Estimated Total Reporting/ Recordkeeping Burden: 61,000 hours.

Clearance Officer: Lois K. Holland (202) 622–1563, Departmental Offices, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

OMB Reviewer: Milo Sunderhauf (202) 395–7340, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 94–18469 Filed 7–28–94; 8:45 am]

BILLING CODE 4810–25–P

Public Information Collection Requirements Submitted to OMB for Review

July 22, 1994.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Internal Revenue Service (IRS)

OMB Number: 1545–0062.

Form Number: IRS Forms 3903 and 3903–F.

Type of Review: Extension.

Title: Moving Expenses and Foreign Moving Expenses.

Description: Internal Revenue Code (IRC) Section 217 requires itemization of various allowable moving expenses. Forms 3903 and 3903–F are filed with Form 1040 by individuals claiming employment related moves. The data is used to help verify that the expenses are deductible and that the deduction is computed correctly.

Respondents: Individuals or households.

Estimated Number of Respondents/ Recordkeepers: 1,607,278.

Estimated Burden Hours Per Respondent/Recordkeeper:

	Recordkeeping	Learning about the law or the form	Preparing the form	Copying, assembling, and sending the form to the form
Form 3903:				
Part I only	33 minutes	3 minutes	13 minutes	20 minutes.
Parts I & II only	1 hour, 5 minutes	0 hours, 4 minutes	0 hours, 31 minutes	0 hours, 20 minutes.
Parts I, II & III	1 hour, 38 minutes	0 hours, 5 minutes	0 hours, 42 minutes	0 hours, 35 minutes
Form 3903–F:				
Part I only	20 minutes	3 minutes	13 minutes	20 minutes.
Parts I & II only	52 minutes	4 minutes	35 minutes	20 minutes.
Parts I, II & III	1 hour, 12 minutes	0 hours, 5 minutes	0 hours, 46 minutes	0 hours, 35 minutes.

Frequency of Response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 2,083,396 hours.

Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Milo Sunderhauf (202) 395–7340, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 94–18470 Filed 7–28–94; 8:45 am]

BILLING CODE 4830–01–P

Public Information Collection Requirements Submitted to OMB for Review

July 21, 1994.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

Office of Thrift Supervision (OTS)

OMB Number: 1550–0074.

Form Number: None.

Type of Review: Extension.

Title: Supervisory Stock Conversion.

Description: 12 CFR, 563b Subpart C—Voluntary Supervisory Stock Conversions grants the OTS authority to act upon supervisory stock conversion applications.

Respondents: Businesses or other for-profit.

Estimated Number of Respondents: 20

Estimated Burden Hours Per Respondent: 500 hours.

Frequency of Response: Other (only once for a savings association which converts to stock form).

Estimated Total Reporting Burden: 10,000 hours.

Clearance Officer: Colleen Devine (202) 906–6025, Office of Thrift Supervision, 2nd Floor, 1700 G. Street, N.W., Washington, DC 20552.

OMB Reviewer: Milo Sunderhauf (202) 395–7340, Office of Management and Budget, room 10226, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 94–18468 Filed 7–28–94; 8:45 am]

BILLING CODE 4810–25–P

Sunshine Act Meetings

Federal Register
Vol. 58, No. 145
Friday, July 29, 1994

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

BLACKSTONE RIVER VALLEY NATIONAL HERITAGE CORRIDOR COMMISSION

Notice is hereby given in accordance with Section 552b of Title 5, United States Code, that a meeting of the Blackstone River Valley National Heritage Corridor Commission will be held on Thursday, August 11, 1994.

The Commission was established pursuant to Public Law 99–647. The purpose of the Commission is to assist federal, state and local authorities in the development and implementation of an integrated resource management plan for those lands and waters within the Corridor.

The meeting will convene at 7:00 pm at Blackstone Valley Electric, Route 116, Lincoln, RI for the following reasons:

1. Presentation from Town of Lincoln
2. Commission Business
3. Other

It is anticipated that about twenty people will be able to attend the session in addition to the Commission members.

Interested persons may make oral or written presentations to the Commission or file written statements. Such requests should be made prior to the meeting to: James R. Pepper, Executive Director, Blackstone River Valley National Heritage Corridor Commission, One Depot Square, Woonsocket, RI 02895, Tel.: (401) 762–0250.

Further information concerning this meeting may be obtained from James R. Pepper, Executive Director of the Commission at the aforementioned address.

James R. Pepper,

Executive Director.

[FR Doc. 94–18688 Filed 7–27–94; 3:32 pm]

BILLING CODE 4310–70–P

FEDERAL COMMUNICATIONS COMMISSION

FCC To Hold Open Commission Meeting Tuesday, August 2, 1994

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Tuesday, August 2, 1994, which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street, N.W., Washington, D.C.

Item No., Bureau, Subject

1—Common Carrier—Title: Amendment of Part 36 of the Commission's Rules and Establishment of a Joint Board (CC Docket No. 80–286). Summary: The Commission will consider action concerning high cost assistance.

2—Common Carrier—Title: Policies and Rules Implementing the Telephone Disclosure and Dispute Resolution Act (CC Docket No. 93–22). Summary: The Commission will consider action concerning rules governing pay-per-call information services.

3—Common Carrier—Title: Revision of Part 22 of the Commission's Rules Governing the Public Mobile Services (CC Docket No. 92–115). Title: Amendment of Part 22 of the Commission's Rules to Delete Section 22.119 and Permit the Concurrent Use Transmitters in Common Carrier and Non-common Carrier Service (CC Docket No. 94–46, RM–8367). Title: Amendment of Part 22 of the Commission's Rules Pertaining to Power Limits for Paging Stations Operating in the 931 MHz Band in the Public Land Mobile Service (CC Docket No. 93–116). Summary: The Commission will consider actions in three dockets that concern various aspects of Part 22 of the Commission's Rules.

4—Private Radio—Title: Eligibility Requirements for the Specialized Mobile Radio Service and Radio Services in the 220–222 MHz Land Mobile Band and Use of Radio Dispatch Communications. Summary: The Commission will consider eligibility restrictions for holding specialized mobile radio and commercial 220 MHz licenses and the prohibition on the provision of dispatch service by mobile service common carriers.

5—Cable Services—Title: Implementation of the Cable Television Consumer Protection and Competition Act of 1992: Development of Competition and Diversity in Video Programming Distribution and Carriage (MM Docket No. 92–265). Summary: The Commission will consider action concerning standing to bring a complaint before the Commission under Section 616 of the Commission Act as amended.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Audrey Spivack or Susan Lewis Sallet, Office of Public Affairs, telephone number (202) 418–0500.

Dated: July 26, 1994.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 94–18625 Filed 7–27–94; 10:27 am]

BILLING CODE 6712–01–M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:05 a.m. on Tuesday, July 26, 1994, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the probable failure of a certain insured depository institution and matters relating to the Corporation's supervisory activities.

In calling the meeting, the Board determined, on motion of Mr. John F. Downey, acting in the place and stead of Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), seconded by Director Eugene A. Ludwig (Comptroller of the Currency), concurred in by Acting Chairman Andrew C. Hove, Jr., that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Dated: July 26, 1994.

Federal Deposit Insurance Corporation.

Leneta G. Gregorie,

Acting Assistant Executive Secretary.

[FR Doc. 94–18590 Filed 7–27–94; 8:45 am]

BILLING CODE 6714–01–M

AGENCY HOLDING THE MEETING: BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: Approximately 11:00 a.m., Wednesday, August 3, 1994, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: July 27, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94–18626 Filed 7–27–94; 10:52 am]

BILLING CODE 6210–01–P

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., Wednesday, August 3, 1994.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Summary Agenda:

Because of its routine nature, no substantive discussion of the following item is anticipated. This matter will be voted on without discussion unless a member of the Board requests that the item be moved to the discussion agenda.

1. Proposed amendments to the Board's risk-based capital guidelines for state member banks and bank holding companies regarding concentration of credit risk and risks of nontraditional activities (proposed earlier for public comment; Docket No. R–0764).

Discussion Agenda:

2. Request for public comment of a proposed amendment to the Board's risk-based capital guidelines for state member banks and bank holding companies regarding the treatment of derivative contracts.

3. Any items carried forward from a previously announced meeting.

Note: This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452–3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: July 27, 1994.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 94–18627 Filed 7–27–94; 10:52 am]

BILLING CODE 6210–01–P

SECURITIES AND EXCHANGE COMMISSION

Agency Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of August 1, 1994.

A closed meeting will be held on Wednesday, August 3, 1994, at 10:00 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Wallman, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the closed meeting scheduled for Wednesday, August 3, 1994, at 10:00 a.m., will be:

Institution of administrative proceedings of an enforcement nature.

Settlement of administrative proceedings of an enforcement nature.

Institution of injunctive actions.

Settlement of injunctive actions.

Report of investigation.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Barbara Hannigan (202) 942–0100.

Dated: July 27, 1994.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–18629 Filed 7–27–94; 11:00 am]

BILLING CODE 8010–01–M

Federal Register

Friday
July 29, 1994

Part II

Environmental Protection Agency

40 CFR Parts 141 and 142
National Primary Drinking Water Regulations; Disinfectants and Disinfection Byproducts; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[WH-FRL-4998-2]

Drinking Water; National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this document, EPA is proposing maximum residual disinfectant level goals (MRDLGs) for chlorine, chloramines, and chlorine dioxide; maximum contaminant level goals (MCLGs) for four trihalomethanes (chloroform, bromodichloromethane, dibromochloromethane, and bromoform), two haloacetic acids (dichloroacetic acid and trichloroacetic acid), chloral hydrate, bromate, and chlorite; and National Primary Drinking Water Regulations (NPDWRs) for three disinfectants (chlorine, chloramines, and chlorine dioxide), two groups of organic disinfection byproducts (total trihalomethanes (TTHMs)—a sum of the four listed above, and haloacetic acids (HAA5)—a sum of the two listed above plus monochloroacetic acid and mono- and dibromoacetic acids), and two inorganic disinfection byproducts (chlorite and bromate). The NPDWRs consist of maximum residual disinfectant levels or maximum contaminant levels or treatment techniques for these disinfectants and their byproducts. The NPDWRs also include proposed monitoring, reporting, and public notification requirements for these compounds. This notice proposes the best available technology (BAT) upon which the MRDLs and MCLs are based and the BAT for purposes of issuing variances.

DATES: Written comments must be postmarked or hand-delivered by December 29, 1994. Comments received after this date may not be considered. Public hearings will be held at the addresses indicated below under "ADDRESSES" on August 29 (and 30, if necessary) in Denver, CO and on September 12 (and 13, if necessary) in Washington, DC.

ADDRESSES: Send written comments on the proposed rule to Disinfectant/Disinfection By-Products Comment Clerk, Drinking Water Docket (MC 4101), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. Commenters are requested to submit three copies of their comments and at least one copy of any references cited in their written or oral comments. A copy of the comments and supporting documents are available for review at the EPA, Drinking Water Docket (4101), 401 M Street, S.W., Washington, DC 20460. For access to the docket materials, call (202) 260–3027 between 9:00 a.m. and 3:30 p.m.

The Agency will hold public hearings on the proposal at two different locations indicated below:

1. Denver Federal Center, 6th and Kipling Streets, Building 25, Lecture Halls A and B (3d Street), Denver, CO 80225 on August 29 (and 30, if necessary), 1994.
2. EPA Education Center Auditorium, 401 M Street SW., Washington, D.C. 20460, on September 12 (and 13, if necessary), 1994.

The hearings will begin at 9:30 a.m., with registration at 9:00 a.m. The Hearings will end at 4:00 p.m., unless concluded earlier. Anyone planning to attend the public hearings (especially those who plan to make statements) may register in advance by writing the D/DBPR Public Hearing Officer, Office of Ground Water and Drinking Water (4603), USEPA, 401 M Street, S.W., Washington, D.C. 20460; or by calling Tina Mazzocchetti, (703) 931–4600. Meeting dates are tentative and should be confirmed by calling the Safe Drinking Water Hotline prior to making travel plans. Oral and written comments may be submitted at the public hearing. Persons who wish to make oral presentations are encouraged to have written copies (preferably three) of their complete comments for inclusion in the official record.

Copies of draft health criteria, analytical methods, and regulatory impact analysis documents are available at some Regional Offices listed below and for a fee from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll-free number is (800) 336–4700 or local at (703) 487–4650.

FOR FURTHER INFORMATION CONTACT: General information may be obtained from the Safe Drinking Water Hotline, telephone (800) 426–4791; Stig Regli, Office of Ground Water and Drinking Water (4603), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, telephone (202) 260–7379; Tom Grubbs, Office of Ground Water and Drinking Water (4603), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, telephone (202) 260–7270; or one of the EPA Regional Office contacts listed below.

SUPPLEMENTARY INFORMATION:

EPA Regional Offices

I. Robert Mendoza, Chief, Water Supply Section, JFK Federal Bldg., Room 203, Boston, MA 02203, (617) 565–3610
II. Robert Williams, Chief, Water Supply Section, 26 Federal Plaza, Room 824, New York, NY 10278, (212) 264–1800
III. Jeffrey Hass, Chief, Drinking Water Section (3WM41), 841 Chestnut Building, Philadelphia, PA 19107, (215) 597–9873
IV. Phillip Vorsatz, Chief, Water Supply Section, 345 Courtland Street, Atlanta, GA 30365, (404) 347–2913
V. Charlene Denys, Chief, Water Supply Section, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 353–2650
VI. F. Warren Norris, Chief, Water Supply Section, 1445 Ross Avenue, Dallas, TX 75202, (214) 655–7155
VII. Ralph Flournoy, Chief, Water Supply Section, 726 Minnesota Ave., Kansas City, KS 66101, (913) 234–2815
VIII. Doris Sanders, Chief, Water Supply Section, One Denver Place, 999 18th Street, Suite 500, Denver, CO 80202–2405, (303) 293–1424
IX. Bill Thurston, Chief, Water Supply Section, 75 Hawthorne Street, San Francisco, CA 94105, (415) 744–1851
X. William Mullen, Chief, Water Supply Section, 1200 Sixth Avenue, Seattle, WA 98101, (206) 442–1225.

Abbreviations used in this document.

AECL: Alternate enhanced coagulant level
AOC: Assimilable organic carbon
ASDWA: Association of State Drinking Water Administrators
AWWA: American Water Works Association
AWWARF: AWWA Research Foundation
BAC: Biologically active carbon
BAF: Biologically active filtration
BAT: Best Available Technology
BCAA: Bromochloroacetic acid
BDOC: Biodegradable organic carbon
BTGA: Best Technology Generally Available
CI: Confidence interval
CWS: Community Water System
DBP: Disinfection byproducts
D/DBP: Disinfectants and disinfection byproducts
D/DBPR: Disinfectants and disinfection byproducts rule
DBPP: Disinfection byproduct precursors
DBPRAM: DBP Regulatory Assessment model
DPD: N,N-diethyl-p-phenylenediamine
DWEL: Drinking Water Equivalent Level
EBCT: Empty bed contact time
EMSL: EPA Environmental Monitoring and Support Laboratory (Cincinnati)
EPA: United States Environmental Protection Agency
ESWTR: Enhanced Surface Water Treatment Rule
FY: Fiscal year
GAC: Granular Activated Carbon
GWDR: Ground Water Disinfection Rule
GWSS: Ground Water Supply Survey
HAA5: Haloacetic acids (five)
HOBr: Hypobromous acid
IC: Ion chromotography
ICR: Information Collection Rule
IOC: Inorganic chemical
LOAEL: Lowest observed adverse effect level
LOQ: Limit of Quantitation

MCL: Maximum Contaminant Level (expressed as mg/l, 1,000 micrograms (µg) = 1 milligram (mg))
MCLG: Maximum Contaminant Level Goal
MDL: Method Detection Limit
MF: Modifying factor
mg/dl: Milligrams per deciliter
mg/l: Milligrams per liter
MGD: Million Gallons per Day
MRDL: Maximum Residual Disinfectant Level (as mg/l)
MRL: Minimum reporting level
MRDLG: Maximum Residual Disinfectant Level Goal
NCI: National Cancer Institute
ND: Not detected
NIPDWR: National Interim Primary Drinking Water Regulation
NOAEL: No observed adverse effect level
NOMS: National Organic Monitoring Survey
NORS: National Organics Reconnaissance Survey for Halogenated Organics
NPDWR: National Primary Drinking Water Regulation
NTNCWS: Nontransient noncommunity water system
OBr: Hypobromite ion
OR: Odds ratio
PE: Performance evaluation
POE: Point-of-Entry Technologies
POU: Point-of-Use Technologies
ppb: Parts per billion
PQL: Practical Quantitation Level
PTA: Packed Tower Aeration
PWS: Public Water System
RIA: Regulatory Impact Analysis
RMCL: Recommended Maximum Contaminant Level
RNDB: Regulations Negotiation Data Base
RSC: Relative Source Contribution
SDWA: Safe Drinking Water Act, or the "Act," as amended in 1986
SM: Standard Method
SMCL: Secondary Maximum Contaminant Level
SMR: Standardized mortality ratios
SOC: Synthetic Organic Chemical
SWTR: Surface Water Treatment Rule
THMFP: Trihalomethane formation potential
TOC: Total organic carbon
TTHM: Total trihalomethanes
TWG: Technologies Working Group
VOC: Volatile Synthetic Organic Chemical
WIDB: Water Industry Data Base
WS: Water Supply

Table of Contents

I. Summary of Today's Action
A. Applicability.
B. Proposed MRDLGs and MRDLs for disinfectants
C. Proposed MCLGs and MCLs for organic byproducts
D. Treatment technique for DBP precursors
E. Proposed Stage 1 MCLGs and MCLs for inorganic byproducts
F. Proposed BAT for disinfectants
G. Proposed BAT for organic byproducts
H. Proposed BAT for inorganic byproducts
I. Proposed Compliance Monitoring Requirements
J. Analytical Methods
K. Laboratory Certification Criteria
L. Variances and Exemptions
M. State Primacy, Recordkeeping, Reporting Requirements
N. System Reporting Requirements
O. D/DBP Stage 2 Rule requirements
P. Guidance
Q. Triennial Regulation Review
II. Statutory Authority
A. MCLGs, MCLs, and BAT
B. Variances and Exemptions
C. Primacy
D. Monitoring, Quality Control, and Records
E. Public Water Systems
F. Public Notification
III. Overview of Existing Interim Standard for TTHMs
IV. Overview of Preproposal Regulatory Development
A. October 1989 Strawman Rule
B. June 1991 Status Report on D/DBP rule development
C. Initiation of Regulatory Negotiation Process
V. Establishing MCLGs
A. Background
B. Proposed MRDLGs and MCLGs
1. Chlorine, hypochloriteion and hypochlorous acid
2. Chloramines
3. Epidemiology Studies of Chlorinated and Chloraminanted Water
4. Chlorine dioxide, chlorite, and chlorate
5. Chloroform
6. Bromodichloromethane
7. Dibromochloromethane
8. Bromoform
9. Dichloroacetic acid
10. Trichloroacetic acid
11. Chloral hydrate
12. Bromate
VI. Occurrence of TTHMs, HAA5, and other DBPs
A. Relationship of TTHMs, HAA5 to disinfection and source water quality
B. Chlorination Byproducts
C. Other Disinfection Byproducts
1. Ozonation Byproducts
2. Chlorine Dioxide Byproducts
3. Chloramination Byproducts
VII. General Basis for Criteria of Proposed rule
A. Goals of regulatory negotiation
B. Concern for downside microbial risks and unknown risks from DBPs of different technologies
C. Ecological concerns
D. Watershed protection
E. Narrowing of regulatory options through reg-neg process
VIII. Summary of the Proposed National Primary Drinking Water Regulation for Disinfectants and Disinfection Byproducts
A. Schedule and coverage
B. Summary of DBP MCLs, BATs, and monitoring and compliance requirments
C. Summary of disinfectant MRDLs, BATs, and Monitoring and compliance requirements
D. Enhanced coagulation and enhanced softening requirements
E. Requirement for systems to use qualified operators
F. Basis for analytical method requirements
G. Public Notice Requirements
H. Variances and Exemptions
I. Reporting and Record Keeping requirements for PWSs
J. State Implementation Requirements
IX. Basis for Key Specific Criteria of Proposed Rule
A. 80/60 TTHM/HAA5 MCLs, enhanced coagulation requirements, and BAT
1. basis for umbrella concept vs. individual MCLs
2. basis for level of stringency in MCLs, BAT, and concurrent enhanced coagulation requirements
3. basis for enhanced coagulation and softening criteria
4. basis for GAC definitions
5. basis for monitoring requirements
B. Bromate MCL and BAT
C. Chlorite MCL and BAT
D. Chlorine MRDL and BAT
E. Chloramine MRDL and BAT
F. Chlorine dioxide MRDL and BAT
G. Basis for analytical method requirements
H. Basis for compliance schedule and applicability to different groups of systems, timing with other regulations
I. Basis for qualified operator requirements and monitoring plans
J. Basis for Stage 2 proposed MCLs
X. Laboratory Certification and Approval
A. PE-Sample Acceptance Limits for Laboratory Certification
B. Approval Criteria for Disinfectants and Other Parameters
C. Other Laboratory Performance Criteria
XI. Variances and Exemptions
A. Variances
B. Exemptions
XII. State Implementation
A. Special primacy requirements
B. State recordkeeping
C. State reporting
XIII. System Reporting and Recordkeeping Requirements
XIV. Public Notice Requirements
XV. Economic Analysis
A. Executive Order 12866
B. Predicted cost impacts on public water systems
1. Compliance treatment cost forecasts
2. Compliance treatment forecasts
3. DBP exposure estimates
4. System level cost estimates
5. Effect on household costs
6. Monitoring and State implementation costs, labor burden estimates
C. Concepts of cost analysis
D. Benefits
XVI. Other Requirements
A. Consultation with State, Local, and Tribal Governments
B. Regulatory Flexibility Act
C. Paperwork Reduction Act
D. National Drinking Water Advisory Council and Science Advisory Board
XVII. Request for Public Comment
XVIII. References and Public Docket

I. Summary of Today's Action

In 1992 EPA initiated a negotiated rulemaking to develop a disinfectant/disinfection byproduct rule. The Agency decided to use the negotiated rulemaking process because it believed that the available occurrence, treatment, and health effects data were inadequate to address EPA's concerns about the

tradeoff between risks from disinfectants and disinfection byproducts and microbial pathogen risk, and wanted all stakeholders to participate in the decision-making on setting proposed standards. The negotiators included State and local health and regulatory agency staff and elected officials, consumer groups, environmental groups, and representatives of public water systems. The group met from November 1992 through June 1993.

Early in the process, the negotiators agreed that large amounts of information necessary to understand how to optimize the use of disinfectants to concurrently minimize microbial and disinfectant/disinfection byproduct risk were unavailable.

Therefore, the group agreed to propose a disinfectant/disinfection byproduct rule to extend coverage to all community water systems that use disinfectants, reduce the current total trihalomethane (TTHM) maximum contaminant level (MCL), regulate additional disinfection byproducts, set limits for the use of disinfectants, and reduce the level of compounds that may react with disinfectants to form byproducts. These requirements were based on available information. The group further agreed that revisions to the current Surface Water Treatment Rule might be required at the same time to ensure that microbial risk is not increased as byproduct rules go into effect. Finally, the group agreed that additional information on health risk, occurrence, treatment technologies, and analytical methods needed to be developed in order to better understand the risk-risk tradeoff, whether further control was needed, and how to accomplish this overall risk reduction.

The outcome of the negotiation was three rules: a Disinfectant/Disinfection Byproduct rule (this notice), an Enhanced Surface Water Treatment Rule (also proposed today and appearing separately in today's **Federal Register**), and an Information Collection Rule (proposed February 10, 1994, 59 FR 6332). The Information Collection Rule will provide information necessary to determine whether the Enhanced Surface Water Treatment Rule needs to be promulgated and, if so, what requirements it should set. The Information Collection Rule will also provide information on the need for, and content of, long-term rules. The schedule to produce these rules has also been negotiated and is provided elsewhere in this document. A summary of today's rule follows.

A. Applicability. This action applies to all community water systems and nontransient noncommunity water systems that add a disinfectant during any part of the treatment process including addition of a residual disinfectant. In addition, certain provisions apply to transient noncommunity water systems that use chlorine dioxide.

B. Proposed MRDLGs and MRDLs for disinfectants. EPA is proposing the following maximum disinfectant residual level goals and maximum residual disinfectant levels.

Disinfectant Residual	MRDLG (mg/l)	MRDL (mg/l)
(1) Chlorine	4 (as Cl_2)	4.0 (as Cl_2).
(2) Chloramines	4 (as Cl_2)	4.0 (as Cl_2).
(3) Chlorine dioxide	0.3 (as ClO_2)	0.8 (as ClO_2).

C. Proposed MCLGs and MCLs for organic byproducts. EPA is proposing the following maximum contaminant level goals and maximum contaminant levels.

	MCLG (mg/l)	MCL (mg/l)
Total trihalomethanes (TTHM)	[1] N/A	0.080
Haloacetic acids (five) (HAA5)	[2] N/A	.060
Chloroform	0	[1] N/A
Bromodichloromethane	0	[1] N/A
Dibromochloromethane	0.06	[1] N/A
Bromoform	0	[1] N/A
Dichloroacetic acid	0	[2] N/A
Trichloroacetic acid	0.3	[2] N/A
Chloral hydrate	0.04	[3] N/A

[1] Total trihalomethanes are the sum of the concentrations of bromodichloromethane, dibromochloromethane, bromoform, and chloroform.

[2] Haloacetic acids (five) are the sum of the concentrations of mono-, di-, and trichloroacetic acids and mono- and dibromoacetic acids.

[3] EPA did not set an MCL for chloral hydrate because the TTHM and HAA5 MCLs and the treatment technique (i.e., enhanced coagulation) for disinfection byproduct precursor removal will control for chloral hydrate. (See Section IX.)

D. Treatment Technique for DBP Precursors. EPA is proposing that water systems that use surface water or ground water under the direct influence of surface water and use conventional filtration treatment be required to remove specified amounts of organic materials (measured as total organic carbon) that may react with disinfectants to form disinfection byproducts. Removal would be achieved through a treatment technique (enhanced coagulation or enhanced softening) unless the system met certain criteria.

E. Proposed Stage 1 MCLGs and MCLs for inorganic by-products. EPA is proposing the following maximum contaminant level goals and maximum contaminant levels.

	MCLG (mg/l)	MCL (mg/l)
Chlorite	0.08	1.0
Bromate	0	0.010

F. Proposed BAT for disinfectants. EPA is proposing the following best available technologies for limiting residual disinfectant concentrations in the distribution system.

Chlorine residual—control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels

Chloramine residual—control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels

Chlorine dioxide residual—control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.

G. Proposed BAT for organic byproducts. EPA is proposing the following best available technologies for control of organic disinfection byproducts in each stage of the rule.

