 2 DBPR regulatory alternatives. A detailed description of these analyses can be found in the *Economic Analysis for the Stage 2 DBPR* (USEPA 2003i).

2. Predicted Technology Distributions Post-Stage 2 DBPR

The treatment compliance forecast for the Stage 2 DBPR has two components—1) the percent of plants that must add treatment to comply with Stage 2 DBPR requirements, and 2) the treatment technologies these plants are predicted to select. This information, coupled with the baseline data discussed before, provides an estimate of the total number of plants using specific technologies to meet the requirements of the proposed Stage 2 DBPR. National costs are then generated using technology unit cost information.

The four step process EPA used to develop a Stage 2 DBPR compliance forecast is summarized in table VII–10. The difference between the Stage 1 DBPR Technology Selections and Stage 2 DBPR Technology Selections (Step 4—Incremental Technology Selections) was used to develop national cost estimates for today's proposed rule. Tables VII–11 a and b (surface water) and VII–12 a and b (ground water) show the incremental technology selections shown as the percent change between Stage 1 and Stage 2 DBP rules.

TABLE VII–10.—STAGE 2 DBPR COMPLIANCE FORECAST SUMMARY

Step	Description of Step
1	Model a pre-Stage 1 *baseline scenario* using Information Collection Rule data to allow consistent comparison between different rule alternatives.
2	Model *technology selection* to meet Stage 1 DBPR requirements (Stage 1 DBPR Technology Selection).
3	Model *technology selection* to meet Stage 2 DBPR requirements (Stage 2 DBPR Technology Selection).
4	Subtract the results in Step 2 from Step 3 and adjust to obtain the *incremental impact of an alternative (Stage 2 DBPR incremental technology selection*).

Table VII-11a. Technology Usage for CWS Surface Water Plants - Percent Change From Stage 1 to Stage 2 Compliance

System Size (Population Served)	Converting to CLM Only		Advanced Technologies: Chlorine Dioxide		UV		Ozone		MF/UF		GAC10		GAC10 + Advanced Disinfectants		GAC20		GAC20 + Advanced Disinfectants		Membranes		Total Converting to CLM		Total Adding Technology	
	A		B		C		D		E		F		G		H		I		J		K		L = SUM(A:J)	
≤100	0.8%	4			3.1%	14			0.0%	0					0.0%	0	0.6%	3	0.0%	0	3.0%	14	4.4%	21
101-500	2.1%	17	0.0%	0	0.4%	3	0.0%	0	0.0%	0					0.0%	0	0.7%	6	0.0%	0	3.6%	29	3.3%	26
501-1,000		11		0		2		0		0						0		4		0		18		17
1,001 - 3,300	2.5%	27	0.0%	0	0.5%	5	0.0%	0	0.0%	0					0.0%	0	0.7%	8	0.0%	0	4.0%	45	3.7%	41
3,301-10,000		30		0		6		0		0						0		9		0		49		45
10,001-50,000	3.6%	46	0.4%	5	0.7%	9	0.0%	0	0.0%	0	0.0%	0	0.7%	9	0.4%	5	0.0%	0	0.0%	0	5.1%	66	5.8%	75
50,001-100,000		19		2		4		0		0		0		4		2		0		0		28		31
100,001-1 Million	3.6%	21	0.4%	2	0.7%	4	0.0%	0	0.0%	0	0.0%	0	0.7%	4	0.4%	2	0.0%	0	0.0%	0	5.1%	29	5.8%	33
> 1 Million		3		0		1		0		0		0		1		0		0		0		4		4
Total %, Plants	2.7%	178	0.1%	9	0.7%	49	0.0%	0	0.0%	0	0.0%	0	0.3%	18	0.1%	9	0.4%	29	0.0%	0	4.3%	282	4.5%	293

Note: Detail may not add due to independent rounding (some plant results are rounded to zero if less than 0.5 plants).
Source : Economic Analysis (USEPA 2003i) Exhibit 6.14a

Table VII-11b. Technology Usage for NTNCWS Surface Water Plants - Percent Change From Stage 1 to Stage 2 Compliance

System Size (Population Served)	Converting to CLM Only		Advanced Technologies: Chlorine Dioxide		UV		Ozone		MF/UF		GAC10		GAC10 + Advanced Disinfectants		GAC20		GAC20 + Advanced Disinfectants		Membranes		Total Converting to CLM		Total Adding Technology	
	A		B		C		D		E		F		G		H		I		J		K		L = SUM(A:J)	
≤100	0.8%	2			3.1%	9			0.0%	0					0.0%	0	0.6%	2	0.0%	0	3.0%	9	4.4%	13
101-500	2.1%	6	0.0%	0	0.4%	1	0.0%	0	0.0%	0					0.0%	0	0.7%	2	0.0%	0	3.6%	11	3.3%	10
501-1,000		2		0		0		0		0						0		1		0		4		4
1,001 - 3,300	2.5%	2	0.0%	0	0.5%	0	0.0%	0	0.0%	0					0.0%	0	0.7%	1	0.0%	0	4.0%	3	3.7%	3
3,301-10,000		1		0		0		0		0						0		0		0		1		1
10,001-50,000	3.6%	0	0.4%	0	0.7%	0	0.0%	0	0.0%	0	0.0%	0	0.7%	0	0.4%	0	0.0%	0	0.0%	0	5.1%	0	5.8%	1
50,001-100,000		0		0		0		0		0		0		0		0		0		0		0		0
100,001-1 Million	3.6%	0	0.4%	0	0.7%	0	0.0%	0	0.0%	0	0.0%	0	0.7%	0	0.4%	0	0.0%	0	0.0%	0	5.1%	0	5.8%	0
> 1 Million		0		0		0		0		0		0		0		0		0		0		0		0
Total %, Plants	1.7%	14	0.0%	0	1.4%	11	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.7%	5	0.0%	0	3.5%	28	3.8%	31

Note: Detail may not add due to independent rounding (some plant results are rounded to zero if less than 0.5 plants).
Source : Economic Analysis (USEPA 2003i) Exhibit 6.14b

Table VII-12a. Technology Usage for Disinfecting CWS Ground Water Plants - Percent Change From Stage 1 to Stage 2 Compliance

System Size (Population Served)	CLM Only		UV CL2		UV CLM		Ozone CL2		Ozone CLM		GAC20 CL2		GAC20 CLM		embranes CL2		Membranes CLM		Total Converting to CLM		Total Adding Technology	
	A		B		C		D		E		F		G		H		I		J = A+C+E+G+I		K = SUM(A:I)	
≤100	1.0%	80	0.0%	0	1.3%	98	0.0%	0	0.0%	0	0.4%	33	0.0%	0	0.0%	0	0.0%	0	2.3%	178	2.7%	211
101-500	1.3%	210	0.0%	0	1.4%	225	0.0%	0	0.0%	0	0.2%	25	0.0%	0	0.0%	0	0.0%	0	2.8%	436	2.9%	461
501-1,000		82		0		88		0		0		10		0		0		0		170		180
1,001 - 3,300	1.0%	79	0.0%	0	1.3%	102	0.0%	0	0.0%	0	0.0%	0	0.0%	3	0.0%	0	0.0%	0	2.3%	184	2.3%	184
3,301-10,000		50		0		64		0		0		0		2		0		0		116		116
10,001-50,000	1.4%	76					0.1%	3	0.2%	12	0.0%	0	0.2%	8	0.0%	2	0.2%	11	2.0%	108	2.1%	112
50,001-100,000		10						0		2		0		1		0		2		15		15
100,001-1 Million	1.3%	11					0.1%	0	0.2%	2	0.0%	0	0.1%	1	0.0%	0	0.2%	2	1.9%	16	1.9%	17
> 1 Million		0						0		0		0		0		0		0		0		0
Total %, Plants	1.21%	599	0.00%	0	1.17%	578	0.01%	4	0.03%	15	0.14%	68	0.03%	16	0.00%	2	0.03%	15	2.5%	1,223	2.6%	1,296

Note: Detail may not add due to independent rounding (some plant results are rounded to zero if less than 0.5 plants).
Source : Economic Analysis (USEPA 2003i) Exhibit 6.16a

Table VII-12b. Technology Usage for Disinfecting NTNCWS Ground Water Plants - Percent Change from Stage 1 to Stage 2 Compliance

System Size (Population Served)	CLM Only		UV CL2		UV CLM		Ozone CL2		Ozone CLM		GAC20 CL2		GAC20 CLM		embranes CL2		Membranes CLM		Total Converting to CLM		Total Adding Technology	
	A		B		C		D		E		F		G		H		I		J = A+C+E+G+I		K = SUM(A:I)	
≤100	1.0%	38	0.0%	0	1.3%	46	0.0%	0	0.0%	0	0.4%	15	0.0%	0	0.0%	0	0.0%	0	2.3%	84	2.7%	99
101-500	1.3%	35	0.0%	0	1.4%	38	0.0%	0	0.0%	0	0.2%	4	0.0%	0	0.0%	0	0.0%	0	2.8%	73	2.9%	77
501-1,000		10		0		10		0		0		1		0		0		0		20		21
1,001 - 3,300	1.0%	3	0.0%	0	1.3%	3	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	2.3%	6	2.3%	6
3,301-10,000		0		0		0		0		0		0		0		0		0		1		1
10,001-50,000	1.4%	0					0.1%	0	0.2%	0	0.0%	0	0.2%	0	0.0%	0	0.2%	0	2.0%	0	2.1%	0
50,001-100,000		0						0		0		0		0		0		0		0		0
100,001-1 Million	1.3%	0					0.1%	0	0.2%	0	0.0%	0	0.1%	0	0.0%	0	0.2%	0	1.9%	0	1.9%	0
> 1 Million		0						0		0		0		0		0		0		0		0
Total %, Plants	1.17%	85	0.00%	0	1.34%	98	0.00%	0	0.00%	0	0.28%	21	0.00%	0	0.00%	0	0.00%	0	2.5%	183	2.8%	204

Note: Detail may not add due to independent rounding (some plant results are rounded to zero if less than 0.5 plants).
Source : Economic Analysis (USEPA 2003i) Exhibit 6.16b

F. Estimated Household Costs of the Proposed Rule

This analysis considers the potential increase in a household's water bill if a system passed the entire cost increase resulting from this rule on to their customers. It is a tool to gauge potential impacts and should not be construed as precise estimates of potential changes to individual water bills.

Overall, the potential increase in mean annual water bill per household is estimated to be $8.38 for those systems that need to install technology to comply with this rule. Table VII–13 shows the range of household costs for all surface and ground water systems subject to the rule and also only for those systems installing technology to comply with this rule. For all systems, including those that may not have to take any additional action to comply with this rule but are still subject to its provisions, the mean annual household cost is $0.51. The last two columns of Table VII–13 show the potential impact as the percent of households that will incur either less than a $1 or less than a $10 increase in their monthly water bills (shown in the table as annual values). For systems adding treatment, 84% of households will face less than a $1 increase in their monthly bill, while 99% are expected to face less than a $10 increase.

Table VII-13. Potential Annual Household Cost Impacts

All Households Subject to the Stage 2 DBPR							
	Total Number of Households Served (Percent of Total)	Mean Annual Household Cost Increase	Median Annual Household Cost Increase	90th Percentile Annual Household Cost Increase	95th Percentile Annual Household Cost Increase	Percentage of Annual Household Cost Increase < $12	Percentage of Annual Household Cost Increase < $120
All Systems	98,254,000 (100.0%)	$0.51	$0.02	$0.47	$0.79	99.24%	99.96%
All Small Systems	14,522,000 (100.0%)	$1.66	$0.18	$0.90	$2.96	98.23%	99.74%
SW ≤ 10,000	3,165,000 (3.2%)	$3.72	$0.90	$2.96	$5.51	97.89%	99.09%
SW > 10,000	58,876,000 (59.9%)	$0.34	$0.00	$0.32	$0.33	99.35%	100.00%
GW ≤ 10,000	11,357,000 (11.6%)	$1.08	$0.11	$0.53	$1.37	98.37%	99.92%
GW > 10,000	24,857,000 (25.3%)	$0.23	$0.01	$0.47	$0.47	99.57%	100.00%
Households Served by Plants Adding Treatment							
	Number of Households Served (Percent of Total)	Mean Annual Household Cost Increase	Median Annual Household Cost Increase	90th Percentile Annual Household Cost Increase	95th Percentile Annual Household Cost Increase	Percentage of Household Cost Increase < $12	Percentage of Household Cost Increase < $120
All Systems	4,793,000 (4.9%)	$8.52	$1.22	$20.57	$33.98	84.47%	99.18%
All Small Systems	422,000 (2.9%)	$43.78	$19.05	$117.68	$166.67	39.38%	91.12%
SW ≤ 10,000	142,000 (4.5%)	$60.64	$9.08	$166.67	$270.04	54.36%	79.78%
SW > 10,000	3,868,000 (6.6%)	$5.02	$1.02	$11.58	$23.56	90.16%	99.96%
GW ≤ 10,000	279,000 (2.5%)	$35.18	$19.22	$72.07	$117.68	33.71%	96.94%
GW > 10,000	504,000 (2.0%)	$5.90	$1.33	$26.33	$33.24	78.73%	100.00%

Note: Detail may not to total add due to independent rounding. The last two columns show the % change as < $1 or < $10 increase in monthly water bills

Source : Economic Analysis (USEPA 2003i) Exhibit 6.20

Both household cost estimates reflect costs for rule implementation (*e.g.*, reading and understanding the rule), IDSE, additional routine monitoring, and treatment changes. Although implementation and the IDSE represent relatively small, one-time costs, they have been annualized and included in the analysis to provide a complete picture of household costs.

Overall, EPA estimates that 99 percent of the 98 million households that are provided disinfected drinking water would face less than $1 increase in their monthly water bill. Approximately 86 percent of the households impacted by the rule are served by systems serving at least 10,000 people; these systems experience the lowest increases in costs due to significant economies of scale. Households served by small systems that install advanced technologies will face the greatest increases in annual costs. The cumulative distributions of household costs for all systems are presented in the Economic Analysis (USEPA 2003i).

When interpreting the results of the household cost analysis, it is important to remember that systems, especially small systems, may have other options that were not included in the compliance forecast. For example, the system may identify another water source that may form lower levels of TTHM and HAA5. Systems that can identify such an alternate water source may not have to treat that water as much as their current source, resulting in lower treatment costs that may offset the costs of obtaining water from the alternate source. Systems may also be able to connect to a neighboring water system. While connecting to another system may not be feasible for some remote systems, EPA estimates that more than 22 percent of all small water systems are located within metropolitan regions (USEPA 2000c) where distances between potential connecting water systems may not present a prohibitive barrier. Consolidation was not an element used in developing the compliance forecasts for small systems. Costs for consolidation may be either greater or less than the costs for changing technologies, and consolidation may have other benefits (*e.g.*, lower costs for compliance with future regulations). In addition, potentially lower cost alternatives such as controlling water residence time in the distribution systems were not included in the compliance forecast.

Also, more small systems than projected in the primary analysis may already be in compliance with Stage 2 DBPR. A sensitivity analysis discussed in the subsection VII.D.2 describes this issue in more detail. Also, certain technologies installed to treat DBPs may treat many other contaminants thus eliminating the need to install additional equipment to comply with future drinking water regulations.

G. Incremental Costs and Benefits of the Proposed Stage 2 DBPR

Incremental costs and benefits are those that are incurred or realized in reducing DBP exposures from one alternative to the next more stringent alternative. Estimates of incremental costs and benefits are useful in considering the economic efficiency of different regulatory options considered by the Agency. However, as pointed out by the Environmental Economics Advisory Committee of the Science Advisory Board, efficiency is not the only appropriate criterion for social decision making (USEPA 2000n).

Generally, the goal of an incremental analysis is to identify the regulatory option where net social benefits are maximized. If net incremental benefits

are positive, society is incurring greater costs as a result of the health damages compared to the costs society could pay to reduce those health damages (*i.e.* society would be better off to invest more in controlling the health damage). If net incremental benefits are negative, than the cost of the additional control is higher than the value of the additional health damages avoided. Therefore, the ''efficient'' regulatory level is where the next additional incremental reduction in health damages equals the incremental cost of achieving that reduction. However, the usefulness of this analysis is constrained when major benefits and/or costs are unquantified or not monetized.

For the proposed Stage 2 DBPR, presentation of incremental quantitative benefit and cost comparisons may be unrepresentative of the true net benefits of the rule because a significant portion of the rule's potential benefits are non-quantifiable (*see* section C.1). Tables VII–14 and VII–15 show the total estimated costs and benefits for each alternative. Evaluation of the incremental changes between different rows in the tables shows that incremental costs generally fall within the range of incremental benefits for each more stringent alternative. Equally important, the addition of any benefits attributable to the non-quantified categories would add to the benefits without any increase in costs.

TABLE VII–14.—TOTAL ANNUALIZED PRESENT VALUE COSTS BY RULE ALTERNATIVE

($millions, 2000$)

Rule alternative	Total annualized cost ($millions)					
	3 Percent discount rate			7 Percent discount rate		
	Mean estimate	90 Percent confidence bound		Mean estimate	90 Percent confidence bound	
		Lower (5th % tile)	Upper (95th % tile)		Lower (5th % tile)	Upper (95th % tile)
Preferred	$59.1	$54.3	$63.9	$64.6	$59.2	$70.0
Alt. 1	182.2	165.1	199.6	195.1	175.9	214.3
Alt. 2	409.6	383.6	435.7	442.7	413.4	472.2
Alt. 3	594.3	556.3	631.9	644.2	601.1	686.9

Note: Costs represent values in millions of 2000 dollars. Estimates are discounted to 2003—90 percent Confidence Intervals reflect uncertainty in technology unit cost estimates

Source: Economic Analysis (USEPA 2003i) exhibit 6.24

Table VII-15. Total Annualized Present Value Benefits by Rule Alternative ($millions, 2000$)

	Discount Rate, WTP for Non-Fatal Cases	Preferred Alternative	Alternative 1	Alternative 2	Alternative 3
Number and Value of Estimated Bladder Cancer Cases Avoided[1]					
Causality has not been established; however, the weight of evidence supports PAR estimates of potential benefits. Zero is within the range of potential benefits, but evidence indicates that both the number of cases and the value of preventing those cases could be significant (see below).					
2% PAR					
Average Annual Number of Cases Avoided		21	22	135	161
Annualized Benefits of Cases Avoided (90% Confidence Bounds)[2]	3 %, Lymphoma	$113 ($18 - 258)	$117 ($19 - 268)	$773 ($116 - 1,675)	$873 ($139 - 1,995)
	7 % Lymphoma	$98 ($16 - 224)	$102 ($16 - 232)	$636 ($101 - $1,452)	$757 ($120 - 1,730)
	3 % Bronchitis	$55 ($13 - 120)	$57 (13 - 124)	$356 ($81 - 776)	$424 ($97 - 924)
	7 % Bronchitis	$48 ($11 - 104)	$49 ($11 - 108)	$309 ($71 - 673)	$368 ($84 - 802)
17% PAR Value					
Average Number of Cases Avoided		182	189	1,182	1,408
Annualized Benefits of Cases Avoided (90% Confidence Bounds)[2]	3 %, Lymphoma	$986 ($157 - 2,253)	$1,024 ($163 - 2,340)	$6,398 ($1,016 - 14,619)	$7,621 ($1,211 - 17,415)
	7 % Lymphoma	$854 ($136 - 1,952)	$887 ($141 - 2,027)	$5,546 ($881 - 12,672)	$6,607 ($1,050 - 15,097)
	3 % Bronchitis	$479 ($109 - 1,044)	$498 ($114 - 1,084)	$3,109 ($709 - 6,771)	$3,704 ($845 - 8,066)
	7 % Bronchitis	$415 ($95 - 905)	$431 ($99 - 940)	$2,697 ($616 - 5,871)	$3213 ($734 - 6,995)
Adverse Reproductive and Developmental Health Effects Avoided					
Causality has not been established, and numbers and types of cases avoided, as well as the value of such cases, were not quantified in the primary benefits analysis. Given the numbers of women of child bearing age exposed (58 million), the evidence indicates that the number of cases and the value of preventing those cases could be significant. See results of the illustrative calculation in VII.C.1.					
Other Health Benefits					
Qualitative assessment indicates that the value of other health benefits could be positive and significant.					
Non-Health Benefits					
Qualitative assessment indicates that the value of non-health benefits could be positive.					