1. Proposed Stage 1 BAT for organic by-products. Total trihalomethanes—enhanced coagulation or GAC10, with chlorine as the primary and residual disinfectant. Total haloacetic acids—enhanced coagulation or GAC10, with chlorine as the primary and residual disinfectant.

2. Proposed Stage 2 BAT for organic byproducts. Total trihalomethanes—enhanced coagulation and GAC10, or GAC20; with chlorine as the primary and residual disinfectant. Total haloacetic acids—enhanced coagulation and GAC10, or GAC20; with chlorine as the primary and residual disinfectant.

H. Proposed BAT for inorganic by-products. EPA is proposing the following best available technologies for control of inorganic disinfection byproducts.

Chlorite—control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.

Bromate—control of ozone treatment process to reduce production of bromate.

I. Proposed Compliance Monitoring Requirements. Compliance monitoring requirements are explained in Section IX of the preamble and were developed during the negotiated rulemaking. EPA has developed routine and reduced monitoring schemes that address the health effects of each disinfectant or contaminant in an individually appropriate manner.

J. Analytical Methods. EPA is proposing to withdraw one method for measurement of chlorine residual and to approve three new methods for measurement of chlorine residuals. EPA is proposing to approve one new method for measurement of trihalomethanes; two new methods for measurement of haloacetic acids; one new method for measurement of bromate, chlorite, and bromide; and two new methods for measurement of total organic carbon.

K. Laboratory Certification Criteria. Consistent with other drinking water regulations, EPA is proposing that only certified laboratories be allowed to analyze samples for compliance with the proposed MCLs and treatment technique requirements. For disinfectants and other specified parameters in today's rule that the Agency believes can be adequately measured by other than certified laboratories and for which there is a good reason to allow analysis at other locations (e.g., for samples which normally deteriorate before reaching a certified laboratory, especially when taken at remote locations), EPA is requiring that such analyses be conducted by a party acceptable to EPA or the State.

L. Variances and Exemptions. Variances and exemptions will be permitted.

M. State Primacy, Recordkeeping, Reporting Requirements. Requirements for States to maintain primacy are listed in Section XII of the preamble. In addition to routine requirements, EPA has included special primacy requirements.

N. System Reporting Requirements. System reporting requirements remain consistent with requirements in previous rules.

O. D/DBP Stage 2 Rule requirements. EPA is proposing a total trihalomethane MCL of 0.040 mg/l and a haloacetic acid (five) MCL of 0.030 mg/l, to apply only to systems using surface water or ground water under the direct influence of surface water and serving at least 10,000 persons, as part of a plan to develop new standards which incorporates the results of additional research conducted under the Information Collection Rule (59 *FR* 6332).

P. Guidance. EPA is in the process of developing guidance for both systems and States for implementation of this rule.

Q. Triennial Regulation Review. Under the provisions of the Safe Drinking Water Act (SDWA or the Act) (Section 1412(b)(9)), the Agency is required to review national primary drinking water regulations at least once every three years. As mentioned previously, today's proposed rule revises, updates, and (when promulgated) supersedes the regulations for total trihalomethanes, initially published in 1979. Since that time, there have been significant changes in technology, treatment techniques, and other regulatory controls that provide for greater protection for health of persons. As such, in proposing today's rule, EPA has analyzed innovations and changes in technology and treatment techniques that have occurred since promulgation of the initial TTHM regulations. This analysis, contained primarily in the cost and technology document supporting this proposal, supports amendment of the TTHM regulation for the greater protection of persons. EPA believes that the innovations and changes in technology and treatment techniques will result in amendments to the TTHM regulations that are feasible within the meaning of SDWA Section 1412(b)(9).

II. Statutory Authority

Section 1412 of the Safe Drinking Water Act, as amended in 1986 ("SDWA" or "the Act"), requires EPA to publish Maximum Contaminant Level Goals (MCLGs) and promulgate National Primary Drinking Water Regulations (NPDWRs) for contaminants in drinking water which may cause any adverse effect on the health of persons and which are known or anticipated to occur in public water systems. Under Section 1401, the NPDWRs are to include Maximum Contaminant Levels (MCLs) and "criteria and procedures to assure a supply of drinking water which dependably complies" with such MCLs. Under Section 1412(b)(7)(A), if it is not economically or technically feasible to ascertain the level of a contaminant in drinking water, EPA may require the use of a treatment technique instead of an MCL.

Under Section 1412(b), EPA was to establish MCLGs and promulgate NPDWRs for 83 contaminants by June 19, 1989. An additional 25 contaminants are to be regulated every 3 years. To meet this latter requirement, EPA has developed a list of contaminants (National Drinking Water Priority List; 53 *FR* 1892) including pesticides, organic and inorganic elements or compounds, and disinfectants and disinfection by-products (D/DBP), plus the protozoan Cryptosporidium. From this list, EPA is to choose at least 25 contaminants for regulation every three years. Today's regulatory proposal represents part of the first group of 25 chemicals to be regulated. Both the general contaminants (organics, inorganics, and pesticides), and the D/DBPs were considered for regulation. In today's notice, EPA is proposing to regulate certain disinfectants and disinfection byproducts; Cryptosporidium is proposed to be regulated in a separate Notice today.

In October of 1990, EPA entered into a consent order with Citizens Concerned about Bull Run Inc. regarding a timeframe for proposing the first group of 25. The consent decree stipulated a June 1993 date for proposal. That decree was subsequently amended to establish a proposal date of May 30, 1994, for the Disinfectants/Disinfection Byproducts Rule and a proposal date of February 28, 1995, for the other contaminants that comprise the required group of 25.

A. MCLGs, MCLs, and BAT

Under Section 1412 of the Act, EPA is to establish MCLGs at the level at which no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety. MCLGs are nonenforceable health goals based only on health effects and exposure information.

MCLs are enforceable standards which the Act directs EPA to set as close to the MCLGs as feasible. "Feasible" means feasible with the use of the best technology, treatment techniques, and other means which the Administrator finds available (taking cost into consideration) after examination for efficacy under field conditions and not solely under laboratory conditions (SDWA, section 1412(b)(5)). Also, the SDWA requires the Agency to identify the best available

technology (BAT) which is feasible for meeting the MCL for each contaminant.

Also, in this proposal, EPA is introducing several new terms—"maximum residual disinfectant level goals (MRDLGs)" and "maximum residual disinfectant levels (MRDLs)"—to reflect the fact that these substances have beneficial disinfection properties. As with MCLGs, EPA has established MRDLGs at the level at which no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety. MRDLGs are nonenforceable health goals based only on health effects and exposure information and do not reflect the benefit of the addition of the chemical for control of waterborne microbial contaminants.

MRDLs are enforceable standards, analogous to MCLs, which recognize the benefits of adding a disinfectant to water on a continuous basis and in addressing emergency situations such as distribution system pipe breaks. As with MCLs, EPA has set the MRDLs as close to the MRDLGs as feasible. The Agency has also identified the best available technology (BAT) which is feasible for meeting the MRDL for each disinfectant.

B. Variances and Exemptions

Section 1415 authorizes the State to issue variances from NPDWRs (the term "State" is used in this preamble to mean the State agency with primary enforcement responsibility for the public water supply system program or EPA if the State does not have primacy). The State may issue a variance if it determines that a system cannot comply with an MCL despite application of the best available technology (BAT). Under Section 1415, EPA must propose and promulgate its finding of the best available technology, treatment techniques, or other means available for each contaminant, for purposes of section 1415 variances, at the same time that it proposes and promulgates a maximum contaminant level for such contaminant. EPA's finding of BAT, treatment techniques, or other means for purposes of issuing variances may vary among systems, depending upon the number of persons served by the system or for other physical conditions related to engineering feasibility and costs of complying with MCLs, as considered appropriate by EPA. The State may not issue a variance to a system until it determines that an unreasonable risk to health (URTH) does not exist. When a State grants a variance, it must at the same time prescribe a schedule for (1) compliance with the NPDWR and (2) implementation of any additional control measures.

Under Section 1416(a), the State may exempt a public water system from any MCL or treatment technique requirement if it finds that (1) due to compelling factors (which may include economic factors), the system is unable to comply, (2) the system was in operation on the effective date of the MCL or treatment technique, or, for a newer system, that no reasonable alternative source of drinking water is available to that system, and (3) the exemption will not result in an unreasonable risk to health. Under section 1416(b), at the same time it grants an exemption, the State is to prescribe a compliance schedule and a schedule for implementation of any required interim control measures. The final date for compliance may not exceed three years after the initial date of issuance unless the public water system establishes that: (1) the system cannot meet the standard without capital improvements which cannot be completed within the period of such exemption; (2) the system has entered into an agreement to obtain financial assistance for necessary improvements; or (3) the system has entered into an enforceable agreement to become part of a regional public water system. For systems which serve 500 or fewer service connections and which need financial assistance to come into compliance, the State may renew the exemption for additional two-year periods if the system is taking all practicable steps to meet the above requirements.

For exemptions resulting from a NPDWR promulgated after June 19, 1986, the system's final compliance date must be within 12 months of issuance of the exemption. However, the State may extend the final compliance date for up to three years if the public water system shows that capital improvements to meet the MCL or treatment technique requirement cannot be completed within the exemption period and, if the system needs financial assistance for the improvements, it has an agreement to obtain this assistance or the system has an enforceable agreement to become part of a regional public water system. For systems that have 500 or fewer service connections that need financial assistance to comply with the MCLs, the State may renew the exemption for additional two-year periods if the system is taking all practicable steps to comply.

C. Primacy

As indicated above, States, territories, and Indian Tribes may assume primary enforcement responsibility (primacy) for public water systems under Section 1413 of the SDWA. To date, 55 States and territories have primacy. To assume or retain primacy, States, territories, or Indian Tribes need not adopt the MCLGs but must adopt, among other things, NPDWRs (i.e., MCLs, monitoring, analytical, and reporting requirements) that are no less stringent than those EPA promulgates.

D. Monitoring, Quality Control, and Records

Under Section 1401(1)(D) of the Act, NPDWRs are to contain "criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including quality control and testing procedures to insure compliance with such levels * * *."

E. Public Water Systems

Public water systems are defined in section 1401 of the Act as those systems which provide piped water for human consumption and have at least 15 connections or regularly serve at least 25 people. By regulation EPA has divided public water systems into community, nontransient noncommunity, and (transient) noncommunity water systems. Community water systems (CWSs) serve at least 15 service connections used by year-round residents or regularly serve at least 25 year-round residents (40 CFR 141.2). Nontransient noncommunity water systems (NTNCWSs) regularly serve at least 25 of the same people over six months of the year. Schools and factories which serve water to 25 or more of the same people for six or more months of the year are examples of NTNCWSs. Transient noncommunity systems, by definition, are all other public water systems. Transient noncommunity systems may include, for example, restaurants, gas stations, campgrounds, and churches.

This rule would apply to all CWSs, all NTNCWSs, and any transient noncommunity water systems that use chlorine dioxide as a disinfectant or oxidant.

F. Public Notification

Section 1414(c) of the Act requires the owner or operator of a public water system which does not comply with an applicable maximum contaminant level or treatment technique, testing procedure, or Section 1445(a) (unregulated contaminant) monitoring requirement to give notice to the persons served by the system. Notice must also be given if a variance or exemption is in effect or the system fails to comply with a compliance schedule resulting from a variance or exemption.

EPA's public notification regulations are codified at 40 CFR Section 141.32. Those regulations were amended by EPA on October 28, 1987 (52 FR 41534).

III. Overview of Existing Interim Standard for TTHMS

In 1974, researchers in The Netherlands and the United States clearly demonstrated that total trihalomethanes (TTHMs) are formed as a result of drinking water chlorination (Rook, 1974; Bellar *et al*, 1974). EPA subsequently conducted surveys confirming widespread occurrence of TTHMs in chlorinated water supplies (Symons, 1975; USEPA, 1978). During this time toxicological studies became available which supported the contention that chloroform, one of the four trihalomethanes, is carcinogenic in at least one strain of rat and one strain of mouse (National Academy of Sciences, 1977).

EPA then set an interim maximum contaminant level (MCL) for the TTHMs of 100 µg/l as an annual average in November 1979 (USEPA, 1979). This standard was based on the need to balance the requirement for continued disinfection of water to reduce exposure to pathogenic microorganisms while simultaneously lowering exposure to animal carcinogens like chloroform.

The interim TTHM standard only applies to systems serving at least 10,000 people that add a disinfectant (oxidant) to the drinking water during any part of the treatment process. At their discretion, States are allowed to extend coverage to smaller size systems. About 80 percent of the smallest systems are served by groundwater systems that are mostly low in THM precursor content (USEPA, 1979).

The proportion of these small groundwater systems that use chlorine is less than that of large systems; currently, less than half of these systems disinfect. Also, the shorter hydraulic detention and chlorine contact times in the small system distribution systems results in lower TTHM concentrations. Therefore, drinking water systems serving less than ten thousand people are less likely to have high concentrations of TTHMs.

Moreover, these small systems are most likely to have greater risks of significant microbiological contamination, especially if they reduce or eliminate chlorination. In 1979, the majority of outbreaks attributable to inadequate disinfection occurred in small systems. Further, small systems have limited or no access to the financial resources and technical expertise needed for TTHM control. Therefore, EPA concluded that small system resources would best be spent on maintaining and improving microbiological quality and safety. The revised drinking water regulations now under consideration will extend to these small systems as required by the Safe Drinking Water Act Amendments of 1986 (P.L. 99–339, 1986). EPA will also be considering disinfection as a treatment technique requirement and maximum contaminant levels (MCLs) for the residual disinfectants. The impacts these requirements will have on small systems is an important component of the regulation development process.

Technology Basis for the Interim TTHM Standard

When an MCL is established for TTHMs or any other contaminant that can be measured, EPA is not required to specify any particular method for achieving that standard. Instead, the requirement for the interim regulations was to set an MCL which could be achieved using technology generally available in 1974. Three general control alternatives were available:

(1) use of a disinfectant (oxidant) that does not generate (or produces less) THMs in water;
(2) treatment to lower precursor concentrations prior to chlorination; and
(3) treatment to remove THMs after their formation.

There are many possible choices among these broad options and in some cases a combination of approaches might be necessary. The ultimate choice was left up to the water supplier based on its individual circumstances.

EPA's evaluation led to the following conclusions concerning generally available technologies for setting the TTHM MCL:

(1) alternate oxidants like ozone, chloramines, and chlorine dioxide are available;
(2) precursor removal strategies like changing the point of disinfection, off-line raw water storage, and improved coagulation are available; and,
(3) precursor removal using granular activated carbon (GAC) as a replacement for existing filter media with a regeneration frequency of one year is feasible as well as biologically activated carbon (ozone plus GAC) with a regeneration frequency of every two years.

Three conditions concerning modifications of disinfection processes were also proposed by EPA:

(1) the total quantity of chlorine dioxide added during the treatment process should not exceed 1 mg/l;
(2) chloramines should not be utilized as a primary disinfectant; and
(3) monitoring for heterotrophic plate count bacteria (HPC) should be conducted as determined by the State, but at least every day for a minimum of one month prior to and six months subsequent to the modifications.

These recommendations concerning disinfection, although useful, were deleted from the final regulation to allow States greater discretion. The basis for the MCL became alternate oxidants and precursor removal.

Technology Basis for Variances

Later, in 1983, EPA promulgated regulations specifying best technology generally available for obtaining variances (USEPA, 1983). A variance is granted by the State when a system has installed the best technology generally available as specified in the regulation and still cannot meet the MCL. The best technologies generally available for variances to the TTHM MCL are:

(1) Use chloramines as an alternate or supplemental disinfectant or oxidant.
(2) Use chlorine dioxide as an alternate or supplemental disinfectant or oxidant.
(3) Improve existing clarification for THM precursor reduction.
(4) Move the point of chlorination to reduce TTHM formation and, where necessary, substituting for the use of chlorine as a pre-oxidant chloramines, chlorine dioxide, or potassium permanganate.
(5) Use of powdered activated carbon for THM precursor or TTHM reduction seasonally or intermittently at dosages not to exceed 10 mg/l on an annual average basis.

EPA also identified Group II technologies, which are not "generally available," but may be available to some systems:

(1) Introduction of off-line water storage for THM precursor reduction.
(2) Aeration for TTHM reduction, where geographically and environmentally appropriate.
(3) Introduction of clarification where not currently practiced.
(4) Consideration of alternative sources of raw water.
(5) Use of ozone as an alternate or supplemental disinfectant or oxidant.

Note that GAC and BAC are not mentioned as either Group I or Group II technologies even though they were discussed as technologies for standard setting purposes (USEPA, 1979). EPA concluded in its cost and technologies document for the removal of trihalomethanes from drinking water that (USEPA, 1981):

(1) GAC in the sand replacement mode of operation is often inappropriate due to the short performance life and high frequency of regeneration required to achieve substantial TTHM or THM-formation potential reduction;
(2) the finding took into consideration costs, but primarily was made due to the complexities of the modifications to prior unit operations, i.e., disinfection, and in the logistics of the carbon replacement;
(3) greater operating, maintenance, and monitoring than for other treatments; and
(4) on-site regeneration had only been demonstrated at one U.S. site.

Thus, EPA decided to defer the decision to include GAC and BAC as best generally available technology for granting variances under the Safe Drinking Water Act Amendments of 1974.

EPA also did not list ozonation as being "generally available" because:
(1) lack of experience in the U.S.;
(2) mixed results in experimental studies; and
(3) most States require a residual in the distribution system which is not obtainable with ozone.

Thus, EPA decided to defer the decision to include ozone as best generally available technology for granting variances under the Safe Drinking Water Act Amendments of 1974.

Economic Impacts of the Interim Standard

Currently, there are 2,700 community water supply systems serving at least 10,000 people required to comply with the interim TTHM regulation. In 1988, a survey of large systems found that, on average, the MCL of 0.10 mg/l had reduced the concentration of TTHMs by 40 to 50 percent (McGuire and Meadows, 1988). Of these, 33 were in violation of the standard in FY88 (average=115 µg/l, range=108–180 µg/l). However, by FY92, only nine systems (a decrease of 73 percent) violated the requirements, for a total of 14 violations. Seven of the nine violating systems and 12 of the 14 violations occurred in systems serving 10,000 to 50,000 people. This indicates that even when systems violate, they are able to return to compliance after one or two violations of the running annual average.

In 1979, approximately 500 systems were estimated to exceed 100 µg/l TTHMs. Most of these were able to come into compliance with minor modifications of chlorination practices. A smaller portion used alternate oxidants like chlorine dioxide and chloramines. No system installed ozone or GAC to meet the interim TTHM regulations. Compliance with the interim TTHM standard involved estimated capital expenditures of between $31 million and $102 million and yearly operating and maintenance costs of between $8 million and $29 million for systems required to comply with the TTHM MCL (i.e., community water systems serving a population of at least 10,000 people) (McGuire and Meadows, 1988).

IV. Overview of Preproposal Regulatory Development

A. October 1989 Strawman Rule

1. Purpose. EPA was required to develop rules for additional contaminants under the 1986 Amendments to the Act. In order to solicit public comment in developing a rule, EPA released a strawman rule (preproposal draft) in October 1989. A strawman was used because of the complexity of the problem, the large amount of (occasionally contradictory) information, and the ability to reorient the rule approach based on public comment or new data. In this strawman, EPA included a lead option of setting MCLGs and MCLs for TTHMs, haloacetic acids, chlorine, chloramines, chlorine dioxide, chlorite, and chlorate. The Agency also identified potential add-on compounds: chloropicrin, cyanogen chloride, hydrogen peroxide, bromate, iodate, and formaldehyde. Some of these compounds could also conceivably be used as surrogate monitoring compounds for the compounds identified in Table IV–1 below.

ADDITIONAL CANDIDATE BYPRODUCT COMPOUNDS

Chlorination byproducts	Ozonation byproducts
—Individual THMs: chloroform, bromodichloromethane, dibromochloromethane, bromoform	—Aldehydes: acetaldehyde, hexanal, heptanal.
—Individual haloacetic acids: mono-, di-, and trichloroacetic acids; mono- and dibromoacetic acids	—Organic acids.
	—Ketones.
	—Epoxides.
—Individual haloacetonitriles: di- and trichloroacetonitrile; bromochloroacetonitrile, dibromoacetonitrile	—Peroxides.
	—Nitrosamines.
—Haloketones: 1,1 di- and 1,1,1- trichloropropanone.	
—Chlorophenols: 2-; 2,4-di; and 2,4,6-trichlorophenol	—N-oxy compounds.
	—Quinones.
—Others: chloral hydrate, N- organochloroamines	—Bromine substituted compounds.

In addition, the strawman provided that EPA would set treatment technique requirements or provide guidance for control of the following: MX, as a surrogate for mutagenicity; total oxidizing substances, as a surrogate for organic peroxides and epoxides; and assimilable organic carbon, as a surrogate for microbiological quality of oxidized waters. Monitoring parameters based on the particular disinfection process were also identified.

As BAT, EPA included precursor removal (conventional treatment modifications, GAC of up to 30 minute duration and three months regeneration), alternate oxidants (ozone plus chloramines, chlorine dioxide with chlorite removal plus chloramines), and byproduct removal (aeration, GAC adsorption, reducing agents, AOC removal). Each of the options had problems. GAC was not universally applicable to all waters for either precursor removal or DBP removal. Membranes were not included as BAT because of lack of full-scale experience.

As lead options, EPA included a TTHM MCL of 25 or 50 µg/l and other MCLs based on feasibility analyses similar to those that would be used to develop the TTHM MCL.

2. Summary of Public Comments. Several commentors expressed a desire for EPA to look at coordination of requirements with those for other

regulations, including issues such as requirements for maintenance of distribution system disinfectant residuals and system optimization for multiple contaminants. Many commentors were concerned about the lack of health data and the interpretation of existing data. Many system operators were also concerned about the effects of modifying their treatment processes to meet DBP MCLs. These concerns included lowered microbiological protection, creation of conditions that favored distribution system microbiological growth (e.g., use of ozone would create biodegradable organics and use of chloramines would create a nitrogen source), and creation of other environmental problems when changing treatment (e.g., residual handling with precursor removal and GAC regeneration). While commentors expressed concern about use of alternate disinfectants, several offered to provide data and others recommended epidemiological studies in systems with long histories of alternative disinfectant use.

B. June 1991 Status Report on D/DBP Rule Development

1. Purpose and transition from Strawman Rule. EPA published a status report on the development of D/DBPR in June 1991 that was designed to indicate the Agency's thinking on rule criteria. The status report indicated that EPA was considering extending coverage under the rule to all nontransient systems (instead of just those serving at least 10,000 people, as under the 1979 TTHM rule) and proposing a shorter list of compounds for regulation than were included in the 1989 strawman. The 1991 list included disinfectants (chlorine, chloramines, and chlorine dioxide), THMs, haloacetic acids, chloral hydrate, bromate, chlorite, and chlorate). For both THMs and haloacetic acids, three options were included: MCLs for individual compounds, a single MCL for the total, and a combination of the two. Individual MCLs were considered because health risks for compounds differed, in some cases significantly. The total MCL was considered because of the precedent established in the 1979 TTHM rule and to act as a surrogate to limit other DBPs for which the Agency lacked adequate health effects and/or occurrence data.

The list of compounds was shorter than that in the 1989 strawman for several reasons. Several compounds were deleted because they did not appear to pose significant health effects at levels present in drinking water (e.g., haloacetonitriles, chloropicrin). Others were deleted because the health risks were not expected to be adequately characterized in time for rule proposal (e.g., certain aldehydes and organic peroxides), although it was noted that these compounds might be regulated in the future when more data became available.

2. Major issues. In the status report, EPA identified several major issues that needed to be considered as the D/DBP rule was developed. The first was that of trade-offs with microbial and DBP risks. The goal was to ensure that the water remained microbiologically safe at the level that disinfectant and DBP MCLs were set. The discussion raised questions regarding uncertainties in defining microbial and DBP risks, levels of risks that would be considered acceptable and at what cost, and defining practical (implementable) criteria to demonstrate that an achievable risk had been reached.

The second issue was the use of alternate disinfectants to limit chlorination byproducts. The Agency recognized that while alternate disinfection schemes (e.g., ozone and chloramines) could greatly reduce byproducts typical of chlorination, little was known about the byproducts of the alternate disinfectants and their associated health risks. EPA did not want to promulgate a standard that encouraged the shift to alternate disinfectants unless the associated risks (including both those from byproducts and differential microbial risks from a change in disinfectants) were adequately understood.

The third issue was integration with the Surface Water Treatment Rule. Although the rule only mandated 3-log removal or inactivation of Giardia and 4-log of viruses, EPA guidance recommended higher levels for poorer quality source waters. EPA was concerned that systems would reduce microbial protection to levels nearer to the regulatory requirements by reducing disinfection and possibly greatly increase microbial risks in an effort to meet DBP MCLs. The Agency wanted to ensure adequate microbial protection while reducing risk from DBPs.

The last issue was the best available technology. The BAT defined would determine the levels at which MCLs were set. For example, allowing alternate disinfectants as BAT would drive the chlorination byproduct MCLs down, but could result in increased exposure to (not well characterized) alternate byproducts. EPA believed that it therefore might be appropriate to define chlorine and a precursor removal technology as BAT.

To address these issues, EPA suggested two possible regulatory strategies. One was to define the MCL(s) based on what was possible to achieve using the most effective DBP precursor removal strategy as BAT (e.g., GAC or membrane filtration). While installing such precursor removal technology might minimize health concerns, the costs would be substantial (without finding out if other less costly technologies, such as use of alternative disinfectants, provided similar benefits). Also, since systems are not required to install BAT to meet MCLs, EPA believed that many systems would attempt to meet the MCLs by lower-cost alternative disinfectants (ozone, chloramines, chlorine dioxide). Since health effects for alternative disinfectant byproducts are not adequately characterized, risks may not be reduced.

The second strategy was a two-phase regulation, with the first phase designed to address risks using lower cost options during concurrent efforts to obtain more data on treatment alternatives and health effects of compounds not currently adequately characterized. This strategy would prevent major shifts into use of new treatment technology until the full consequences of such shifts (both costs and benefits) are better understood.

3. Suggested monitoring scenario. In its fact sheet accompanying the status report, EPA recommended that routine TTHM and haloacetic acid monitoring for systems serving at least 10,000 people have the same monitoring requirements as were in the 1979 TTHM rule. Smaller systems would have less frequent monitoring requirements, but would have compliance based on worst-case samples. EPA included provisions for reduced monitoring (compliance based on worst-case samples or surrogate monitoring), waiver criteria, and requirements for disinfectant and other DBP monitoring.

4. Summary of public comments. EPA received comments on the status report from numerous parties. Many commentors agreed with EPA's concerns with issues such as alternative disinfectant DBPs and balancing microbial and DBP risks. Several commentors supported the two-phase regulatory approach, but expressed concern about timing. Others recommended that DBP MCLs not be set so low as to force many systems to install expensive technology or decrease microbial protection. Several commentors were concerned with the availability of both analytical methods and certified laboratories for the low levels that were being considered. One commentor recommended that EPA make it clear that MCLs set for disinfectants should allow temporary

high levels to address distribution system microbiological problems. Finally, many commentors supported allowing reduced monitoring wherever possible.