1. Based on TTHM as indicator. EPA recognizes that the lower bound estimate may be as low as zero since causality has not yet been established between exposure to chlorinated water and bladder cancer.
2. The 90 percent confidence bounds shown in the exhibit reflect uncertainty in the VSL, WTP, and income elasticity adjustment.
Source: Economic Analysis (USEPA 2003i) exhibit 5.28

The range of quantified benefits increases significantly with Alternatives 2 and 3. However, the associated costs also increase significantly—cost figures presented in Table VII–14 show values approaching or exceeding $500 million

per year. Although the estimated benefits for Alternatives 2 and 3 are potentially significant, EPA rejected these alternatives because the Agency believes that the uncertainty about the health effects data does not warrant the additional expense associated with these regulatory alternatives.

Given the uncertainty in the health effects, and the resulting rejection of Alternatives 2 and 3, a comparison of Alternative 1 with the Preferred Alternative shows that Alternative 1 would have approximately the same benefits as the Preferred Alternative but with greater costs. This results from the inability of the Agency to estimate the additional benefits of reducing the bromate MCL. Alternative 1 was also determined to be unacceptable due to the potential for increased risk of microbial exposure. See section VII.A of today's action for a description of regulatory alternatives.

H. Benefits From the Reduction of Co-Occurring Contaminants

Installing certain technologies to control DBPs also has the added benefit of controlling other drinking water contaminants. For example, some membrane technologies (depending on pore size) installed to reduce DBP precursors can also reduce or eliminate many other drinking water contaminants, including arsenic and microbial pathogens. EPA has finalized a rule to further control arsenic level in drinking water and has proposed the Ground Water Rule to address microbial contamination. The Stage 2 DBPR is also being concurrently proposed with the Long Term 2 Enhanced Surface Water Treatment Rule. Because of the difficulties in establishing which systems would have multiple problems such as microbial contamination, arsenic, and DBPs (or any combination of the three), no estimate was made of the potential cost savings from addressing more than one contaminant simultaneously.

I. Are There Increased Risks From Other Contaminants?

Today's proposed rule may slightly shift the distribution of TTHM and HAAs to brominated species. Some systems, depending on bromide and organic precursor levels in the source water and technology selection, may experience a shift to higher ratios or concentrations of brominated DBPs while the overall TTHM or HAA5 concentration decreases. However, EPA anticipates that this phenomenon may only occur in a small percentage of systems affected. For most systems, overall levels of DBPs, as well as brominated DBP species, should decrease as a result of this rule.

EPA's analysis shows that a large portion of systems that do not currently meet Stage 2 requirements will do so by switching from chlorination to chloramination; approximately 5% of surface water plants and 1.3% of ground water plants in systems serving greater than 10,000 are estimated to convert to chloramination in order to comply with the Stage 2 DBPR from the Stage 1 DBPR (USEPA 2003i). A potential chloramination byproduct is N-nitrosodimethylamine (NDMA), a probable human carcinogen. The concern over the formation of NDMA in the treatment process is based on the compound's ability to persist for a long period of time in the distribution system. The mechanism of formation of NDMA, however, is still under examination. A number of ongoing studies will also evaluate occurrence, factors that affect NDMA formation, mechanisms, treatment effectiveness and improved analytical methods for measuring NDMA.

Another contaminant of concern to the Agency is chlorite. Levels may increase slightly because of technology shifts to chlorine dioxide resulting from this rule but very few systems (<0.1 percent) are predicted to install this technology. However, individual systems will not shift to chlorine dioxide unless they can meet the chlorite MCL (established under the Stage 1 DBPR) which is considered protective of public health.

EPA also considered the impact this rule may have on microbial contamination that may result from altering disinfection practices. To address this concern, the Agency developed this rule jointly with the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR). EPA expects that the LT2ESWTR provisions will prevent significant increases in microbial risk resulting from the Stage 2 DBPR. EPA also expects the Ground Water Rule, scheduled for promulgation in 2003, to prevent any increases in microbial risk in ground water systems deemed vulnerable to source water contamination.

J. Effects on General Population and Subpopulation Groups

Section III of today's proposed rule discusses the health effects associated with DBPs on the general population as well as the effects on pregnant women and fetuses. In addition, health effects associated with children and pregnant women are discussed in greater detail in subsection VIII.G of this preamble.

K. Uncertainties in Baseline, Risk, Benefit, and Cost Estimates

Today's proposal models the current baseline risk from DBP exposure as well as the reduction in risk and the cost for various rule options. There is uncertainty regarding many aspects of this analysis including the risk calculation, the benefit estimate, and the cost estimates. EPA has tried to capture much of the uncertainty and also the variability associated with many of the inputs used in the economic analysis by using distributions or ranges as model inputs instead of point estimates whenever possible. The Stage 2 DBPR EA contains a more extensive discussion of the modeling techniques used to address uncertainty and variability (USEPA 2003i).

In addition, the Agency conducted sensitivity analyses to address uncertainty. The sensitivity analyses focus on various benefit and cost factors that may have a significant influence on the outcome of the rule. All of these sensitivity analyses are explained in more detail in the EA for the Stage 2 DBPR (USEPA 2003i).

The major source of benefit uncertainty is the scientific uncertainty regarding the impact of DBP exposure on reproductive and developmental outcomes. However, the Agency believes that the monetized value of these outcomes could be significant. As discussed in subsection VII.C.1, EPA performed an illustrative calculation that explored the potential implications for the proposed rule using some of the published results on fetal loss, but did not attempt to quantify benefits associated with reducing other reproductive and developmental endpoints potentially associated with DBP exposure.

Another possible underestimation of today's monetized benefits results from the inability of the Agency to quantify or monetize the potential benefit from avoiding other cancers associated with DBP exposure such as colon and rectal cancers. Furthermore, while the Agency estimated the range of bladder cancer risks avoided to be 0 to 182 cases per year, the true risk of bladder cancer avoided from decreased DBP exposure may be higher than this range.

While EPA believes it has accounted for the significant costs of today's proposed rule, there are uncertainties about some of the cost inputs. As discussed in subsection VII.D.4, cost estimates do not include some alternatives to installing treatment (*e.g.*, improving management of distribution system residence time) that may be a less costly means of complying with the

Stage 2 DBPR. The Agency also explored two additional uncertainties which might have the greatest impact on our current estimates by conducting sensitivity analyses. These include the impact of IDSE monitoring and the possibility that the primary analysis overestimates the compliance forecast for small surface water systems and all ground water systems. A detailed discussion of these analyses can be found in chapter 7 of the Economic Analysis (USEPA 2003i).

Last, EPA has recently proposed or finalized new regulations for arsenic, radon, and microbials in ground water systems (Ground Water Rule); *Cryptosporidium* in small surface water systems and filter backwash in all system sizes (LT1ESWTR and Filter Backwash Rule); as well as concurrently proposing additional microbial control in surface water systems (Long Term 2 Enhanced Surface Water Treatment Rule). These rules may have overlapping impacts on some drinking water systems but it is not possible to estimate these because of lack of information on co-occurrence. However, it is possible for a system to choose treatment technologies that would address multiple contaminants. Therefore, the total cost impact of these drinking water rules is uncertain; however, it may be less than the estimated total cost of all individual rules combined.

L. Benefit/Cost Determination for the Proposed Stage 2 DBPR

The Agency has determined that the quantified and unquantified benefits of the proposed Stage 2 DBPR justify the costs. As discussed previously, the main concern for the Agency and the Advisory Committee involved in the Stage 2 rulemaking process was to address potential reproductive and developmental impacts associated with exposure to high DBP levels. The proposed rule achieves this objective using the least cost alternative by modifying how the annual average DBP level is calculated. This will reduce both average DBP levels associated with bladder cancer (and possibly other cancers) and peak DBP levels which are potentially associated with reproductive and developmental effects. In addition, this rule may reduce uncertainty about drinking water quality and may allow some systems to avoid installing additional technology to meet future drinking water regulations.

Compared to other rule options consider by the Agency, the proposed rule option is also the most cost-effective. The cost-effectiveness analysis compares the annual dollar cost of the rule to the annual number of bladder cancer cases potentially avoided. For bladder cancer reduction, the cost per case avoided for the proposed rule would be $0.3 million if the PAR is 17%, and $3.1 million if the PAR is 2%, and also varies depending on the discount rate used.

M. Request for Comment

The Agency requests comment on all aspects of the rule's economic impact analysis. Specifically, EPA seeks input into the following issues: (1) To what extent can systems install treatment to address multiple contaminants?; (2) Are there methods for monetizing potential reproductive and developmental endpoints associated with DBP exposure?; (3) To what extent will use of chloramination increase levels of NDMA and potentially associated health risks, and how should this be considered in this rule making; and (4) How should the Agency value nonfatal cancers? Specifically, EPA uses a range of severities to calculate the WTP estimate to avoid a case of chronic bronchitis. Should the Agency only consider the most severe case of chronic bronchitis as a better proxy for a non-fatal cancer? Also, should the Agency use the risk-risk trade-off estimate of WTP to avoid a case of chronic bronchitis instead of the risk-dollar trade-off estimate (see the EA (USEPA 2003i) for a complete discussion of these issues)?

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

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

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

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

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

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

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action.'' As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned ICR No. 2068.01 (USEPA 2003m).

The information collected as a result of this rule will allow the States and EPA to determine appropriate requirements for specific systems, and to evaluate compliance with the rule. For the first 3 years after Stage 2 DBPR promulgation, the major information requirements involve monitoring activities, which include conducting the IDSE and submission of the IDSE report, and tracking compliance. The information collection requirements are mandatory (Part 141), and the information collected is not confidential.

The estimate of annual average burden hours for the Stage 2 DBPR for systems and States is 248,568 hours. This estimate covers the first three years of the Stage 2 DBPR and includes implementation of Stage 2A and most of the IDSE (small system reports are not due until the fourth year). The annual average aggregate cost estimate is $18.0 million for operation and maintenance as a purchase of service for lab work, and $6.8 million is associated with labor. The annual burden hour per response is 2.59 hours. The frequency of response (average responses per respondent) is 11.8 annually. The estimated number of likely respondents is 8,131 per year (the product of burden hours per response, frequency, and respondents does not total the annual average burden hours due to rounding). Because disinfecting systems have already purchased basic monitoring equipment to comply with the Stage 1 DBPR, EPA assumes no capital start-up costs are associated with the Stage 2 DBPR ICR.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time

needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this rule, which includes this ICR, under Docket ID No. OW–2002–0043. Submit any comments related to the ICR for this proposed rule to EPA and OMB. See **ADDRESSES** section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, *Attention:* Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after August 18, 2003, a comment to OMB is best assured of having its full effect if OMB receives it by September 17, 2003. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Analysis (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, 5 U.S.C. 601 *et seq.,* generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute, unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, ''which are appropriate to the activities of the agency'' after proposing the alternative definition(s) in the **Federal Register** and taking comment. 5 U.S.C. 601(3) through (5). In addition to the above, to establish an alternative small business definition, agencies must consult with SBA's Chief Counsel for Advocacy.

For purposes of assessing the impacts of today's proposed rule on small entities, EPA considered small entities to be public water systems serving 10,000 or fewer persons. This is the cut-off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. In accordance with the RFA requirements, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7620 (February 13, 1998)), requested public comment, consulted with the Small Business Administration (SBA), and expressed its intention to use the alternative definition for all future drinking water regulations in the Consumer Confidence Reports regulation (63 FR 44511 (August 19, 1998)). As stated in that final rule, the alternative definition is applied to this regulation.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. We have determined that 75 small systems using surface water or ground water under the direct influence of surface water (GWUDI), which are 1.67% of all such systems affected by the Stage 2 DBPR, will experience an impact of greater than or equal to 1% of their revenues, and 49 small systems using surface water or GWUDI, which are 1.09% of all such systems affected by the Stage 2 DBPR, will experience an impact of greater than or equal to 3% of their revenues; further, 109 small ground water systems, which are 0.28% of all such systems affected by the Stage 2 DBPR, will experience an impact of greater than or equal to 1% of their revenues, and 38 small ground water systems, which are 0.10% of all such systems affected by the Stage 2 DBPR, will experience an impact of greater than or equal to 3% of their revenues (*see* Tables VIII–1 and VIII–2).

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Table VIII-1. Annualized Compliance Cost as a Percentage of Revenues or Expenditures for All Small Entities Using Surface Water and GWUDI.

Entity by System Size	Number of Small Systems (Percent)		Average Annual Estimated Revenues[1] per System ($)	Experiencing Costs of ≥1% of their Revenues		Experiencing Costs of ≥3% of their Revenues	
				Percent of Systems	Number of Systems	Percent of Systems	Number of Systems
	A		B	E	F=A*E	G	H=A*G
Small Governments	**2,238**	**50%**	**$2,396,249**	**1.67%**	**37**	**1.09%**	**24**
<100	384		$2,396,249	1.27%	5	0.00%	-
101-500	513		$2,396,249	1.53%	8	1.17%	6
501-1,000	283		$2,396,249	1.58%	4	1.46%	4
1,001-3,300	538		$2,396,249	1.79%	10	1.32%	7
3,301-10,000	519		$2,396,249	5.61%	29	3.71%	19
Small Businesses	**1,835**	**41%**	**$2,391,978**	**1.67%**	**31**	**1.09%**	**20**
<100	315		$2,391,978	1.27%	4	0.00%	-
101-500	421		$2,391,978	1.57%	7	1.17%	5
501-1,000	232		$2,391,978	1.58%	4	1.46%	3
1,001-3,300	441		$2,391,978	1.79%	8	1.32%	6
3,301-10,000	426		$2,391,978	5.61%	24	3.71%	16
Small Organizations	**403**	**9%**	**$4,446,165**	**1.27%**	**5**	**0.76%**	**3**
<100	69		$4,446,165	0.00%	-	0.00%	-
101-500	92		$4,446,165	1.44%	1	0.61%	1
501-1,000	51		$4,446,165	1.46%	1	0.75%	0
1,001-3,300	97		$4,446,165	1.32%	1	0.93%	1
3,301-10,000	94		$4,446,165	5.02%	5	3.71%	3
All Small Entities	**4,476**	**100%**	**$2,578,991**	**1.67%**	**75**	**1.09%**	**49**
<100	768		$2,578,991	1.27%	10	0.00%	-
101-500	1,027		$2,578,991	1.44%	15	1.17%	12
501-1,000	567		$2,578,991	1.58%	9	1.46%	8
1,001-3,300	1,075		$2,578,991	1.55%	17	1.32%	14
3,301-10,000	1,039		$2,578,991	5.61%	58	3.71%	39

[1] Revenue information was used whenever available. When it was not available, different measures, such as sales or annual operating expenditures, were used. Data were not available to differentiate revenue by system size.

Note: Detail may not add due to independent rounding.

Source: Economic Analysis (USEPA 2003i)

Table VIII-2. Annualized Compliance Cost as a Percentage of Revenues or Expenditures for All Small Entities Using Ground Water Only.

Entity by System Size	Number of Small Systems (Percent)		Average Annual Estimated Revenues[1] per System ($)	Experiencing Costs of ≥1% of their Revenues		Experiencing Costs of ≥3% of their Revenues	
				Percent of Systems	Number of Systems	Percent of Systems	Number of Systems
	A		B	E	F=A*E	G	H=A*G
Small Governments	**19,133**	**50%**	**$2,396,249**	**0.28%**	**54**	**0.10%**	**19**
<100	5,641		$2,396,249	0.00%	-	0.00%	-
101-500	7,269		$2,396,249	0.13%	9	0.00%	-
501-1,000	2,403		$2,396,249	0.75%	18	0.07%	2
1,001-3,300	2,599		$2,396,249	1.26%	33	0.04%	1
3,301-10,000	1,221		$2,396,249	1.32%	16	1.32%	16
Small Businesses	**15,689**	**41%**	**$2,391,978**	**0.28%**	**44**	**0.10%**	**16**
<100	4,625		$2,391,978	0.00%	-	0.00%	-
101-500	5,960		$2,391,978	0.13%	8	0.00%	-
501-1,000	1,970		$2,391,978	0.75%	15	0.07%	1
1,001-3,300	2,131		$2,391,978	1.26%	27	0.04%	1
3,301-10,000	1,001		$2,391,978	1.32%	13	1.32%	13
Small Organizations	**3,444**	**9%**	**$4,446,165**	**0.10%**	**4**	**0.01%**	**0**
<100	1,015		$4,446,165	0.00%	-	0.00%	-
101-500	1,308		$4,446,165	0.00%	-	0.00%	-
501-1,000	433		$4,446,165	0.14%	1	0.00%	-
1,001-3,300	468		$4,446,165	0.04%	0	0.02%	0
3,301-10,000	220		$4,446,165	1.32%	3	0.04%	0
All Small Entities	**38,265**	**100%**	**$2,578,991**	**0.28%**	**109**	**0.10%**	**38**
<100	11,282		$2,578,991	0.00%	-	0.00%	-
101-500	14,537		$2,578,991	0.13%	19	0.00%	-
501-1,000	4,806		$2,578,991	0.14%	7	0.07%	3
1,001-3,300	5,198		$2,578,991	1.26%	66	0.04%	2
3,301-10,000	2,443		$2,578,991	1.32%	32	1.32%	32

[1] Revenue information was used whenever available. When it was not available, different measures, such as sales or annual operating expenditures, were used. Data were not available to differentiate revenue by system size.
Note: Detail may not add due to independent rounding.
Source: Economic Analysis (USEPA 2003i)

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As a result of the input received from stakeholders, the EPA workgroup, the Advisory Committee, and other interested parties, EPA has developed MCLs using locational running annual averages (LRAA) of 0.080 and 0.060 mg/L for TTHM and HAA5 respectively, in combination with Initial Distribution Systems Evaluations (IDSE), as the preferred Stage 2 DBPR option. LRAAs are running annual averages calculated for each sample location in the distribution system. Since many small systems only monitor at one location, they will effectively base their compliance with the Stage 1 DBPR on an LRAA and therefore will not be significantly affected by the Stage 2 DBPR. In addition to meeting the MCLs for TTHM and HAA5, systems will be required to conduct IDSEs. The purpose of the IDSE is to identify compliance monitoring sites representing high TTHM and HAA5 levels in the distribution system. According to the Stage 2 DBPR Economic Analysis (USEPA 2003i), only 17% of all small water systems will conduct IDSE monitoring because small NTNCWSs are exempt from IDSE monitoring, systems serving fewer than 500 people may receive a waiver from their States, and other systems are eligible for a 40/30 certification if all compliance monitoring samples have been ≤ 0.040 and ≤ 0.030 mg/L for TTHM and HAA5 respectively during the previous two years. A large number of small ground water systems will qualify for this certification. This provision is described in more detail in section V.H. of this preamble.