C. Initiation of the Regulatory Negotiation Process

EPA became interested in pursuing a negotiated rulemaking process for the development of the D/DBP rule, in large part, because no clear path for addressing all the major issues identified in the June 1991 Status Report on D/DBP rule was apparent. EPA's most significant concern was developing regulations for DBPs while also ensuring that adequate treatment be maintained for controlling microbiological concerns. A negotiated rule process would help people understand the complexities of the risk-risk tradeoff issue and, hopefully, reach a consensus on the most appropriate regulation to address concerns from both DBPs and microorganisms.

It also appeared to EPA that the criteria for initiating a negotiated rule under the Negotiated Rulemaking Act of 1990 for establishing a negotiated rulemaking could be met. These include:

(1) there is a need for a rule,

(2) there are a limited number of identifiable interests that will be significantly affected by the rule,

(3) there is a reasonable likelihood that a committee can be convened with a balanced representation of persons who—

(A) can adequately represent the interests identified under paragraph (2); and

(B) are willing to negotiate in good faith to reach a consensus on the proposed rule,

(4) there is a reasonable likelihood that a committee will reach a consensus on the proposed rule within a fixed period of time,

(5) the negotiated rulemaking procedure will not unreasonably delay the notice of proposed rulemaking and the issuance of a final rule,

(6) the Agency has adequate resources and is willing to commit such resources, including technical assistance, to the committee, and

(7) the Agency, to the maximum extent possible consistent with the legal obligations of the Agency, will use the consensus of the committee with respect to the proposed rule as the basis for the rule proposed by the Agency for notice and comment.

In 1992 EPA hired a contractor, Resolve, which added a subcontractor, Endispute, to assess the feasibility and usefulness of convening a negotiated rulemaking. Resolve and Endispute conducted more than forty interviews during the summer of 1992 with representatives of State and local health and regulatory agencies, water suppliers, manufacturers of equipment and supplies used in drinking water treatment, and consumer and environmental organizations. These interviews revealed that:

(1) The entities interested in or affected by the rulemaking were readily identifiable and relatively few in number.

(2) The rulemaking required resolution of a limited number of interdependent issues, about which there appeared to be a sufficiently well-developed factual base to permit meaningful discussion. Further, there appeared to be several ways to resolve these issues, providing a potential basis for productive joint problem-solving.

(3) The parties expressed some common goals, along with an unusually strong degree of good faith interest in resolving the issue through negotiation.

(4) The Agency had adequate staff and technical resources and was willing to commit such resources to the negotiated rulemaking.

Resolve and Endispute recommended to EPA that the negotiated rulemaking proceed. EPA concurred with this recommendation.

However, it was also noted that reaching consensus on the proposed rule would be a challenge. The interviews revealed that parties differed in their perceptions about the nature and magnitude of the risks associated with DBPs, and many expressed strong doubts about the adequacy of available scientific and technical information. Moreover, some parties stated that marginal improvements in disinfection technology were all that should be done until the relative risks are better understood, while others said that a fundamentally new approach focusing on precursor reduction should be considered.

EPA published a notice of intent to proceed with a negotiated rulemaking on September 15, 1992 (57 FRN 42533), proposing 17 parties to be Negotiating Committee members. In general, comments indicated very positive support for the negotiated rulemaking.

As part of the convening process, an organizational meeting was held September 29–30, 1993. Participants discussed Negotiating Committee composition and organizational protocols. Between comments expressed at the meeting and submitted in writing, eleven additional parties—including water suppliers not substantially represented by the Committee's original proposed membership, and chemical and equipment suppliers—asked to be added to the Committee. In addition, participants discussed the need to develop accurate scientific and technical information.

On November 13, 1992, EPA published a notice of establishment for the Negotiating Committee (57 FRN 53866), and an 18th member was added to the Negotiating Committee.

Based on comments received at the organizational meeting, a Technical Workshop was organized and conducted on November 4–5, 1992. Composed of presentations and panel discussion by 23 of the Nation's leading experts on drinking water treatment, the workshop provided participants with opportunities to familiarize themselves with the technical elements in this rulemaking and to explore the range of scientific opinions about: (1) The nature and magnitude of potential health effects from exposure to DBPs and microbial contaminants in drinking water, (2) available information on the cost and efficacy of precursor removal and drinking water disinfection technologies, and (3) EPA's efforts to model and compare chemical and microbial risks in drinking water.

Additional presentations were given throughout the rulemaking process, as new information became available and more questions were raised by participants.

At the first formal negotiating session, on November 23–24, 1992, participants formed a technologies working group (TWG) to develop reliable and consistent information about the cost and efficacy of drinking water treatment technologies. This approach provided a forum for participants to arrive at a shared understanding of complex issues in the rulemaking, setting a cooperative tone for the rest of their discussions. The working group, which continued to meet throughout the rulemaking, also provided a formal opportunity for input from the chemical and equipment suppliers who had not been named to the Committee.

In addition, three experts were hired through EPA's contract with Resolve to provide ongoing scientific advice and technical support to participants in the Committee and on the technologies working group, principally for members without access to similar resources within their own organizations.

Based on scientific data presented and discussed through the November 23–24 meeting, participants agreed that some type of DBP Rule was warranted.

The Committee developed and reached agreement on criteria for a "good" DBP Rule at the September 29–

30 and November 23–24 meetings. A good rule is one which would be flexible and affordable and would protect public health from chemical and microbial risks. It was noted that limiting some DBPs could encourage changes in treatment that might increase the formation of other DBPs, or compromise protections against microbial contaminants.

Next, Committee members and other participants were invited to present regulatory options as a starting point for further discussion. Sixteen options were introduced at the December 17–18 meeting, and discussed at the meeting on January 13–14, 1993. These were merged into three consolidated options at the January 13–14 meeting, and discussion continued at the meeting on February 9–10. At this point, areas of disagreement included:

(1) Whether to regulate DBPs through Maximum Contaminant Levels (MCLs) or through a treatment technique (i.e., by exceeding DBP "action levels," systems would trigger additional steps to minimize chemical and microbial risks).

(2) Whether to minimize formation of the DBPs about which relatively little is known by establishing a regulatory limit for their naturally occurring organic precursors (e.g., Total Organic Carbon, or TOC) in the water prior to the point of disinfection.

(3) Whether to provide greater protection against microbial contaminants in drinking water, in conjunction with new DBP limits, by developing an enhanced Surface Water Treatment Rule (ESWTR).

(4) Whether to develop a second round of DBP controls along with the first (assuring broad improvements in drinking water quality), or to wait until better scientific information becomes available.

Concurrently, the TWG modelled systems' potential compliance choices under several regulatory scenarios, and presented revised household and national compliance cost estimates at several meetings.

Using a "strawman" developed from the consolidated options by EPA staff as the starting point for negotiation, the Committee worked out an "agreement in principle" on the first round of DBP controls at its February 24–25 meeting. The "Stage 1" agreement set MCLs for trihalomethanes and haloacetic acids—two principal classes of chlorination by-products—at levels the Committee deemed protective of public health, based on current information: 80 and 60 micrograms per liter, respectively. To limit DBP precursors, the Committee agreed to develop a series of "enhanced coagulation" requirements, to vary according to systems' influent water quality and treatment plant configurations. Members also agreed to reconvene in several years to develop a second stage of DBP regulations, when the results of more health effects research and water quality monitoring are available. In addition, members agreed that more expeditious changes to the rules may be necessary if additional information becomes available on short-term or acute health effects of DBPs. Members also agreed that, if data on short-term or acute health effects warrant earlier action, a meeting shall be convened to review the results and to develop recommendations.

A drafting group was named at the February 24–25 meeting. Assisted by the TWG, these members drafted an "agreement in principle" for presentation and discussion at the March 18–19 meeting. Using "straw" provisions from the facilitators, the Committee devised a regulatory "backstop" (i.e., Stage 2 MCLs of 0.040 mg/l for TTHMs and 0.030 mg/l for HAA5 for surface water systems serving at least 10,000 people) at this meeting to assure participants favoring further DBP controls that other members would return for the "Stage 2" negotiation. The Committee also agreed to recommend that EPA propose several ESWTR options for comment, developed a collaborative process to guide the health effects research program, and agreed to formulate short-term water quality and technical data collection provisions within an Information Collection Rule.

Based on the discussion to this point, one member withdrew from the Committee at the March 18–19 meeting.

The drafting group presented regulatory language for the DBP Rule, ESWTR, and ICR at each of the Committee's last two meetings, held May 12–13 and June 22–23, 1993. These texts provided a framework for further discussion and resolution of remaining issues, including: limits for residual disinfectants and individual by-products; public notification and affordability provisions; and timing, applicability, and conditions under which systems might qualify for exceptions from various requirements. Committee members agreed to reserve their rights to comment on the draft preambles.

The drafting group continued working through the summer of 1993, and revisions to each of the rules and their preambles were mailed to the Committee for comment on July 8, 1993, September 8, 1993, February 8, 1994, and May 12, 1994. Each member had signed the agreement by June 7, 1994.

Unless otherwise noted, EPA has adopted the recommendations of the Negotiating Committee and its Technologies Working Group and reflects those recommendations in the following preamble and proposed regulations.

V. Establishing MCLGs

A. Background

1. MCLGs and MCLs Must Be Proposed and Promulgated Simultaneously

Congress revised the Safe Drinking Water Act in 1986 to require that MCLGs and National Primary Drinking Water Regulations (NPDWRs) be proposed simultaneously and promulgated simultaneously [SDWA section 1412 (a)(3)]. Simultaneous promulgation was intended to streamline the development of drinking water regulations.

2. How MCLGs Are Developed

MCLGs are set at concentration levels at which no known or anticipated adverse health effects occur, allowing for an adequate margin of safety. Establishment of an MCLG for each specific contaminant depends on the evidence of carcinogenicity from drinking water exposure or an assessment for adverse noncarcinogenic health effects.

a. *MCLG Three Category Approach.* EPA currently follows a three-category approach in developing MCLGs for drinking water contaminants (Table V–1).

TABLE V–1.—EPA'S THREE-CATEGORY APPROACH FOR ESTABLISHING MCLGS

Category	Evidence of carcinogenicity via drinking water [1]	MCLG approach
I	Strong evidence considering weight of evidence, pharmacokinetics, potency and exposure.	Zero.
II	Limited evidence considering weight of evidence, pharmacokinetics, potency and exposure.	RfD approach with added safety margin of 1 to 10 or 10^{-5} to 10^{-6} cancer risk range.

TABLE V–1.—EPA'S THREE-CATEGORY APPROACH FOR ESTABLISHING MCLGs—Continued

Category	Evidence of carcinogenicity via drinking water [1]	MCLG approach
III	Inadequate or no animal evidence.	RfD approach.

[1] Considering oral exposure data such as drinking water, dietary and gavage studies.

Each chemical is evaluated for evidence of carcinogenicity from drinking water. For volatile contaminants, inhalation data are also considered. EPA takes into consideration the overall weight of evidence for carcinogenicity, pharmacokinetics, potency and exposure.

EPA's policy is to set MCLGs for Category I contaminants at zero. The MCLG for Category II contaminants is calculated by using the Reference dose (RfD) approach (described below) with an added margin of safety to account for possible cancer effects. If adequate data are not available to calculate an RfD, then the MCLG is based on a cancer risk level of 10^{-5} to 10^{-6}. MCLGs for Category III contaminants are calculated using the RfD approach.

Category I contaminants are those for which EPA has determined that there is strong evidence of carcinogenicity from drinking water. The MCLG for Category I contaminants is set at zero because it is assumed, in the absence of other data, that there is no threshold dose for carcinogenicity. In the absence of route specific (e.g., oral) data on the potential cancer risk from drinking water, chemicals classified as Group A or B carcinogens (see section c below) are generally placed in Category I.

Category II contaminants include those contaminants for which EPA has determined that there is limited evidence of carcinogenicity from drinking water, considering weight of evidence, pharmacokinetics, potency, and exposure. In the absence of route specific data, chemicals classified in Group C (see section c below) are generally placed in Category II.

For Category II contaminants, one of two options have traditionally been used to set the MCLG. The first option sets the MCLG based upon noncarcinogenic endpoints of toxicity (the RfD), then applies an additional safety factor of 1 to 10 to the MCLG to account for possible carcinogenicity. An MCLG set by the option 1 approach is compared with the cancer risk, if quantified. The second option is to set the MCLG based upon a theoretical lifetime excess cancer risk level of 10^{-5} to 10^{-6} using a conservative mathematical extrapolation model. EPA generally uses the first option; however, the second approach is used when valid noncarcinogenic data are not available to calculate an RfD and adequate experimental data are available to quantify the cancer risk.

Category III contaminants include those contaminants for which there is inadequate or no evidence of carcinogenicity from drinking water. If there is no additional information to consider, contaminants classified in Group D or E (see section c below) are generally placed in Category III. For these contaminants, the MCLG is established using the RfD approach.

b. *Assessment of Noncancer Health Effects.* The risk assessment for noncancer health effects can be characterized by a Reference Dose (RfD). The oral RfD (expressed in mg/kg/day) is an estimate, with uncertainty spanning perhaps an order of magnitude, of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious health effects during a lifetime. The RfD is derived from a no- or lowest-observed-adverse-effect level (called a NOAEL or LOAEL, respectively) that has been identified from a subchronic or chronic study of humans or animals. The NOAEL or LOAEL is then divided by an uncertainty factor(s) to derive the RfD. Although the RfD is represented as a point estimate, it is actually a range since the RfD is a number with an inherent uncertainty of an order of magnitude.

Uncertainty factors are used to estimate the comparable "no-effect" level for a large heterogeneous human population. The use of uncertainty factors accounts for several data gaps including intra- and inter-species differences in response to toxicity, the small number of animals tested compared to the size of the population, sensitive subpopulations and the possibility of synergistic action between chemicals (see 52 FR 25690 for further discussion on the use of uncertainty factors).

EPA has established certain guidelines (shown below) to determine how to apply uncertainty factors when establishing an RfD (USEPA, 1986).

- Use a 1- to 10-fold factor when extrapolating from valid experimental results from studies in average healthy humans. This factor is intended to account for the variation in sensitivity among the members of the human population.
- Use an additional 10-fold factor when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. This factor is intended to account for the uncertainty in extrapolating animal data to the case of humans.
- Use an additional 10-fold factor when extrapolating from less than chronic results on experimental animals when there are no useful long-term human data. This factor is intended to account for the uncertainty in extrapolating from less than chronic NOAELs to chronic NOAELs.
- Use an additional 10-fold factor when deriving an RfD from a LOAEL instead of a NOAEL. This factor is intended to account for the uncertainty in extrapolating from LOAELs to NOAELs.
- An additional uncertainty factor may be used according to scientific judgment when justified.
- Use professional judgment to determine another uncertainty factor (also called a modifying factor, MF) that is greater than zero and less than or equal to 10. The magnitude of the MF depends upon the professional assessment of scientific uncertainties of the study and data base not explicitly treated above, e.g., the completeness of the overall data base and the number of species tested. The default value for the MF is 1.

To determine the MCLG, the RfD is adjusted by the body weight of the protected (or most sensitive) individual (usually a 70 kg adult), average volume of water consumed daily over a lifetime (2 L/day for an adult) and exposure to the contaminant from a drinking water source (relative source contribution or RSC).

Generally, EPA assumes that the RSC from drinking water is 20 percent of the total exposure, unless other exposure data for the chemical are available [see 54 FR 22069 and 56 FR 3535]. When adequate data are available and the data indicate that drinking water exposure contributes between 20 and 80 percent of total exposure, EPA uses the actual percentage to determine the MCLG, as is indicated by equation (3), below. When data indicate that contributions from drinking water are between zero and 20 percent, or between 80 and 100 percent, EPA utilizes a 20 percent floor and an 80 percent ceiling, respectively.

The calculations below express the derivation of the MCLG based on noncancer health effects:

$$MCLG = \frac{(NOAEL \text{ or } LOAEL \text{ in mg/kg/d}) \times \text{body weight} \times RSC}{\text{uncertainty factor(s)} \times \text{water consumption}} = ___ \text{ mg/L (rounded to one significant figure)}$$

c. *Assessment of Carcinogenic Health Effects.* For chemicals suspected of being carcinogenic to humans, the assessment for non-threshold toxicants consists of the weight of evidence of carcinogenicity in humans, using bioassays in animals and human epidemiological studies as well as information that provides indirect evidence (i.e., mutagenicity and other short-term test results). The objectives of the assessment are to determine the level or strength of evidence that the substance is a carcinogen and to provide an upperbound estimate of the possible risk of human exposure to the substance in drinking water. A summary of EPA's general carcinogen classification scheme is (USEPA, 1986):

Group A—Human carcinogen based on sufficient evidence from epidemiological or other human studies.

Group B—Probable human carcinogen based on limited evidence of carcinogenicity in humans (Group B1) or based on sufficient evidence in animals with inadequate or no data in humans (Group B2).

Group C—Possible human carcinogen based on limited evidence of carcinogenicity in animals in the absence of human data.

Group D—Not classifiable based on lack of data or inadequate evidence of carcinogenicity from animal data.

Group E—No evidence of carcinogenicity for humans (no evidence for carcinogenicity in at least two adequate animal tests in different species or in both epidemiological and animal studies).

d. *MRDLGs—appropriateness of a new concept?* As stated in section II.A of this preamble, EPA is proposing a new term, "maximum residual disinfectant level goal" (MRDLG), in lieu of MCLGs for all disinfectants because disinfectants are intentionally added to drinking water as a treatment technique to kill disease-causing microorganisms. The proposal of this concept was agreed to through the negotiated rulemaking process.

Certain members of the Negotiating Committee were concerned that if "MCLGs," which included the term "contaminant," were set for disinfectants, water treatment plant operators might be reluctant to apply disinfectant dosages above the MCLG during short periods of time to control for microbial risk, even though such exposure to elevated disinfectant concentration levels would pose little or no risk. For example, NOAELs for chlorine and chloramines are based upon animal studies following long term exposure to high levels of the disinfectants in drinking water. Short-term exposures at elevated levels would not be a concern (see the following discussion on health effects for chlorine and chloramines). During emergency situations such as distribution system pipe breaks or significant fluctuations in source water quality, systems will on occasion need to apply short term disinfectant residual concentrations of chlorine or chloramines, well above the regulatory goal, to protect from waterborne disease.

The MRDLGs are developed in the same way as MCLGs. EPA solicits comment on the appropriateness of adopting the term "MRDLG" in lieu of MCLGs for disinfectants in the final rule.

B. Proposed MRDLGs and MCLGs

The following includes a summary of the health effects information available for each disinfectant or by-product. These summaries are taken from more complete and comprehensive descriptions of the data given in the cited Health Criteria Documents that have been developed for each of these chemicals. These documents are available in the water docket.

1. Chlorine, hypochlorite ion and hypochlorous acid

The following assessment for both chlorine and chloramines includes a consideration of available animal data, as well as epidemiology studies which have been conducted on chlorinated or chloraminated drinking water. The epidemiology data are discussed in section C of this preamble.

Chlorine (CAS # 7782–50–5) hydrolyses in water to form hypochlorite (CAS # as sodium salt 7790–92–3) and hypochlorous acid (CAS # 7681–52–9). Because of their oxidizing characteristic and solubility, chlorine and hypochlorites are used in water treatment to disinfect drinking water, sewage and wastewater, swimming pools, and other types of water reservoirs. They are also used for general sanitation and control of bacterial odors in the food industry.

Chlorine is a highly reactive and water soluble species. The fate, transport, and distribution of chlorine in natural waters is not well understood. Much of the available information comes from the addition and oxidation reactions with inorganic and organic compounds known to occur in aqueous solutions. Factors such as reactant concentrations, pH, temperature, salinity and sunlight influence these reactions.

Occurrence and Human Exposure. For the purpose of setting an MRDLG, consideration is given to chlorine levels resulting from disinfection of drinking water. Chlorine exposures from swimming pools and hot tubs are not evaluated in determining the MRDLG. Persons who swim frequently or use a hot tub may have greater dermal and possibly inhalation exposure to chlorine.

Chlorine is added to drinking water as chlorine gas (Cl_2) or as calcium or sodium hypochlorite. In drinking water, the chlorine gas hydrolyses to hypochlorous acid and hypochlorite ion and can be measured as the free chlorine residual. Maintenance of a chlorine residual throughout the distribution system is important for minimizing bacterial growth and for indicating (by the absence of a residual) water quality problems in the distribution system. Currently, maximum chlorine dosage is limited by taste and odor constraints and for systems needing to comply with the total trihalomethane (TTHM) standard regularly. Additionally, for systems using chlorination, the surface water treatment rule (SWTR) requires a minimum residual of 0.2 mg/L prior to the entry point to the distribution system, and the presence of a detectable residual throughout the distribution system.

Table V–2 presents occurrence information available for chlorine in drinking water. Descriptions of these surveys and other data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," USEPA 1992a. The table lists five surveys conducted by Federal, as well as private agencies. Median concentrations of chlorine in drinking water appear to range from <1 to 2 mg/L.

TABLE V–2.—SUMMARY OF OCCURRENCE DATA FOR CHLORINE

Occurrence of chlorine in drinking water						
Survey (year)[1]	Location	Sample information (No. of samples)	Concentration (mg/L)			
			Range	Mean	Median	Other
EPA, 1992b[2] (1987–1991).	Disinfection By-Products Field Studies.	Finished Water: At the Plant (71)	0.1–5.0	1.7	1.4	
		Distribution System (45)	0.0–3.2	0.7	0.5	
AWWARF (1987) McGuire & Meadow, 1988.	National Survey	Finished Water From: Lakes				(Typical doses). 2.2[3]
		Flowing Streams				2.3[3]
		Ground Waters				1.2[3]
		Mixed-supplies				1.0[3]
EPA/AMWA/CDHS[2] (1988–1989) Krasner et al., 1989b.	35 Water Utilities Nationwide.	Samples from Clearwell Effluent, 4 Quarters (17).	0.3–5.2	1.5	1.0	
WIDB (1989–1990)	228 SW Plants. 215 GW Plants	Residual Chlorine Provided to the Average Customer (systems >50,000 people).	0–3.5 0–5	0.937 0.872	0.8 0.325	
AWWA Disinfection Survey (1991).	283 Utilities in the U.S..	Finished Water Entering Distribution System.		0.07–5.0	1.1	

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.
[3] Typical dosage used by treatment plants.

SW: Surface Water.
GW: Ground Water.
AMWA: Association of Metropolitan Water Agencies.
AWWA: American Water Works Association.
AWWARF: American Water Works Association Research Foundation.
CDHS: California Department of Health Services.
EPA: Environmental Protection Agency.
WIDB: Water Industry Data Base.

Exposure to chlorine residual varies both between systems and within systems. Chlorine residual within systems will vary based on where customers are located within the distribution system and changes in the system's disinfection needs over time. Using residual concentrations from the 1989–1991 AWWA Disinfection Survey and WIDB, exposure to chlorine due to drinking water can be estimated using a consumption rate of 2 liters per day. Based on the estimated 25th percentile and 75th percentile chlorine residuals in the 1991 AWWA Disinfection Survey, exposure was determined to range from 1.5 to 3.8 mg/day and the median would be 2.2 mg/day. Using the WIDB data, exposures to the average customer from surface and ground water sources using chlorination, respectively, were determined to be 1.9 mg/day and 1.7 mg/day.

Little information is available concerning the occurrence of chlorine in food and indoor air in the United States. The Food and Drug Administration (FDA) does not analyze for chlorine in foods. However, there are several uses of chlorine in food production, such as the disinfection of chicken in poultry plants and the superchlorination of water at soda and beer bottling plants (Borum, 1991). Therefore, the possibility exists for dietary exposure to chlorine from its use in food production. However, monitoring data are not available to characterize adequately the extent of such potential exposures. Additionally, preliminary discussions with FDA suggest that there are no approved uses for chlorine in most foods consumed in the typical diet. Similarly, EPA's Office of Air and Radiation is not currently conducting any sampling studies for chlorine in indoor air. Data on levels of chlorine in ambient air are forthcoming.

Considering the limited number of food groups that are believed to contain chlorine and that no significant levels of chlorine are expected in ambient or indoor air, it is anticipated that drinking water is the predominant source of exposure to chlorine. Air and food are believed to provide only small contributions, although the magnitude and frequency of these potential exposures are issues currently under review. EPA, therefore, is considering setting an MRDLG for chlorine in drinking water using an RSC value of 80%, the current exposure assessment policy ceiling. EPA requests any additional data on known concentrations of chlorine in drinking water, food and air.

Health Effects. The health effects information for chlorine is summarized from the draft Drinking Water Health Criteria Document for Chlorine, Hypochlorous Acid and Hyperchlorite Ion (USEPA, 1994a). The studies cited within this section are summarized in the draft criteria document.

Chlorine and the hypochlorites are very reactive and thus can react with the constituents of saliva and possibly food and gastric fluid to yield a variety of reaction by-products (e.g., trihalomethanes). Thus, the health effects associated with the administration of high levels of chlorine and/or the hypochlorites in various animal studies may be due to these reaction by-products and not the disinfectant itself. Oxidizing species such as chlorine and the hypochlorites are probably short-lived in biological systems due to both their reactivity and the large number of organic compounds found in vivo. Scully and White (1991) noted that reactions of aqueous chlorine with sulfur-containing amino acids appear to be so fast in saliva that all free available chlorine is dissipated before the water is swallowed.

Oral studies with radiolabeled (i.e., ^{36}Cl) hypochlorite and hypochlorous acid indicate that, as measured by the radiolabel, these compounds may be well absorbed and distributed throughout the body with the highest levels measured in plasma and bone marrow. However, considering the reactivity of the hypochlorites, these

results may only reflect the presence of reaction by-products (e.g., chloride). The major route of excretion appears to be urine and then the feces.

Acute oral LD_{50} values for calcium and sodium hypochlorite have been reported at 850 mg/kg in rats and 880 mg/kg in mice, respectively. Humans have consumed hyperchlorinated water for short periods of time at levels as high as 50 mg/L (1.4 mg/kg) with no apparent adverse effects.

Short-term oral studies in animals have indicated decreases in blood-glutathione levels, hemolysis and biochemical changes in liver in rodents following a gavage dose of hypochlorite in water. No adverse effects on reproduction (Druckery, 1968) or development were observed in rats administered chlorine in drinking water at concentrations of 100 mg/L or less. However, Meier et al. (1985) observed an increase in sperm-head abnormalities in mice receiving hypochlorite at 200 mg/L, but not at 100 mg/L or less.

No systemic effects were observed in rodents following oral exposure to chlorine as hypochlorite in distilled water at levels up to 275 mg/L over a 2 year period (NTP, 1990).

Chlorinated water has been shown to be mutagenic to bacterial strains and mammalian cells. Investigations with rodents to determine the potential carcinogenicity of chlorine, or chlorinated water have been negative. In the most recent study, no apparent carcinogenic potential was demonstrated following oral exposure to chlorine in distilled drinking water as hypochlorite, at levels up to 275 mg/L over a 2 year period (NTP, 1990). However, NTP observed a marginal increase in the incidence of mononuclear cell leukemia in mid-dose female F344 rats but not in male rats or male and female mice (NTP, 1990). Mononuclear cell leukemia has a high spontaneous rate of occurrence in female F344 rats. The levels reported in the NTP study are within the historical control range of incidence for the sex and strain of rat. EPA believes that mononuclear cell leukemia can not be solely attributed to exposures to chlorine in drinking water but rather may reflect the high background rate of mononuclear cell leukemia in the test species.

EPA has classified chlorine in Group D, not classifiable as to human carcinogenicity (IRIS, 1993). This classification stems from the findings of the NTP (1990) study indicating equivocal evidence in female rats (increased mononuclear cell leukemia) and no evidence in male rats or male and female mice. The International Agency for Research on Cancer (IARC, 1991) also evaluated chlorinated drinking water and hypochlorite for potential human carcinogenicity. IARC determined that there was inadequate evidence for carcinogenicity of chlorinated drinking water and hypochlorite salts in humans and animals. (See section C for a description of these studies.) IARC concluded that chlorinated drinking water and hypochlorite salts were not classifiable as to their carcinogenicity to humans and thus assigned these chemicals to IARC Group 3. This category is similar to EPA cancer classification Group D.

Based on the previous discussion, EPA is proposing that chlorine, hypochlorite and hypochlorous acid be placed in Category III for the purpose of setting an MRDLG. The study selected for determining an RfD is the previously mentioned 2 year rodent study that was conducted by the National Toxicology Program (NTP, 1990). In this study, male and female F344 rats and B6C3F1 mice were given chlorine in distilled drinking water at levels of 0, 70, 140 and 275 mg/L for 2 years. Based on body weight and water consumption values, these concentrations correspond to doses of approximately 0, 4, 7 and 14 mg/kg/day for male rats; 0, 4, 8, and 14 mg/kg/day for female rats; 0, 7, 14, and 24 mg/kg/day for male mice and 0, 8, 14 and 24 mg/kg/day for female mice. There was a dose related decrease in water consumption for both rats and mice, presumably due to taste aversion. No effect on body weight or survival were observed for any of the treated animals. Using a NOAEL of 14 mg/kg/d identified from female rats in the NTP (1990) study an MRDLG of 4 mg/L, based on lack of toxicity in a chronic study is derived as follows.

$$\text{MRDLG} = \frac{(14\ \text{mg/kg/d}) \times 70\ \text{kg} \times 0.8}{100 \times 2\ \text{L/d}} = 4\ \text{mg/L (rounded)}$$

Where 14 mg/kg/d is the NOAEL for female rats in the NTP study, and 100 is the uncertainty factor applied to account for inter and intra-species differences in accordance with EPA guidelines when a NOAEL from a chronic animal study is the basis for the RfD. The MRDLG is based on a 70 kg adult consuming an average of 2 liters water per day over their lifetime. In addition, an 80% RSC is assumed in the absence of data to the contrary.

Public comments are requested on the following issues: 1) placing chlorine in Category III for developing an MRDLG, 2) selection of the study and NOAEL as the basis for the MRDLG, 3) the 80% RSC, 4) the appropriateness of the UF of 100, 6) the cancer classification for chlorine.

2. Chloramines

Inorganic chloramines (CAS Nos. 10599–90–3 and 10025–85–1 for mono- and trichloramine, respectively) are formed in waters undergoing chlorination which contain ammonia. Monochloramines, dichloramines and trichloramines may be formed. Monochloramine is the principal chloramine formed in chlorinated natural and wastewater at a neutral pH and is much more persistent in the environment.

Chloramine is used as a disinfectant in drinking water to control taste and odor problems, limit the formation of chlorinated disinfection by-products, and maintain a residual in the distribution system for controlling biofilm growth. At typical pHs of most drinking waters, the predominant chloramine specie is monochloramine. For purposes of this regulation, only monochloramine will be considered since the other chloramines occur at much lower concentrations in almost all drinking waters. Monochloramine has also been much more extensively studied.

Monochloramine, the principal chloramine formed in chlorinated natural and wastewaters at neutral pH, is relatively stable when discharged to the environment. First-order decay rate constants of 0.03 to 0.075 hr^{-1} for monochloramine in the laboratory, and higher rate constants of 0.28 to 0.31 hr^{-1} outdoors using chlorinated effluents, have been reported. If discharged into receiving waters containing bromide, monochloramine will decompose faster, probably through the formation of NHBrCl and decomposition of the dihalamine. The rate of monochloramine disappearance is primarily a function of pH and salinity.

For example, at pH 7 and 25°C, the half-life of monochloramine is 6 hr at 5 parts per thousand (ppt) salinity and 0.75 hr at 35 ppt salinity; at pH 8.5 and 25°C, the half-life is 188 hr at 5 ppt salinity and 25 hr at 35 ppt salinity. Monochloramine is expected to decompose in wastewater discharges receiving waters via chlorine transfer to organic nitrogen-containing compounds.

Occurrence and Human Exposure. Chloramine occurs in drinking water both as a by-product and intentionally for disinfection. Chloramine is formed during chlorination when source waters contain ammonia. It is also used as a primary or secondary disinfectant, usually with chloramine being generated on site by the addition of ammonia to water following treatment by chlorination. The use of chloramines has been shown to reduce the formation of certain by-products, notably trihalomethanes, relative to the by-products formed with chlorination alone. Chlorination by-product formation can be minimized when the ammonia is added prior to or in combination with chlorine by reducing the chlorine residual of the water being treated. In most plants, however, ammonia is added some time after the addition of chlorine, to allow for more effective disinfection since chlorine is a much stronger disinfectant than chloramines.

Table V–3 presents occurrence information available for chloramine in drinking water. Descriptions of these surveys and other data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," USEPA, 1992a. Typical dosages of chloramine used as a disinfectant in drinking water treatment facilities range from 1.5 to 2.7 mg/L. Median concentrations of chloramine in drinking water were found to range from 1.1 to 1.8 mg/L.

TABLE V–3.—SUMMARY OF OCCURRENCE DATA FOR CHLORAMINES

Occurrence of chloramine in drinking water						
Survey (year)[1]	Location	Sample information (No. of samples)	Concentration (mg/L)			
			Range	Mean	Median	Other
AWWARF (1987) McGuire & Meadow, 1988.	National Survey ..	Finished Water From: Lakes ..... Flowing Streams	.....[2]	.....	.....	Typical dosages: 1.5 mg/L 2.7 mg/L
EPA/AMWA/ CDHS[2] (1988–1989) Krasner et al., 1989b.	35 Water Utilities Nationwide.	Samples from Clearwell Effluent, 4 Quarters (13).	0.9–5.5	2.3	1.8	
EPA, 1992b[2] (1987–1991).	Disinfection By-Products Field Studies.	At the Plant (11)	1.2–3.6	2.1	1.5	
		Distribution System (8)	0.1–3.3	1.4	1.1	

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.

AMWA: Association of Metropolitan Water Agencies.
AWWARF: American Water Works Association Research Foundation.
CDHS: California Department of Health Services.
EPA: Environmental Protection Agency.

Based on the residual concentrations given above, a high and low estimate for exposure to chloramine from drinking water can be calculated using an assumed consumption of 2 liters per day. Using the target range of 1.5 to 2 mg/L, the exposure may range from 3 to 4 mg/day. Some systems may deviate significantly from this range.

No information is available on the occurrence of chloramine in food or air. Currently, the Food and Drug Administration (FDA) does not measure for chloramine in foods since the analytical methods have not been developed. Preliminary discussions with FDA suggest that there are not approved uses for chloramine in foods consumed in the typical diet. Similarly, EPA's Office of Air and Radiation is not sampling chloramines in air (Borum, 1991).

Based on the previous discussion, EPA assumes that drinking water is the predominant source of exposure to chloramine. Air and food intakes are believed to provide only small contributions, although the magnitude and frequency of these potential exposures are issues currently under review. EPA, therefore, is proposing to establish an MRDLG for chloramine in drinking water with an RSC value of 80%, the current exposure assessment policy ceiling. EPA requests any additional data on known concentrations of chloramine in drinking water, food and air.

Health Effects. The health effects information in this section is summarized from the draft Drinking Water Health Criteria Document for Chloramines (USEPA, 1994b). Studies mentioned in this section are summarized in the Criteria Document.

Short-term inhalation exposures to high levels (500 ml of 5% household ammonia mixed with 5% hypochlorite bleach) of chloramines in humans result in burning in the eyes and throat, dyspnea, coughing, nausea and vomiting. Inhalation of the chloramine fumes resulted in pneumonitis but did not result in permanent pulmonary damage.

Short-term exposures to chloramines in drinking water, in which human subjects were administered single concentrations ranging between 1 and 24 mg/L (1, 8, 18 or 24 mg/L), have not resulted in any adverse effects in human subjects. Following human exposure, the subject's physical condition, urinalysis, hematology, and clinical chemistry were evaluated. No adverse clinical effects were noted in any of the studies.

In another study, acute hemolytic anemia, characterized by oxidation of hemoglobin to methemoglobin and denaturation of hemoglobin, was reported in hemodialysis patients when tap water disinfected with chloramines was used for dialysis baths. Chloramines were reported to produce oxidant damage to red blood cells and inhibit the metabolic pathway used by red blood cells to prevent and repair such damage. Many dialysis centers have installed reverse osmosis units

coupled with charcoal filtration or the addition of ascorbic acid to prevent hemolytic anemia.

Animal studies indicate varying sensitivity and conflicting results among different animal species. Toxic effects noted among rats are changes in blood glutathione and methemoglobin. Both monkeys and mice were unaffected during short-term assays with doses up to 200 mg/L chloramines. Based on studies up to 6 weeks in length, rats appear to be more sensitive to monochloramine than mice and monkeys.

Toxicokinetic studies of chloramines indicate that the absorption of chloramines is rapid, peaking within 8 hours of administration. In the rat, chloramines are metabolized to chloride ion and excreted mostly through the urine with a small portion excreted through the feces.

Longer-term oral studies (90 days or longer) showed decreased body and organ weights in rodents. Some effects to the liver (weight changes, hypertrophy, and chromatid pattern changes) appear to be related to overall body weight changes caused by decreased water consumption due to the unpalatibility of chloramines to the test animals.

In addition, chloramine may induce immunotoxicity in rats in the form of increased prostaglandin E_2 synthesis, reduced antibody synthesis, and spleen weight at levels as low as 9 to 19 mg/L chloramines for 90 days. The significance of these findings for risk use in risk assessment is compromised by the design flaws of the study (i.e., animals were exposed to two antigens) and the lack of corroboration of these findings by a follow-up study.

Two lifetime rodent studies involving oral exposures to rats and mice via drinking water have been considered by EPA for the derivation of the MRDLG for monochloramine. Both studies were performed by the National Toxicology Program (NTP, 1990) and involved 70 animals/sex/dose exposed to distilled drinking water containing 0, 50, 100 or 200 ppm chloramines.

The first NTP (1990) study was a 2-year study in mice to determine the potential chronic toxicity or carcinogenic activity of chloraminated drinking water. $B6C3F_1$ mice were administered chloramine at doses of 0, 50, 100 and 200 ppm in distilled drinking water. These doses were calculated based on a time-weighted average to be 0, 5.0, 8.9 and 15.9 mg/kg/day for male mice and 0, 4.9, 9.0 and 17.2 mg/kg/day for female mice. There was a dose-related decrease in the amount of water consumed by both sexes; this decrease was noted during the first week and continued throughout the study. Dosed male and female mice had similar food consumption as controls except for females in the 200 ppm dose group that exhibited slightly lower consumption than controls.

Study results indicated that there was a dose-related decrease in mean body weights of dosed male and female mice throughout the study. Mean body weights of high-dose male mice were 10–22% lower than their control group after week 37 and the body weights of high-dose female mice were 10–35% lower after week 8. However, the survival of mice receiving monochloramine in drinking water was not significantly different than controls. Clinical findings observed were not attributed to the consumption of chloraminated drinking water. Body weight loss and systemic toxicity were not considered related to the toxicity of chloramine, but rather due to decreased water consumption resulting from the unpalatability of chloramines in drinking water to the test animals. Therefore, the highest dose tested, 17.2 mg/kg/day, is considered a NOAEL in mice.

In the second study F344/N rats were administered monochloramine for 2 years at doses of 0, 50, 100 and 200 ppm in distilled drinking water. These doses were calculated on the basis of a time-weighted average to be 0, 2.1, 4.8 and 8.7 mg/kg/day for male rats and 0, 2.8, 5.3 and 9.5 mg/kg/day for female rats. There was a dose-related decrease in the amount of water consumed by both sexes; this decrease was noted during the first week and continued throughout the study. Food consumption of treated rats was the same as the controls with males consuming more. In addition, mean body weights of 200 ppm dosed rats (both sexes) were lower than their control groups. However, mean body weights of rats receiving monochloramine in drinking water (at all levels) were within 10% of controls until week 97 for females and week 101 for males. Though several clinical changes were noted, no clinical changes were attributable to chloraminated drinking water. The survival of rats receiving chloraminated drinking water was not significantly different than controls except that, for the 50 ppm dose groups, survival was greater than that of controls. Therefore, EPA considers the highest dose tested, 9.5 mg/kg/day, as the NOAEL.

Based on two bacterial assays, monochloramine appears to be weakly mutagenic. One study examining the reproductive effects and another which examined developmental effects of chloramines concluded that there are no chemical-related effects due to chloramines.

The NTP evaluation, using the results of the two lifetime NTP bioassays, concluded that chloramines exhibited equivocal evidence of carcinogenic activity of chloraminated drinking water in female F344/N rats. This conclusion results from an increase in mononuclear cell leukemia. There was no evidence of carcinogenic activity in male rats or mice of either sex. The findings do not establish a link between chloramine exposure and carcinogenicity because of the high historical background occurrence of this type of cancer in test animals. The incidence of mononuclear cell leukemia in the female control groups (16%) was substantially less than the incidence reported in untreated historical controls (25%). Incidence of mononuclear cell leukemia in test animals reached a high of 32% in the high dose female rats. This study also discovered incidence of renal tubular cell neoplasms in two high-dose male mice receiving chloraminated water. Since this type of tumor is rarely seen in historical controls, there is some concern that these may be treatment related. However, the overall evidence regarding the potential carcinogenicity of chloramines in drinking water can be described as inconclusive since no long-term study has linked any tumor development to actual chloramination exposure. On this basis, as well as consideration of those studies described in section C, EPA placed chloramine in Group D: not classifiable based on inadequate evidence of carcinogenicity.

EPA selected the lifetime study in rats (NTP, 1990) as the basis for calculating the MRDLG for chloramines. The NOAEL for the rat (9.5 mg/kg/d) is proposed because the rat was not tested at the higher doses where mice were tested (17.2 mg/kg/d). Rats appear to be more sensitive considering observed changes in biochemistry. Following a Category III approach and using the rat NOAEL of 9.5 mg/L from the NTP study, an MRDLG of 4 mg/L (measured as total chlorine), based on lack of toxic effects in a chronic study can be derived for the 70-kg adult consuming 2 liters of water per day applying an uncertainty factor of 100, which is appropriate for use of a NOAEL derived from an animal study and assuming an RSC drinking water contribution of 80 percent.

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* Since chloramines, on a practical basis, will be measured as total chlorine, it is necessary to present the MRDLG in terms of a chlorine equivalent concentration. Three mg/L chloramine is equivalent to 4 mg Cl_2/liter, based on the molecular weights of Cl_2 and NH_2Cl.

$$MRDLG = \frac{(9.5\ mg/kg/day) \times 70\ kg \times 0.8}{100 \times 2\ L/day} = 3\ mg/L\ *$$

EPA requests comments on the proposed MRDLG for chloramines and the RSC of 80%, the significance of the findings of immunotoxicity for setting the RfD instead of the NTP study, the significance of the finding of mononuclear cell leukemia in female F344 rats, the significance of the finding of tubular cell neoplasms in high-dose exposed mice, and whether the adjusted MRDLG, which takes into account the measurement of monochloramine as total chlorine, is appropriate.

$$3\ mg\ NH_2Cl/L \times \frac{70.9\ mg\ Cl_2}{51.48\ mg\ NH_2Cl} = 4\ mg\ Cl_2/L\ (rounded)$$

3. Epidemiology Studies of Chlorinated and Chloraminated Water

Several studies have been conducted to evaluate the association of chlorination or chloramination with the risk of cancer, cardiovascular disease or adverse reproductive effects in humans. A summary of some of these studies is given below. This discussion reflects EPA's assessment of these data and is summarized from the draft Drinking Water Criteria Documents for Chlorine (USEPA, 1994a] and Chloramines (USEPA, 1994b), respectively.

Introduction to Epidemiology Studies. Two distinct types of epidemiology studies have been conducted: ecologic and analytical. These types of studies differ markedly in what they reveal about the association between water quality and disease. In an ecological epidemiology study, information is available on exposure and disease for groups of people rather than for individuals, and therefore, the results are difficult to interpret. What is considered to be an important or relevant group variable may not be important for or may not pertain to individuals within that group. Theoretical and empirical analyses have offered no consistent guidelines for the interpretation of ecological associations, and results from these studies are appropriate only to suggest hypotheses for further study by analytical epidemiological methods (Piantiadosi et al., 1988; Connor and Gillings, 1974).

Analytical epidemiology studies provide an estimate of the magnitude of risk and information which can be used to evaluate causality. For each individual in the study, information is obtained about disease status and exposure to various contaminants and other characteristics. In several of the studies reported here, individual exposures to disinfected water or specific disinfection by-products were estimated using group exposure information. All reported epidemiological associations from analytical studies require an evaluation of random error (statistical significance) and potential sources of systematic bias (misclassification, selection, observation, and confounding biases) so that results can be interpreted properly. It must be noted that random error or chance can never be completely ruled out as the explanation for an observed association and that statistical significance does not necessarily imply biological significance. Regardless of statistical significance, it is important to consider potential biological mechanisms. Random error does not address the possibility of systematic error or bias. Misclassification of exposure and disease, selection bias, and observation bias must be avoided; confounding bias, on the other hand, can be prevented both in study design and during analysis if information is obtained about possible confounders. It is important to determine for each specific epidemiology study the validity of the association observed between exposure and disease before considering possible causality between exposure and disease or inferring that the results apply to a larger or target population. Systematic bias can lead to spurious associations; in some but not all instances, the direction of the bias can be determined. For example, a random misclassification of exposure usually biases a study toward not observing an effect or observing a smaller risk than may actually be present, but nonrandom misclassification can result in either higher or lower estimates of risk depending upon the distribution of misclassification.

In addition, because of the observational nature of epidemiology, the interpretation of epidemiology studies requires a sufficient number of well designed and well conducted epidemiology studies, and must include appropriate toxicological and biological information. Judging causality from epidemiology studies is based largely on guidelines developed over the years, including sequence of events, strength of association (relative risk or odds ratio), consistency of results under different conditions of study, biological plausibility, dose or exposure response relationship, and specificity of effect. The relative risk represents a basic measure of an association between exposure and disease. It is defined as the rate of disease in the exposed population divided by the rate of disease in an unexposed population.

a. *Cancer Studies.* Since the early 1970's, numerous epidemiologic studies have attempted to assess the association between cancer and the long term consumption of water from various sources with and without disinfection and of various chemical quality, especially chlorinated surface waters which supply the majority of the U.S. population. Ecological, case control, and cohort studies have been conducted. Case control studies have included incident and decedent cases; in some studies information about various risk factors has been collected through interviews, but in others information was obtained primarily from death certificates.

i. Ecological Studies. The earliest studies were analyses of group or aggregate data available on drinking water exposures and cancer. Usually the variables selected for analyses were readily available in published census, vital statistics, or public records and easily abstracted and assembled. These analyses, referred to as ecological but also called aggregate, geographical, or correlational, were designed to investigate cancer mortality rates, usually on a county or State level. Areas of different water quality, source, and chlorination status were compared to identify possible statistical associations for further study. Drinking water exposures were most often characterized as simple dichotomous variables which served as indicators of exposure to differing source water quality, e.g., the drinking water source for the county or

geographic area was categorized as a surface or groundwater source. In some instances exposure variables included estimates of the proportion of the area's or county's population that received surface or groundwater and whether it was chlorinated. Surface water was assumed to be more contaminated with synthetic organics than groundwater, but no attempt was made to estimate levels of contaminants.

In 1974 it was discovered that when surface waters were disinfected with chlorine, the chlorine reacted with pre-existing organic materials in the water to create a great number of chemical by-products (Craun, 1988). The major group of disinfection by-products (by weight) was the trihalomethanes (THMs) which included an animal carcinogen, chloroform. Chlorinated surface water was evaluated as an exposure variable in several of the ecological studies, and since almost all surface waters are chlorinated, the analyses usually compared cancer mortality among populations receiving chlorinated surface water with those receiving unchlorinated groundwater. Chlorinated water was assumed to contain disinfection by-products, and at higher levels than chlorinated groundwaters. However, the quality of surface and groundwater may also differ for other contaminants, and this was not considered. Any observed association might be due to other water quality differences among surface and groundwaters (e.g., organic contaminants from nonpoint and point source discharges to surface waters from industrial, urban, and agricultural sources before pollution control regulations).

In some ecological analyses, the investigators attempted to study the association between cancer mortality and an estimate of group exposure to levels of chlorinated by-products based on THM or chloroform levels was determined from a limited number of water samples. The exposure information used in ecological studies was available in only broad geographic units such as census tracts or counties (Crump and Guess, 1982; Shy, 1985). Although these exposure variables were statistically associated with mortality rates for all cancers combined and several site-specific cancers, the interpretation must necessarily be cautious due to limitations of ecological studies. In several of these studies, aggregate or group information on several covariates, e.g., occupation, income, or population density, also was included in the statistical analysis in an attempt to adjust for potential confounding factors. In one study the statistical significance of the observed associations between stomach and rectal cancer mortality and group exposures to current THM levels disappeared when migration patterns and ethnic data were included in the regression model (Tuthill and Moore, 1980). A wide range of cancer sites was found to be statistically associated with estimates of population group exposures based on current levels of THM or chloroform including gall bladder, esophagus, kidney, breast, liver, pancreas, prostate, stomach, bladder, colon, and rectum. The most frequent associations observed were for the last four sites; however, these associations were not consistent when viewed by gender, race, and geographic region.

The ecologic design coupled with the lack of specific exposure indicators in these studies precludes the inference of a causal relationship (Morgenstern, 1982). A subcommittee of the National Academy of Sciences (NAS, 1980) reviewed 12 of the ecological studies and noted "Results of these studies demonstrate the problems of establishing relationships between health statistics and environmental variables, and lend emphasis to the caution with which they should be interpreted." The NAS further commented that the ecological studies in which the current THM exposures were estimated were deemed to be more informative than others and "suggest that higher concentrations of THM in drinking water may be associated with an increased frequency of cancer of the bladder. The results do not establish causality, and the quantitative estimates of increased or decreased risk are extremely crude. The effects of certain potentially important confounding factors, such as cigarette smoking, have not been determined." The studies are useful, however, as an initial step for identification of potential hazards and they indicated the need for further epidemiologic studies or analytic studies of individuals with a specific etiologic hypothesis.

ii. Cohort Studies. A cohort study (or follow-up) study (the study can be called either retrospective or prospective) is one in which two or more groups (referred to as 'cohorts') of people that differ according to the extent of exposure to a potential cause of disease are compared with respect to incidence of the disease of interest in each of the groups. The essential element of this study type is that incidence rates are calculable directly for each study group (Rothman, 1986). One advantage of this study type is the ability to study multiple disease endpoints. One disadvantage of this study type is that a large study population is needed to detect a relatively small risk. In addition, because of the latency period for carcinogenicity, a long follow-up time may be required for the study.

There exists one cancer drinking water cohort study where individual data were available for a well-defined, fairly homogeneous area that allowed disease rates to be computed by presumed degree of exposure to by-products of chlorination, although the population was relatively small. Wilkins and Comstock (1981) studied the residents of Washington County, Maryland and ascertained the source of drinking water at home for each county resident in a private census conducted in 1963. In addition to water source, information was collected on age, marital status, education, smoking history, number of years lived in the household, and frequency of church attendance. Death certificates and cancer registry information was sought for county residents whose date of death or diagnosis occurred in the 12 year period following the census. Sex and site-specific cancer rates were constructed for malignant neoplasms of biliary passages and liver, kidney, and bladder. Several additional causes of death were analyzed as well for comparison purposes. The population was stratified into three separate exposure subgroups: chlorinated surface water, unchlorinated deep wells, and small municipal systems with a mixture of chlorinated and unchlorinated water, each reflecting a different history of exposure to by-products of chlorination. The study group which included individuals who obtained drinking water from small municipal systems were not included as a comparison with the other drinking water cohorts because of their exposure to both chlorinated and unchlorinated water.

Both crude and adjusted incidence rates for liver cancer in males and females and for cancer of the liver among males were essentially the same for persons supplied with chlorinated surface water at home (high THM exposure) and for persons with deep wells (low THM exposure). The adjusted rates for bladder cancer (RR=1.6; 95% CI=0.54,6.32) and cancer of the liver (RR=1.8; 95% CI=0.64,6.79) among females were highest among persons using chlorinated surface water. Given the low relative risk and broad confidence intervals, the authors indicated that this finding could be attributed to chance (Wilkins and Comstock, 1981). Confounding bias may also influence the interpretation of a small relative risk. EPA considers that

the results of this study are inconclusive because the results are based on small numbers of cases, hence, the reported rates are statistically unstable and subject to random variation.

iii. Case Control Studies. In a case control study, persons with a given disease (the cases) and persons without the given disease (the controls) are selected for study. The proportions of cases and controls who have certain background characteristics or who have been exposed to possible risk factors are then determined and compared. Exposure odds ratios (ORs) are determined. The odds of exposure among cases is compared with that of controls. For rare diseases, the ORs are considered good estimates of relative risk. These studies are sometimes called case-referent or retrospective studies. Because there are many variations of this study design (e.g., how cases and controls are selected, how information on exposures, risk factors, and confounding factors are obtained, and who is interviewed), each case control study should be evaluated individually to determine if the specific study design parameters introduce systematic bias (Kelsy et al., 1986). As previously noted, all epidemiology studies require careful evaluation of systematic bias. For those studies with major bias, the results are generally considered inconclusive. Those studies with minor bias may still provide useful information.

Two types of studies were conducted: (1) Decedent cases without interviewing survivors for information about residential histories and risk factors and (2) incident cases with interviews.