Although not required by the RFA to convene a Small Business Advocacy

Review (SBAR) Panel because EPA determined that this proposal would not have a significant economic impact on a substantial number of small entities, EPA did convene a panel to obtain advice and recommendations from representatives of the small entities potentially subject to this rule's requirements.

Before convening the SBAR Panel, EPA consulted with a group of 24 SERs likely to be impacted by the Stage 2 M–DBP Rules. The SERs included small system operators, local government officials, and small nonprofit organizations. The SERs were provided with background information on the Safe Drinking Water Act, Stage 1 DBPR, IESWTR, and Stage 2 DBPR alternatives and unit cost analyses resulting from using different technologies to meet the required MCLs in preparation for the teleconferences on January 28, 2000, February 25, 2000, and April 7, 2000. This information package included data on options and preliminary unit costs for treatment enhancements under consideration. It is important to note that, since EPA did not consider the IDSE requirements until after these consultations with SERs and the SBAR panel, no comments were received on the IDSE requirements from the SERs or the SBAR panel. However, small system representatives were included in the Advisory Committee that recommended the IDSE.

During these conference calls, the information was discussed and EPA provided feedback and noted these initial SER comments. Following the calls, the SERs were asked to provide input on the potential impacts of the rule. Seven SERs provided written comments on these materials. These comments were provided to the SBAR Panel when the Panel convened in April 25, 2000. After a teleconference between the SERs and the Panel on May 25, 2000, the SERs were invited to provide additional comments on the information provided. Seven SERs provided additional comments on the rule components.

In general, the SERs consulted on the Stage 2 M–DBP rules were concerned about the impact of these proposed rules on small water systems. They were particularly concerned with acquiring the technical and financial capability to implement requirements, maintaining flexibility to tailor requirements to their needs, and the limitations of small systems.

The Small Business Advocacy Review (SBAR) Panel members for the Stage 2 DBPR were: the Small Business Advocacy Chair of the Environmental Protection Agency, the Chief of the Standards and Risk Reduction Branch of the Office of Ground Water and Drinking Water within EPA's Office of Water, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel for Advocacy of the Small Business Administration. The Panel convened on April 25, 2000, and met five times before the end of the 60-day Panel period on June 23, 2000. The SBAR Panel's report, ''Final Report of the Small Business Advocacy Review Panel on Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBPR) and Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR)'', the Small Entity Representatives (SERs) comments on components of the Stage 2 MDBP Rules, and the background information provided to the SBAR Panel and the SERs are available for review in the Office of Water Docket.

Today's proposal takes into consideration the recordkeeping and reporting concerns identified by the Panel and the SERs. The Panel recommended that EPA evaluate ways to minimize the rule recordkeeping and reporting burdens by ensuring that States have appropriate capacity for rule implementation and that EPA provide as much monitoring flexibility as possible to small systems. Continuity with the Stage 1 DBPR was maintained to the extent possible to ease the transition to the Stage 2 DBPR, especially for small systems. EPA's decision to maintain the same MCLs for TTHM and HAA5 will also help to minimize the additional implementation burden. Generally, routine monitoring will be similar in frequency to monitoring for the Stage 1 DBPR, and systems with low DBP levels will still be eligible for reduced monitoring. Many small systems will conduct the same amount of monitoring for the Stage 2 DBPR as for the Stage 1 DBPR. Surface and ground water community water systems (CWSs) serving 500 to 9,999 people and ground water systems serving at least 10,000 people may be required to add one sampling site and take an additional quarterly TTHM/HAA5 sample at that site. Also, EPA has specified consecutive system requirements; these will be new requirements in States where consecutive systems are not required to comply with some or all Stage 1 DBPR requirements. As noted before, since some small systems will be effectively complying with such requirements under the Stage 1 DBPR, the Stage 2 DBPR will not impose any additional burden on them.

The Panel also noted the concern of several SERs that flexibility should be provided in the compliance schedule of the rule. SERs noted the technical and financial limitations that some small systems will have to address, the significant learning curve for operators with limited experience, and the need to continue providing uninterrupted service as reasons why additional compliance time may be needed for small systems. The panel encouraged EPA to keep these limitations in mind in developing the proposed rule and provide as much compliance flexibility to small systems as is allowable under the SDWA. EPA believes that the proposed compliance schedules provides sufficient time for small systems to achieve compliance.

Under the proposed LT2ESWTR, certain subpart H systems with low levels of indicators such as *E. coli* will not have to monitor for *Cryptosporidium*. The efficacy of *E. coli* as an indicator will be evaluated using the large system data. Thus, small systems *E. coli* monitoring cannot be initiated until large and medium system monitoring has been completed. The LT2ESWTR compliance time line for small systems thus lags 1.5 to 2.5 years behind the large and medium systems; timeline. Because the Stage 2 DBPR must be implemented on a simultaneous schedule, the compliance timeline is similarly delayed 1.5 to 2.5 years behind large and medium systems. In addition, if capital improvements are necessary for a particular PWS to comply, a State may allow the system up to an additional two years to comply with the MCL. The Agency is developing guidance manuals to assist small entities with their compliance efforts.

The Panel considered a wide range of options and regulatory alternatives for providing small businesses with flexibility in complying with the Stage 2 DBPR. The Panel recognized the concern shared by most stakeholders regarding the need to reduce DBP variability in the distribution system. This concern comes from recent studies that, while not conclusive, suggest that there may be adverse reproductive effects associated with relatively short-term exposure to high levels of DBPs. Many small systems will be monitoring at only a single point in the distribution system (designed to represent the point of maximum TTHM and HAA5 exposure), and many small systems will be monitoring only once during the year, at a time which corresponds to the season with the highest potential occurrence.

Since there is a chance for this single sample to exceed an MCL, today's proposal requires systems that exceed an MCL on an annual or less frequent sample to begin increased (quarterly) monitoring rather than immediately being in violation of the MCL. The system must comply with the MCL as an LRAA once it has collected four quarterly samples. This allows small systems to generally monitor less frequently (to reduce their monitoring burden) during the period when the highest DBP levels are expected (to protect public health) without penalizing them (by requiring them to meet an MCL that would effectively be based on a single highest value if the systems were immediately in violation after a single sample exceeds an MCL). This compliance determination is consistent with requirements for systems that monitor quarterly for whom compliance is based on the compliance monitoring results of the previous four quarters.

It is important to note that based on the IDSE results, some small systems will have a high TTHM site that is different from the high HAA5 site. These systems will need to monitor at two sites under the Stage 2 DBPR. EPA believes that an approach based on compliance with 0.080 mg/L TTHM and 0.060 mg/L HAA5 LRAAs is an effective way of addressing concerns regarding locational variability.

In addressing seasonal variability, the Panel was concerned about a regulatory alternative requiring compliance with 0.080 mg/L TTHM and 0.060 mg/L HAA5 single highest value MCL (Alternative 2), because it would impose significant additional cost on some small systems. The Panel recommended that EPA instead explore an approach under which individual high values might trigger additional assessment and/or notification requirements, rather than an MCL violation.

EPA agrees with the panel recommendations on a single highest value MCL. Under today's proposal, public water systems are required to maintain a record of TTHM and HAA5 concentrations detected at each sample location. As part of the sanitary survey process, systems are required to conduct an evaluation and consult with their State regarding significant excursions in TTHM and HAA5 occurrence that have occurred. EPA is developing guidance for public water systems and States on how to identify significant excursions and conduct significant excursion evaluations, and how to reduce DBP levels through actions such as distribution system operational changes (USEPA 2003n) (Section V.E.).

The Panel noted the strong concerns expressed by some SERs about the uncertainty in the current scientific evidence regarding health effects from exposure to DBPs, particularly regarding short term exposure. A Panel member recommended that EPA give further serious consideration to making a determination that the currently available scientific evidence does not warrant imposing additional regulatory requirements beyond those in the Stage 1 DBPR at this time. This Panel member recommended that EPA instead continue to vigorously fund ongoing research in health effects, occurrence, and appropriate treatment techniques for DBPs, and reconsider whether additional requirements are appropriate during its next SDWA required six-year review of the standard. This panel member also recommended that EPA separately explore whether adequate data exist to warrant regulation of NTNCWSs at a national level at this time.

EPA has considered these recommendations and believes the Stage 2 DBPR is needed at this time to protect public health. 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. Therefore, while recognizing the uncertainties in the available information, EPA believes that the weight of evidence represented by the available epidemiology and toxicology studies on chlorinated water and DBPs supports a hazard concern and a protective public health approach to regulation. In addition, EPA has an ongoing research program to study DBP health effects, occurrence, and treatment.

EPA continues to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under 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 by State, local, and Tribal governments, in the aggregate, or by 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 why that alternative was not adopted.

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

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local and Tribal governments, in the aggregate, or the private sector in any one year. Based on total estimated nominal costs incurred by year, costs for public or private systems are not expected to exceed $100 million in any one year. In addition, total estimated annualized costs of this rule are $59 to $65 million for all systems, including labor burdens that States would face, such as training employees on the requirements of the Stage 2 DBPR, responding to PWS reports, and record keeping. Thus, today's proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that the Stage 2 DBPR contains no regulatory requirements that might significantly or uniquely affect small governments (see Tables VIII–1 and VIII–2). Since the Stage 2 DBPR affects all size systems

and the impact on small entities will be 0.00 to 0.11 percent of revenues, the Stage 2 DBPR is not subject to the requirements of section 203 of UMRA.

Nevertheless, in developing this rule, EPA consulted with small governments (*see* sections VIII.B., VIII.C. and VIII.F.). In preparation for the proposed Stage 2 DBPR, EPA conducted an analysis of small government impacts and included small government officials or their designated representatives in the rulemaking process. As noted previously, a variety of stakeholders, including small governments, had the opportunity for timely and meaningful participation in the regulatory development process through the SBREFA process, public stakeholder meetings, and Tribal meetings. Representatives of small governments took part in the SBREFA process for this rulemaking and they attended public stakeholder meetings. Through such participation and exchange, EPA notified several 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 this regulatory proposal.

The Agency has developed fact sheets that describe requirements of the proposed Stage 2 DBPR. These fact sheets are available by calling the Safe Drinking Water Hotline at 800–426–4791.

E. Executive Order 13132: Federalism

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

This proposed rule will not have federalism implications. It will not impose substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The proposed rule has one-time costs for implementation of approximately $68.5 million. Thus, Executive Order 13132 does not apply to this rule.

Although Executive Order 13132 does not apply to this rule, EPA did consult with State and local officials in developing this proposed regulation. On February 20, 2001, EPA held a dialogue on both the Stage 2 DBPR and LT2ESWTR with representatives of State and local governmental organizations including those that represent elected officials. Representatives from the following organizations attended the consultation meeting: Association of State Drinking Water Administrators (ASDWA), the National Governors' Association (NGA), the National Conference of State Legislatures (NCSL), the International City/County Management Association (ICMA), the National League of Cities (NLC), the County Executives of America, and health departments. At the consultation meeting, questions ranged from a basic inquiry into how *Cryptosporidium* gets into water to more detailed queries about anticipated implementation guidance, procedures, and schedules. No concerns were expressed. Some of the State and local organizations who attended the governmental dialogue on upcoming microbial and disinfection byproduct rulemakings were also participants in the Advisory Committee meetings and signed the Agreement in Principle. In addition, EPA consulted with a mayor in the SBREFA consultation described in section VIII B.

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

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop ''an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

Under Executive Order 13175, EPA may not issue a regulation that has Tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by Tribal governments, or EPA consults with Tribal officials early in the process of developing the proposed regulation and develops a Tribal summary impact statement.

EPA has concluded that this proposed rule may have Tribal implications because it may impose substantial direct compliance costs on Tribal governments, and the Federal government will not provide the funds necessary to pay those costs.

Total Tribal costs are estimated to be approximately $199,372 per year (at a 3 percent discount rate) and this cost is distributed across 559 Tribal systems. The cost for individual systems depend on system size and source water type. Of the 559 Tribes that may be affected in some form by the Stage 2 DBPR, 502 use ground water as a source and 57 systems use surface water or GWUDI. Since the majority of Tribal systems are ground water systems serving fewer than 500 people, less than 10 percent of all Tribal systems will likely have to conduct an IDSE. As a result, the Stage 2 DBPR is most likely to have an impact on Tribes using surface water or GWUDI serving more than 500 people. Accordingly, EPA provides the following Tribal summary impact statement as required by section 5(b) of Executive Order 13175. EPA provides further detail on Tribal impact in the *Economic Analysis for the Stage 2 Disinfectants and Disinfection Byproduct Rule* (USEPA 2003i).

EPA consulted with Tribal officials early in the process of developing this regulation to permit them to have meaningful and timely input into its development. Consistent with Executive Order 13175, EPA engaged in outreach and consultation efforts with Tribal officials in the development of this proposed regulation. The most long-term participation of Tribes was on the Advisory Committee through a representative of the All Indian Pueblo Council (AIPC), which is associated with approximately 20 Tribes.

In addition to obtaining Tribal input during the Advisory Committee negotiations, EPA presented the Stage 2 DBPR at the 16th Annual Consumer Conference of the National Indian Health Board, the Environmental Council's Annual Conference, and the EPA/Inter-Tribal Council of Arizona, Inc. Over 900 attendees representing Tribes from across the country attended the National Indian Health Board's Consumer Conference and over 100

Tribes were represented at the annual conference of the National Tribal Environmental Council. Representatives from 15 Tribes participated at the EPA/Inter-Tribal Council of Arizona meeting. At the first two conferences, an EPA representative conducted workshops on EPA's drinking water program and upcoming regulations, including the Stage 2 DBPR. EPA sent the presentation materials and a meeting summary to over 500 Tribes and Tribal organizations.

Fact sheets describing the requirements of the proposed rule and requesting Tribal input were distributed at an annual EPA Tribal meeting in San Francisco, and at a Native American Water Works Association meeting in Scottsdale, Arizona. EPA also worked through its Regional Indian Coordinators and the National Tribal Operations Committee to raise awareness of the development of the proposed rule. EPA mailed fact sheets on the Stage 2 DBPR to all of the federally recognized Tribes in November 2000, as well as the Tribal Caucus of the National Tribal Operations Committee.

A few Tribes responded by requesting more information and expressing concern about having to implement too many regulations. Some members of the Tribal Caucus noted that the rule would have a benefit. They also expressed a concern about infrastructure costs and the lack of funding attached to the rule. In response to one Tribal representative's comments on the November 2000 mailout, EPA explained the health protection benefit expected to be gained by this proposed rule. EPA also directed those who asked for more information to the Agreement in Principle on the EPA Web site.

EPA also held a teleconference for Tribal representatives on January 24, 2002. Prior to the teleconference, invitations were sent to all of the Federally-recognized Tribes, along with fact sheets explaining the rule. Twelve Tribal representatives and four regional Tribal Program Coordinators attended. The Tribal representatives requested further explanation of the rule and expressed concerns about funding sources. EPA also received calls from Tribes after the teleconference which provided EPA with further feedback. In the spirit of Executive Order 13175, and consistent with EPA policy to promote consultation between EPA and Tribal governments, EPA specifically solicits additional comment on this proposed rule from Tribal officials.

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

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

While this proposed rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, EPA nonetheless has reason to believe that the environmental health or safety risk (*i.e.,* the risk associated with DBPs) addressed by this action may have a disproportionate effect on children. As a matter of EPA policy, we have therefore assessed the environmental health or safety effect of DBPs on children. EPA has consistently and explicitly considered risks to infants and children in all assessments developed for this rulemaking. The results of the assessments are contained in section III of this preamble, *Health Risks to Fetuses, Infants, and Children: A Review* (USEPA 2003a), and in the Economic Analysis (USEPA 2003i). A copy of all documents has been placed in the public docket for this action.

EPA's Office of Water has historically considered risks to sensitive subpopulations (including fetuses, infants, and children) in establishing drinking water assessments, health advisories or other guidance, and standards (USEPA 1989c and USEPA 1991a). Waterborne disease from pathogens in drinking water is a major concern for children and other subgroups (elderly, immune compromised, pregnant women) because of their increased vulnerabilities (Gerba *et al.* 1996). There is a concern for potential reproductive and developmental risks posed by DBPs to children and pregnant women (USEPA 1994b; USEPA 1998c, Reif *et al.* 2000; Tyl, 2000). Specific to this action, human epidemiology and animal toxicology studies on DBPs have shown potential increased risks for spontaneous abortion, still birth, neural tube defects, cardiovascular effects and low birth weight. This rule is designed to lower those risks. EPA has provided an illustrative calculation of potential fetal losses avoided in section VII.C.1.

Section V.D of this preamble presents the regulatory alternatives that EPA evaluated for the proposed Stage 2 DBPR, and the Economic Analysis (USEPA 2003i) provides a more detailed discussion. The Agency considered four alternatives involving different MCLs and different compliance calculations. The proposed alternative was recommended by the Advisory Committee and selected by EPA as the Preferred Regulatory Alternative because it provides significant public health benefits for an acceptable cost. EPA's analysis of benefits and costs indicates that the proposed alternative is superior among those evaluated with respect to maximizing net benefits, as shown in the Economic Analysis (USEPA 2003i). The result of the Stage 2 DBPR may include a reduction in reproductive and developmental risk to children and pregnant women and a reduction in cancer risk.

It should also be noted that the LT2ESWTR, which will be implemented at the same time as this proposed rule, provides better controls of pathogens and achieves the goal of increasing microbial drinking water protection for children. The public is invited to submit or identify peer-reviewed studies and data, of which EPA may not be aware that assessed results of early life exposure to DBPs.

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

The proposed Stage 2 DBPR is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This determination is based on the following analysis.