Decedent Case-Control Studies. Several case-control studies were conducted to continue to investigate the possibility that there was a causal relationship between chlorinated drinking water, including byproducts such as THMs, and gastrointestinal or urinary tract cancers. Most of these case-control studies used deceased cases of the specific cancers of interest, although some continued their investigations in a relatively nonspecific way by using both total cancer mortality as well as several of the site- specific cancers studied in the ecologic studies (Crump and Guess, 1982; Shy, 1985). Controls were noncancer deaths from the same geographic area and in all but one study matched for several potentially confounding variables including age, race, sex, and year of death. As in all studies of this design (i.e., death certificate studies with no available interviews), control of confounding factors was restricted to information that is routinely recorded on death certificates and no information was obtained from next-of-kin interviews. The exposure variables of interest at this time included a comparison of surface v ground water sources, or chlorinated v nonchlorinated ground water sources. The place of residence listed on the death certificate was linked to public records of water source and treatment practices in order to classify the drinking water exposure variable for a particular case or control (Shy, 1985).

Similar to the earlier ecologic studies, the Agency considers the results from these studies to be inconsistent in their findings. The calculated ORs, varied by cancer site and sex, as well as in their magnitude and statistical significance. This variability was found for all the cancer endpoints studied including those of specific interest, i.e., bladder, colo-rectal, and/or colon. These endpoints were found to vary by geographic region. For example, a statistically significant increased bladder cancer risk was observed in North Carolina for males and females combined (OR=1.54) and New York for males (OR=2.02), but not for females; no statistically significant risk was seen in Louisiana, Wisconsin or Illinois. Increased colon cancer risk was observed in Wisconsin (OR=1.35) and North Carolina (OR=1.30) for males, but not females; no increased risk was seen in Louisiana or Illinois. Increased rectal cancer risk was observed in North Carolina (OR=1.54) and Louisiana (OR=1.68) for males and females combined, in Illinois for females (OR=1.35) but not males, and in New York for males (OR=2.33) but not females; no increased risk was seen in Wisconsin. Although increased risk was observed for cancer of the liver and kidney (OR=2.76), esophagus (OR=2.39), and pancreas (OR=2.23) among males in New York, no increased risk for these cancers was seen among females in New York, Illinois, Wisconsin or Louisiana.

Although many of the ORs were statistically significant, these decedent case control studies with extremely limited information on confounding factors and potential exposures to chlorinated water are of limited usefulness in assessing whether cancer is associated with chlorinated drinking water, or judging the causality of such as association. Although some of the ORs were large enough to cause concern about an exposure association, the magnitude of the OR was such that the association could be attributed to incomplete control of confounding factors and the ORs might represent spurious elevations (Crump and Guess, 1982).

Although not subject to all the same limitations as ecologic studies, decedent case-control studies are considered more limited by some epidemiologists than others as a tool for causal inference because of a high probability of systematic bias associated with the use of information obtained only from the death certificate (e.g., inadequate or no information on residential history, water exposures, and major potential confounders). The variability seen in these five studies is likely a combination of several factors, including available sample size, choice of causes of death included as controls, regional variability in true composition of the raw and treated drinking waters, definition of exposure variables, a high probability of exposure misclassification from imputing a lifetime exposure to a certain water source or treatment from residence listed on the death certificate, and uncontrolled confounding (e.g., diet and smoking).

Given the limitations of decedent case control studies without interviews, the evidence from these studies are considered insufficient to determine a causal association between any or all the components which exist in the complex mixture created during the chlorination of surface waters and any site-specific cancer. The findings provided a stimulus for a further refined epidemiologic study using incident cases of bladder and colon cancer and appropriate controls who could be interviewed for residential history and numerous other covariates.

Case-Control Studies with Interviews. At the time when these more recent studies were planned, it was still believed that THMs were the major by-products of chlorinated drinking water that should be investigated and studies were designed and conducted in areas where a THM difference might be expected and somehow measurable. Exposure assessment for individuals remained problematic in the study design. The best available means of exposure measurement, however, was at best a surrogate for the true exposure of interest which is the actual level of THMs or other by-products ingested over a person's lifetime through consumption of surface water disinfected with chlorine. Only two studies attempted to estimate long-term exposure to THMs. Most studies used residence at a location served by chlorinated drinking water. In all except one of the studies, comparisons of exposure were between chlorinated surface water and unchlorinated groundwater. As previously discussed in the section on ecological studies, the water quality for surface and ground water differ for many other consituents.

Because it was known that disinfection of surface water using chloramine produced very low levels of THMs and other by-products compared to the same water disinfected with chlorine, a study was conducted in Massachusetts to compare the patterns of mortality in communities which used these different disinfectants (Zierler et al., 1986). Statewide mortality records for 1969–1983 were analyzed using standardized mortality ratios (SMRs) and showed little variation by community. However, mortality odds ratios (MORs) comparing bladder cancer deaths to all other deaths were considered by the authors to indicate a slight elevation for last residence in a chlorinated community compared to a chloraminated community (MOR=1.7; 95% CI=1.3, 2.2). The authors noted that the results were preliminary and "crude descriptions of the relationship under study" (Zierler et al., 1986). The authors further indicated that the results may have been caused by unidentified or uncontrolled confounding factors.

Bladder cancer deaths were investigated further using a case-control design with proxy interviews to determine residential and smoking histories (Zierler et al., 1988). The association of bladder cancer was assessed for individuals with lifetime and usual exposure to chlorinated and chloraminated water depending on the number of years of residence at a particular water source. Residence in a community using chlorinated drinking water was used as an index for exposure to chlorinated by-products, while residence in a community using chloramine for disinfection was considered an index for no exposure to chlorinated by-products. An association was observed between bladder cancer and both lifetime (MOR=1.6; 95% CI=1.2–2.1) and usual (MOR=1.4; 95% CI=1.1–1.8) exposure to chlorinated water. A subgroup of study participants was noted to have lived their entire lives in an area served with water supplied by the Massachusetts Water Resources Authority, disinfected with either chlorine or chloramine (same water source, different disinfectant, lifetime exposure). Within this group the bladder cancer mortality risk was 1.6 times higher (MOR=1.6; 95% CI=1.1, 2.4) when the water had been disinfected with chlorine compared to chloramine (Zierler et al., 1988).

In addition to analyses using a control group which consisted of deaths from cardiovascular disease, cerebrovascular disease, chronic obstructive lung disease, lung cancer, and lymphatic cancer, a separate analysis was done using only the lymphatic cancer controls. This was considered necessary by the authors because of the possibility that some of the other deaths among controls may also be related to the exposure of interest. If true, then the MOR estimate would be biased toward the hypothesis of no increased risk. When the analysis considered only lymphatic cancer controls, the magnitude of the association with chlorinated water increased for lifetime exposure (MOR=2.7; 95% CI=1.7–4.3), usual exposure (MOR=2.0; 95% CI=1.4–3.0), and lifetime exposure in the previously mentioned subgroup (MOR=3.5; 95% CI=1.8–6.7). Sources of misclassification bias that may have been present were considered to be randomly distributed among the cases and controls which implies that the observed MOR would be an underestimate of risk (Zierler et al., 1988). It is also possible that nondifferential misclassification of the variables used to control confounding, leading to residual confounding of the summary estimates, could have caused a systematic spurious elevation in the MORs.

The largest study to date investigating the relationship of chlorinated water and bladder cancer incidence involved an ancillary study to the National Cancer Institute's (NCI) 10 area study of bladder cancer and artificial sweeteners (Cantor et al., 1985, 1987, 1990). The original study conducted interviews with 2,982 newly diagnosed bladder cancer cases and 5,782 population controls; lifetime information on source and treatment of drinking water was collected and analyzed for only a subset of the original study population (1,244 cases and 2,550 controls). Subgroup analyses of nonsmokers among participants and those reporting beverage intake necessarily involved even smaller numbers. Duration of exposure, measured by years of residence at a chlorinated surface or nonchlorinated ground water source was presumed to be a surrogate for dose of disinfectant by-products. Overall, there was no association of duration of exposure with bladder cancer risk (Cantor et al., 1985, 1987). In nonsmokers who never smoked, a 2-fold increased risk was reported for those exposed for 60 or more years to chlorinated surface water (n=46 cases, 77 controls) compared to unchlorinated ground water (n=61 cases, 268 controls) users (OR=2.3; 95% CI=1.3, 4.2). These data were further analyzed according to beverage intake level, type of water source and treatment (Cantor et al., 1987, 1990). It was observed that people who reported drinking the most tap water-based beverages from any source (>1.96 liters/day) had a bladder cancer risk about 40% higher (OR=1.43; 95% CI=1.23–1.67, males and females combined) than people who drank the least. The association between water ingestion and bladder cancer risk for males was an OR=1.47; 95% CI=1.2–1.8, and for females an OR=1.29; 95% CI=0.9–1.8.

Evaluation of bladder cancer risk by both duration of exposure and amount of water consumed showed that the risk increased with higher water consumption only among those who drank chlorinated surface water for 40 or more years. Evaluation of risk by smoking status revealed that most of the duration effect was observed in nonsmokers. Among nonsmokers who consumed tap water in amounts above the population median (>1.4 L/day), a risk gradient was apparent only for males. However, a higher risk was also seen for nonsmoking females who consumed less than the median level. The increasingly smaller numbers of cases and controls available for these subgroup analyses produce statistically unstable OR estimates making it difficult to evaluate the trend results.

This is the first study of incident bladder cancer cases that obtained and analyzed fluid consumption patterns in this way. The noted inconsistencies in the reported data must be more thoroughly explored and indicate a need for replication before any causal relationship can be assumed (Devesa et al., 1990). An additional consideration is a more refined exposure measurement; many of the disinfection by-products are volatile. Thus exposure may occur through inhalation as well as ingestion.

Two conflicting studies of colon cancer and presumed THM exposure have been reported. The first one (Cragle et al., 1985) was a hospital based case control study that included 200 incident colon cancer cases from seven hospitals and 407 hospital controls with no history of cancer who were diagnosed with diseases unrelated to colon cancer. It should be noted that both colon and rectal cancer cases were included as cases in the study. Controls were matched to cases on hospital and admission date, as well as age, race, sex and vital status. Residential histories were linked with water source and disinfectant information for the 25 years prior to diagnosis. Logistic regression analysis using qualitative data groupings for the variables of interest showed a strong interaction of age and chlorination status (Table V–4). THM levels were not estimated. Odds ratios computed from the regression

coefficients increased with age, and within age groups. The ORs are higher for a longer duration of exposure.

TABLE V–4.—COMPARISON OF OR'S BY EXPOSURE DURATION AND AGE

Age (years)	OR (95% CI) 1–15 years exposure	OR (95% CI) > 15 years exposure
20–29	0.23 (0.11, 0.49)	0.48 (0.23, 1.01)
30–39	0.36 (0.2, 0.66)	0.6 (0.33, 1.09)
40–49	0.57 (0.36, 0.88)	0.75 (0.48, 1.18)
50–59	0.89 (0.83, 1.12)	0.94 (0.69, 1.29)
60–69	1.18 (0.94, 1.47)	1.38 (1.1, 1.72)
70–79	1.47 (1.16, 1.84)	2.15 (1.7, 2.69)
80–89	1.83 (1.32, 2.53)	3.36 (2.41, 4.61)

From these data, it appears that risk is increased only in those persons 60 years old and older with greater than 15 years of exposure to chlorinated water and in those greater than 70 years of age, regardless of exposure duration.

A second colon cancer study (Young et al., 1987) conducted in Wisconsin involved 366 incident colon cancer cases, 785 controls diagnosed with other cancers, and 654 population controls. Extensive interviews were conducted with all participants to obtain information on past drinking water sources, drinking water habits and a number of potentially confounding covariates. This information was combined with data provided by water companies to construct models to predict historical levels of THMs to be used as both cross-sectional and cumulative exposure variables. Simpler methods of defining exposure were also used, (e.g., surface vs. ground, chlorinated v. nonchlorinated), and all methods looked at the data by period specific exposure levels. The results did not indicate any association between THMs in Wisconsin drinking water and colon cancer risk. Odds ratios for all exposure variables were uniformly close to 1.0 with few exceptions. It should be noted, however, that in this study the majority of the water supplies contained less than 20 µg/l of THMs. No excess risk was observed at these levels, given the limitations of this study design in detecting a small risk.

The association of THM and colo-rectal cancer was studied in New York where the THM levels were higher than those in the above Wisconsin study (Lawrence et al., 1984). A total of 395 colon and rectal cancer deaths among white female teachers in New York State (excluding New York City) was compared with an equal number of deaths of teachers from causes of death other than cancer. All deaths were ascertained using the defined cohort of the New York State Teachers Retirement System. Cumulative chloroform exposure was estimated by the application of a statistical model to operational records from water systems that served the home and work addresses of the study participants during the 20 years prior to death. The distribution of chloroform exposure was not significantly different between cases and controls. No effect of cumulative chloroform exposure was observed in a logistic analysis controlling for type, population density, marital status, age, and year of death. No excess risk was associated with exposure to a surface water source containing THMs (OR=1.07; 90% CI=0.79, 1.43). Although the data were not presented in the article, the authors reported that no appreciable differences were seen when the colon and rectal cases were analyzed separately, compared to the combined analyses reported above.

Although most all the studies reviewed here have looked at colon, colo-rectal or bladder cancer risk, one recently published work investigated the risk of pancreatic cancer in relation to presumed exposure to chlorinated drinking water. Ijsselmuiden et al. (1992) conducted a population-based case-control study in Washington County, Maryland, using the same population data that were originally ascertained during a private population census for an earlier cohort study (Wilkins and Comstock, 1981). The original cohort study did not find any association between pancreatic cancer and chlorinated drinking water (OR=0.80, 95% CI=0.44–1.52).

This case-control study was conducted to reexamine chlorinated drinking water as a possible independent risk factor for pancreatic cancer in this population. It is not reported of any of the other endpoints from the original study also were reexamined, e.g., bladder, kidney, or liver cancer. Cases were those residents who were reported to the County cancer registry with a first time pancreatic cancer diagnosis during the period July, 1975 through December 1989, and who had been included in the 1975 census (n=101). Controls were randomly selected by computer from the 1975 census population (n=206). Drinking water source, as obtained during the 1975 census, was the exposure variable used. In univariate analyses, municipal water as a source of drinking water, increasing age, and unemployment were significantly associated with increased risk of pancreatic cancer. Multivariable analyses that controlled for confounding variables indicated that the use of municipal chlorinated water at home was associated with a significant OR of 2.23 (95% CI=1.24–4.10). The OR adjusted is 2.18 (95% CI=1.20–3.95); only age and smoking were assessed as potential confounders.

Interpretation of these findings is hampered by several problems regarding the assessment of exposure, including the fact that information obtained in 1975 on type of water and other variables is an exposure collected at one point in time and may not reflect actual exposure patterns prior to 1975. In addition, there is no information on the actual amounts of water consumed. Additionally, different residential

criteria were used for the cases and controls. The cases had to still be residing in the County at the time of their cancer diagnosis to be included in the study, but the controls may not have been current residents. If controls emigrated out of the county differentially on the basis of exposure, the ORs may be an over- or underestimate of the risk depending on emigration patterns. Finally, it can not be ruled out that the exposure variable used for this and other studies—residence served by a particular water source—is simply a surrogate for some other unidentified factor associated with nonrural living. The nonspecific relationship of several different causes of death and water source at home observed in the earlier cohort study (Wilkins and Comstock, 1981) lends some support to this possibility. More valid individual exposure information over a long period of time for both specific contaminants and the use of chlorinated/unchlorinated water are needed to assess the results of this and other analytical epidemiology studies.

Morris et al. (1992) conducted a meta-analysis, evaluating 12 studies and pooling the relative risks from 10 epidemiological studies of cancer and a presumed exposure to chlorinated water and its byproducts. Meta-analysis refers to the application of quantitative methods to combine the published results of a related body of literature (Dickerson and Berlin, 1992). Morris et al. (1992) reported a pooled relative risk estimate of 1.21 (95% CI, 1.09–1.34) for bladder cancer and 1.38 (95% CI, 1.01–1.87) for rectal cancer (i.e., 9% of bladder cancer cases and 15% of the rectal cancer cases in the U.S. or approximately 10,000 additional cases of cancer per year could be attributed to chlorinated water and its by-products). Pooled relative risk estimates for ten other site specific cancers including colon, colo-rectal and pancreas were not felt to be significantly elevated nor were they statistically significant.

If the indications from this analysis are true such that water chlorination could result in as many as 10,000 cases of cancer a year, then chlorination could represent a significant cause of rectal and bladder cancer in the U.S. However, there was disagreement among the negotiating parties over the appropriateness of this meta-analysis. Some believed that the use of the meta-analysis may not be appropriate for these data. Others disagreed, expressing their view that the analysis was statistically probative and otherwise valuable. Meta-analysis has been used successfully to combine the results of small clinical trials and of some epidemiology studies that have similar experimental design and exposure conditions. Application of meta-analysis to the water chlorination data requires careful consideration of exposure variables and systematic bias in each of the studies. Chlorinated drinking water is a complex mixture of many substances that vary geographically and seasonally. There is even variability within a geographic region. In addition, the information on exposure and potential confounding is much more limited for the four decedent case control studies used in the meta-analysis. Their study design is dissimilar to the other studies included, resulting in concerns about their inclusion in the meta-analysis. Study-specific methodological problems, systematic bias, and problems of exposure definition and assessment could not be corrected by this analysis (Murphy, 1993). Thus, the overall results of the Morris et al. analysis may over- or underestimate the risk. However, the estimate of risk in regard to rectal cancer might be particularly affected by the inclusion of these case control studies. It should also be noted that the results of the Morris et al. analysis does not provide additional information to establish causality.

The chlorinated drinking water epidemiology studies have been reviewed extensively by EPA, the National Academy of Sciences, the International Agency for Research on Cancer (IARC), and the International Society for Environmental Epidemiology (ISEE). In 1987, the National Academy of Sciences Subcommittee on Disinfectants and Disinfectant By-Products concluded that there was a major health concern with the chronic ingestion of low levels of disinfection byproducts (NRC, 1987). The Subcommittee commented that some of the epidemiology studies reported "increased rates of bladder cancer associated with trends of levels of certain contaminants in water supplies. Interpretation of these studies is hampered by a lack of control for confounding variables (e.g., age, sex, individual health, smoking history, other exposures)." The Subcommittee recommended that epidemiologists continue to improve protocols and conduct studies on drinking water and bladder cancer where exposure data can be obtained from individuals, rather than through estimation from exposure models.

EPA and IARC, along with other individual scientists, have interpreted the epidemiologic evidence as inadequate. IARC concluded that "there is inadequate evidence for carcinogenicity of chlorinated drinking water in humans."

The ISEE presented a full spectrum of opinion regarding the epidemiology data (Neutra and Ostro, 1992). The ISEE reported a "general consensus that the results of the recent EPA-sponsored studies of cancer endpoints have strengthened the evidence for linking bladder cancer with long term exposure to chlorinated drinking water. The evidence for links with colon cancer are not convincing. * * * Any risks, if real, are low when compared to the risk of infection from not disinfecting water."

In 1992, the International Life Sciences Institute sponsored a conference with the Pan American Health Organization, EPA, Food and Drug Administration, World Health Organization, and the American Water Works Association on the safety of water disinfection. Although they do not necessarily reflect the views of the sponsoring organizations, conclusions prepared by the conference's editor and editorial board (Craun et al., 1993) noted that "Adverse human health effects may be associated with the chemical disinfection of drinking water. However, current scientific evidence is inadequate to conclude that water chlorination poses a significant risk to humans. Uncertainties about the available toxicologic evidence limit assessment of human health risks associated with chlorine, chloramine, chlorine dioxide, and ozone disinfection. The epidemiologic evidence for increased cancer risks of chlorinated drinking water is equivocal."

Some members of the reg-neg committee felt that the epidemiology data, taken in conjunction with the results from toxicological studies, provide an ample and sufficient basis to conclude that the usual exposure to disinfection by-products in drinking water could result in an increased cancer risk at levels encountered in some public water supplies.

Because of the spectrum of conclusions concerning these data, the Agency is pursuing additional research to reduce the uncertainties associated with these data and better characterize the potential of cancer risks associated with the consumption of chlorinated drinking water.

b. Serum Lipids/Cardiovascular Disease. Laboratory studies on animals, conducted in the early 1980's indicated a possible link between consumption of chlorinated drinking water and elevated serum lipid profiles which are indicators of cardiovascular disease (USEPA 1994a). The animal work was followed by a cross-sectional study in humans (Zeighami et al., 1990) that

included 1,520 adult residents, aged 40 to 70 years, in 46 Wisconsin communities supplied with either chlorinated or unchlorinated drinking water of varying hardness. The study was designed to determine whether differences in calcium or magnesium intake from water and food and chlorination of drinking water affect serum lipids.

The communities selected for study had the following characteristics: (1) They were small in population size (300–4,000) and not suburbs of larger communities; (2) they had not undergone more than 20% change in population between 1970 and 1980; (3) they had been in existence for at least 50 years; and (4) all obtained water from groundwater sources with no major changes in water supply characteristics since 1980 and did not artificially soften water. The water for the communities contained total hardness of either ≤ 80 mg/l $CaCO_3$ (soft water) or ≥ 200 mg/l CaCO3 (hard water); 24 communities used chlorine for disinfection and 22 communities did not disinfect. Eligible residents were identified through state driver's license tapes and contacted by telephone; an age-sex stratified sampling technique was used to choose a single participant from each eligible household. Only persons residing in the community for at least the previous 10 years were included. A questionnaire was administered to each participant to obtain data on occupation, health history, medications, dietary history water use, water supply and other basic demographic information. Water samples were collected from a selected subset of homes and analyzed for chlorine residual, pH, calcium, magnesium, lead, cadmium, and sodium. Fasting blood specimens were collected from each participant and analyzed for total cholesterol, triglycerides and high- and low-density lipoprotein (HDL and LDL, respectively) subfractions.

Among females, adjusted mean total serum cholesterol levels were statistically significantly higher in the chlorinated communities compared to the nonchlorinated communities (249 mg/dl and 238 mg/dl, respectively). These changes are not considered biologically significant as they reflect background variation. Total serum cholesterol levels were also higher for males in chlorinated communities, on the average, but the difference was smaller and not statistically significant (236 mg/dl vs. 232 mg/dl). LDL mean values followed a similar pattern to that for total cholesterol, higher in chlorinated communities for females, but not different for males. However, for both sexes, HDL cholesterol levels are nearly identical in chlorinated and nonchlorinated communities and there were no significant differences found in the HDL/LDL ratios. The implications of these findings for cardiovascular disease risk are unclear at this time given the inconsistencies in the data. The possibility exists that the observed association in females may have resulted from some unknown or undetermined variable in the chlorinated communities.

The results from a second study, designed to further explore the findings among female participants in the Wisconsin study (Zieghami et al., 1990), were presented in 1992 (Riley et al., 1992, manuscript submitted for publication). Participants were 2,070 white females, aged 65 to 93 years who were enrolled in the Study of Osteoporotic Fractures (University of Pittsburgh Center) and had completed baseline questionnaires on various demographic and lifestyle factors. Total serum cholesterol was determined for all participants. Full lipid profiles (total cholesterol, triglycerides, LDL, total HDL, HDL–2, HDL–3, Apo–A–I, and Apo–B) were available from fasting blood samples for a subset of 821 women. Interviews conducted in 1990 ascertained residential histories and type of water source used back to 1950 and all reported public water sources were contacted for verification of disinfectant practices. Private water sources were presumed to be nonchlorinated. A total of 1,896 women reported current use of public, chlorinated water, 201 reported current use of nonchlorinated springs, cisterns, or wells and 35 reported having mixed sources of water. Most of the women had been living in the same home with the same water service for at least 30 years.

Overall, there were no meaningful differences detected in any of the measured serum lipid levels between women currently exposed to nonchlorinated water and those exposed to chlorinated water (246 mg/dl vs. 247 mg/dl, respectively, for total cholesterol). The data were also stratified by age and person-years of exposure to chlorinated water at home. There was some suggestion that women with no exposure to chlorine had lower total cholesterol levels but this finding was inconsistent and may represent random fluctuation since there was no trend noted with LDL cholesterol or Apo–B, both of which are known to correlate with total cholesterol. There was also no association between increasing duration of exposure to chlorine and HDL cholesterol, Apo–A–I, or triglycerides.

The only notable differences were that women with chlorinated water reported significantly more cigarette and alcohol consumption than the women with nonchlorinated drinking water (Riley et al., 1992). This was evident in all age groups and across strata of duration of exposure. This finding lends support to the possibility that the previously reported association of chlorinated drinking water and elevated total serum cholesterol (Zeighami et al., 1990) may have arisen due to incomplete control of lifestyle factors which were differentially distributed across chlorination exposure groups.

c. *Reproductive/Developmental Outcomes.* Several recently conducted epidemiologic studies have examined the relationship between different reproductive or developmental endpoints and various components of drinking water. Kramer et al. (1992) conducted a population-based case-control study to determine whether water supplies containing relatively high levels of chloroform and other THMs within the state of Iowa are associated with low birthweight, prematurity, or intrauterine growth retardation (IUGR). Iowa birth certificate data from January, 1989 through June, 1990 served as the source of both cases and controls. Definitions for cases and controls were as follows: the low birthweight group included 159 live singleton infants weighing <2,500 grams and 795 randomly selected control infants weighing ≥2,500 grams from the same population; the prematurity group included 342 live singleton infants with gestational ages of <37 weeks as determined from the mother's reported last menstrual period, and 1,710 randomly selected control infants with gestational ages ≥37 weeks; IUGR analyses included 187 IUGR infants (defined as weighing less than the 5th percentile for a particular gestational age based on California standards for non-Hispanic whites) and 935 randomly selected controls. Exposure status was assigned to infants according to reported maternal residence in a given municipality at the time of birth. The assigned THM levels came from a water survey conducted in 1987 in the state of Iowa so the exposure information came from aggregate data. Odds ratios were computed using multiple logistic regression to control for measured confounders (including smoking, but not alcohol consumption). The authors reported an increased risk for IUGR associated with residence in communities where chloroform levels exceeded 10 ug/l (OR=1.8; 95% CI=1.1–

2.9). Prematurity was not associated with chloroform exposure and the risk for low birthweight was only slightly increased (OR=1.3; 95% CI=0.8–2.2).

The authors considered the results of this study to be preliminary. Accordingly, they should be interpreted with caution. They considered the major limitations of the study to involve assessment and classification of individual exposure, the potential misclassification due to residential mobility and the fluctuation of THM levels.

Aschengrau et al. (1993) conducted a case-control study in Massachusetts to determine the relationship between community drinking water quality and a wide range of adverse pregnancy outcomes, including congenital anomalies, stillbirths, and neonatal deaths. The data were obtained during a previous study of 14,130 pregnant women who delivered infants at Brigham and Women's Hospital in Boston between 1977 and 1980. Drinking water quality information came from routine analyses of the metal and chemical content of Massachusetts public water. An attempt was made to link each woman in the study to the result of the water analyses conducted in her town at the time of her pregnancy. Information was also obtained on drinking water source and chlorination of surface water. Drinking water samples from 155 towns were linked to 2,348 pregnant women to estimate exposure for the case-control study.

A large number of exploratory analyses were conducted with this data set, which demonstrated both increases and decreases in risk associated with various water quality parameters. A higher frequency of stillbirths was correlated with chlorination and detectable lead levels, cardiovascular defects were associated with lead levels, CNS defects with potassium levels, and face, ear, and neck anomalies with detectable silver levels. A decrease in neonatal deaths was associated with detectable fluoride levels.

The authors indicated that the findings from this study, being non-specific, must be considered as preliminary given the problems and limitations of the exposure assessment and the lack of an a priori study hypothesis. They indicated a need for further research (Aschengrau et. al. 1993).

The New Jersey Department of Health recently reported the results of a cross-sectional study and a case-control study evaluating the association of drinking water contaminants with birth weight and selected birth defects (Bove et al. 1992a and b). Four counties selected for the study were included because they had the highest levels of monitored drinking water and they were served by well defined public water systems which used ground and surface water, or a mixture of these sources. The exposures evaluated total volatile organic contaminants (VOCs) as well as individual VOCs such as trichloroethylene, tetrachloroethylene, carbon tetrachloride, benzene and THMs. The cross sectional study base included 81,055 live single births and 599 single fetal deaths between January, 1985 and December, 1988; 593 mothers were interviewed in the case control study. Exposure scenarios to THMs were stratified as follows: >20–40 µg/L, >40–60 µg/L, >60–80 µg/L, and >80 µg/L.

In the cross sectional study, ORs with exposure to THMs >80 µg/L were elevated for low term birth weight (OR=1.34; 95% CI=1.13–1.6; adjusted OR=1.29; 95% CI=1.08–1.5), small for gestational age (OR=1.22; 95% CI=1.12–1.3; adjusted OR=1.14; 95% CI=1.04–1.3), and prematurity (OR=1.09; 95% CI=0.99–1.2; adjusted OR=1.04; 95% CI=0.94–1.1). Among birth defects, the ORs were elevated for all surveillance malformations: OR=1.53; 95% CI=1.14–2.1; central nervous system defects OR=2.6; 95% CI=1.48–4.6; neural tube defects: OR=2.98; 95% CI=1.25–7.1; and cardiac defects: OR= 1.44; 95% CI=0.97–2.1. In the case control study, associations were found between THMs >80 µg/L and neural tube defects (OR=4.25; 95% CI=1.02–17.7) and between THM levels >15 µg/L and cardiac defects (OR=2.0; 95% CI= 0.94–4.5). The authors note their findings should be interpreted with caution because of possible exposure misclassification, unmeasured confounding, and associations which could be due to chance occurrences. Although the case control study included interviews of mothers for information about residence and various risk factors, the authors reported a number of limitations in the interpretation of the results from the case control study, especially as a result of selection bias. Evaluation of selection bias indicated that the bias led to an overestimate of the associations with THM levels.

Some members of the Reg Neg committee viewed that these studies indicate the possibility of a reproductive risk related to exposure to disinfectant by-products. As a result of this concern, EPA convened a panel of experts to review the epidemiology studies described above (USEPA, 1993a). The panel concluded that the studies by Bove et al. (1992a and b) were useful for hypothesis generation and identification of a number of areas for further research. The panel further concluded that the findings were limited by a number of issues surrounding study design and data analysis. Some of the limitations included untested assumptions of maternal exposure to chlorinated water, limitations in the exposure assessment for THMs and other disinfection by-products, possibility for exposure misclassification, confounding risk factors and that some of these findings may have been due to chance.

d. *Request for Public Comments.* EPA requests comments on the significance of the epidemiological studies with chlorine and chloramines as indicators of risk. EPA recognizes that there are different interpretations of these epidemiological studies and specifically solicits comment on the rationale for EPA's interpretations. EPA further requests comments on the studies suggesting a reproductive risk related to disinfectant by-product exposure.

4. Chlorine Dioxide, Chlorite and Chlorate

Chlorine dioxide is used as a disinfectant in drinking water treatment as well as an additive with chlorine to control tastes and odors in water treatment. It has also been used for bleaching pulp and paper, flour and oils and for cleaning and tanning of leather. Chlorine dioxide is a strong oxidizer that does not react with organics in the water, as does chlorine, to produce by-products such as the trihalomethanes. Chlorine dioxide is fairly unstable and rapidly dissociates into chlorite, and chloride in water. Chlorate may also be formed as a result of inefficient generation or generation of chlorine dioxide under very high or low pH conditions. The dissociation of chlorine dioxide into chlorite and chloride may be reversible with some chlorite converting back to chlorine dioxide if free chlorine is available. Chlorite ion is generally the primary product of chlorine dioxide reduction. The distribution of chlorite, chloride and chlorate is influenced by pH and sunlight. Chlorite, (as the sodium salt), is used in the onsite production of chlorine dioxide and as a bleaching agent by itself, for pulp and paper, textiles and straw. Chlorite is also used to manufacture waxes, shellacs and varnishes. Chlorate, as the sodium salt, was once a registered herbicide to defoliate cotton plants during harvest, to tan leather and in the manufacture of dyes, matches, explosives as well as chlorite.

Occurrence and Human Exposure. Based on information from the Water Industry Data Base (WIDB), it has been estimated that for large systems (serving greater than 10,000 people), approximately 10% of community surface water systems serving 12.4 million people and 1% of community ground water systems, serving 0.2 million people currently use chlorine dioxide for disinfection in the United States. It was assumed that none of the smaller community systems (fewer than 10,000 people) use chlorine dioxide (WIDB, 1990).

Table V–5 presents occurrence information available for chlorine dioxide, chlorate, and chlorite in drinking water. Descriptions of these surveys and other data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," (USEPA, 1992a). Typical dosages of chlorine dioxide used as a disinfectant in drinking water treatment facilities appear to range from 0.6 to 1.0 mg/L. For plants using chlorine dioxide, median concentrations of chlorite and chlorate were found to be 240 and 200 µg/L, respectively. However, tne data base upon which these numbers are based is very limited. A more extensive discussion of chlorine dioxide and chlorite occurrence is described in section VI. of this preamble.

TABLE V–5:—SUMMARY OF OCCURRENCE DATA FOR CHLORINE DIOXIDE AND CHLORITE

Occurrence of Chlorine Dioxide, Chlorate, and Chlorite in Drinking Water

Survey (year)[1]	Location	Sample information (No. of samples)	Concentration (µg/L)			
			Range	Mean	Median	Other
AWWARF (1987) McGuire & Meadow, 1988.		Finished Water From:				
		Lakes		1.0 mg/L[3]		
		Flowing Streams		0.6 mg/L[3]		
		Plants Using ClO_2:				Positive Detections
		Chlorite at the Plant (4)	15–740	240	110	100%
EPA, 1992b[2] (1987–1991).	Disinfection By-Products Field Studies	Chlorate at the Plant (4)	21–330	200	220	100%
		Plants Not Using ClO_2:				
		Chlorate at the Plant (30)	<10–660	87	16	60%
		Chlorate, Distr. System (4)	<10–47	18	13	75%

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.
[3] Typical dosage used by treatment plants.
AWWARF American Water Works Association Research Foundation.
EPA Environmental Protection Agency.

No information is available on the occurrence of chlorine dioxide, chlorate, and chlorite in food or ambient air. Currently, the Food and Drug Administration (FDA) does not analyze for these compounds in foods. Preliminary discussions with FDA suggest that there are not approved uses for chlorine dioxide in foods consumed in the typical diet. In addition, the EPA Office of Air and Radiation does not require monitoring for these compounds in air. However, chlorine dioxide is used as a sanitizer for air ducts (Borum, 1991).

EPA believes that drinking water is the predominant source of exposure for these compounds. Air and food exposures are considered to provide only small contributions to the total chlorine dioxide, chlorate, and chlorite exposures, although the magnitude and frequency of these potential exposures are issues currently under review. Therefore, EPA is considering proposing to regulate these compounds in drinking water with an RSC value of 80 percent, the current exposure assessment policy ceiling. EPA requests any additional data on known concentrations of chlorine dioxide, chlorate and chlorite in drinking water, food and air.

Health Effects. The following health effects information is summarized from the draft Drinking Water Health Criteria Document for Chlorine Dioxide, Chlorite and Chlorate (USEPA, 1994c). Studies cited in this section are summarized in the draft criteria document.

As noted above, chlorine dioxide is fairly unstable and rapidly dissociates predominantly into chlorite and chloride, and to a lesser extent, chlorate. There is a ready interconversion among chemical species in water (before administration to animals) and in the gut (after ingestion). Therefore, what exists in water or the stomach is a mixture of these chemical species and possibly their reaction products with the gastrointestinal contents. Thus, the toxicity information on chlorite, the predominant degradation product of chlorine dioxide, may also be relevant to characterizing chlorine dioxide toxicity. In addition, studies conducted with chlorine dioxide may be relevant to characterizing the toxicity of chlorite. As a result, the toxicity data for one compound are considered applicable for addressing toxicity data gaps for the other.

The main health effects associated with chlorine dioxide and its anionic by-products include oxidative damage to red blood cells, delayed neurodevelopment and decreased thyroxine hormone levels. Chlorine dioxide, chlorite and chlorate are well absorbed by the gastrointestinal tract and excreted primarily in urine. Once absorbed, ^{36}Cl-radiolabeled chlorine dioxide, chlorite and chlorate are distributed throughout the body. Lethality data for ingested chlorine dioxide have not been located in the available literature. A lethal concentration for guinea pigs by inhalation was reported at 150 ppm. Oral LD_{50} values for chlorite have been reported at 100 to 140 mg/kg in rats. A more recent study indicates that the oral LD_{50} may be closer to 200 mg/L. Limited

data suggest an oral LD_{50} value between 500 to 1500 mg/kg for chlorate in dogs.

In subchronic and chronic studies, animals given chlorine dioxide treated water exhibited osmotic fragility of red blood cells (1 mg/kg/d), decreased thyroxine hormone levels (14 mg/kg/d), possibly due to altered iodine metabolism and hyperplasia of goblet cells and inflammation of nasal tissues. The nasal lesions are not considered related to ingested chlorine dioxide. However, it is not clear if the nasal effects are due to off-gassing of chlorine dioxide from the sipper tube of the animal water bottles, or from dermal contact while the animal drinks from the sipper tube. In addition, the chlorine dioxide treated group drank water at a pH of 4.7 which may also have contributed to the nasal tissue inflammation. The concentration associated with this effect (25 mg/L) is considerably greater than what would be found in drinking water.

Studies evaluating developmental or reproductive effects have described decreases in the number of implants and live fetuses per dam in female rats given chlorine dioxide in drinking water before mating and during pregnancy. Delayed neurodevelopment has been reported in rat pups exposed perinatally to chlorine dioxide (14 mg/kg/d) or chlorite (3 mg/kg/d) treated water. Delayed neurodevelopment was assessed by decreased locomotor activity and decreased brain development.

Subchronic studies with chlorite administered to rats via drinking water resulted in transient anemia, decreased red blood cell glutathione levels and increased hydrogen peroxide formation at doses greater than 5 mg/kg/d. Chlorite administration orally to cats at a dose of 7 mg/kg/d produced 10 to 40 percent methemoglobin formation within a couple of hours following dosing. Exposure to chlorite in drinking water resulted in an increased turnover of red blood cells in cats rather than oxidation of hemoglobin.

Oral studies with chlorate also demonstrate effects on hematological parameters and formation of methemoglobin, but at much higher doses than chlorite (157–256 mg/kg/d).

No clear tumorigenic activity has been observed in animals given oral doses of chlorine dioxide, chlorite or chlorate. Chlorine dioxide concentrates did not increase the incidence of lung tumors in mice nor was any initiating activity observed in mouse skin or rat liver bioassays. Lung and liver tumors were increased in mice given sodium chlorite; however, the incidence was within the historical range for these tumor types. Carcinogenic studies on chlorate were not located in the available literature. Chlorate has been reported to be mutagenic in bacterial and *Drosophila* tests. EPA has classified chlorine dioxide and chlorite in Group D: not classifiable as to human carcinogenicity. This classification is for chemicals with inadequate evidence or no data concerning carcinogenicity in animals in the absence of human data. EPA has not classified chlorate with respect to carcinogenicity.

There are a number of cases of poisoning in humans who used chlorate as an herbicide. Effects observed following exposures to 11 to 3,400 mg/kg include cyanosis, renal failure, convulsions and death. The lowest lethal dose reported in adults is approximately 200 mg/kg. It is not clear if this is the actual dose received or if other components in the formulation were contributors to the toxicity. In an epidemiology study of a community where chlorine dioxide was used as the primary drinking water disinfectant for 12 weeks, no consistent changes were observed in the clinical parameters measured.

Three studies have been selected as the basis for the RfD and MRDLG for chlorine dioxide. These studies identify a NOAEL of 3 mg/kg/d and a LOAEL of approximately 10 mg/kg/d. A NOAEL of 3 mg/kg/d has been identified in an 8 week rat study by Orme et al. (1985). In this study, chlorine dioxide was administered to female rats via drinking water at concentrations of 0, 2, 20 and 100 mg/L before mating, during gestation and lactation until the pups were 21 days old. Based on body weight and water consumption data, these concentrations correspond to doses of 1, 3 and 14 mg/kg/d. No effects were noted in dams. Pups in the high dose group (14 mg/kg/d) exhibited decreased exploratory and locomotor activity and a significant depression of thyroxine. These effects were not observed at the 3 mg/kg/d dose level. In a second experiment, pups were given 14 mg/kg/d chlorine dioxide directly by gavage during postnatal days 5 through 20. A greater and more consistent delay in neurobehavioral activity was observed along with a greater depression in thyroxine. Analysis of the DNA content of cells in the cerebellum from animals in the high dose drinking water group (14 mg/kg/day) at postnatal day 21 and the gavage group at day 11 indicated a significant depression (Taylor and Pfohl, 1985). Another study confirmed 14 mg/kg/d as a LOAEL based on decreased brain cell proliferation in rats exposed postnatally by gavage (Toth et al., 1990).

The no-effect level of 3 mg/kg/day is also supported by a monkey study (Bercz et al., 1982), where animals were given chlorine dioxide at concentrations of 0, 30, 100 or 200 mg/L in drinking water following a rising dose protocol. These concentrations correspond to doses of 0, 3.5, 9.5 and 11 mg/kg/d based on animal body weight and water consumption. Animals showed signs of dehydration at the high dose; exposure was discontinued at that dose (11 mg/kg/d). A slight depression of thyroxine was observed following exposure to 9.5 mg/kg/d. No effects were seen with 3.5 mg/kg/d, which is considered the NOAEL.

MRDLG for Chlorine Dioxide. EPA is proposing an MRDLG for chlorine dioxide based on developmental neurotoxicity following a Category III approach. Using a NOAEL of 3 mg/kg/d and an uncertainty factor of 300, an RfD of 0.01 mg/kg/d for chlorine dioxide is calculated. An uncertainty factor of 300 is used to account for differences in response to toxicity within the human population and between humans and animals. This factor also accounts for lack of a two-generation reproductive study. Availability of an acceptable two-generation reproduction study would likely reduce the total uncertainty factor to 100. The Chlorine Dioxide panel of the Chemical Manufacturers Association is conducting a two-generation reproductive study with chlorite to address this data gap. EPA will review the results of this study and determine if any changes to the RfD for chlorine dioxide are warranted.

After adjusting for an adult consuming 2 L water per day, an RSC of 80 percent is applied to calculate an MRDLG of 0.3 mg/L. An RSC of 80% is used since most chlorine dioxide exposure is likely to come from a drinking water source.

$$\text{MRDLG} = \frac{3\ \text{mg/kg/d} \times 70\ \text{kg} \times 0.8}{300 \times 2\ \text{L/day}} = 0.3\ \text{mg/L (rounded)}$$

The Drinking Water Committee of the Science Advisory Board (SAB) agreed with the use of the Orme et al. (1985) study as the basis for the MRDLG and suggested that an uncertainty factor of 100 be applied (USEPA, 1992c). They also suggested that a child's body weight of 10 kg and water consumption of 1 L/d may be more appropriate for setting the MRDLG than the adult parameters, given the acute nature of the toxic effect. EPA requests comments on the SAB's suggestion.

EPA also requests comment on the appropriateness of the 300-fold uncertainty factor, the studies selected as the basis for the RfD, and the 80% relative source contribution.

MCLG for Chlorite. The developmental rat study by Mobley et al. (1990) has been selected to serve as the basis for the RfD and MCLG for chlorite. Other studies reported effects at doses higher than the Mobley et al. study. In this study, female Sprague-Dawley rats (12/group) were given drinking water containing 0, 20, or 40 mg/L chlorite (0, 3, or 6 mg chlorite ion/kg/day) as the sodium salt beginning 10 days prior to breeding with untreated males until the pups were sacrificed at 35 to 42 days postconception (a total exposure of 9 weeks). Exploratory activity was depressed in the pups treated with 3 mg/kg/day chlorite on postconception days 36–37 but not on days 38–40. Pups from the high exposure group also exhibited depressed exploratory behavior during days 36–39 postconception ($p<0.05$). Exploratory activity was comparable among the treated and control groups on postconception days 39–41. No significant differences in serum total thyroxine or triiodothyronine were observed between treated and control pups. Free thyroxine was significantly elevated in the 6 mg/kg/day pups. A LOAEL of 3 mg/kg/day was determined in this study based on the neurobehavioral effect (depressed exploratory behavior) in rats. This endpoint is similar to that reported for chlorine dioxide.

EPA had considered using a study by Heffernan et al. (1979) which described dose-related decreases in red blood cell glutathione levels from rats orally exposed to chlorite in drinking water for up to 90 days. The decreases in glutathione were accompanied by decreases in red blood cell concentration, hemaglobin concentration and packed red cell volume. Taken together, these effects were considered reflective of oxidative stress resulting from the ingested chlorite. In this study, a NOAEL of 1 mg/kg/d and LOAEL og 5 mg/kg/d were identified.

The EPA Science Advisory Board had cautiously agreed with the selection of the Heffernan et al. (1979) study as the basis for the RfD, but noted that the endpoint would likely be controversial since normal fluctuations occur with glutatione levels. Thus this effect, alone, may not necessarily be the result of chlorite exposure. The EPA RfD workgroup was unable to reach consensus on decreased glutathione levels as an appropriate endpoint to base an RfD. They agreed with the selection of the Mobley et al. (1990) study since the endpoint, developmental neurotoxicity, represented the next critical effect and was consistent with the toxicity observed with chlorine dioxide.

Following a Category III approach, EPA is proposing an MCLG of 0.08 for chlorite. The MCLG is based on an RfD of 0.003 determined from the LOAEL of 3 mg/kg/day from the Mobley et al. study. This endpoint was selected since it is similar to that reported for chlorine dioxide. An uncertainty factor of 1,000 is used in the derivation of the RfD and MCLG to account for use of a LOAEL from an animal study.

After adjusting for an adult consuming 2 L water per day, an RSC of 80% is applied to calculate an MCLG of 0.08 mg/L. An RSC of 80% was used since most exposure to chlorite is likely to come from drinking water.

$$\text{MCLG} = \frac{3\ \text{mg/kg/day} \times 70\ \text{kg} \times 0.8}{1{,}000 \times 2\ \text{L/day}} = 0.08\ \text{mg/L (rounded)}$$

The Drinking Water Committee of the EPA Science Advisory Board suggested that EPA consider basing the MCLG on the child body weight of 10 kg and water consumption of 1 L/day instead of the adult default values. EPA requests comments on the SAB's suggestion along with the study selected as the basis for the MCLG, the uncertainty factor and the RSC of 80%.

MCLG for Chlorate. Data are considered inadequate to develop an MCLG for chlorate at this time. A NOAEL of 0.036 mg/kg/d (the only dose tested) was identified in the Lubbers et al. (1982) human clinical study following a 12-week exposure to chlorate in drinking water. NOAELs identified from animal studies are considerably higher (approximately 78 mg/kg/d). However, doses that are lethal to humans (200 mg/kg/d) are only 2-fold greater than this animal no-effect level. No information is available to characterize the potential human toxicity between the doses of 0.036, the only human NOAEL and 200 mg/kg/d, the apparent human lethal dose. Thus, EPA considers the data base too weak to derive a separate MCLG for chlorate at this time. The Agency will continue to evaluate the animal data and any new information that become available for future consideration of an MCLG for chlorate.

EPA requests comments on the decision not to propose an MCLG for chlorate at this time.

5. Chloroform

Chloroform [trichloromethane, CAS No. 67–66–3] is a nonflammable, colorless liquid with a sweet odor and high vapor pressure (200 mm Hg at 25 °C). It is moderately soluble in water (8 gm/L at 20 °C) and soluble in organic solvents (log octanol/water partition coefficient of 1.97). Chloroform is used primarily to manufacture fluorocarbon-22 (chlorodifluoromethane) which in turn is used for refrigerants and fluoropolymer synthesis. A small percentage of the manufactured chloroform is used as an extraction solvent for various products (e.g. resins, gums). In the past, chloroform was used in anesthesia and medicinal preparations and as a grain fumigant ingredient. Chloroform can be released to the environment from direct (manufacturing) and indirect (processing/use) sources and chloroform is a prevalent chlorination disinfection by-product. Volatilization is the principle mechanism for removal of chloroform from lakes and rivers. Chloroform bioconcentrates slightly in aquatic organisms and adsorbs poorly to sediments and soil. Chloroform can be biodegraded in water and soil (half-life of weeks to months) and ground water (half-life of months to years), and photo-oxidized in air (half-life of months).

Occurrence and Human Exposure. The principle source of chloroform in drinking water is the chemical interaction of chlorine with commonly present natural humic and fulvic

substances and other precursors produced by either normal organic decomposition or by the metabolism of aquatic biota. Because humic and fulvic material are generally found at much higher concentrations in surface water sources than in ground water sources, surface water systems have higher frequencies of occurrence and higher concentrations of chloroform than ground water systems. Several water quality factors affect the formation of chloroform including Total Organic Carbon (TOC), pH, and temperature. Different treatment practices can reduce the formation of chloroform. These include the use of precursor removal technologies such as coagulation/filtration, granular activated carbon (GAC), and membrane filtration and the use of chlorine dioxide, chloramination, and ozonation.

Table V–6 presents occurrence information available for chloroform in drinking water. Descriptions of these surveys and other data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," [USEPA, 1992a). The table lists six surveys conducted by Federal and private agencies. Median concentrations of chloroform in drinking water appear to range from 14 to 57 µg/L for surface water supplies and ≤0.5 µg/L for ground-water supplies (many of which do not disinfect). The lower bound median concentration for chloroform in surface water supplies is biased to the low side because concentrations in this survey were measured in the plant effluent; the formation of chloroform would be expected to increase in the distribution in systems using chlorine as their residual disinfectant.

TABLE V6.—SUMMARY OF OCCURRENCE DATA FOR CHLOROFORM

[Occurrence of Chloroform in Drinking Water]

Survey (year)	Location	Sample information (No. of samples)	Concentration (µg/L			
			Rage	Mean	Median	Other
CWSS (1978) Brass et al., 1981.	450 Water Supply Systems	Finished Water (1,100):				Positive Detections:
		Surface Water		[3]60		[4]97%
		Ground Water		[3]<0.5		[4]34%
RWS (1978–1980) Brass, 1981.	>600 Rural Systems (>2,000 Households)	Drinking Water from:				Postive Detection:
		Surface Water		[3]84	57	[4]82%
		Ground Water		[3]8.9	<0.5	[4]17%
GWSS (1980–1981) Westrick et al. 1983.	945 GW Systems:					90th percentile:
	(466 Random and 479 Nonrandom)	Serving >10,000 (327)	Max. 300		0.5	17
		Serving <10,000 (618)	Max. 430		0	7.8
EPA, 1991a[2] (1984–1991).	Unregulated Contaminant Data Base—Treatment Facilities from 19 States	Sampled at the Plant (5,806)		17	5	
EPA, 1992b[2] (1987–1991).	Disinfection By-Products Field Studies	Finished Water:				Positive Detections:
		At the Plant (73)	<0.2–240	36	28	96%
		Distribution System (56)	<0.2–340	57	42	98%
EPA/AMWA/CDHS[2] (1988–1989).	35 Water Utilities Nationwide	Samples from Clearwell	Max. 130		[5]9.6–15	75% of Data was Below 33 µgL
Krasner et al., 1989b		Effluent for 4 Quarters			14	

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.
[3] Mean of the positives.
[4] Of systems sampled.
[5] Range of medians for individual quarters.
AMWA Association of Metropolitan Agencies.
CDHS California Department of Health Services.
CWSS Community Water Supply Survey.
GWSS Ground Water Supply Survey.
RWS Rural Water Survey.
EPA Environmental Protection Agency.

Several studies have assessed inhalation exposure to chloroform. The major source of these data is from the USEPA's Total Exposure Assessment Methodology (TEAM) studies, which measured chloroform exposure to approximately 750 persons in eight geographic areas from 1980 to 1987. Personal exposure to chloroform from air was measured over a 12-hour period (excluding showers) for individuals in three areas. The average exposures were reported to range from 4 to 9 $\mu g/m^3$ in New Jersey and Baltimore, and about 0.5 to 4 $\mu g/m^3$ in California cities (Wallace, 1992). In the 1987 Los Angeles TEAM study, chloroform in indoor air was measured in the living room and kitchen of private residences. Observed mean indoor concentrations ranged from 0.9 to 1.5 $\mu g/m^3$ (Pellizzari et al., 1989 and Wallace et al., 1990 in Wallace, 1992). For outdoor levels, the 12-hour average outdoor concentrations measured in the California and New Jersey TEAM studies ranged from 0.2 to 0.6 $\mu g/m^3$ and 0.1 to 1.5 $\mu g/m^3$, respectively (Pellizzari et al., 1989, Wallace et al., 1990 and PEI et al., 1989 in Wallace, 1992).

Given the limited exposure data in air, inhalation exposure can be estimated using an inhalation rate of 20 m^3/day. Resulting estimates for average ambient air exposures range from 2 to 30 $\mu g/d$ and 18–30 $\mu g/d$ for average indoor air exposures. However, based on the personal air monitoring data, a potentially higher average inhalation exposure is indicated with a range of 10 to 180 $\mu g/d$.

Two studies analyzed some foods for chloroform. In a pilot market basket survey of four food groups at five sites, measured chloroform levels were as follows: dairy composite, 17 ppb (1 of 5 sites); meat composite, not detected; oil and fat composite, trace amounts (1 of 5 sites); beverage composite, 6 to 32 ppb (4 of 5 sites) (Entz et al., 1982). In a study of 15 table-ready food items, chloroform was detected in 53% of the foods tested: butter, 670 ppb; cheddar cheese, 80 ppb; plain granola, 57 ppb; peanut butter, 29 ppb; chocolate chip cookies, 22 ppb; frozen fried chicken dinner, 29 ppb; and high meat dinner, 17 ppb (Heikes, 1987).

Limited data are available to characterize dietary exposure to chloroform. Although some uses of chlorine have been identified in the food production/food processing area, monitoring data are not adequate to characterize the magnitude or frequency of exposure to chloroform. Based on the limited number of food groups that are believed to contain chloroform and low levels expected in ambient and indoor air, EPA assumes that drinking water is the predominant source of chloroform intake. The characterization of potential food and air exposures are issues currently under review. EPA requests any additional data on known concentrations of chloroform in drinking water, food, and air.