The first consideration is whether the Stage 2 DBPR would adversely affect the supply of energy. The Stage 2 DBPR does not regulate power generation, either directly or indirectly. The public and private utilities that the Stage 2 DBPR regulates do not, as a rule, generate power. Further, the cost increases borne by customers of water utilities as a result of the Stage 2 DBPR are a low percentage of the total cost of water, except for a very few small systems that might install advanced technologies that must spread that cost over a narrow customer base. Therefore,

the customers that are power generation utilities are unlikely to face any significant effects as a result of the Stage 2 DBPR. In sum, the Stage 2 DBPR does not regulate the supply of energy, does not generally regulate the utilities that supply energy, and is unlikely significantly to affect the customer base of energy suppliers. Thus, the Stage 2 DBPR would not translate into adverse effects on the supply of energy.

The second consideration is whether the Stage 2 DBPR would adversely affect the distribution of energy. The Stage 2 DBPR does not regulate any aspect of energy distribution. The utilities that are regulated by the Stage 2 DBPR already have electrical service. As derived later in this section, the proposed rule is projected to increase peak electricity demand at water utilities by only 0.007 percent. Therefore, EPA estimates that the existing connections are adequate and that the Stage 2 DBPR has no discernable adverse effect on energy distribution.

The third consideration is whether the Stage 2 DBPR would adversely affect the use of energy. Because some drinking water utilities are expected to add treatment technologies that use electrical power, this potential impact is evaluated in more detail. The analyses that underlay the estimation of costs for the Stage 2 DBPR are national in scope and do not identify specific plants or utilities that may install treatment in response to the rule. As a result, no analysis of the effect on specific energy suppliers is possible with the available data. The approach used to estimate the impact of energy use, therefore, focuses on national-level impacts. The analysis estimates the additional energy use due to the Stage 2 DBPR, and compares that to the national levels of power generation in terms of average and peak loads.

The first step in the analysis is to estimate the energy used by the technologies expected to be installed as a result of the Stage 2 DBPR. Energy use is not directly stated in *Technologies and Costs for Control of Microbial Contaminants and Disinfection By-Products* (USEPA 2003k), but the annual cost of energy for each technology addition or upgrade necessitated by the Stage 2 DBPR is provided. An estimate of plant-level energy use is derived by dividing the total energy cost per plant for a range of flows by an average national cost of electricity of $0.076/kilowatt hours per year (kWh/yr) (U.S. Department of Energy, Energy Information Administration (USDOE EIA) 2002). These calculations are shown in detail in Chapter 8 of the *Economic Analysis for the Stage 2 DBPR* (USEPA 2003i). The energy use per plant for each flow range and technology is then multiplied by the number of plants predicted to install each technology in a given flow range. The energy requirements for each flow range are then added to produce a national total. No electricity use is subtracted to account for the technologies that may be replaced by new technologies, resulting in a conservative estimate of the increase in energy use. Table VIII–3 shows the estimated energy use for each Stage 2 DBPR compliance technology in kilowatt hours per year (kWh/yr). The incremental national annual energy usage is 0.08 million megawatt-hours (mWh).

Table VIII-3. Total Increased Annual National Energy Usage Attributable to the Stage 2 DBPR

Technology	Number of Plants Selecting the Technology (a)	Total Increase in Energy Usage as a Result of the Stage 2 DBPR (b)
Chloramines (with and without advanced tech.)	1,719	2,610,918
Chlorine Dioxide	9	37,335
UV	736	11,033,906
Ozone	19	1,545,741
MF/UF	0	1,821
GAC10	-	-
GAC10 + Adv. Disinfectants	18	14,914,955
GAC20	113	24,049,135
GAC20 + Adv. Disinfectants	34	4,366,613
NF	-	-
Membranes	17	17,680,345
TOTAL	**2,667**	**76,240,768**

Notes: Detail may not add due to independent rounding

To determine if the additional energy required for systems to comply with the rule would have a significant adverse effect on the use of energy, the numbers in Table VIII–3 are compared to the national production figures for electricity. According to the U.S. Department of Energy's Information Administration, electricity producers generated 3,800 million mWh of electricity in 2001 (USDOE EIA 2002). Therefore, even using the highest assumed energy use for the Stage 2 DBPR, the rule when fully implemented would result in only a 0.002 percent increase in annual average energy use.

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

incremental power demand by water utilities.

Both energy use and water use peak in the summer months, so the most significant effects on supply would be seen then. In the summer of 2001, U.S. generation capacity exceeded consumption by 15 percent, or approximately 120,000 mW (USDOE EIA 2002). Assuming around-the-clock operation of water treatment plants, the total energy requirement can be divided by 8,760 hours per year to obtain an average power demand of 8.3 mW. A more detailed derivation of this value is shown in Chapter 8 of the *Economic Analysis for the Stage 2 DBPR* (USEPA 2003i). Assuming that power demand is proportional to water flow through the plant and that peak flow can be as high as twice the average daily flow during the summer months, about 16.6 mW could be needed for treatment technologies installed to comply with the Stage 2 DBPR. This is only 0.014 percent of the capacity margin available at peak use.

Although EPA recognizes that not all areas have a 15 percent capacity margin and that this margin varies across regions and through time, this analysis reflects the effect of the rule on national energy supply, distribution, and use. While certain areas, notably California, have experienced shortfalls in generating capacity in the recent past, a peak incremental power requirement of 16.6 mW nationwide is not likely to significantly change the energy supply, distribution, or use in any given area. Considering this analysis, EPA has concluded that Stage 2 DBPR will not have any significant effect on the use of energy, based on annual average use and on conditions of peak power demand.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, Pub. L. No. 104–113, 12(d) (15 U.S.C. 272 *note*) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking involves technical standards. EPA proposes to use American Society for Testing and Materials (ASTM) Method D 6581–00 for chlorite, bromide, and bromate compliance monitoring, which can be found in the Annual Book of ASTM Standards Volume 11.01. In the Stage 1 DBPR, EPA approved 13 methods from the Standard Methods Committee for measuring disinfectants, DBPs, and other parameters. Today's rule proposes to add the most recent versions of these 13 methods as approved methods. These consist of Standard Methods 4500–Cl D, 4500–Cl F, 4500–Cl G, 4500–Cl E, 4500–Cl I, 4500–Cl H, 4500–ClO_2 D, 4500–ClO_2 E, 6251 B, 5310 B, 5310 C, 5310 D, and 5910 B for chlorine, chlorine dioxide, HAA5, chlorite, TOC/DOC, and UV_{254}. These methods can be found in the 19th and 20th editions of *Standard Methods for the Examination of Water and Waste Water* (APHA 1995; APHA 1996; APHA 1998). Standard Methods 4500–Cl D, 4500–Cl F, 4500–Cl G, 4500–Cl E, 4500–Cl I, 4500–Cl H, 4500–ClO_2 E, 6251 B, 5310 B, 5310 C, 5310 D, and 5910 B for chlorine, chlorine dioxide, HAA5, chlorite, TOC/DOC, and UV_{254} are also available in the On-Line Version of *Standard Methods for the Examination of Water and Waste Water* (APHA 2003).

EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

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

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

Two aspects of the Stage 2 DBPR comply with the order that requires the Agency to consider environmental justice issues in the rulemaking and to consult with stakeholders representing a variety of economic and ethnic backgrounds. These are: (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 has served as a template for the development of the Stage 2 DBPR. As such, the Agency built on the efforts conducted during the development of the Stage 1 DBPR to comply with Executive Order 12898. On March 12, 1998, the Agency held a stakeholder meeting to address various components of pending drinking water regulations and how they might impact sensitive subpopulations, minority populations, and low-income populations. This meeting was a continuation of stakeholder meetings that started in 1995 to obtain input on the Agency's Drinking Water Programs. Topics discussed included treatment techniques, costs and benefits, data quality, health effects, and the regulatory process. Participants were national, State, Tribal, municipal, and individual stakeholders. EPA conducted the meeting by video conference call between eleven cities. The major objectives for the March 12, 1998, meeting were the following:

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

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

The Stage 2 DBPR and other drinking water regulations promulgated or under development are expected to have a positive effect on human health regardless of the social or economic status of a specific population. The Stage 2 DBPR serves to provide a similar level of drinking water protection to all groups. Where water systems have high DBP levels, they must reduce levels to meet the MCLs. Thus, the Stage 2 DBPR meets the intent of Federal policy requiring incorporation of environmental justice into Federal agency missions.

The Stage 2 DBPR applies uniformly to community water systems and nontransient noncommunity water systems that apply a chemical disinfectant or deliver water that has been chemically disinfected. Consequently, the health protection from DBP exposure that this rule provides is equal across all income and minority groups served by systems regulated by this rule.

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

In accordance with sections 1412 (d) and (e) of SDWA, the Agency has consulted with the Science Advisory Board (SAB), the National Drinking Water Advisory Council (NDWAC), and will consult with the Secretary of Health and Human Services regarding the proposed Stage 2 DBPR during the public comment period.

EPA met with the SAB to discuss the Stage 2 DBPR on June 13, 2001 (Washington, DC), September 25–26, 2001 (teleconference), and December 10–12, 2001 (Los Angeles, CA). Written comments from the December 2001 meeting of the SAB addressing the occurrence analysis and risk assessment were generally supportive. EPA met with the NDWAC on November 8, 2001, in Washington, DC to discuss the Stage 2 DBPR proposal. The Advisory Committee generally supported the need for the Stage 2 DBPR based on health and occurrence data, but also stressed the importance of providing flexibility to the systems implementing the rule. The results of these discussions are included in the docket for this rule.

L. Plain Language

Executive Order 12866 encourages Federal agencies to write rules in plain language. EPA invites comments on how to make this proposed rule easier to understand. For example: Has EPA organized the material to suit commenters' needs? Are the requirements in the rule clearly stated? Does the rule contain technical language or jargon that is not clear? Would a different format (grouping and ordering of sections, use of headings, paragraphs) make the rule easier to understand? Could EPA improve clarity by adding tables, lists, or diagrams? What else could EPA do to make the rule easier to understand?

IX. References

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List of Subjects

40 CFR Part 141

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

40 CFR Part 142

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

40 CFR Part 143

Chemicals, Indians-lands, Water supply.

Dated: July 11, 2003.

Linda J. Fisher,

Acting Administrator.

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

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. 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.

2. Section 141.2 is amended by adding, in alphabetical order, definitions for ''Combined distribution system'', ''Consecutive system'', ''Consecutive system entry point'', ''Dual sample sets'', ''Finished water'', ''Locational running annual average'', and ''Wholesale system'' to read as follows:

§ 141.2 Definitions.

* * * * *

Combined distribution system is the interconnected distribution system consisting of the distribution systems of wholesale systems and of the consecutive systems that receive finished water from those wholesale system(s).

* * * * *

Consecutive system is a public water system that buys or otherwise receives some or all of its finished water from one or more wholesale systems, for at least 60 days per year.

Consecutive system entry point is a location at which finished water is delivered at least 60 days per year from a wholesale system to a consecutive system.

* * * * *

Dual sample set is a set of two samples collected at the same time and same location, with one sample analyzed for TTHM and the other sample analyzed for HAA5. Dual sample sets are collected for the purposes of conducting an IDSE under subpart U of this part and determining compliance with the TTHM and HAA5 MCLs under subpart V of this part.

* * * * *

Finished water is water that is introduced into the distribution system of a public water system and is intended for distribution without further treatment, except that necessary to maintain water quality.

* * * * *

Locational running annual average (LRAA) is the average of sample analytical results for samples taken at a particular monitoring site during the previous four calendar quarters.

* * * * *

Stage 2A is the period beginning [date three years following publication of the final rule] until the dates specified in subpart V of this part for compliance with Stage 2B, during which systems must comply with Stage 2A MCLs in § 141.64(b)(2).

* * * * *

Wholesale system is a public water system that treats source water and then sells or otherwise delivers finished water to another public water system for at least 60 days per year. Delivery may be through a direct connection or through the distribution system of one or more consecutive systems.

3. In § 141.23, the table in paragraph (k)(1) is amended by revising entries 13, 18, 19, and 20; revising the undesignated text after the table; and adding a new footnote 19 to read as follows:

§ 141.23 Inorganic chemical sampling and analytical requirements.

* * * * *

(k) Inorganic analysis:

* * * * *

Contaminant and methodology [13]	EPA	ASTM [3]	SM [4] (18th, 19th ed.)	SM [4] (20th ed.)	Other
* * *		*	*	*	*
13. Fluoride:					
Ion Chromatography	[6] 300.0 [19] 300.1	D4327–97	4110 B	4110 B	
Manual Distill.; Color. SPADNS.		.	4500–F B, D	4500–F B, D	
Manual Electrode		D1179–93B	4500–F C	4500–F C	
Automated Electrode		.	.	.	380–75WE [11]
Automated Alizarin		.	4500–F E	4500–F E	129–71W [11]
* * *		*	*	*	*
18. Nitrate:					
Ion Chromatography	[6] 300.0 [19] 300.1	D4327–97	4110 B	4110 B	B1011 [8]
Automated Cadmium Reduction	[6] 353.2	D3867–90A	4500–NO_3 F	4500–NO_3 F	
Ion Selective Electrode		.	4500–NO_3 D	4500–NO_3 D	601 [7]
Manual Cadmium Reduction		D3867–90B	4500–NO_3 E	4500–NO_3 E	
19. Nitrite:					
Ion Chromatography	[6] 300.0 [19] 300.1	D4327–97	4110 B	4110 B	B–1011[8]
Automated Cadmium Reduction	[6] 353.2	D3867–90A	4500–NO_3 F	4500–NO_3 F	
Manual Cadmium Reduction		D3867–90B	4500–NO_3 E	4500–NO_3 E	
Spectrophotometric			4500–NO_2 B	4500–NO_2 B	
20. Orthophosphate: [12]					

Contaminant and methodology [13]	EPA	ASTM [3]	SM [4] (18th, 19th ed.)	SM [4] (20th ed.)	Other
Colorimetric, automated, ascorbic acid	[6]365.1	.	4500–P F	4500–P F	
Colorimetric, ascorbic acid, single reagent		D515–88A	4500–P E	4500–P E	
Colorimetric, phosphomolybdate		.	.	.	I–1601–85[5]
Automated–segmented flow		.	.	.	I–2601–90[5]
Automated discrete		.	.	.	I–2598–85[5]
Ion Chromatography	[6] 300.0 [19] 300.1	D4327–97	4110 B	4110 B	
* * *		*	*	*	*

Note: The procedures shall be done in accordance with the documents listed below. The incorporation by reference of the following documents listed in footnotes 1–11 and 16–19 was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the documents may be obtained from the sources listed below. Information regarding obtaining these documents can be obtained from the Safe Drinking Water Hotline at 800–426–4791. Documents may be inspected at EPA's Drinking Water Docket, EPA West, 1301 Constitution Avenue NW., Room B102, Washington, DC 20460 (Telephone: 202–566–2426); or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

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[3] *Annual Book of ASTM Standards*, 1994, 1996, or 1999, Vols. 11.01 and 11.02, ASTM International; any year containing the cited version of the method may be used. The previous versions of D1688–95A, D1688–95C (copper), D3559–95D (lead), D1293–95 (pH), D1125–91A (conductivity) and D859–94 (silica) are also approved. These previous versions D1688–90A, C; D3559–90D, D1293–84, D1125–91A and D859–88, respectively are located in the Annual Book of ASTM Standards, 1994, Vol. 11.01. Copies may be obtained from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428.

[4] *Standard Methods for the Examination of Water and Wastewater*, 18th edition (1992), 19th edition (1995), or 20th edition (1998). American Public Health Association, 1015 Fifteenth Street, NW, Washington, DC 20005. The cited methods published in any of these three editions may be used, except that the versions of 3111 B, 3111 D, 3113 B and 3114 B in the 20th edition may not be used.

[5] Method I–2601–90, Methods for Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Inorganic and Organic Constituents in Water and Fluvial Sediment, Open File Report 93–125, 1993; For Methods I–1030–85; I–1601–85; I–1700–85; I–2598–85; I–2700–85; and I–3300–85 See Techniques of Water Resources Investigation of the U.S. Geological Survey, Book 5, Chapter A–1, 3rd ed., 1989; Available from Information Services, U.S. Geological Survey, Federal Center, Box 25286, Denver, CO 80225–0425.

[6] ''Methods for the Determination of Inorganic Substances in Environmental Samples'', EPA/600/R–93/100, August 1993. Available at NTIS, PB94–120821.

[7] The procedure shall be done in accordance with the Technical Bulletin 601 ''Standard Method of Test for Nitrate in Drinking Water'', July 1994, PN 221890–001, Analytical Technology, Inc. Copies may be obtained from ATI Orion, 529 Main Street, Boston, MA 02129.

[8] Method B–1011, ''Waters Test Method for Determination of Nitrite/Nitrate in Water Using Single Column Ion Chromatography,'' August 1987. Copies may be obtained from Waters Corporation, Technical Services Division, 34 Maple Street, Milford, MA 01757.

* * * * * * *

[11] Industrial Method No. 129–71W, ''Fluoride in Water and Wastewater'', December 1972, and Method No. 380–75WE, ''Fluoride in Water and Wastewater'', February 1976, Technicon Industrial Systems. Copies may be obtained from Bran & Luebbe, 1025 Busch Parkway, Buffalo Grove, IL 60089.

[12] Unfiltered, no digestion or hydrolysis.

[13] Because MDLs reported in EPA Methods 200.7 and 200.9 were determined using a 2X preconcentration step during sample digestion, MDLs determined when samples are analyzed by direct analysis (*i.e.*, no sample digestion) will be higher. For direct analysis of cadmium and arsenic by Method 200.7, and arsenic by Method 3120 B sample preconcentration using pneumatic nebulization may be required to achieve lower detection limits. Preconcentration may also be required for direct analysis of antimony, lead, and thallium by Method 200.9; antimony and lead by Method 3113 B; and lead by Method D3559–90D unless multiple in-furnace depositions are made.

* * * * * * *

[19] ''Methods for the Determination of Organic and Inorganic Compounds in Drinking Water'', Vol. 1, EPA 815–R–00–014, August 2000. Available at NTIS, PB2000–106981.

* * * * *

4. Section 141.24 is amended by revising paragraph (e)(1) and by revising entry 30 in the table in paragraph (e)(1) to read as follows:

§ 141.24 Organic chemicals, sampling and analytical requirements.

* * * * *

(e) * * *

(1) The following documents are incorporated by reference. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies may be inspected at EPA's Drinking Water Docket, 1301 Constitution Avenue, NW., EPA West, Room B102, Washington, DC 20460 (Telephone: 202–566–2426); or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. Method 508A and 515.1 are in *Methods for the Determination of Organic Compounds in Drinking Water*, EPA/600/4–88–039, December 1988, Revised, July 1991. Methods 547, 550 and 550.1 are in *Methods for the Determination of Organic Compounds in Drinking Water—Supplement I*, EPA/600–4–90–020, July 1990. Methods 548.1, 549.1, 552.1 and 555 are in *Methods for the Determination of Organic Compounds in Drinking Water—Supplement II*, EPA/600/R–92–129, August 1992. Methods 502.2, 504.1, 505, 506, 507, 508, 508.1, 515.2, 524.2 525.2, 531.1, 551.1 and 552.2 are in *Methods for the Determination of Organic Compounds in Drinking Water—Supplement III*, EPA/600/R–95–131, August 1995. Method 1613 is titled ''Tetra-through Octa-Chlorinated Dioxins and Furans by Isotope-Dilution HRGC/HRMS'', EPA/821–B–94–005, October 1994. These documents are available from the National Technical Information Service, NTIS PB91–231480, PB91–146027, PB92–207703, PB95–261616 and PB95–104774, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll-free number is 800–553–6847. Method 6651 shall be followed in accordance with *Standard Methods for the Examination of Water and Wastewater*, 18th edition (1992), 19th edition (1995), or 20th edition (1998), American Public Health Association (APHA); any of these three editions may be used. Method 6610 shall be followed in accordance with *Standard Methods for the Examination of Water and Wastewater, (18th Edition Supplement)* (1994), or with the 19th edition (1995) or 20th edition (1998) of *Standard Methods for the Examination of Water and Wastewater*; any of these publications may be used. The APHA documents are available from APHA, 1015 Fifteenth Street NW., Washington, D.C. 20005. Other required analytical test procedures germane to the conduct

of these analyses are contained in *Technical Notes on Drinking Water Methods*, EPA/600/R–94–173, October 1994, NTIS PB95–104766. EPA Methods 515.3 and 549.2 are available from U.S. Environmental Protection Agency, National Exposure Research Laboratory (NERL)—Cincinnati, 26 West Martin Luther King Drive, Cincinnati, OH 45268. ASTM Method D 5317–93 is available in the *Annual Book of ASTM Standards*, (1999), Vol. 11.02, ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428, or in any edition published after 1993. EPA Method 515.4, ''Determination of Chlorinated Acids in Drinking Water by Liquid-Liquid Microextraction, Derivatization and Fast Gas Chromatography with Electron Capture Detection,'' Revision 1.0, April 2000, EPA/815/B–00/001 and EPA Method 552.3, ''Determination of Haloacetic Acids and Dalapon in Drinking Water by Liquid-Liquid Microextraction, Derivatization, and Gas Chromatography with Electron Capture Detection,'' Revision 1.0, July 2003 can be accessed and downloaded directly on-line at *http://www.epa.gov/safewater/methods/sourcalt.html*. The Syngenta AG–625, ''Atrazine in Drinking Water by Immunoassay'', February 2001 is available from Syngenta Crop Protection, Inc., 410 Swing Road, Post Office Box 18300, Greensboro, NC 27419, Phone number (336) 632–6000. Method 531.2 ''Measurement of N-methylcarbamoyloximes and N-methylcarbamates in Water by Direct Aqueous Injection HPLC with Postcolumn Derivatization,'' Revision 1.0, September 2001, EPA 815/B/01/002 can be accessed and downloaded directly on-line at *http://www.epa.gov/safewater/methods/sourcalt.html*.

Contaminant	EPA method [1]	Standard methods	ASTM	Other
* * *	*	*	*	*
30. Dalapon	552.1, 515.1, 552.2, 515.3, 515.4, 552.3			
* * *	*	*	*	*

[1] For previously approved EPA methods which remain available for compliance monitoring until June 1, 2001, *see* paragraph (e)(2) of this section.

* * * * *

5. Section 141.33 is amended by revising the first sentence of paragraph (a) introductory text, and adding paragraph (f) to read as follows:

§ 141.33 Record maintenance.

* * * * *

(a) Records of microbiological analyses and turbidity analyses made pursuant to this part shall be kept for not less than 5 years. * * *

* * * * *

(f) Copies of monitoring plans developed pursuant to this part shall be kept for the same period of time as the records of analyses are required to be kept under paragraph (a) of this section or for three years after modification, whichever is longer.

6. Section 141.53 is amended by revising the table to read as follows:

§ 141.53 Maximum contaminant level goals for disinfection byproducts.

* * * * *

Disinfection byproduct	MCLG (mg/L)
Bromodichloromethane	zero.
Bromoform	zero.
Bromate	zero.
Chlorite	0.8
Chloroform	0.07
Dibromochloromethane	0.06
Dichloroacetic acid	zero.
Monochloroacetic acid	0.03
Trichloroacetic acid	0.02

7. Section 141.64 is revised to read as follows:

§ 141.64 Maximum contaminant levels for disinfection byproducts.

(a) *Bromate and chlorite.* The maximum contaminant levels (MCLs) for bromate and chlorite are as follows:

Disinfection byproduct	MCL (mg/L)
Bromate	0.010
Chlorite	1.0

(1) *Compliance dates for CWSs and NTNCWSs.* Subpart H systems serving 10,000 or more persons must comply with this paragraph (a) beginning January 1, 2002. 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 paragraph (a) beginning January 1, 2004.

(2) *Best available technology.* 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 bromate and chlorite identified in this paragraph (a):

Disinfection byproduct	Best available technology
Bromate	Control of ozone treatment process to reduce production bromate.
Chlorite	Control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.

(b) *TTHM and HAA5.*

(1) *Subpart L—RAA compliance. (i) Compliance dates.* Subpart H systems serving 10,000 or more persons must comply with this paragraph (b)(1) beginning January 1, 2002 until the date specified for subpart V of this part compliance in § 141.620(c). 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 paragraph (b)(1) beginning January 1, 2004 until the date specified for subpart V of this part compliance in § 141.620(c).

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

(ii) *Best available technology.* 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 TTHM and HAA5 identified in this paragraph (b)(1):

Disinfection byproduct	Best available technology
Total trihalomethanes (TTHM) and Halaocetic acids (five) (HAA5).	Enhanced coagulation or enhanced softening or GAC10, with chlorine as the primary and residual disinfectant.

(2) *Stage 2A—LRAA compliance. (i) Compliance dates.* The Stage 2A MCLs for TTHM and HAA5 must be complied with as a locational running annual average at each subpart L of this part compliance monitoring location under § 141.136 beginning [date three years after publication of the final rule] until the date specified for subpart V of this part compliance in § 141.620(c).

Disinfection byproduct	MCL (mg/L)
Total trihalomethanes (TTHM)	0.120
Haloacetic acids (five) (HAA5)	0.100

(ii) *Best available technology.* 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 TTHM and HAA5 identified in this paragraph (b)(2):

Disinfection byproduct	Best available technology
Total trihalomethanes (TTHM) and Haloacetic acids (five) (HAA5).	Enhanced coagulation or enhanced softening or GAC10, with chlorine as the primary and residual disinfectant.

(3) *Subpart V LRAA compliance. (i) Compliance dates.* The subpart V of this part MCLs for TTHM and HAA5 must be complied with as a locational running annual average at each monitoring location beginning the date specified for Subpart V of this part compliance in § 141.620(c).

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

(ii) *Best technology for systems that disinfect their source water.* 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 TTHM and HAA5 identified in this paragraph (b)(3) for all systems that disinfect their source water:

Disinfection byproduct	Best available technology
Total trihalomethanes (TTHM) and Haloacetic acids (five) (HAA5).	Enhanced coagulation or enhanced softening, plus GAC10; or nanofiltration with a molecular weight and cutoff ≤1000 Daltons; or GAC20.

(iii) *Best available technology for systems that buy disinfected water.* 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 TTHM and HAA5 identified in this paragraph (b)(3) for systems that buy disinfected water:

Disinfection byproduct	Best available technology
Total trihalomethanes (TTHM) and Haloacetic acids (five) (HAA5).	Improved distribution system and storage tank management to reduce detention time plus the use of chloramines for disinfectant residual maintenance.

(c) *Extensions.* A system that is installing GAC or membrane technology to comply with the MCLs in paragraphs (a) or (b)(1) of this section may apply to the State for an extension of up to 24 months past January 1, 2002, but not beyond January 1, 2004. 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 any interim treatment requirements constitutes a violation of a National Primary Drinking Water Regulation.

Subpart L—[Amended]

8. Section 141.131 is amended by revising paragraphs (a), (b), (d)(2), (d)(3), (d)(4)(i), (d)(4)(ii), and the table in paragraph (c)(1), and adding paragraph (d)(6) to read as follows:

§ 141.131 Analytical requirements.

(a) *General.* (1) Systems must use only the analytical methods specified in this section, or their equivalent as approved by EPA, to demonstrate compliance with the requirements of this subpart and with the requirements of subparts U and V. These methods are effective for compliance monitoring February 16, 1999, unless a different effective date is specified in this section or by the State.

(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, 1301 Constitution Avenue, NW., EPA West, Room B102, 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 for chlorite and bromide 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 Methods 300.1 for chlorite, bromate, and bromide and 321.8 for bromate are in *Methods for the Determination of Organic and Inorganic Compounds in Drinking Water, Volume 1,* USEPA, August 2000, EPA 815–R–00–014 (available through NTIS, PB2000–106981). EPA Method 317.0, Revision 2.0, ''Determination of Inorganic Oxyhalide Disinfection By-Products in Drinking Water Using Ion Chromotography with the Addition of a Postcolumn Reagent for Trace Bromate Analysis,'' USEPA, July 2001, EPA 815–B–01–001, EPA Method 326.0, Revision 1.0, ''Determination of Inorganic Oxyhalide Disinfection By-Products in Drinking Water Using Ion Chromatography Incorporating the Addition of a Suppressor Acidified Postcolumn Reagent for Trace Bromate Analysis,'' USEPA, June 2002, EPA 815–R–03–007, EPA Method 327.0, Revision 1.0, ''Determination of Chlorine Dioxide and Chlorite Ion in Drinking Water Using Lissamine Green B and Horseradish Peroxidase with Detection by Visible Spectrophotometry,'' USEPA, July 2003, and EPA Method 552.3, Revision 1.0, ''Determination of Haloacetic Acids and Dalapon in Drinking Water by Liquid-liquid Extraction, Derivatization, and Gas Chromatography with Electron Capture Detection,'' USEPA, July 2003, can be

accessed and downloaded directly on-line at *www.epa.gov/safewater/methods/sourcalt.html.* EPA Method 415.3, Revision 1.0, ''Determination of Total Organic Carbon and Specific UV Absorbance at 254 nm in Source Water and Drinking Water,'' USEPA, June 2003, is 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 E, 6251 B, and 5910 B shall be followed in accordance with *Standard Methods for the Examination of Water and Wastewater, 19th or 20th Editions or the On-Line Version,* American Public Health Association, 1995, 1998, and 2003, respectively. The cited methods published in any of these three editions may be used. Standard Method 4500–ClO_2 D shall be followed in accordance with *Standard Methods for the Examination of Water and Wastewater, 19th or 20th Editions,* American Public Health Association, 1995 and 1998, respectively. 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,* or the *Standard Methods for the Examination of Water and Wastewater, 20th Edition,* or *the On-Line Version,* American Public Health Association, 1995, 1998, and 2003, respectively. The cited methods published in any of these editions may be used. 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 or any year containing the cited version of the method may be used. ASTM D 6581–00 shall be followed in accordance with the *Annual Book of ASTM Standards,* Volume 11.01, American Society for Testing and Materials, 2001 or any year containing the cited version of the method may be used; copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohoken, PA 19428–2959.

(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

Contaminant and methodology [1]	EPA method	Standard Method [2]	ASTM Method [3]
TTHM:			
P&T/GC/ElCD & PID	502.2 [4]		
P&T/GC/MS	524.2		
LLE/GC/ECD	551.1		
HAA5:			
LLE (diazomethane)/GC/ECD		6251 B [5].	
SPE (acidic methanol)/GC/ECD	552.1 [5]		
LLE (acidic methanol)/GC/ECD	552.2, 552.3.		
Bromate:			
Ion chromatography	300.1		D 6581–00
Ion chromatography & post column reaction	317.0 Rev 2.0 [6], 326.0 [6]		
IC/ICP–MS	321.8 [6, 7]		
Chlorite:			
Amperometric titration		4500–C1O_2 E [8].	
Spectrophotometry	327.0 [8].	.	
Ion chromatography	300.0, 300.1, 317.0 Rev. 2.0, 326.0		D 6581–00

[1] P&T = purge and trap; GC = gas chromatography; ElCD = electrolytic conductivity detector; PID = photoionization detector; MS = mass spectrometer; LLE = liquid/liquid extraction; ECD = electron capture detector; SPE = solid phase extraction; IC = ion chromatography; ICP-MS = inductively coupled plasma/mass spectrometer

[2] 219th or 20th editions or the On-Line Version of *Standard Methods for the Examination of Water and Wastewater,* 1995, 1998, and 2003, respectively, American Public Health Association; any of these editions may be used.

[3] *Annual Book of ASTM Standards,* 2001 or any year containing the cited version of the method, Vol 11.01.

[4] If TTHMs are the only analytes being measured in the sample, then a PID is not required.

[5] The samples must be extracted within 14 days of sample collection.

[6] Ion chromatography & post column reaction or IC/ICP-MS must be used for monitoring of bromate for purposes of demonstrating eligibility of reduced monitoring, as prescribed in § 141.132(b)(3)(ii).

[7] Samples must be preserved at the time of sampling with 50 mg ethylenediamine (EDA)/L of sample and must be analyzed within 28 days.

[8] Amperometric titration or spectrophotometry 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, except as specified under paragraph (b)(3)of this section. To receive certification to conduct analyses for the DBP contaminants in §§ 141.64, 141.135, and subparts U and V of this part, the laboratory must:

(i) Analyze Performance Evaluation (PE) samples that are acceptable to EPA or the State at least once during each consecutive 12 month period by each method for which the laboratory desires certification.

(ii) Achieve quantitative results on the PE sample analyses that are within the following acceptance limits which become effective [date 60 days after date of final rule publication] for purposes of certification:

DBP	Acceptance limits (percent)	Comments
TTHM:		
Chloroform	±20	Laboratory must meet all 4 individual THM acceptance limits in order to successfully pass a PE sample for TTHM.
Bromodichloromethane	±20	
Dibromochloromethane	±20	
Bromoform	±20	
HAA5:		
Monochloroacetic Acid	±40	Laboratory must meet the acceptance limits for 4 out of 5 of the HAAS compounds in order to successfully pass a PE sample for HAA5.
Dichloroacetic Acid	±40	
Trichloroacetic Acid	±40	
Monobromacetic Acid	±40	
Dibromoacetic Acid	±40	
Chlorite	±30	
Bromate	±30	

(iii) Report quantitative data for concentrations at least as low as the ones listed in the following table for all DBP samples analyzed for compliance with §§ 141.64, 141.135, 141.136, and subparts U and V of this part:

DBP	Minimum reporting level (ug/L) [7]	Comments
TTHM [2]:		
Chloroform	1.0	
Bromodichloromethane	1.0	
Dibromochloromethane	1.0	
Bromoform	1.0	
HAA5: [2]		
Monochloroacetic Acid	2.0	
Dichloroacetic Acid	1.0	
Trichloroacetic Acid	1.0	
Monobromoacetic Acid	1.0	
Dibromoacetic Acid	1.0	
Chlorite	200.	
Bromate	5.0 or 1.0	Laboratories that use EPA Methods 317.0 Revision 2.0, 326.0 or 321.8 must meet a 1.0 μg/L MRL for bromate.

[1] The calibration curve must encompass the minimum reporting level (MRL) concentration and the laboratory must verify the accuracy of the calibration curve at the lowest concentration for which quantitative data are reported by analyzing a calibration check standard at that concentration at the beginning of each batch of samples. The measured concentration for the check standard must be within ±50% of the expected value. Data may be reported for concentrations lower than the MRL as long as the precision and accuracy criteria are met by analyzing a standard at the lowest reporting limit chosen by the laboratory.

[2] When adding the individual trihalomethane or haloacetic acid concentrations to calculate the TTHM or HAA5 concentrations, respectively, a zero is used for any analytical result that is less than the MRL concentration for that DBP.

(3) A party approved by EPA or the State must measure daily chlorite samples at the entrance to the distribution system.

(c) * * *

(1) * * *

Methodology	Standard method	ASTM method	EPA 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	
Syringaldazine (FACTS)	4500–Cl			X			
Iodometric Electrode	4500–Cl					X	
DPD	4500–ClO_2						X
Amperometric Method II	4500–ClO_2 E						X
Lissamine Green Spectrophotometric			327.0				X

[1] X indicates method is approved for measuring specified disinfectant residual. Free chlorine or total chlorine may be measured for demonstrating compliance with the chlorine MRDL and combined chlorine or total chlorine may be measured for demonstrating compliance with the chloramine MRDL.

* * * * *

(d) * * *

(2) *Bromide.* EPA Methods 300.0, 300.1, 317.0 Revision 2.0, 326.0, or ASTM D 6581–00.

(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) or EPA Method 415.3. Inorganic carbon must be removed from the samples prior to analysis. TOC samples may not be filtered prior to analysis. TOC samples must be acidified at the time of sample collection to achieve pH less than or equal to 2 with minimal addition of the acid specified in the method or by the instrument manufacturer. Acidified TOC samples must be analyzed within 28 days.

(4) * * *

(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) or EPA Method 415.3. DOC samples must be filtered through the 0.45 µm pore-diameter filter as soon as practical after sampling, not to exceed 48 hours. After filtration, DOC samples must be acidified to achieve pH less than or equal to 2 with minimal addition of the acid specified in the method or by the instrument manufacturer. Acidified DOC samples must be analyzed within 28 days. Inorganic carbon must be removed from the samples prior to analysis. 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.

(ii) Ultraviolet Absorption at 254 nm (UV^{254}). Standard Method 5910 B (Ultraviolet Absorption Method) or EPA Method 415.3. 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.

* * * * *

(6) *Magnesium.* All methods allowed in § 141.23(k)(1) for measuring magnesium.

9. Section 141.132 is amended by revising paragraphs (b)(3)(ii) and (e) to read as follows:

§ 141.132 Monitoring requirements.

* * * * *

(b) * * *

(i) * * *

(ii) *Reduced monitoring.*

(A) Until [date three years from final rule publication], systems required to analyze for bromate may reduce monitoring from monthly to quarterly, if the system's average source water bromide concentration is less than 0.05 mg/L based on 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 on 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.

(B) Beginning [date three years from final rule publication], systems may no longer use the provisions of paragraph (b)(3)(ii)(A) of this section to qualify for reduced monitoring. A system required to analyze for bromate may reduce monitoring from monthly to quarterly, if the system's running annual average bromate concentration is less than 0.0025 mg/L based on monthly bromate measurements under paragraph (b)(3)(i) of this section for the most recent four quarters, with samples analyzed using Method 317.0 Revision 2.0, 325.0 or 321.8. If a system has qualified for reduced bromate monitoring under paragraph (b)(3)(ii)(A) of this section, that system may remain on reduced monitoring as long as the running annual average of quarterly bromate samples does not exceed 0.0025 mg/L based on samples analyzed using Method 317.0 Revision 2.0, 325.0, or 321.8. If the running annual average bromate concentration is >0.0025 mg/L, the system must resume routine monitoring required by paragraph (b)(3)(i) of this section.