Health Effects. The health effects information is summarized from the draft Drinking Water Criteria Document for Trihalomethanes (USEPA, 1994d). Studies cited in this section are summarized in the criteria document.

Chloroform has been shown to be rapidly absorbed upon oral, inhalation and peritoneal administration and subsequently metabolized. The reported mean human lethal dose, from clinical observations of overdoses, was around 630 mg/kg. The LD_{50} values in mice and rats have been reported in the range of 908–1,400 mg/kg. Several reactive metabolic intermediates (e.g. phosgene, carbene, dichloromethyl radicals) can be produced via oxidation (major pathway) or reduction (minor pathway) by microsomal preparations. Experimental studies suggested that these active metabolic intermediates are responsible for the hepatic and renal toxicity and possibly, carcinogenicity, of the parent compound. Animal studies suggest that the extent of chloroform metabolism varies with species and sex. The retention of chloroform in organs after dosing was small. Due to the lipophilic nature of the compound, the residual concentration is in tissues with higher fatty content. In humans, the majority of the tested oral intake doses (0.1 to 1 gm) were excreted through the lungs in the form of a metabolite CO_2 or as the unchanged compound. Urinary excretion levels were below 1%.

Mammalian bioeffects following exposure to chloroform include effects on the central nervous system (CNS), hepatotoxicity, nephrotoxicity, reproductive toxicity and carcinogenicity. Chloroform caused CNS depression and affected liver and kidney function in humans in both accidental and long term occupational exposure situations. In experimental animals, chloroform caused changes in kidney, thyroid, liver, and serum enzyme levels. These responses are discernible in mammals from exposure to levels of chloroform ranging from 15 to 290 mg/kg; the intensity of response was dependent upon the dose and the duration of the exposure. Ataxia and sedation were noted in mice receiving a single dose of 500 mg/kg chloroform. Short-term exposure to the low levels of chloroform typically found in air, food, and water are not known to manifest acute toxic effects. The potential for human effects from chronic lifetime exposure is the basis for this regulation.

Developmental toxicity and reproductive toxicity have been investigated in animals. One developmental study reported maternal toxicity in rabbits administered chloroform by the oral route. Decreased weight gain and mild fatty changes in liver were observed in dams receiving 50 mg/kg/day (LOAEL); the maternal NOAEL was noted to be 35 mg/kg/day. There was no evidence of developmental effects.

The data from a 7.5-year oral study in dogs conducted by Heywood et al. (1979) were used to calculate the RfD. EPA considers this study suitable for the RfD derivation since it is a chronic study and sensitive indices of hepatotoxicity (serum enzyme levels, liver histology) of sufficient numbers of experimental animals were monitored. In this study, chloroform was administered to beagle dogs (16 per dose group) in toothpaste base gelatin capsules at dose levels of 15 or 30 mg/kg/day 6 days/week for 7.5 years. A LOAEL of 15 mg/kg/day was established based on the observation of hepatic fatty cysts in treated animals at both doses. An RfD of 0.01 mg/kg/day has been derived from this LOAEL by the application of an uncertainty factor of 1,000, in accordance with EPA guidelines.

The results of a number of assays to determine the mutagenicity potential of chloroform are inconclusive. Studies on the *in vitro* genotoxicity of chloroform reported negative results in bacteria (Ames assays), negative results for gene mutations and chromosomal aberrations in mammalian cells, and mixed results in yeasts. *In vivo* and *in vitro* DNA damage tests indicate that chloroform will bind to DNA. Gene mutation tests in *Drosophila* were marginal, whereas tests for chromosomal aberrations and sperm abnormalities were mixed.

Several chronic animal studies confirmed the carcinogenicity of chloroform. Chloroform induced hepatocellular carcinomas in mice when administered by gavage in corn oil (NCI, 1976). Chloroform also induced renal adenomas and adenocarcinomas in male rats regardless of the carrier vehicle (oil or drinking water) employed (NCI, 1976; Roe et al., 1979; Jorgenson et al., 1985).

In the study by Jorgenson et al. (1985), chloroform was administered in drinking water to male Osborne-Mendel rats and female B6C3F_1 mice at doses of 0, 200, 400, 900 or 1,800 ppm (0, 19, 38, 81 or 160 mg/kg/day in rats and 0, 34, 65, 130 or 263 mg/kg/day in mice) for 2 years. Chloroform increased the incidence of kidney tumors in male rats

in a dose-related manner. The combined incidence of renal tubular cell adenomas, renal tubular cell adenocarcinomas, and nephroblastomas in control, 200, 400, 900 and 1,800 ppm groups were 5/301, 6/313, 7/148, 3/48, and 7/50, respectively. Jorgenson's study reported no statistically significant increase in the incidence of hepatocellular carcinomas in the female mice exposed to similar doses of chloroform as reported in the 1976 NCI study.

Since hepatic changes appeared to be related to the corn oil vehicle, the interaction of corn oil and chloroform could account for the enhanced hepatic toxicity and thus for the difference in the NCI and Jorgenson studies. Because the drinking water study did not replicate hepatic tumors in female mice and the potential role of corn oil in enhancing toxicity, the National Academy of Science Subcommittee on the Health Effects of Disinfectants and Disinfection By-Products (NAS, 1987) recommended that male rat kidney tumor data obtained from Jorgenson's study be used to estimate the carcinogenic potency of chloroform. EPA agreed with the NAS Subcommittee recommendation for estimating risks of chloroform from drinking water exposures.

Based on all kidney tumor data in male Osborne-Mendel rats reported by Jorgenson et al. (1985), EPA used a linearized multistage model and derived a carcinogenic potency factor for chloroform of 6.1×10^{-3} $(mg/kg/day)^{-1}$. Assuming a daily consumption of two liters of drinking water and an average human body weight of 70 kg, the 95% upper bound limit lifetime cancer risk levels of 10^{-6}, 10^{-5}, and 10^{-4} are associated with concentrations of chloroform in drinking water of 6, 60 and 600 µg/L, respectively.

In 1987 the Commission on Life Sciences of the National Research Council published *Drinking Water and Health* (NAS, 1987). Volume 7, *Disinfectants and Disinfectant By-Products*, prepared by the Subcomittee on Disinfectants and Disinfection By-Products, discussed the available data on chloroform, which are the same data summarized above. The Subcommittee concluded that "[n]oting that chloroform is the principal THM produced by chlorination, the subcommittee found [the 100 THM] level to be unsupportable on the basis of the risk values for chloroform developed in this review," and that the level should be reduced.

EPA has classified chloroform in Group B2, probable human carcinogen, based on sufficient evidence of carcinogenicity in animals and inadequate evidence in humans (IRIS, 1985). The International Agency for Research on Cancer (IARC) has classified chloroform as a Group 2B carcinogen, agent possibly carcinogenic to humans. (IARC, 1982).

According to EPA's three-category approach for establishing MCLGs, chloroform is placed in Category I since there is sufficient evidence of carcinogenicity via ingestion considering weight of evidence, potency, pharmacokinetics, and exposure. Thus, EPA is proposing an MCLG of zero for this contaminant. EPA requests comment on the basis for the proposed MCLG for chloroform.

6. Bromodichloromethane

Bromodichloromethane (BDCM; CAS No. 75–27–4) is a nonflammable, colorless liquid with a relatively high vapor pressure (50 mmHg at 20°C). BDCM is moderately soluble in water (3.3 gm/L at 30°C) and soluble in organic solvents (log octanol/water partition coefficient of 1.88). Only a small amount of BDCM is currently produced commercially in the United States. The chemical is used as an intermediate for organic synthesis and as a laboratory reagent. The principle source of BDCM in drinking water is the chemical interaction of chlorine with the commonly present organic matter and bromide ions. Degradation of BDCM is not well studied, but probably involves photooxidation. The estimated atmospheric half-life of BDCM is two to three months. Volatilization is the principal mechanism for removal of BDCM from rivers and streams (half-life of hours to weeks). Limited studies reported that BDCM adsorbed poorly to sediments and soils. No study of bioaccumulation of BDCM was located. Based on the data of a few structurally similar chemicals such as chloroform, the bioconcentration potential of BDCM in aquatic organisms is low. Biodegradation of BDCM is limited under aerobic conditions and extensive (completion within days) under anaerobic conditions.

Occurrence and Human Exposure. BDCM, occurs in public water systems that chlorinate water containing humic and fulvic acids and bromine that can enter source waters through natural and anthropogenic means. Several water quality factors affect the formation of BDCM including Total Organic Carbon (TOC), pH, bromide, and temperature. Different treatment practices can reduce the formation of BDCM. These include the use of chlorine dioxide, chloramination, and ozonation prior to chloramination, as well as the use of precursor removal technologies such as coagulation/filtration, granular activated carbon (GAC), and membrane filtration.

Table V–7 presents occurrence information available for BDCM in drinking water. Descriptions of these surveys and other data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," (USEPA, 1992a). The table lists six surveys conducted by Federal and private agencies. Median concentrations of BDCM in drinking water appear to range from 6.6 to 15 µg/L for surface water supplies and <0.5 µg/L for ground-water supplies. The lower bound median concentration for BDCM in surface water supplies is biased to the low side because concentrations in this survey were measured in the plant effluent; the formation of BDCM would be expected to increase in the distribution system when chlorine is used as the residual disinfectant.

TABLE V–7: SUMMARY OF OCCURRENCE DATA FOR BROMODICHLOROMETHANE

Occurrence of Bromodichloromethane						
Survey (Year) [1]	Location	Sample Information (No. of Samples)	Concentration (µg/L)			
			Range	Mean	Median	Other
CWSS (1978, Brass et al., 1981.	450 Systems ...	Finished Water (1,100):				Positive Detections:
		Surface Water		[3]12	6.8	94% [4]
		Ground Water		[3]5.8	<0.5	33% [4]

TABLE V–7: SUMMARY OF OCCURRENCE DATA FOR BROMODICHLOROMETHANE—Continued

Occurrence of Bromodichloromethane						
Survey (Year)[1]	Location	Sample Information (No. of Samples)	Concentration (µg/L)			
			Range	Mean	Median	Other
RWS (1978–1980) Brass, 1981.	>600 Rural Systems (>2,000 households).	Drinking Water from: Surface Water			11	Positive Detections: 76%[4]
		Ground water			<0.5	13%[4]
GWSS (1980–1981) Westrick et al. 1983.	945 GW Systems: (466 Random and 479 Nonrandom).	Serving >10,000 (327)	Max. 110		0.4	90Percentile 9.2
		Serving <10,000 (618)	Max. 79		0	6.1
EPA, 1991a[2] (1984–1991).	Unregulated Contaminant Data Base—Treatment Facilities from 19 States.	Finished Water at Treatment Plants (4,439).		5.6	3	
EPA, 1992b[2] (1987–1989).	Disinfection By-Products Field Studies.	Finished Water: At the Plant (73)	<0.2–90	13	11	Positive Detections: 96%
		Distribution System (56)	<0.2–100	17	15	98%
EPA/AMWA/CDHS[2] (1988–1989) Krasner et al., 1989b.	35 Water Utilities Nationwide.	Samples from Clearwell Effluent for 4 Quarters.	Max. 82	4.1–10[5]	6.6	75% of Data was Below 14 µg/L.

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.
[3] Mean of the positives.
[4] Of systems sampled.
[5] Range of medians for individual quarters.

AMWA: Association of Metropolitan Water Agencies.
CDHS: California Department of Health Services.
CWSS: Community Water Supply Survey.
GWSS: Ground Water Supply Survey.
RWS: Rural Water Survey.
EPA: Environmental Protection Agency.

BDCM is usually found in air at low concentrations. Based on information obtained through a literature review, Howard (1990) estimated the average daily intake of BDCM from air using an inhalation rate of 20 m^3/day. Assuming a range of 6.7 to 670 ng/m^3, the average exposure may be as low as 0.134 µg/day or as high as 13.4 µg/day.

BDCM is not a common contaminant in food. In one market study of 39 different food items, BDCM was detected in one dairy composite (1.2 ppb), butter (7 ppb), and two beverages (0.3 and 0.6 ppb). Analysis of cola soft drinks found BDCM in three samples with reported concentrations of 2.3 ppb, 3.4 ppb, and 3.8 ppb (Entz et al., 1982 in Howard, 1990).

Limited data are available to characterize food and air exposures to BDCM. Although some uses of chlorine have been identified in the food production/food processing area, monitoring data are inadequate to characterize the magnitude and frequency of potential BDCM exposures. Based on the limited number of food groups that are believed to contain BDCM and that there are not significant levels expected in ambient or indoor air, EPA assumes that drinking water is the predominant source of BDCM intake. EPA requests any additional data on known concentrations of BDCM in drinking water, food, and air.

Health Effects. The health effects information in this section is summarized from the draft Drinking Water Criteria Document for Trihalomethanes (USEPA, 1994d). Studies mentioned below are summarized in the criteria document.

Studies indicated that gastrointestinal absorption of BDCM is high in animals. No studies were located regarding BDCM in humans or animals following inhalation or dermal exposure. By analogy with the experimental data of a structurally-related halomethane chloroform, inhalation and dermal absorption may be high for BDCM. The reported LD_{50} values in mice and rats ranged from 450 to 969 mg/kg. Under both *in vivo* and *in vitro* conditions, several active metabolic intermediates (e.g. dichlorocarbonyl, dichloromethyl radicals) were produced via oxidation or reduction by microsomal preparations. Experimental studies suggested that these active metabolic intermediates may be responsible for hepatic and renal toxicity and possibly, carcinogenicity of the parent compound. Animal studies suggest that the extent of BDCM metabolism varies with species and sex. The retention of BDCM in organs after dosing was small, even after repeated doses. Urinary excretion levels were below 3 percent.

Mammalian bioeffects following exposure to BDCM include effects on the central nervous system (decreased operant response), hepatotoxicity, nephrotoxicity, reproductive toxicity, and carcinogenicity. In experimental mice and rats, BDCM caused changes in kidney, liver, serum enzyme levels, and decreased body weight. These responses were discernible in rodents from exposure to levels of BDCM that ranged from 6 to 300 mg/kg; the intensity of response was dependent upon the dose and the duration of the exposure. Ataxia and sedation were observed in mice receiving a single dose of 500 mg/kg BDCM.

One study investigated developmental and reproductive toxicity of BDCM in rodents. Ruddick et al. (1983) administered BDCM in corn oil to groups of pregnant rats by gavage at doses of 0, 50, 100 or 200 mg/kg/day on

days 6 to 15 of gestation. At 200 mg/kg/day, BDCM significantly ($p < 0.05$) decreased maternal weight (25%) and increased relative kidney weights. There were no increases in the incidence of fetotoxicity or external/visceral malformations, but sternebral anomalies were more prevalent at 100 and 200 mg/kg than at 50 mg/kg. The sternebral anomalies were not considered by the authors to be evidence of a teratogenic effect, but rather evidence of maternal toxicity.

Data from a National Toxicology Program (NTP) chronic oral study in $B6C3F_1$ mice (NTP, 1987) was used to calculate the RfD. BDCM in corn oil was given to mice by gavage 5 days/week for 102 weeks. Male mice (50/dose) were administered doses of 0, 25 or 50 mg/kg/day while female mice (50/dose) received doses of 0, 75 or 150 mg/kg/day. Following treatment, mortality, body weight and histopathology were observed. Renal cytomegaly and fatty metamorphosis of the liver was observed in male mice ≥25 mg/kg/day). Compound-related follicular cell hyperplasia of the thyroid gland was observed in both males and females. The survival rate decreased in females and decreases in mean body weights were observed in both males and females at high doses. Based on the observed renal, liver and thyroid effects in male mice, a LOAEL of 25 mg/kg/day was identified. A RfD of 0.02 mg/kg/day has been derived from the LOAEL of 25 mg/kg/day in mice by the application of an uncertainty factor of 1,000, in accordance with EPA guidelines for use of a LOAEL derived from a chronic animal study.

In vitro genotoxicity studies reported mixed results in bacterial *Salmonella* strains and yeasts. BDCM was not mutagenic in mouse lymphoma cells without metabolic activation, but induced mutation with activation. An increase in frequency of sister chromatid exchange was reported in cultured human lymphocytes, rat liver cells, and mouse bone marrow cells (*in vivo*), but not in Chinese hamster ovary cells. Overall, more studies yielded positive results and evidence of mutagenicity for BDCM is considered adequate.

Evidence of the carcinogenicity of BDCM has been confirmed by a NTP (1987) chronic animal study. In this study BDCM in corn oil was administered via gavage to groups of 50 rats (Fischer 344/N) of each sex at doses of 0, 50 or 100 mg/kg, 5 days/week, for 102 weeks (NTP, 1987). Male $B6C3F_1$ mice (50/dose) were administered 0, 25 or 50 mg/kg by the same route while females received 0, 75 or 150 mg/kg/day. BDCM caused statistically significant increases in kidney tumors in male mice, the liver in female mice, and the kidney and large intestine in male and female rats. In male mice, the combined incidence of tubular cell adenomas or adenocarcinomas of the kidneys increased significantly in the high-dose group (vehicle control, 1/46; low-dose, 2/49; high-dose 9/50). The combined incidences of hepatocellular adenomas or carcinomas in vehicle control, low-dose and high-dose female mice groups were 3/50, 18/48 and 29/50, respectively.

In rats from the NTP study, the combined incidences of tubular cell adenomas or adenocarcinomas in vehicle control, low-dose and high-dose groups were 0/50, 1/49 and 13/50 for males and 0/50, 1/50 and 15/50 for females, respectively. Tumors of large intestines were significantly increased in a dose-dependent manner in male rats, and only observed in high-dose female rats. The combined incidences of adenocarcinomas or adenomatous polyps were 0/50, 13/49, 45/50 for males and 0/46, 0/50, 12/47 for females, respectively. The combined tumor incidences of large intestine and kidney were 0/50, 13/49, 46/50 for male rats and 0/46, 1/50, 24/48 for female rats, respectively.

Using the linearized multistage model, several cancer potency factors for BDCM were derived based on the observed cancer incidence of various tumor types (large intestine, kidney, or combined) in mice or rats reported in the NTP bioassay. The resulting cancer potency factors are in the range of 4.9×10^{-3} to 6.2×10^{-2} $(mg/kg/day)^{-1}$. A potency factor of 1.3×10^{-1} $(mg/kg/day)^{-1}$ was derived from the incidence of hepatic tumors in female mice (IRIS, 1990). However, hepatic tumor data should be interpreted with caution because studies of an analog chloroform indicated a possible role of the corn oil vehicle in induction of these tumors. Until future studies can provide a better understanding of the corn oil effect on hepatic carcinogenicity, EPA considers carcinogenic risk quantification for BDCM based on kidney or large intestine tumor data to be more appropriate. EPA is presently conducting a cancer bioassay with BDCM in drinking water for comparison with the NTP study. EPA will evaluate the results of this study when available to determine if changes to the risk assessment are warranted.

Following the Agency's Cancer Risk Assessment Guidelines (USEPA, 1986), when two or more significantly elevated tumor sites or types are observed in the same study, the slope factor of the greatest sensitivity preferably should be used for carcinogenic risk estimation. Based on the potency factor of 6.2×10^{-2} $(mg/kg/day)^{-1}$ derived from the kidney tumor incidence in male mice, the estimated concentrations of BDCM in drinking water associated with excess cancer risks of 10^{-4}, 10^{-5} and 10^{-6} are 60, 6 and 0.6 µg/L, respectively.

EPA has classified BDCM in Group B2, probable human carcinogen, based on sufficient evidence of carcinogenicity in animals and inadequate evidence in humans. The International Agency for Research on Cancer (IARC) has recently classified BDCM as a Group 2B carcinogen, agent probably carcinogenic to humans (IARC, 1991).

Following EPA's three-category approach for establishing MCLGs, BDCM is placed in Category I since there is sufficient evidence for carcinogenicity via ingestion considering weight of evidence, potency, pharmacokinetics, and exposure. Thus, EPA is proposing an MCLG of zero for this contaminant. EPA requests comments on the basis of the proposed MCLG for BDCM and the use of tumor data of large intestine and kidney, but not liver, in quantitative estimation of carcinogenic risk of BDCM from oral exposure.

7. Dibromochloromethane

Dibromochloromethane (DBCM; CAS No. 124–48–1) is a nonflammable, colorless liquid with a relatively high vapor pressure (76 mmHg at 20 °C). DBCM is moderately soluble in water (4 gm/l at 20 °C) and soluble in organic solvents (log octanol/water partition coefficient of 2.09). Currently DBCM is not produced commercially in the United States. The chemical has only limited uses as a laboratory agent. The principal source of DBCM in drinking water is the chemical interaction of chlorine with commonly present organic matter and bromide ions. Degradation of DBCM has not been well studied, but probably involves photooxidation. The estimated atmospheric half-life of DBCM is one to two months. Volatilization is the principle mechanism for removal of DBCM from rivers and streams (half-life of hours to weeks). Several studies reported that DBCM adsorbs poorly to soil and sediments. No experimental study was found regarding the bioconcentration of DBCM. Based on the data of a few structurally similar chemicals, the bioconcentration potential of DBCM in aquatic organisms is assumed to be low. Biodegradation of DBCM is limited under aerobic conditions and more extensive under anaerobic conditions.

Occurrence and Human Exposure. DBCM occurs in public water systems that chlorinate water containing humic and fulvic acids and bromine that can enter source waters through natural and anthropogenic means. Several water quality factors can affect the formation of DBCM, including Total Organic Carbon (TOC), pH, bromide, and temperature. Different treatment practices can reduce the formation of DBCM in drinking water. These include the use of precursor removal technologies such as coagulation/filtration, granular activated carbon (GAC), membrane filtration, and the use of chlorine dioxide, chloramination, and ozonation.

Table V–8 presents occurrence information available for DBCM in drinking water. Descriptions of these surveys and other data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," (USEPA, 1992a). The table lists six surveys conducted by Federal and private agencies. Median concentrations of DBCM in drinking water appear to range from 0.6 to 3.6 µg/L for surface water supplies and <0.5 µg/L for ground-water supplies. The lower bound median concentration for DBCM in surface water supplies is biased to the low side because concentrations in this survey were measured in the plant effluent; the formation of DBCM would be expected to increase in the distribution in systems using chlorine as their residual disinfectant.

TABLE V–8.—SUMMARY OF OCCURRENCE DATA FOR DIBROMOCHLOROMETHANE

Occurrence of dibromochloromethane in drinking water						
Survey (year)[1]	Location	Sample information (No. of samples)	Concentration (µg/L)			
			Range	Mean	Median	Other
CWSS (1978) Brass et al., 1981.	450 Systems	Finished Water (1,100):				Positive Detections:
		Surface Water		[3]5.0	1.5	67%[4]
		Ground Water		[3]6.6	<0.5	34%[4]
RWS (1978–1980) Brass, 1981	>600 Rural Systems (>2,000 households).	Drinking Water from:				Positive Detections:
		Surface Water		[3]8.5	0.8	[4]56%
		Ground Water		[3]9.9	<0.5	[4]13%
GWSS (1980–1981) Westrick et al. 1983.	945 GW Systems: (466 Random and 479 Nonrandom)	Serving >10,000 (327).	Max. 59.		0.7	90th Percentile: 9.2
		Serving <10,000 (618)	Max. 63		0	5.6
EPA, 1991[a2] (1984–1991)	Unregulated Contaminant Data Base—Treatment Facilities from 19 States.	Sampled at the Plant (4,439).		3.0	1.7	
EPA, 1992[b2] (1987–1989)	Disinfection By-Products Field Studies.	Finished Water:				Positive Detections:
		At the Plant (73)	<0.2–41.	4.9	2.0	92%
		In Distribution System (56)	<0.2–41	6.6	3.4	93%
EPA/AMWA/CDHS[2] (1988–1989) Krasner et al., 1989b.	35 Water Utilities Nationwide.	Samples from Clearwell Effluent for 4 Quarters.	Max. 63		3.6 2.6–4.5[5]	75% of Data was Below 9.1 µg/L

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.
[3] Mean of the positives.
[4] Of systems sampled.
[5] Range of medians for individual quarters.

AMWA: Association of Metropolitan Water Agencies.
CDHS: California Department of Health Services.
CWSS: Community Water Supply Survey.
GWSS: Ground Water Supply Survey.
RWS: Rural Water Survey.
EPA: Environmental Protection Agency.

No information is available concerning the occurrence of DBCM in food in the United States. The Food and Drug Administration (FDA) does not analyze for DBCM in foods. However, there are several uses of chlorine in food production, such as disinfection of chicken in poultry plants and the superchlorination of water at soda and beer bottling plants (Borum, 1991). Therefore, the possibility exists for dietary exposure from the by-products of chlorination in food products.

Based on information obtained through a literature review, Howard (1990) estimated the average daily intake of DBCM from air using an inhalation rate of 20m³/day. Assuming a range of 8.25 to 425 ng/m³ the exposure may be as low as 0.17 µg/day or as high as 8.5µg/day.

Although some uses of chlorine have been identified in the food production/food processing area, monitoring data are not available to adequately characterize the magnitude or frequency of potential exposure to DBCM

Additionally, preliminary discussions with FDA suggest that there are not approved uses for chlorine in most foods consumed in the typical diet. Based on the limited number of food groups that are believed to contain chlorinated chemicals and that there are not significant levels expected in ambient or indoor air, EPA assumes that drinking water is the predominant source of DBCM intake. Characterization of food and air exposure are issues currently under review. EPA, therefore, is proposing to regulate DBCM in drinking water with an RSC value at the ceiling level of 80 percent. EPA requests any additional data on known concentration of DBCM in drinking water, food, and air.

Health Effects. The health effects information in this section is summarized from the Drinking Water Health Criteria Document for Trihalomethanes (USEPA, 1994d). Studies mentioned in this section are summarized in the criteria document.

Studies indicated that gastrointestinal absorption of DBCM is high in animals. No studies were located regarding DBCM in humans or animals following inhalation or dermal exposure. Based on the physical-chemical properties of DBCM, and by analogy with the structurally-related halomethanes such as chloroform, it is expected that the inhalation and dermal absorption could be significant for DBCM.

The LD_{50} values in mice and rats range from 800 to 1,200 mg/kg. Under both *in vivo and in vitro* conditions, several active metabolic intermediates (e.g. dihalocarbonyl, bromochloromethyl radicals) can be produced via oxidation or reduction by microsomal preparations. Environmental studies suggest that these active metabolic intermediates are responsible for the hepatic and renal toxicity, and possibly carcinogenicity, of the parent compound. Animal studies suggest that the extent of DBCM metabolism varies with species and sex. The retention of DBCM in organs after dosing was small and relatively higher concentrations were found in stomach, liver and kidneys. Urinary excretion levels were below 2 percent.