* * * * *

(e) *Monitoring requirements for source water TOC.* In order to qualify for reduced monitoring for TTHM and HAA5 under paragraph (b)(1)(ii) of this section, subpart H systems not monitoring under the provisions of paragraph (d) of this section must take monthly TOC samples approximately every 30 days at a location prior to any treatment. In addition to meeting other criteria for reduced monitoring in paragraph (b)(1)(ii) of this section, the source water TOC running annual average must be ≤4.0 mg/L (based on the most recent four quarters of monitoring) on a continuing basis at each treatment plant to reduce or remain on reduced monitoring for TTHM and HAA5.

* * * * *

10. Section 141.134 is amended by revising paragraph (b) introductory text to read as follows:

§ 141.134 Reporting and recordkeeping requirements.

* * * * *

(b) *Disinfection byproducts.* In addition to reporting required under § 141.136(e), systems must report the information specified in the following table:

* * * * *

11. Section 141.135 is amended by revising paragraph (a)(3)(ii) to read as follows:

§ 141.135 Treatment technique for control of disinfection byproduct (DBP) precursors.

(a) * * *

(3) * * *

(ii) Softening that results in removing at least 10 mg/L of magnesium hardness (as $CaCO_3$), measured monthly according to § 141.131(d)(6) and calculated quarterly as a running annual average.

* * * * *

12. Section 141.136 is added to subpart L to read as follows:

§ 141.136 Additional compliance requirements for Stage 2A.

(a) *Applicability.* Any system that takes TTHM and HAA5 compliance samples under this subpart at more than one location in its distribution system is subject to additional MCL requirements beginning [date 3 years after publication of final rule] until the dates identified for compliance with subpart V in § 141.620(c). Any system that takes samples at more than one location must calculate a locational running annual average (LRAA) for each sampling point and comply with the MCLs of 0.120 mg/L for TTHM and 0.100 mg/L for HAA5 listed in § 141.64(b)(2), except as provided for under paragraph (c) of this section.

(b) *Compliance.* (1) Systems must calculate a locational running annual average each quarter for each monitoring location at which they took TTHM and HAA5 samples under their monitoring plan developed under § 141.132(f) by averaging the results of TTHM or HAA5 monitoring at that sample location during the four most recent quarters.

(2) Systems required to conduct quarterly monitoring under this subpart must begin to make compliance calculations under paragraph (b) of this

section at the end of the fourth calendar quarter that follows the compliance date in paragraph (a) of this section and at the end of each subsequent quarter. Systems required to conduct monitoring at a frequency that is less than quarterly under this subpart must make compliance calculations under paragraph (b) of this section beginning with the first compliance sample taken after the compliance date in paragraph (a) of this section.

(3) Failure to monitor will be treated as a monitoring violation for each quarter that a monitoring result would be used in a locational running annual average compliance calculation.

(c) *Consecutive systems.* A consecutive system must comply with the TTHM and HAA5 MCLs in § 141.64(b)(2) at each monitoring location in its distribution system identified in its monitoring plan developed under § 141.132(f).

(d) *Reporting.* Systems must submit the compliance calculations and locational running annual averages under this section as part of the reports required under § 141.134.

Subpart O—[Amended]

13. Section 141.151 is amended by revising paragraph (d) to read as follows:

§ 141.151 Purpose and applicability of this subpart.

* * * * *

(d) For the purpose of this subpart, *detected* means: At or above the levels prescribed by § 141.23(a)(4) for inorganic contaminants, at or above the levels prescribed by § 141.24(f)(7) for the contaminants listed in § 141.61(a), at or above the levels prescribed by § 141.24(h)(18) for the contaminants listed in § 141.61(c), at or above the levels prescribed by § 141.131(b)(2)(iii) for the contaminants or contaminant groups listed in § 141.64 and § 141.153(d)(iv), and at or above the levels prescribed by § 141.25(c) for radioactive contaminants.

* * * * *

14. Section 141.153 is amended by revising paragraphs (d)(4)(iv)(B) and (d)(4)(iv)(C) to read as follows:

§ 141.153 Content of the reports.

* * * * *

(d) * * *

(4) * * *

(iv) * * *

(B) When compliance with the MCL is determined by calculating a running annual average of all samples taken at a sampling point: the highest average of any of the sampling points and the range of all sampling points expressed in the same units as the MCL. For the MCLs for TTHM and HAA5 in § 141.64(b)(2) and (3), systems must include the highest locational running annual average for TTHM and HAA5 and the range of individual sample results for all sampling points expressed in the same units as the MCL. If more than one site exceeds the MCL, the system must include the locational running annual averages for all sites that exceed the MCL.

(C) When compliance with the MCL is determined on a system-wide basis by calculating a running annual average of all samples at all sampling points: the average and range of detection expressed in the same units as the MCL. The system is not required to include the range of individual sample results for the IDSE conducted under subpart U of this part.

* * * * *

Subpart Q—[Amended]

15. In Appendix A, the table is amended by revising entries 1.G.1 and 1.G.2, and endnotes 12 and 20, to read as follows:

APPENDIX A TO SUBPART Q OF PART 141.—NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE [1]

Contaminant	MCL/MRDL/TT violations[2]		Monitoring and testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
I. Violations of National Primary Drinking Water Regulations (NPDWR):[3]				
* * *	*	*	*	*
G. Disinfection Byproducts, * * *				
1. Total trihalomethanes (TTHM)	2	141.12[12], 141.64(b)[20]	3	141.30[12], 141.132(a)–(b)[20], 141.620–.630
2. Haloacetic acids (HAA5)	2	141.64(b)[20]	3	141.132(a)–(b)[20], 141.620–.630

* * * * *

Appendix A—Endnotes

12. §§ 141.12 and 141.30 will no longer apply after December 31, 2003.

* * * * *

20. §§ 141.64(b)(1) and 141.132(a)-(b) apply until §§ 141.64(b)(3) and 141.620–.630 take effect under the schedule in § 141.620(c). § 141.64(b)(2) takes effect on [date three years following final rule publication] and remains in effect until the effective dates for subpart V of this part compliance in the table in § 141.620(c).

* * * * *

16. In Appendix B the table is amended by revising entries H.79, H.80, and endnote 17, and adding endnote 23, to read as follows:

APPENDIX B TO SUBPART Q OF PART 141—STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
* * * * * * *			
H. Disinfection Byproducts (DBPs), * * *[17]:			
79. Total trihalomethanes (TTHLM)	N/A	0.10/0.120/0.080[18, 19, 23]	* * *
80. Haloacetic acids (HAA5).	N/A	0.060/0.100[20, 23]	* * *

* * * * *

Appendix B—Endnotes

* * * * *

17. Surface water systems and ground water systems under the direct influence of surface water are regulated under subpart H of 40 CFR 141. Subpart H community and non-transient non-community systems serving ≥10,000 must comply with subpart L DBP MCLs and disinfectant maximum residual disinfectant levels (MRDLs) beginning January 1, 2002. All other community and non-transient non-community systems must comply with subpart L DBP MCLs and disinfectant MRDLs beginning January 1, 2004. Subpart H transient non-community systems serving ≥10,000 that use chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning January 1, 2002. All other transient non-community systems that use chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning January 1, 2004.

* * * * *

23. Community and non-transient non-community systems must comply with TTHM and HAA5 MCLs of 0.120 mg/L and 0.100 mg/L, respectively (with compliance calculated as a locational running annual average) beginning [date three years following publication of final rule] until they are required to comply with subpart V TTHM and HAA5 MCLs of 0.080 mg/L and 0.060 mg/L, respectively (with compliance calculated as a locational running annual average). Community and non-transient non-community systems serving ≥10,000 must comply with subpart V TTHM and HAA5 MCLs (with compliance calculated as a locational running annual average) beginning [date six years following publication of final rule]. Community and non-transient non-community systems serving <10,000 must comply with subpart V TTHM and HAA5 MCLs (with compliance calculated as a locational running annual average) beginning [date 90 months following publication of final rule].

* * * * *

17. Part 141 is amended by adding new subpart U to read as follows:

Subpart U—Initial Distribution System Evaluations

Sec.
141.600 General requirements.
141.601 Initial Distribution System Evaluation (IDSE) requirements.
141.602 IDSE monitoring.
141.603 Alternatives other than IDSE monitoring.
141.604 IDSE reports.
141.605 Subpart V monitoring location recommendations to the State.

Subpart U—Initial Distribution System Evaluations

§ 141.600 General requirements.

(a) The requirements of subpart U constitute national primary drinking water regulations. The regulations in this subpart establish monitoring and other requirements for identifying compliance monitoring locations to be used for determining compliance with maximum contaminant levels for total trihalomethanes (TTHM) and haloacetic acids (five)(HAA5) in subpart V through the use of an Initial Distribution System Evaluation (IDSE). IDSEs are studies, used in conjunction with subpart L compliance monitoring, to identify and select subpart V compliance monitoring sites that represent high TTHM and HAA5 levels throughout the distribution system. The studies will be based on system-specific monitoring as provided in § 141.602. As an alternative, you may use other system-specific data that provide equivalent or better information on site selection for monitoring under subpart V as provided for in § 141.603(a).

(b) *Applicability.* You are subject to these requirements if your system is a community water system that adds a primary or residual disinfectant other than ultraviolet light or delivers water that has been treated with a primary or residual disinfectant other than ultraviolet light or if your system is a nontransient noncommunity water system that serves at least 10,000 people and adds a primary or residual disinfectant other than ultraviolet light or delivers water that has been treated with a primary or residual disinfectant other than ultraviolet light. You must conduct an Initial Distribution System Evaluation (IDSE), unless you meet the 40/30 certification criteria in § 141.603(b) or the State has granted a very small system waiver for the IDSE or you meet the criteria defined by the State for a very small system waiver under § 141.603(c). If you have a very small system waiver for the IDSE under § 141.603(c), you are not required to submit an IDSE report. All other systems must submit an IDSE report, even if you meet the 40/30 certification criteria in § 141.603(c).

(c) *Schedule.* You must comply with the Initial Distribution System Evaluation (IDSE) on the schedule in the following table, based on your system type.

If you are this type of system	You must submit your IDSE report to the state by[1]
(1) Subpart H serving ≥10,000	[date 24 mos. following publication of final rule]
(2) Subpart H serving <10,000	[date 24 mos. following publication of final rule][2]
(3) Ground water serving ≥10,000	[date 24 mos. following publication of final rule]
(4) Ground water serving <10,000	[date 24 mos. following publication of final rule][2]
(5) Consecutive system	at the same time as the system with the earliest compliance date in the combined distribution system[3]

[1] Systems that meet the 40/30 certification criteria in § 141.603(b) are encouraged to submit their IDSE report as soon as the certification criteria are met.

[2] You must comply by [date 24 mos. following publication of final rule] if you are a wholesale system and any system in the combined distribution system serves at least 10,000 people. You must comply by [date 48 mos. following publication of final rule] if no system in the combined distribution system serves at least 10,000 people.

[3] You must comply by [date 24 mos. following publication of final rule] if any system in the combined distribution system serves at least 10,000 people. You must comply by [date 48 mos. following publication of final rule] if no system in the combined distribution system serves at least 10,000 people.

(d) *Violations.* You must comply with specific monitoring and reporting requirements. You must prepare for, conduct, analyze, and submit your IDSE report no later than the date specified in § 141.600(c). Failure to conduct a required IDSE or to submit a required IDSE report by the date specified in paragraph (c) of this section is a monitoring violation. If you do not submit your IDSE report to your State, or if you submit the report after the specified date, you must comply with any additional State-specified requirements, which may include conducting another IDSE.

§ 141.601 Initial Distribution System Evaluation (IDSE) requirements.

(a) You must conduct an IDSE that meets the requirements in § 141.602 or § 141.603(a) or meet the 40/30 certification criteria in § 141.603(b) or have received a very small system waiver for the IDSE from the State under § 141.603(c). If you do not take the full complement of TTHM and HAA5 compliance samples required of a system with your population and source water under subpart L, but are required to conduct an IDSE under this subpart, you are not eligible for either the 40/30 certification in § 141.603(b) or the very small system waiver in § 141.603(c) and must conduct an IDSE that meets the requirements in § 141.602 or § 141.603(a).

(b) You may use any alternative listed in the table below for which you qualify.

IDSE ALTERNATIVES

Alternatives	Eligibility	Regulatory reference
(1) Monitoring	All systems required to conduct an IDSE	§ 141.602
(2) System-specific study	All systems required to conduct an IDSE	§ 141.603(a)
(3) 40/30 certification	Any system with all TTHM compliance samples ≤0.040 mg/L and all HAA5 compliance samples ≤0.030 mg/L during the period specified in § 141.603(b).	§ 141.603(b)
(4) Very small system waiver.	Any system serving <500 for which the State has granted a waiver	§ 141.603(c)

(c) IDSE results will not be used for the purpose of determining compliance with MCLs in § 141.64.

(d) *Additional provisions:*

(1) You 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(h)(5) of this chapter. State approvals made under § 141.132(a)(2) to treat multiple wells drawing water from a single aquifer as one treatment plant remain in effect unless withdrawn by the State.

(2) If you are a consecutive system, you must comply with the IDSE requirements in this subpart based on whether you buy some or all of your water from another PWS during 2004 for systems with an IDSE report due [date 24 months after publication of final rule] or during 2006 for systems with an IDSE report due [date 48 months after publication of final rule]. A consecutive system that buys some, but not all, of its finished water during the period identified in this paragraph must treat each consecutive system entry point from a wholesale system as a treatment plant for the consecutive system for the purpose of determining monitoring requirements of this subpart if water is delivered from the wholesale system to the consecutive system for at least 60 consecutive days through any of the consecutive system entry points. A consecutive system that buys all its finished water during the period identified in this paragraph must monitor based on population and source water for the purpose of determining monitoring requirements of this subpart.

(i) You may request that the State allow multiple consecutive system entry points from a single wholesale system to a single consecutive system to be considered one treatment plant.

(ii) In the request to the State for approval of multiple consecutive system entry points to be considered one treatment plant, you must demonstrate that factors such as relative locations of entry points, detention times, sources, and the presence of treatment (such as corrosion control or booster disinfection) will have a minimal differential effect on TTHM and HAA5 formation associated with individual entry points.

§ 141.602 IDSE monitoring.

(a) You must conduct IDSE monitoring for each treatment plant as indicated in the table in this paragraph. You must collect dual sample sets at each monitoring location. One sample in the set must be analyzed for TTHM. The other sample in the set must be analyzed for HAA5. If approved by the State under the provisions of § 141.601(d)(1), you may consider multiple wells drawing water from the same aquifer to be one treatment plant for the purpose of determining monitoring requirements. You must conduct one monitoring period during the peak historical month for TTHM levels or HAA5 levels or the month of warmest water temperature. You must review available compliance, study, or operational data to determine the peak historical month for TTHM or HAA5 levels or warmest water temperature.

If you are this type of system	Then you must monitor	At these locations for each treatment plant [1,2]
(1) Subpart H serving ≥10,000	Approximately every 60 days for one year (six monitoring periods).	Eight dual sample sets per monitoring period at locations other than subpart L TTHM/HAA5 monitoring locations based on conditions: If CHLORINE is used as residual disinfectant: one near distribution system entry point, two at average residence time, five at points representative of highest expected TTHM (three sites) and HAA5 concentration (two sites). If CHLORAMINE is used as residual disinfectant for any part of the year: two near distribution system entry point, two at average residence time, four at points representative of highest expected TTHM (two sites) and HAA5 concentration (two sites).
(2) Subpart H serving 500-9,999.	Approximately every 90 days for one year (four monitoring periods).	Two dual sample sets per monitoring period at locations other than the for one year subpart L TTHM/HAA5 monitoring location; one each representative of expected high periods) TTHM level and HAA5 level.
(3) Subpart H serving <500	Approximately every 180 days for one year (two monitoring periods).	Two dual sample sets per monitoring period at locations other than the subpart L TTHM/HAA5 monitoring location; one each representative of expected high periods) TTHM level and HAA5 level.
(4) Ground water serving ≥10,000.	Approximately every 90 days for one year (four monitoring periods).	Two dual sample sets per monitoring period at locations other than the subpart L TTHM/HAA5 monitoring location; one each representative of expected high periods) TTHM level and HAA5 level.
(5) Ground water serving < 10,000.	Approximately every 180 days for one year (two monitoring periods).	Two dual sample sets per monitoring period at locations other than the subpart L TTHM/HAA5 monitoring location; one each representative of expected high periods) TTHM level and HAA5 level.
(6) Consecutive system	At a frequency based on source water and your population [3].	—For a consecutive system that buys all its finished water, number of samples and locations as specified in paragraph (b) of this section. —For a consecutive system that buys some, but not all, of its finished water, serves ≥10,000, and receives water from a subpart H system: at IDSE locations required of a subpart H system serving ≥10,000. —For a consecutive system that does not meet any other criteria in this paragraph: two dual sample sets per monitoring period at locations other than the subpart L TTHM/HAA5 compliance monitoring location; one each representative of expected high TTHM levels and HAA5 levels.

[1] Including treatment plants for consecutive system entry points that operate for at least 60 consecutive days.
[2] The State may require additional monitoring.
[3] You must monitor at the frequency required of a subpart H system with your population if you deliver any water required to be treated under subpart H. You must monitor at the frequency required of a ground water system with your population if you deliver no water required to be treated under subpart H.

(b) *IDSE monitoring for consecutive systems that buy all their water.*

IDSE MONITORING LOCATIONS FOR CONSECUTIVE SYSTEMS THAT BUY ALL THEIR WATER

Population category	Number of dual sample set locations per monitoring period	Distribution system dual sample set locations [1]			
		Near entry points [2]	Average residence time	Highest TTHM locations	Highest HAA5 locations
Subpart H Consecutive Systems that buy all their water					
<500 [3]	2			1	1
500 to 4,999 [4]	2			1	1
5,000 to 9,999 [4]	4		1	2	1
10,000 to 24,999 [5]	8	1	2	3	2
25,000 to 49,999 [5]	12	2	3	4	3
50,000 to 99,999 [5]	16	3	4	5	4
100,000 to 499,999 [5]	24	4	6	8	6
500,000 to 1,499,999 [5]	32	6	8	10	8
1,500,000 to 4,999,999 [5]	40	8	10	12	10
>=5,000,000 [5]	48	10	12	14	12

IDSE MONITORING LOCATIONS FOR CONSECUTIVE SYSTEMS THAT BUY ALL THEIR WATER—Continued

Population category	Number of dual sample set locations per monitoring period	Distribution system dual sample set locations [1]			
		Near entry points [2]	Average residence time	Highest TTHM locations	Highest HAA5 locations
Ground Water Consecutive Systems that buy all their water					
<500 [3]	2			1	1
500 to 9,999 [4]	2			1	1
10,000 to 99,999 [4]	6	1	1	2	2
100,000 to 499,999 [4]	8	1	1	3	3
≥500,000 [4]	12	2	2	4	4

[1] Sampling locations to be distributed through distribution system. You may not use subpart L compliance monitoring locations as IDSE sample sites. You must collect a dual sample set at each sample location.

[2] If the actual number of entry points to the distribution system is fewer than the specified number of ''near entry point'' sampling sites, take additional samples equally at highest TTHM and HAA5 locations. If there is an odd extra location number, take the odd sample at highest TTHM location. If the actual number of entry points to the distribution system is more than the specified number of sampling locations, take samples first at subpart H entry points to the distribution system having the highest water flows and then at ground water entry points to the distribution system having the highest water flows.

[3] You must conduct monitoring during two monitoring periods approximately 180 days apart.

[4] You must conduct monitoring during four monitoring periods approximately 90 days apart.

[5] You must conduct monitoring during six monitoring periods approximately 60 days apart.

(c) You must prepare an IDSE monitoring plan prior to starting IDSE monitoring and implement that plan. In the plan, you must identify specific monitoring locations and dates that meet the criteria in paragraphs (a) and (b) of this section, as applicable.

§ 141.603 Alternatives other than IDSE monitoring.

In lieu of IDSE monitoring under § 141.602, you may use one of the alternatives identified in paragraphs (a) through (c) of this section for which you qualify to comply with this subpart.

(a) *System-specific study.* You may perform an IDSE study based on system-specific monitoring or system-specific data if such a study identifies equivalent or superior monitoring sites representing high TTHM and HAA5 levels as would be identified by IDSE monitoring under § 141.602. You must submit an IDSE report that complies with § 141.604.

(b) *40/30 certification.* In order to qualify for the 40/30 certification, you must not have had any TTHM or HAA5 monitoring violations during the periods specified in paragraphs (b)(1) through (b)(3) of this section.

(1) You are not required to comply with § 141.602 or paragraph (a) of this section if you certify to your State that all compliance samples under subpart L in 2002 and 2003 (for subpart H systems serving ≥10,000 people) or in 2004 and 2005 (for systems serving <10,000 people that are not required to submit an IDSE report by [date 24 months following publication of final rule]) were ≤0.040 mg/L for TTHM and ≤0.030 mg/L for HAA5.

(2) If you are a ground water system serving ≥10,000 people, you are not required to comply with § 141.602 or paragraph (a) of this section if you certify to your State that all TTHM samples taken under § 141.30 in 2003 are ≤0.040 mg/L and that all TTHM and HAA5 compliance samples taken under subpart L during 2004 are ≤0.040 mg/L and ≤0.030 mg/L, respectively.

(3) If you are a consecutive system serving <10,000 required to submit an IDSE report by [date 24 months following publication of final rule], you are not required to comply with § 141.602 or paragraph (a) of this section if you certify to your State that all TTHM and HAA5 compliance samples taken under subpart L during 2004 are ≤0.040 mg/L and ≤0.030 mg/L, respectively.

(4) You must submit an IDSE report that complies with § 141.604 and contains the required certification.

(c) *Very small system waiver.* If you serve fewer than 500 people, the State may waive IDSE monitoring if the State determines that the TTHM and HAA5 monitoring site for each plant under § 141.132 is sufficient to represent both the highest TTHM and the highest HAA5 concentration in your distribution system. If your IDSE monitoring is waived, you are not required to submit an IDSE report. You must monitor under subpart V during the same month and at the same location as used for compliance sampling in subpart L.

§ 141.604 IDSE reports.

You must submit your IDSE report to the State according to the schedule in § 141.600(c).

(a) If you complied by meeting the provisions of §§ 141.602 or 141.603(a), your IDSE report must include the elements required in paragraphs (a)(1) through (a)(3) of this section.

(1) Your report must include all TTHM and HAA5 analytical results from subpart L compliance monitoring conducted during the period of the IDSE presented in a tabular or spreadsheet format acceptable to the State. Your report must also include a schematic of your distribution system, with results, location, and date of all IDSE monitoring, system-specific study monitoring, and subpart L compliance samples noted.

(2) If you conducted IDSE monitoring under § 141.602, your report must include all IDSE TTHM and HAA5 analytical results presented in a tabular or spreadsheet format acceptable to the State. Your report must also include all additional data you relied on to justify IDSE monitoring site selection, plus your original monitoring plan developed under § 141.602(c) and an explanation of any deviations from that plan.

(3) If you used the system-specific study alternative in § 141.603(a), your report must include the basis (studies, reports, data, analytical results, modeling) by which you determined that the recommended subpart V monitoring sites representing high TTHM and HAA5 levels are comparable or superior to those that would otherwise have been identified by IDSE

monitoring under § 141.602. Your report must also include an analysis that demonstrates that your system-specific study characterized expected TTHM and HAA5 levels throughout your entire distribution system.

(b) If you meet the 40/30 certification criteria in § 141.603(b), your IDSE report must include all TTHM and HAA5 analytical results from compliance monitoring used to qualify for the 40/30 certification and a schematic of your distribution system (with results, location, and date of all compliance samples noted). You must also include results of those compliance samples taken after the period used to qualify for the 40/30 certification for State review.

(c) Your IDSE report must include your recommendations and justification for where and during what month(s) TTHM and HAA5 monitoring for Subpart V should be conducted. You must base your recommendations on the criteria in § 141.605. Your IDSE report must also include the population served; system type (subpart H or ground water); whether your system is a consecutive system; and, if you conducted plant-based monitoring, the number of treatment plants and consecutive system entry points.

(d) *Recordkeeping.* You must retain a complete copy of your IDSE report submitted under § 141.604 for 10 years after the date that you submitted your IDSE report. If the State modifies the monitoring requirements that you recommended in your IDSE report or if the State approves alternative monitoring sites, you must keep a copy of the State's notification on file for 10 years after the date of the State's notification. You must make the IDSE report and any State notification available for review by the State or the public.

§ 141.605 Subpart V monitoring location recommendations to the State.

(a) Subpart H systems serving at least 10,000 people. If you are a system required to take four dual sample sets per treatment plant per quarter under routine monitoring under § 141.621, you must base your recommendations on the locations in the distribution system where you expect to find the highest TTHM and HAA5 LRAAs. In determining the highest LRAA, you must evaluate both subpart L compliance data and IDSE data. For each plant, you must recommend locations with:

(1) The two highest TTHM locational running annual averages;

(2) The highest HAA5 locational running annual average; and

(3) An existing subpart L compliance monitoring location identified in the § 141.132(f) monitoring plan that is the location of either the highest TTHM or HAA5 LRAA among the three compliance monitoring locations representative of average residence time (by calculating an LRAA for each compliance monitoring location using the compliance monitoring results collected during the period of the IDSE).

(4) You may recommend locations other than those in paragraphs (a)(1) through (3) of this section if you include a rationale for selecting other locations. If the State approves, you must monitor at these locations to determine compliance under subpart V.

(5) If any of the criteria in this paragraph (a) of this section would cause fewer than four locations per treatment plant to be recommended, you must identify an additional location(s) with the next highest HAA5 LRAA.

(b) *All groundwater systems and subpart H systems serving fewer than 10,000 people.* If you are a system required to take two dual sample sets per treatment plant per quarter or per year or one TTHM and one HAA5 sample per plant per year for routine monitoring under § 141.621, you must select the locations with the highest TTHM locational running annual average and highest HAA5 locational running annual average, unless you include a rationale for selecting other locations. If the State approves, you must monitor at these other locations to determine compliance under subpart V. If any of the criteria in this paragraph would cause only one location per treatment plant to be recommended, you must identify an additional location with the next highest HAA5 LRAA or request that you be allowed to monitor only at that location.

(c) *Systems that qualify for the 40/30 certification.* If you use the 40/30 certification in § 141.603(b), you may use either subpart L compliance monitoring locations or you may identify monitoring locations for Subpart V that are different from those for subpart L. You must include a rationale for changing existing subpart L locations, choosing locations with a long residence time and a detectable residual. If you choose monitoring locations other than those in subpart L as subpart V compliance monitoring locations, you must retain the subpart L locations with the highest TTHM and HAA5 LRAAs. If any of the criteria in this paragraph would cause only one location per treatment plant to be recommended, you must identify an additional location with the next highest HAA5 LRAA or request that you be allowed to monitor only at that location. If you are required to monitor at more locations under subpart V of this part than under subpart L of this part, you must identify additional locations with a long residence time and a detectable residual.

(d) *Consecutive systems that buy some, but not all, of their finished water.* Your recommendations must comply with §§ 141.601(d) and 141.605 (a) through (c).

(e) *Consecutive systems that buy all their finished water.*

(1) You must select the number of monitoring locations specified in the following tables.

SUBPART V.—SAMPLE FREQUENCY FOR TTHM/HAA5 (AS DUAL SAMPLE SETS) FOR CONSECUTIVE SYSTEMS THAT BUY ALL THEIR WATER

Population	Number of samples
Subpart H Consecutive Systems That Buy All Their Water	
<500	1 TTHM and 1 HAA5 sample per year at different locations and time if the highest TTHM and HAA5 occurred at different locations and/or time or 1 dual sample set per year if the highest TTHM and HAA5 occurred at the same location and time of year, taken during the peak historical month for DBP concentrations or (if unknown) month of warmest water temperature.
500 to 4,999	1 TTHM and 1 HAA5 sample per quarter at different locations if the highest TTHM and HAA5 occurred at different locations or 1 dual sample set per quarter if the highest TTHM and HAA5 occurred at the same location.
5,000 to 9,999	2 dual sample sets per quarter.
10,000 to 24,999	4 dual sample sets per quarter.
25,000 to 49,999	6 dual sample sets per quarter.
50,000 to 99,999	8 dual sample sets per quarter.

SUBPART V.—SAMPLE FREQUENCY FOR TTHM/HAA5 (AS DUAL SAMPLE SETS) FOR CONSECUTIVE SYSTEMS THAT BUY ALL THEIR WATER—Continued

Population	Number of samples
100,000 to 499,999	12 dual sample sets per quarter.
500,000 to 1,499,999	16 dual sample sets per quarter.
1,500,000 to 4,999,999	20 dual sample sets per quarter.
>=5,000,000	24 dual sample sets per quarter.
Ground Water Consecutive Systems That Buy All Their Water	
<500	1 TTHM and 1 HAA5 sample per year at different locations and time if the highest TTHM and HAA5 occurred at different locations and/or time or 1 dual sample set per year if the highest TTHM and HAA5 occurred at the same location and time of year, taken during the peak historical month for DBP concentrations, or, if unknown, during month of warmest water temperature.
500 to 9,999	2 dual sample sets per year. Must be taken during the peak historical month for DBP concentrations.
10,000 to 99,999	4 dual sample sets per quarter.
100,000 to 499,999	6 dual sample sets per quarter.
≥500,000	8 dual sample sets per quarter.

(2) You must select Subpart V monitoring locations based on subpart L compliance monitoring results collected during the period of the IDSE and IDSE monitoring results. You must follow the protocol in paragraphs (e)(2)(i) through (iv) of this section, unless you provide a rationale for recommending different locations. If required to monitor at more than four locations, you must repeat the protocol as necessary, alternating between sites with the highest HAA5 LRAA and the highest TTHM LRAA not previously selected as a subpart V monitoring location for choosing locations under paragraph (e)(2)(iii) of this section.

(i) Location with the highest TTHM LRAA not previously selected as a subpart V monitoring location.

(ii) Location with the highest HAA5 LRAA not previously selected as a subpart V monitoring location.

(iii) Existing subpart L average residence time compliance monitoring location.

(iv) Location with the highest TTHM LRAA not previously selected as a subpart V monitoring location.

(3) You may recommend locations other than those in paragraph (e)(2) of this section if you include a rationale for selecting other locations. If the State approves, you must monitor at these locations to determine compliance under subpart V.

(4) If you used the 40/30 certification in § 141.603(b) and do not have sufficient subpart L monitoring locations to identify the required number of Subpart V compliance monitoring locations, you must identify additional locations by selecting a site representative of maximum residence time and then a site representative of average residence time and repeating until the required number of compliance monitoring locations have been identified.

(f) You must schedule samples during the peak historical month for TTHM and HAA5 concentration, unless the State approves another month. Once you have identified the peak historical month, and if you are required to conduct routine monitoring at least quarterly, you must schedule subpart V compliance monitoring at a regular frequency of approximately every 90 days or fewer.

18. Part 141 is amended by adding new subpart V to read as follows:

Subpart V—Stage 2B Disinfection Byproducts Requirements

Sec.
141.620 General requirements.
141.621 Routine monitoring.
141.622 Subpart V monitoring plan.
141.623 Reduced monitoring.
141.624 Additional requirements for consecutive systems.
141.625 Conditions requiring increased monitoring.
141.626 Significant excursions.
141.627 Requirements for remaining on reduced TTHM and HAA5 monitoring based on subpart L results.
141.628 Requirements for remaining on increased TTHM and HAA5 monitoring based on subpart L results.
141.629 [Reserved]
141.630 Reporting and recordkeeping requirements.

Subpart V—Stage 2B Disinfection Byproducts Requirements

§ 141.620 General requirements.

(a) The requirements of subpart V constitute national primary drinking water regulations. These regulations establish requirements for control of certain disinfection byproducts that supercede some requirements in subpart L and that are *in addition* to other requirements that are currently required under subpart L of this part. The regulations in this subpart establish monitoring and other requirements for achieving compliance with maximum contaminant levels for total trihalomethanes (TTHM) and haloacetic acids (five)(HAA5).

(b) *Applicability.* You are subject to these requirements if your system is a community water system or nontransient noncommunity water system that adds a primary or residual disinfectant other than ultraviolet light or delivers water that has been treated with a primary or residual disinfectant other than ultraviolet light.

(c) *Schedule.* You must comply with the requirements in this subpart on the schedule in the following table, based on your system type.

If you are this type of system	You must comply with subpart V by: [1 2 3]
(1) Subpart H serving ≥10,000	[date 72 mos following publication of final rule].
(2) Subpart H serving <10,000	[date 90 mos following publication of final rule] if no *Cryptosporidium* monitoring is required under § 141.706(c) OR [date 102 mos following publication of final rule] if *Cryptosporidium* monitoring is required under § 141.706(c).
(3) Ground water serving ≥10,000	[date 72 mos following publication of final rule].
(4) Ground water serving <10,000	[date 90 mos following publication of final rule].

If you are this type of system	You must comply with subpart V by: [1 2 3]
(5) Consecutive system	—at the same time as the system with the earliest compliance date in the combined distribution system.

[1] The State may grant up to an additional 24 months for compliance if you require capital improvements.

[2] If you are required to conduct quarterly monitoring, you must begin monitoring in the first full calendar quarter that follows the compliance date in this table. If you are required to conduct monitoring at a frequency that is less than quarterly, you must begin monitoring in the calendar month recommended in the IDSE report prepared under § 141.604 no later than 12 months after the compliance date in this table. If you are not required to submit an IDSE report, you must begin monitoring during the calendar month identified in the monitoring plan developed under § 141.622 no later than 12 months after the compliance date.

[3] If you are required to conduct quarterly monitoring, you must make compliance calculations at the end of the fourth calendar quarter that follows the compliance date and at the end of each subsequent quarter (or earlier if the LRAA calculated based on fewer than four quarters of data would cause the MCL to be exceeded regardless of the monitoring results of subsequent quarters). If you are required to conduct monitoring at a frequency that is less than quarterly, you must make compliance calculations beginning with the first compliance sample taken after the compliance date.

(d) *Monitoring and compliance.* You must monitor at sampling locations identified in your monitoring plan developed under § 141.622. To determine compliance with subpart V MCLs, you must calculate locational running annual averages for TTHM and HAA5 using monitoring results collected under this subpart. If you fail to complete four consecutive quarters of monitoring, you must calculate compliance with the MCL based on an average of the available data from the most recent four quarters.

(e) *Violations.* You must comply with specific monitoring and reporting requirements. Failure to monitor in accordance with the monitoring plan required under § 141.622 is a monitoring violation. Failure to monitor will also be treated as a monitoring violation for the entire period covered by a locational running annual average compliance calculation for the subpart V MCLs in § 141.64(b)(3).

(f) *Additional provisions.*

(1) You 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(h)(5) of this chapter. Approvals made under §§ 141.132(a)(2) and 141.601(d) remain in effect unless withdrawn by the State.

(2) *Consecutive systems.* For the purposes of this subpart, you must determine whether you buy all or some of your water based on your categorization for the IDSE under subpart U, unless otherwise directed by the State. If you were not categorized under subpart U, you must determine whether you buy all or some of your water based on your categorization during 2005, unless otherwise directed by the State.

(3) For the purposes of determining monitoring requirements of this subpart, each consecutive system entry point from a wholesale system to a consecutive system that buys some, but not all, of its finished water is considered a treatment plant for that consecutive system.

(i) You may request that the State allow multiple consecutive system entry points from a single wholesale system to a single consecutive system to be considered one treatment plant.

(ii) In the request to the State for approval of multiple consecutive system entry points to be considered one treatment plant, you must demonstrate that factors such as relative locations of entry points, detention times, sources, and the presence of treatment (such as corrosion control or booster disinfection) will have a minimal differential effect on TTHM and HAA5 formation associated with individual entry points.

§ 141.621 Routine monitoring.

(a) You must monitor at the locations and frequencies listed in the following table.

If you are this type of system	Then you must monitor	At these locations for each treatment plant [1]
(1) Subpart H serving ≥10,000.	four dual sample sets per quarter per treatment plant, taken approximately every 90 days. One quarterly set must be taken during the peak historical month for DBP concentrations [2].	—locations recommended to the State in the IDSE report submitted under subpart U.
(2) Subpart H serving 500–9,999.	two dual sample sets per quarter per treatment plant, taken approximately every 90 days. One quarterly set must be taken during the peak historical month for DBP concentrations [2].	—locations recommended to the State in the IDSE report submitted under subpart U.[3]
(3) Subpart H serving <500	one TTHM and one HAA5 sample per year per treatment plant, taken during the peak historical month for DBP concentrations.	—locations recommended to the State in the IDSE report submitted under subpart U.[4]
(4) Ground water serving ≥10,000.	two dual sample sets per quarter per treatment plant, taken approximately every 90 days. One quarterly set must be taken during the peak historical month for DBP concentrations [2].	—locations recommended to the State in the IDSE report submitted under subpart U.[3]
(5) Ground water serving 500–9,999.	two dual sample sets per year per treatment plant, taken during the peak historical month for DBP concentrations [2].	—locations recommended to the State in the IDSE report submitted under subpart U.[3]
(6) Ground water serving <500.	one TTHM and one HAA5 sample per year per treatment plant, taken during the peak historical month for DBP concentrations.	—locations recommended to the State in the IDSE report submitted under subpart U.[4]
(7) Consecutive system that buys some, but not all, of its finished water.	based on your own population and source water, except that consecutive systems that receive water from a subpart H system must monitor as a subpart H system.	—locations recommended to the State in the IDSE report submitted under subpart U.

If you are this type of system	Then you must monitor	At these locations for each treatment plant [1]
(8) Consecutive system that buys all its finished water.	as specified in § 141.605(e)	—locations recommended to the State in the IDSE report submitted under subpart U.

[1] Unless the State has approved or required other locations or additional locations based on the IDSE report or other information, or you have updated the monitoring plan under § 141.622.
[2] A dual sample set is a set of two samples collected at the same time and same location, with one sample analyzed for TTHM and the other sample analyzed for HAA5.
[3] If you have a single location that has both the highest TTHM LRAA and highest HAA5 LRAA, you may take a dual sample set only at that location after approval by the State.
[4] You are required to sample for both TTHM and HAA5 at one location if that location is the highest for both TTHM and HAA5. If different locations have high TTHM and HAA5 LRAAs, you may sample for TTHM only at the high TTHM location and for HAA5 only at the high HAA5 location. If you have received a very small system waiver for IDSE monitoring from the State under § 141.603(c), you must monitor for TTHM and HAA5 as a dual sample set at the subpart L monitoring location (a point representative of maximum residence time) during the month of warmest water temperature.

(b) You must begin monitoring at the locations you have recommended in your IDSE report submitted under § 141.604 following the schedule in § 141.620(c), unless the State requires other locations or additional locations after its review. If you have received a very small system waiver under § 141.603(c), you must monitor at the location(s) identified in your monitoring plan in § 141.132(f), updated as required by § 141.622.

(c) You must use an approved method listed in § 141.131 for TTHM and HAA5 analyses in this subpart. Analyses must be conducted by laboratories that have received certification by EPA or the State as specified in § 141.131.

§ 141.622 Subpart V monitoring plan.

(a) You must develop and implement a monitoring plan to be kept on file for State and public review. You may comply by updating the monitoring plan developed under § 141.132(f) no later than the date identified in § 141.620(c) for subpart V compliance. If you have received a very small system waiver under § 141.603(c), you must comply by updating the monitoring plan developed under § 141.132(f) no later than the date identified in § 141.620(c) for subpart V compliance. The monitoring plan must contain the elements in paragraphs (a)(1) through (a)(5) of this section:

(1) Monitoring locations;

(2) Monitoring dates;

(3) Compliance calculation procedures;

(4) Monitoring plans for any other systems in the combined distribution system if monitoring requirements have been modified based on data from other systems; and

(5) Any permits, contracts, or agreements with third parties (including other PWSs, laboratories, and State agencies) to sample, analyze, report, or perform any other system requirement in this subpart.

(b) The monitoring plan will reflect the recommendations of the IDSE report required under subpart U, along with any State-mandated modifications. The State must approve any monitoring sites for which you are required to provide a rationale in your IDSE report by § 141.605(a)(4).

(c) If you are a subpart H system serving more than 3,300 people, you must submit a copy of your monitoring plan to the State prior to the date you are required to comply with the monitoring plan.

(d) You may modify your monitoring plan to reflect changes in treatment, distribution system operations and layout (including new service areas), or other factors that may affect TTHM or HAA5 formation. If you change monitoring locations, you must replace locations with the lowest LRAA and notify the State how new sites were selected as part of the next report due under § 141.630. The State may also require modifications in your monitoring plan.

§ 141.623 Reduced monitoring.

(a) *Systems other than consecutive systems that buy all their water.* You may reduce monitoring by meeting the criteria in the table in this paragraph at all treatment plants in the system. You may only use data collected under the provisions of this subpart or subpart L of this part to qualify for reduced monitoring.

If you are this type of system	Then you may reduce monitoring if you have monitoring results under § 141.621 and	To reduce monitoring per plant at these locations/frequency	
		TTHM	HAA5
(1) Subpart H serving ≥10,000.	—the LRAA is ≤0.040 mg/L for TTHM and ≤0.030 for HAA5 at ALL monitoring locations, AND —the source water annual average TOC level, before any treatment, is ≤4.0 mg/L at each subpart H treatment plant [1].	—monitor once per quarter by taking a dual sample set at the location with the highest TTHM LRAA or single measurement.	—monitor once per quarter by taking a dual sample set at the location with the highest HAA5 LRAA or single measurement.
(2) Subpart H serving 500–9,999.	—the LRAA is ≤0.040 mg/L for TTHM and ≤0.030 for HAA5 at ALL monitoring locations, AND —the source water annual average TOC level, before any treatment, is ≤4.0 mg/L at each subpart H treatment plant [1].	—monitor once per year by taking a dual sample set at the location with the highest TTHM single measurement during the quarter that the highest single TTHM measurement occurred [2].	—monitor once per year by taking a dual sample set at the location with the highest HHA5 single measurement during the quarter that the highest single HHA5 measurement occurred.[2]
(3) Subpart H serving <500.	—monitoring may not be reduced to fewer than one TTHM sample and one HAA5 sample per year.	not applicable	not applicable.
(4) Ground water serving ≥10,000.	—the LRAA is ≤0.040 mg/L for TTHM and ≤0.030 for HAA5 at ALL monitoring locations.	—monitor once per year by taking a dual sample set at the location with the highest TTHM single measurement during the quarter that the highest single TTHM measurement occurred [2].	—monitor once per year by taking a dual sample set at the location with the highest HHA5 single measurement during the quarter that the highest single HHA5 measurement occurred.[2]

If you are this type of system	Then you may reduce monitoring if you have monitoring results under § 141.621 and	To reduce monitoring per plant at these locations/frequency	
		TTHM	HAA5
(5) Ground water serving 500–9,999.	—the LRAA is ≤0.040 mg/L for TTHM and ≤0.030 for HAA5 at ALL monitoring locations.	—monitor once every third year by taking a dual sample set at the location with the highest TTHM single measurement during the quarter that the highest single TTHM measurement occurred [2].	—monitor once every third year by taking a dual sample set at the location with the highest HHA5 single measurement during the quarter that the highest single HHA5 measurement occurred.[2]
(6) Ground water serving <500.	—the LRAA is ≤0.040 mg/L for TTHM and ≤0.030 for HAA5 at ALL monitoring locations.	—monitor once every third year for TTHM at the location with the highest TTHM single measurement during the quarter that the highest single TTHM measurement occurred [2].	—monitor once every third year for HAA5 at the location with the highest HAA5 single measurement during the quarter that the highest single HAA5 measurement occurred.[2]
(7) Consecutive system that buys some, but not all, of its finished water [3].	—the LRAA is ≤0.040 mg/L for TTHM and ≤0.030 for HAA5 at ALL monitoring locations.	—monitor at the location(s) and frequency associated with a non-consecutive system with the same population and source water type.	—monitor at the location(s) and frequency associated with a non-consecutive system with the same population and source water type.[2]

[1] TOC monitoring must comply with the provisions of either § 141.132(d) or § 141.132(e).
[2] If your location for reduced monitoring for TTHM and HAA5 is the same location and if your quarter for the highest TTHM and HAA5 single measurement is the same, you may take one dual sample set at that location during that quarter.
[3] Consecutive systems that buy some, but not all, of their finished water may reduce monitoring based on their own population and their wholesale system(s)'s source water type to the frequency and location(s) required in this section, unless the consecutive system treats surface water or ground water under the direct influence of surface water. If the consecutive system treats surface water or ground water under the direct influence of surface water, it must base reduced monitoring on its population and classification as a subpart H system.

(b) *Consecutive systems that buy all their water.* You may reduce monitoring to the level specified in the table in this paragraph if the LRAA is ≤0.040 mg/L for TTHM and ≤0.030 mg/L for HAA5 at all monitoring locations. You may only use data collected under the provisions of this subpart or subpart L of this part to qualify for reduced monitoring.

REDUCED MONITORING FREQUENCY FOR CONSECUTIVE SYSTEMS THAT BUY ALL THEIR WATER.

Population	Reduced monitoring frequency and location
Subpart H systems	
<500	Monitoring may not be reduced.
500 to 4,999	1 TTHM and 1 HAA5 sample per year at different locations or during different quarters if the highest TTHM and HAA5 measurements occurred at different locations or different quarters or 1 dual sample set per year if the highest TTHM and HAA5 measurements occurred at the same location and quarter.
5,000 to 9,999	2 dual sample sets per year; one at the location with the highest TTHM single measurement during the quarter that the highest single TTHM measurement occurred, one at the location with the highest HAA5 single measurement during the quarter that the highest single HAA5 measurement occurred.
10,000 to 24,999	2 dual sample sets per quarter at the locations with the highest TTHM and highest HAA5 LRAAs.
25,000 to 49,999	2 dual sample sets per quarter at the locations with the highest TTHM and highest HAA5 LRAAs.
50,000 to 99,000	4 dual sample sets per quarter—at the locations with the two highest TTHM and two highest HAA5 LRAAs.
100,000 to 499,999	4 dual sample sets per quarter—at the locations with the two highest TTHM and two highest HAA5 LRAAs.
500,000 to 1,499,999	6 dual sample sets per quarter—at the locations with the three highest TTHM and three highest HAA5 LRAAs.
1,500,000 to 4,999,999	6 dual sample sets per quarter—at the locations with the three highest TTHM and three highest HAA5 LRAAs.
>=5,000,000	8 dual sample sets per quarter at the locations with the four highest TTHM and four highest HAA5 LRAAs.
Ground water systems	
<500	1 TTHM and 1 HAA5 sample every third year at different locations and time if the highest TTHM and HAA5 measurements occurred at different locations and/or time or 1 dual sample set every third year if the highest TTHM and HAA5 measurements occurred at the same location and time of year.
500 to 9,999	1 TTHM and 1 HAA5 sample every year at different locations and time if the highest TTHM and HAA5 measurements occurred at different locations and/or time or 1 dual sample set every year if the highest TTHM and HAA5 measurements occurred at the same location and time of year.
10,000 to 99,000	2 dual sample sets per year; one at the location with the highest TTHM single measurement during the quarter that the highest single TTHM measurement occurred and one at the location with the highest HAA5 single measurement during the quarter that the highest single HAA5 measurement occurred.
100,000 to 499,999	2 dual sample sets per quarter; at the locations with the highest TTHM and highest HAA5 LRAAs.
≥500,000	4 dual sample sets per quarter; at the locations with the two highest TTHM and two highest HAA5 LRAAs.

(c) You may remain on reduced monitoring as long as the TTHM LRAA ≤0.040 mg/L and the HAA5 LRAA ≤0.030 mg/L at each monitoring location (for systems with quarterly monitoring) or each TTHM sample ≤0.060 mg/L and each HAA5 sample ≤0.045 mg/L (for systems with annual or less frequent monitoring). In addition, the source water annual average TOC level, before any treatment, must be ≤4.0 mg/L at each treatment plant treating surface water or ground water under the direct influence of surface water, based on monitoring conducted under either §§ 141.132(d) or 141.132(e). If the LRAA at any location exceeds either 0.040 mg/L for TTHM or 0.030 mg/L for HAA5 or if the annual (or less frequent) sample at any location exceeds either 0.060 mg/L for TTHM or 0.045 mg/L for HAA5, or if the source water annual average TOC level, before any treatment, >4.0 mg/L at any treatment plant treating surface water or ground water under the direct influence of surface water, the system must resume routine monitoring

under § 141.621 for all treatment plants or begin increased monitoring for all treatment plants if § 141.625 applies.

(d) The State may return your system to routine monitoring at the State's discretion.

§ 141.624 Additional requirements for consecutive systems.

If you are a consecutive system that does not add a disinfectant but delivers water that has been disinfected with other than ultraviolet light, you must comply with monitoring requirements for chlorine and chloramines in § 141.132(c)(1) and the compliance requirements in § 141.133(c)(1) beginning [date three years after publication of final rule] and report monitoring results under § 141.134(c), unless required earlier by the State.

§ 141.625 Conditions requiring increased monitoring.

(a) If you are required to monitor at a particular location yearly or less frequently than yearly under §§ 141.621 or 141.623, you must increase monitoring to dual sample sets once per quarter (taken approximately every 90 days) at all locations if either the annual (or less frequent) TTHM sample >0.080 mg/L or the annual (or less frequent) HAA5 sample >0.060 mg/L at any location.

(b) You are not in violation of the MCL until the LRAA calculated based on four consecutive quarters of monitoring (or the LRAA calculated based on fewer than four quarters of data if the MCL would be exceeded regardless of the monitoring results of subsequent quarters) exceeds the subpart V MCLs in § 141.64(b)(3). You are in violation of the monitoring requirements for each quarter that a monitoring result would be used in calculating an LRAA if you fail to monitor.

(c) You may return to routine monitoring once you have conducted increased monitoring for at least four consecutive quarters and the LRAA for every location is ≤0.060 mg/L for TTHM and ≤0.045 mg/L for HAA5.

§ 141.626 Significant excursions.

If a significant excursion occurs, you must conduct a significant excursion evaluation and prepare a written report of the evaluation no later than 90 days after being notified of the analytical result that shows the significant excursion. You must discuss the evaluation with the State no later than the next sanitary survey for your system. Your evaluation must include an examination of distribution system operational practices that may contribute to TTHM and HAA5 formation (such as flushing programs and storage tank operations and excess capacity) and how these practices may be modified to reduce TTHM and HAA5 levels.

§ 141.627 Requirements for remaining on reduced TTHM and HAA5 monitoring based on subpart L results.

You may remain on reduced monitoring after the dates identified in § 141.620(c) for compliance with this subpart only if you qualify for a 40/30 certification under § 141.603(b) or have received a very small system waiver under § 141.603(c), plus you meet the reduced monitoring criteria in § 141.623(c), and you do not change or add monitoring locations from those used for compliance monitoring under subpart L. If your monitoring locations under this subpart differ from your monitoring locations under subpart L, you may not remain on reduced monitoring after the dates identified in § 141.620(c) for compliance with this subpart.

§ 141.628 Requirements for remaining on increased TTHM and HAA5 monitoring based on subpart L results.

If you were on increased monitoring under subpart L, you must remain on increased monitoring until you qualify for a return to routine monitoring under § 141.625(c). You must conduct increased monitoring under § 141.625 at the monitoring locations in the monitoring plan developed under § 141.622 beginning at the date identified in § 141.620(c) for compliance with this subpart and remain on increased monitoring until you qualify for a return to routine monitoring under § 141.625(c).

§ 141.629 [Reserved]

§ 141.630 Reporting and recordkeeping requirements.

(a) *Reporting.* (1) You must report the following information for each monitoring location to the State within 10 days of the end of any quarter in which monitoring is required:

(i) Number of samples taken during the last quarter.

(ii) Date and results of each sample taken during the last quarter.

(iii) Arithmetic average of quarterly results for the last four quarters (LRAAs).

(iv) Whether the MCL was violated.

(2) If you are a subpart H system seeking to qualify for or remain on reduced TTHM/HAA5 monitoring, you must report the following source water TOC information for each treatment plant that treats surface water or ground water under the direct influence of surface water to the State within 10 days of the end of any quarter in which monitoring is required:

(i) The number of source water TOC samples taken each month during last quarter.

(ii) The date and result of each sample taken during last quarter.

(iii) The quarterly average of monthly samples taken during last quarter.

(iv) The running annual average (RAA) of quarterly averages from the past four quarters.

(v) Whether the RAA exceeded 4.0 mg/L.

(b) *Recordkeeping.* You must retain any subpart V monitoring plans and your subpart V monitoring results as required by § 141.33.

PART 142— NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. 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.

2. Section 142.14 is amended by adding paragraph (a)(8) to read as follows:

§ 142.14 Records kept by States.

(a) * * *

(8) Any decisions made pursuant to the provisions of 40 CFR part 141, subparts U and V of this chapter.

(i) Those systems for which the State has determined that the 40 CFR part 141, subpart L approved monitoring site is representative of the highest TTHM and HAA5 and therefore have been granted a very small system waiver under § 141.603(c) of this chapter. The State must provide a copy of the decision to the system. A copy of the decision must be kept until reversed or revised.

(ii) System IDSE reports, plus any modifications required by the State. Reports must be kept until reversed or revised in their entirety.

* * * * *

3. Section 142.16 is amended by adding paragraph (m) to read as follows:

§ 142.16 Special primacy conditions.

* * * * *

(m) *Requirements for States to adopt 40 CFR part 141, subparts U and V.* In addition to the general primacy requirements elsewhere in this part, including the requirements that State regulations be at least as stringent as federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subparts U

and V, must contain a description of how the State will accomplish the following:

(1) For PWSs serving fewer than 500 people, a very small system waiver procedure for subpart U IDSE requirements that will apply to all systems that serve fewer than 500 people without the State making a system-by-system waiver determination, if the State elects to use such an authority.

(2) A procedure for evaluating system-specific studies under § 141.603(a) of this chapter, if system-specific studies are conducted in the State.

(3) A procedure for determining that multiple consecutive system entry points from a single wholesale system to a single consecutive system should be treated as a single treatment plant for monitoring purposes.

(4) A procedure for addressing consecutive systems outside the provisions of § 141.29 of this chapter or part 141 subparts U and V of this chapter, if the State elects to use such an authority.

(5) A procedure for systems to identify significant excursions.

PART 143—NATIONAL SECONDARY DRINKING WATER REGULATIONS

1. The authority citation for part 143 continues to read as follows:

Authority: 42 U.S.C. 300f *et seq.*

2. In § 143.4, the table in paragraph (b) is amended by revising entries 2 and 9 and footnotes 3 and 4, and by adding footnote 6 to read as follows:

§ 143.4 Monitoring.

* * * * *

(b) * * *

Contaminant	EPA	ASTM [3]	SM [4] 18th and 19th ed.	SM [4] 20th ed.	Other
* *		*	* *	*	*
2. Chloride	300.0 [1]	D4327–97	4110 B	4110 B.	
	300.1 [6]			.	
			4500–Cl^- D	4500–Cl^- D	
		D512–89B	4500–Cl^- B	4500–Cl^- B	
* *		*	* *	*	*
9. Sulfate	300.0 [1]	D4327–97	4110B	4110B.	
	300.1 [6]				
	375.2 [1]		4500–SO_4^{2-} F	4500–SO_4^{2-} F.	
			4500–SO_4^{2-} C, D	4500–SO_4^{2-} C, D.	
		D516–90	4500–SO_4^{2-} E	4500–SO_4^{2-} E.	
* *		*	* *	*	*

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[1] "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R–93–100, August 1993. Available at NTIS, PB94–120821.

* * * * *

[3] *Annual Book of ASTM Standards,* 1994, 1996, or 1999, Vols. 11.01 and 11.02, ASTM International; any year containing the cited version of the method may be used. Copies may be obtained from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428.

[4] *Standard Methods for the Examination of Water and Wastewater,* 18th edition (1992), 19th edition (1995), or 20th edition (1998). American Public Health Association, 1015 Fifteenth Street, NW, Washington, DC 20005. The cited methods published in any of these three editions may be used, except that the versions of 3111 B, 3111 D, and 3113 B in the 20th edition may not be used.

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[6] "Methods for the Determination of Organic and Inorganic Compounds in Drinking Water", Vol. 1, EPA 815-R–00–014, August 2000. Available at NTIS, PB2000–106981.

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