Mammalian bioeffects following oral exposure to DBCM include effects on the central nervous system (decreased operant response), hepatotoxicity, nephrotoxicity, reproductive toxicity and possible carcinogenicity. In experimental mice and rats, DBCM caused changes in kidney, liver, and serum enzyme levels, and decreased body weight. These responses are discernible in mammals from exposure to levels of DBCM ranging from 39 to 250 mg/kg; the intensity of response was dependent upon the dose and the duration of the exposure. Ataxia and sedation were observed in mice receiving a single dose of 500 mg/kg DBCM.

Developmental and reproductive toxicity of DBCM was investigated in rodents. A multi-generation reproductive study of mice treated with)in drinking water showed maternal toxicity (weight loss, liver pathological changes) and fetal toxicity (decreased pup weight & viability). The study identified a NOAEL of 17 mg/kg/day and a LOAEL of 171 mg/kg/day.

The National Toxicology Program (NTP, 1985) evaluated the subchronic and chronic toxicity of DBCM in F344/N rats and $B6C3F_1$ mice. In this study corn oil is used as the gavage vehicle. The chronic data indicated that doses of 40 and 50 mg/kg/day produced histopathological lesions in the liver of rats and mice, respectively. However, the chronic studies did not identify a reliable NOAEL. The subchronic study identified both a LOAEL and a NOAEL for hepatotoxicity, and was used to calculate the RfD of 0.02 mg/kg/d.

In the NTP subchronic study, DBCM in corn oil was administered to Fischer 344/N rats and $B6C3F_1$ mice via gavage at dose levels of 0, 15, 30, 60, 125 or 250 mg/kg/day, 5 days a week for 13 weeks. Following treatment, survival, body weight, clinical signs, histopathology and gross pathology were evaluated. Final body weights of rats that received 250 mg/kg/day were depressed 47% for males and 25% for females. Kidney and liver toxicity was observed in male and female rats and male mice at 250 mg/kg/day. A dose-dependent increase in hepatic vacuolation was observed in male rats. Based on this hepatic effect, the NOAEL and LOAEL in rats were 30 and 60 mg/kg/day, respectively.

Several studies on the mutagenicity potential of DBCM have reported inconclusive results. Studies on the *in vitro* genotoxicity of DBCM reported mixed results in bacteria *Salmonella typhimurium* strains and yeasts. DBCM produced sister chromatid exchange uncultured human lymphocytes and Chinese hamster ovary cells (without activation). An increased frequency of sister chromatid exchange was observed in mouse bone marrow cells from mice dosed orally, but not via the intraperitoneal route.

The carcinogenicity of DBCM was reported in a NTP (1985) chronic animal study. In this study DBCM in corn oil was administered via gavage to groups of male and female F344/N rats at doses of 0, 40 or 80 mg/kg/day, 5 days/week for 104 weeks; and groups of male and female mice at 0, 50 or 100 mg/kg/day, 5 days/week for 105 weeks. Administration of DBCM showed a significant increase in the incidence of hepatocellular adenomas in high-dose female mice (vehicle control, 2/50; low dose, 4/49; high dose, 11/50) and combined incidence of hepatocellular adenomas or carcinomas (6/50, 10/49, 19/50). In high-dose male mice, administration of DBCM showed a significant increase in the incidence of hepatocellular carcinomas (10/50, -, 19/50); however, the combined incidence of hepatocellular adenomas or carcinomas was only marginally increased (23/50, -, 27/50). Administration of DBCM did not result in increased incidence of tumors in treated rats.

Using the linearized multistage model, EPA derived a cancer potency factor of 8.4×10^{-2} $(mg/kg/day)^{-1}$ (IRIS, 1990). The derivation was based on the tumor incidence of the hepatocellular adenomas or carcinomas in the female mice reported in the 1985 NTP study. Due to the possible role of the corn oil vehicle in induction of hepatic tumors as reported in studies on chloroform, some uncertainty exists regarding the relevance of this derived cancer potency factor to exposure via drinking water. However, the only tumor data currently available on DBCM are for liver tumors in mice. Until future studies can provide additional data, EPA considers this cancer potency factor valid for potential carcinogenic risk quantification for DBCM.

EPA has classified DBCM in Group C, possible human carcinogen, based on the limited evidence of carcinogenicity in animals (only in one species) and inadequate evidence of carcinogenicity in humans. The International Agency for Research on Cancer (IARC) has classified DBCM as a Group 3 carcinogen: agent not classifiable as to its carcinogenicity to humans.

Using EPA's three-category approach for establishing MCLG, DBCM is placed in Category II since there is limited evidence for carcinogenicity via drinking water considering weight of evidence, potency, pharmacokinetics, and exposure. As a Category II chemical, EPA proposes to follow the first option and set the MCLG for DBCM on noncarcinogenic endpoints (the RfD) with the application of an additional safety factor to account for possible carcinogenicity. An RfD of 0.02 mg/kg/day has been derived from the NOAEL of 30 mg/kg/d, adjusted for dosing 5 days per week and divided by an uncertainty factor of 1,000. This factor is appropriate for use of a NOAEL derived from a subchronic animal study

EPA is proposing an MCLG of 0.06 mg/L for DBCM based on liver toxicity and possible carcinogenicity. An additional safety factor of 10 for possible carcinogenicity is used to calculate the MCLG along with an assumed drinking water contribution of 80 percent of total exposure.

$$MCLG = \frac{30\ mg/kg/d \times 5/7 \times 70\ k \times 0.8}{1{,}000 \times 2\ L/d \times 10} = 0.06\ mg/l$$

EPA requests comments on the basis for the proposed MCLG for DBCM, the RSC of 80%, and the cancer classification for DBCM.

8. Bromoform

Bromoform (tribromomethane, CAS No. 75–25–2) is a nonflammable, colorless liquid with a sweet odor and a relatively high vapor pressure (5.6 mmHg at 25 °C). Bromoform is moderately soluble in water (3.2 gm/L at 30 °C) and soluble in organic solvents (log octanol/water partition coefficient of 2.38). Bromoform is not currently produced commercially in the United States. The chemical has only limited uses as a laboratory agent and as a fluid for mineral ore separation. The principle source of bromoform in drinking water is the chemical interaction of chlorine with commonly present organic matter and bromide ion. Degradation of bromoform is not well studied, but probably involves photooxidation. The estimated atmospheric half-life of bromoform is one to two months. Volatilization is the principle mechanism for removal of bromoform from rivers and streams (half-life of hours to weeks). Studies reported that bromoform adsorbs poorly to sediments and soils. No experimental studies were located regarding the bioconcentration of bromoform. Based on the data from a few structurally similar chemicals, the potential for bromoform to be bioconcentrated by aquatic organisms is low. Biodegradation of bromoform is limited under aerobic conditions but more extensive under anaerobic conditions.

Occurrence and Human Exposure. Bromoform occurs in public water systems that chlorinate water containing humic and fulvic acids and bromine that can enter source waters through natural and anthropogenic means. Several water quality factors affect the formation of bromoform including Total Organic Carbon (TOC), pH, and temperature. Different treatment practices can reduce the level of bromoform. These include the use of chloride dioxide, chloramination, and ozonation prior to chloramination.

Table V–9 presents occurrence information available for bromoform in drinking water. Descriptions of these surveys and other data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," (USEPA, 1992a). The table lists six surveys conducted by Federal and private agencies. Median concentrations of bromoform in drinking water appear to range from <0.2 to 0.57 µg/L for surface water supplies and <0.5 µg/L for ground- water supplies. The lower bound median concentration for bromoform in surface water supplies is biased to the low side because concentrations in this survey were measured in the plant effluent; the formation of bromoform would be expected to increase in the distribution in systems using chlorine as their residual disinfectant.

TABLE V–9.—SUMMARY OF OCCURRENCE DATA FOR BROMOFORM

Occurrence of bromoform in drinking water						
Survey (year)[1]	Location	Sample information (No. of samples)	Concentration (µg/L)			
			Range	Mean	Median	Other
CWSS (1978) Brass et al., 1981.	450 Systems	Finished Water (1,100):				Positive Detections:
		Surface Water		[3]2.1	<1.0	13%[4]
		Ground Water		[3]11	<0.5	26%[4]
RWS (1978–1980) Brass, 1981.	>600 Rural Systems (>2,000 Households).	Drinking Water from:				Positive Detections:
		Surface Water		[3]8.7	<0.5	18%[4]
		Ground Water		[3]12	<0.5	12%[4]
GWSS (1980–1981) Westrick et al. 1983.	945 GW Systems: (466 Random and 479 Nonrandom).					90th Percentile:
		Serving >10,000 (327).	Max. 68.		0	8.3
		Serving <10,000 (618)	Max. 110		0	4.1
EPA, 1991a[2] (1984–1991)	Unregulated Contaminant Data Base—Treatment Facilities from 19 States.	Sampled at the Plants (1,409).		2.5	1	
EPA, 1992b[2] (1987–1989)	Disinfection By-Products Field Studies.	Finished Water:				Positive Detections:
		At the Plant (73)	<0.2–6.7.	0.7	<0.2	45%
		In Distr. System (56)	<0.2–10	1.0	<0.2	48%

TABLE V–9.—SUMMARY OF OCCURRENCE DATA FOR BROMOFORM—Continued

Occurrence of bromoform in drinking water						
Survey (year)[1]	Location	Sample information (No. of samples)	Concentration (µg/L)			
			Range	Mean	Median	Other
EPA/AMWA/CDHS[2] (1988–1989) Krasner et. al., 1989b.	35 Water Utilities Nationwide.	Samples from Clearwell Effluent for 4 Quarters.	Max. 72	.....	0.33–0.88[5] 0.57	75% of Data was Below 2.8

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.
[3] Mean of the positives.
[4] Of systems sampled.
[5] Range of medians for individual quarters.

AMWA: Association of Metropolitan Water Agencies.
CDHS: California Department of Health Services.
CWSS: Community Water Supply Survey.
GWSS: Ground Water Supply Survey.
RWS: Rural Water Survey.
EPA: Environmental Protection Agency.

No information is available concerning the occurrence of bromoform in food in the United States. The Food and Drug Administration (FDA) does not analyze for bromoform in foods. However, there are several uses of chlorine in food production, such as disinfection of chicken in poultry plants and the superchlorination of water at soda and beer bottling plants (Borum, 1991). Therefore, the possibility exists for dietary exposure from the by-products of chlorination in food products.

Bromoform is usually found in ambient air at low concentrations. One study reported ambient air concentrations from several urban locations across the U.S. The overall mean concentration of positive samples was found to be 4.15 ng/m^3 and the maximum level was 71 ng/m^3 (Brodzinsky and Singh, 1983 in USEPA, 1991b). Although the data are limited for bromoform, an inhalation intake could be estimated using the mean and maximum values from the Brodzinsky and Singh (1983) study, indicating a possible range of 0.08 to 1.4 µg/d.

Based on the limited number of food groups that are believed to contain bromoform and that significant levels are not expected in ambient or indoor air, EPA is assuming that drinking water is the predominant source of bromoform intake. Characterization of food and air exposures are issues currently under review. The EPA requests any additional data on known concentrations of bromoform in drinking water, food, and air.

Health Effects. The health effects information in this section is summarized from the draft Drinking Water Health Criteria Document for Trihalomethanes (USEPA, 1994d) and the draft Drinking Water Health Advisory for Brominated Trihalomethanes (USEPA, 1991b). Studies mentioned in this section are summarized in the criteria document or health advisory.

Studies have indicated that gastrointestinal absorption of bromoform is high in humans and animals. No studies were located regarding bromoform in humans or animals following inhalation or dermal exposure. Based on the physical-chemical properties of bromoform, and by analogy with the structurally-related halomethanes such as chloroform, it is expected that both inhalation and dermal absorption could be significant for bromoform.

Bromoform was used as a sedative for children with whooping cough. Based on clinical observations of accidental overdose cases, the estimated lethal dose for a 10- to 20-kg child is about 300 mg/kg. The clinical signs in fatal cases were central nervous system (CNS) depression followed by respiratory failure.

The LD_{50} values in mice and rats have been reported in the range of 1,147–1550 mg/kg. Under both *in vivo* and *in vitro* conditions, several active metabolic intermediates (e.g., dibromocarbonyl, dibromomethyl radicals) are produced via oxidation or reduction by microsomal preparations. Experimental studies suggested that these active metabolic intermediates are responsible for hepatic and renal toxicity and possibly, carcinogenicity, of the parent compound. Animal studies suggest that the extent of bromoform metabolism varies with species and sex. The retention of bromoform in organs after dosing was small; relatively higher concentrations were found in tissues with higher lipophilic content. Urinary excretion levels were below 5 percent.

Mammalian bioeffects following exposure to bromoform include effects on the central nervous system (CNS), hepatotoxicity, nephrotoxicity, and carcinogenicity. Bromoform causes CNS depression in humans. The reported LOAEL which results in mild sedation in humans is 54 mg/kg. In experimental mice and rats, bromoform caused changes in kidney, liver, serum enzyme levels, decrease of body weight, and decreased operant response. These responses are discernible in mammals from exposure to levels of bromoform ranging from 50 to 250 mg/kg; the intensity of response was dependent upon the dose and the duration of the exposure. Ataxia and sedation were noted in mice receiving a single dose of 1,000 mg/kg bromoform or 600 mg/kg for 14 days.

Few studies have investigated developmental and reproductive toxicity of bromoform in rodents. A developmental study in rats showed no fetal variations in a group fed with 50 mg/kg/day. An increased incidence of minor anomalies was noted at doses of 100 and 200 mg/kg/day. No maternal toxicity in rats was observed. One detailed reproductive toxicity study reported no apparent effects on fertility and reproduction when male and female rats were administered bromoform via gavage in corn oil at doses up to 200 mg/kg/day.

EPA used subchronic data from an oral study (NTP, 1989) to calculate the RfD. In this study, bromoform was administered to rats in corn oil via gavage at dose levels of 0, 12, 25, 50, 100 or 200 mg/kg/day 5 days a week for 13 weeks. Based on the observation of hepatocellular vacuolization in treated male rats, a NOAEL of 25 mg/kg/day was established. An RfD of 0.02 mg/kg/day has been derived from this NOAEL

by the application of an uncertainty factor of 1,000, in accordance with EPA guidelines for use of a NOAEL from a subchronic study.

A number of studies investigated the mutagenicity potential of bromoform. Studies on the *in vitro* genotoxicity of bromoform reported mixed results in bacterial *Salmonella typhimurium* strains. Bromoform produced mutations in cultured mouse lymphoma cells and sister chromatid exchange in human lymphocytes. Under *in vivo* condition bromoform induced sister chromatid exchange, and chromosomal aberration and micronucleus in mouse bone marrow cells. Overall, most studies yielded positive results and evidence of mutagenicity for bromoform is considered adequate.

The National Toxicology Program (NTP, 1989) conducted a chronic animal study to investigate the carcinogenicity of bromoform. In this study bromoform was administered in corn oil via gavage to F344/N rats (50/sex/group) at doses of 0, 100 or 200 mg/kg/day, 5 days/week for 105 weeks. An evaluation of the study results showed that adenomatous polyps or adenocarcinoma (combined) of the large intestine (colon or rectum) were induced in three male rats (vehicle control, 0/50; low dose, 0/50; high dose, 3/50) and in nine female rats (0/50, 1/50, 8/50). The increase was considered to be significant since these tumors are rare in control animals. Neoplastic lesions in the large intestine in female rats reported in the NTP study were used to estimate the carcinogenic potency of bromoform. EPA derived a cancer potency factor of 7.9×10^{-3} (mg/kg/day)$^{-1}$ using the linearized multistage model (IRIS, 1990). Assuming a daily consumption of two liters of drinking water and an average human body weight of 70 kg, the 95% upper bound limit lifetime cancer risks of 10^{-6}, 10^{-5} and 10^{-4} are associated with concentrations of bromoform in drinking water of 4, 40 and 400 µg/L, respectively.

EPA classified bromoform in Group B2, probable human carcinogen, based on the sufficient evidence of carcinogenicity in animals and inadequate evidence of carcinogenicity in humans. The International Agency for Research on Cancer (IARC) has recently classified bromoform in Group 3: agent not classifiable as to its carcinogenicity to humans (IARC, 1991). IARC determined that there was limited evidence of carcinogenicity in animals, in contrast to EPA's judgment that there is sufficient evidence in laboratory animals. EPA requests comments on the different viewpoints between IARC and EPA regarding bromoform's carcinogenic potential.

Using EPA's three-category approach for establishing MCLG, bromoform is placed in Category I since there is sufficient evidence for carcinogenicity from drinking water considering weight of evidence, potency, pharmacokinetics, and exposure. Thus, EPA is proposing an MCLG of zero for this contaminant. EPA requests comments on the basis for the proposed MCLG for bromoform.

9. Dichloroacetic Acid

Chlorination of water containing organic material (humic, fulvic acids) results in the generation of many organic compounds, including dichloroacetic acid (DCA) (CAS. No. 79–43–6), a nonvolatile compound.

Though DCA is generally a concern due to its occurrence in chlorinated drinking water, it is also used as a chemical intermediate, and an ingredient in pharmaceuticals and medicine. Previously, DCA was used experimentally to treat diabetes and hypercholesterolemia in human patients. In addition, DCA was used as an agricultural fungicide and topical astringent. It has also been extensively investigated for potential therapeutic use as a hypoglycemic, hypolactemic and hypolipidemic agent.

Occurrence and Human Exposure. DCA has been found to occur as a disinfection by-product in public water systems that chlorinate water containing humic and fulvic acids.

Table V–10 presents occurrence information available for DCA in drinking water. Descriptions of these surveys and other data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," (USEPA, 1992a). Median concentrations of DCA in drinking water were found to range from 6.4 to 17 µg/L. The lower bound median concentration for DCA in surface water supplies is biased to the low side because concentrations in this survey were measured in the plant effluent; the formation of DCA would be expected to increase in the distribution system in systems using chlorine as their residual disinfectant.

TABLE V–10.—SUMMARY OF OCCURRENCE DATA FOR DICHLOROACETIC ACID

Occurence of dichloroacetic acid in drinking water						
Survey (year)[1]	Location	Sample information (No. of samples)	Concentration (µg/L)			
			Range	Mean	Median	Other
EPA, 1992b[2] (1987–1989).	Disinfection By-Products Field Studies.	Finished Water:		18	16	Positive Detections:
		At the Plant (72)	<0.4–61	21	17	93%
		In the Distr. System (56)	<0.4–75			96%
EPA/AMWA/CDHS[2] (1988–1989) Krasner et al., 1989b.	35 Water Utilities Nationwide.	Samples from Clearwell Effluent for 4 Quarters.	<0.6–46	.....	[3]5.0–7.3	75% of Data was Below 12 µg/L DL = 0.6 µg/L
					6.4	

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.
[3] Range of medians for individual quarters.

AMWA: Association of Metropolitan Water Agencies.
CDHS: California Department of Health Services.
EPA: Environmental Protection Agency.

Based on the above data, a range of exposure to DCA from drinking water can be calculated using a consumption rate of 2 liters per day. The expected median exposure from drinking water would range from 13 to 34 µg/day, using these data sets.

No information is available concerning the occurrence of DCA in food and ambient or indoor air in the United States. The Food and Drug Administration (FDA) does not analyze for DCA in foods. However, there are several uses of chlorine in food production such as the disinfection of

chicken in poultry plants and the superchlorination of water at soda and beer bottling plants. Therefore, the possibility exists for dietary exposure from the by-products of chlorination in food products. However, monitoring data are not available to characterize adequately the magnitude or frequency of potential DCA exposure from diet. Additionally, preliminary discussions with FDA suggest that there are not approved uses for chlorine in most foods consumed in the typical diet. Similarly, EPA's Office of Air and Radiation is not currently sampling for DCA in air (Borum, 1991). Little exposure to DCA from air is expected since DCA is nonvolatile.

Since only a limited number of food groups are expected to contain chlorinated chemicals and no significant DCA levels are expected in ambient or indoor air, EPA believes that drinking water is the predominant source of DCA intake. Characterization of the potential exposures from food and air are issues currently under review. EPA requests any additional data on known concentrations of DCA in drinking water, food, and air.

Health Effects. The health effects information in this section is summarized from the draft Drinking Water Health Criteria Document for Chlorinated Acetic Acids, Alcohols, Aldehydes and Ketones (USEPA, 1994e). Studies mentioned in this section are summarized in the criteria document.

Humans treated with DCA for 6 to 7 days at 43 to 57 mg/kg/day have experienced mild sedation, reduced blood glucose, reduced plasma lactate, reduced plasma cholesterol levels, and reduced triglyceride levels. At the same time, the DCA treatment depressed uric acid excretion, resulting in elevated serum uric acid levels.

A longer term study in two young men receiving 50 mg/kg for 5 weeks up to 16 weeks, indicated that DCA significantly reduces serum cholesterol levels and blood glucose, and causes peripheral neuropathy in the facial, finger, leg and foot muscles.

Estimates of acute oral LD_{50} values range from 2,800 to 4,500 mg/kg in rats and up to 5,500 mg/kg in mice. Short-term studies in dogs and rats indicate an effect on intermediary metabolism, as demonstrated by decreases in blood lactate and pyruvate. Exposures to DCA up to 3 months in dogs and rats result in a variety of adverse effects including effects to the neurological and reproductive systems. These effects are seen above 100 mg/kg/day in dogs and rats.

Studies on the toxicokinetics of DCA indicate that absorption is rapid and that DCA is quickly distributed to the liver and muscles in the rat. DCA is metabolized to glyoxylate which in turn is metabolized to oxalate. Although there are few studies regarding the excretion of DCA, studies in which rats, dogs and humans received intravenous injections of DCA indicated that the half-life of DCA in human blood plasma is much shorter than in rats or dogs. Urinary excretion of DCA was negligible after 8 hours. Total excretion of DCA was less than 1% of total dose.

A drinking water study by Bull et al. (1990) reported a dose-related increase in hepatic effects in mice that received DCA at 270 mg/kg/day for 37 weeks and at 300 mg/kg/day for 52 weeks. Adverse effects included enlarged livers, marked cytomegaly with massive accumulation of glycogen in hepatocyte and focal necrosis. The NOAEL for this study was 137 mg/kg/day for 52 weeks.

DeAngelo et al. (1991) conducted a drinking water study in which mice received DCA at levels of 7.6, 77, 410, and 486 mg/kg/day for 60 or 75 weeks. While this study was intended as an assessment of carcinogenicity, other systemic effects were measured. This study concluded that levels at 77 mg/kg/day and above caused an extreme increase of relative liver weights and a significant increase in neoplasia at levels of 410 mg/kg/day and above. This study indicates a NOAEL of 7.6 mg/kg/day for noncancer liver effects.

Based on the available data, DCA does not appear to be a potent mutagen. Studies in bacteria have indicated that DCA did not induce mutation or activate repair activity. Two studies have shown some potential for mutagenicity but these results have not been reproducible.

DCA appears to induce both reproductive and developmental toxicity. Damage and atrophy to sexual organs has been reported in male rats and dogs exposed to levels from 50 mg/kg/day to 2000 mg/kg/day for up 3 months. Malformation of the cardiovascular system has been observed in rats exposed to 140 mg/kg/day DCA from day 6 to 16 of pregnancy.

A 90-day dog study was selected to determine the RfD for DCA (Cicmanec et al., 1991). In this study, four month old beagle dogs (5/sex/group) were administered gelatin capsules containing 0, 12.5, 39.5, or 72 mg/kg DCA/day for 90 days. Dogs were observed for clinical signs of toxicity; blood samples were collected for hematology and serum chemistry analysis. Clinical signs included diarrhea and dyspnea in the mid and high dose groups. Dyspnea was evident at 45 days and became more severe with continued exposure leading to general depression and decreased activity by day 90. Hindlimb paralysis was observed in 3 dogs in the high dose group. Other effects included conjunctivitis, weight loss, reduced food and water consumption, pneumonia, decreased liver weights, and elevated kidney weights in the dosed animals. Histopathology revealed toxic effects in liver, testis, and brain of the treated dogs. A NOAEL was not identified in this study. The lowest dose tested, 12.5 mg/kg/d, was considered a LOAEL. An uncertainty factor of 3,000 was applied in accordance with EPA guidelines to account for use of a LOAEL from a less-than-lifetime animal study in which frank effects were noted as the critical effect. The resulting RfD is 0.004 mg/kg/d.

Several studies indicate that DCA is a carcinogen in both mice and rats exposed via drinking water lifetime studies. These studies indicate that DCA induces liver tumors. In one study with male $B6F3F_1$ mice, exposure to DCA at 0.5 g/L and 3.5 g/L for 104 weeks resulted in tumor formation in exposed animals at 75% (18/24) and 100% (24/24) respectively. In female mice exposed for 104 weeks to DCA at the same levels, tumor prevalence was 20% and 100%, respectively. In male rats exposed to 0.05, 0.5 or 5 g/L DCA for 104 weeks, tumor prevalence increased to 22% in the highest dose. No tumors were seen at the lower doses. However, at 0.5 g/L, there was an increase in the prevalence of proliferation of liver lesions. Some of these lesions are likely to progress into malignant tumors.

EPA has classified DCA in Group B2: probable human carcinogen, based on positive carcinogenic findings in two animal species exposed to DCA in drinking water. A quantitative risk estimate has not yet been determined for DCA.

Following a Category I approach, EPA is proposing an MCLG for DCA of zero based on the strong evidence of carcinogenicity via drinking water. EPA requests comments on the basis for the proposed MCLG for DCA in drinking water and the cancer classification of Group B2.

10. Trichloroacetic Acid.

Trichloroacetic acid (TCA; CAS No. 76–03–9) is also a major by-product of chlorinated drinking water. Chlorination of source waters containing organic materials (humic, fulvic acids) results in the generation of organic compounds such as TCA.

TCA is also sold as a pre-emergence herbicide. It is used in the laboratory to precipitate proteins and as a reagent for synthetic medicinal products. It is applied medically as a peeling agent for damaged skin, cervical dysplasia and removal of tatoos.

Occurrence and Human Exposure. TCA occurs in public water systems that chlorinate water containing humic and fulvic acids.

Table V–11 presents the most recent and comprehensive occurrence information available for TCA in drinking water. Descriptions of these surveys and other data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," (USEPA, 1992a). Median concentrations of TCA acid in drinking water were found to range from 5.5 to 15 µg/L. The lower bound median concentration for TCA in surface water supplies is biased to the low side because concentrations in this survey were measured in the plant effluent; the formation of TCA would be expected to increase in the distribution system in systems using chlorine as their residual disinfectant. Based on the available data sets, and assuming a drinking water consumption rate of 2 L/day, median exposures from drinking water would range from 11 to 30 µg/day.

TABLE V–11.—SUMMARY OF OCCURRENCE DATA FOR TRICHLOROACETIC ACID

Occurrence of trichloroacetic acid in drinking water						
Survey (year) [1]	Location	Sample information (No. of samples)	Concentration (µg/L)			
			Range	Mean	Median	Other
EPA, 1992b [2] (1987–1989).	Disinfection By-Products Field Studies.	Finished Water:				Positive Detections:
		At the Plant (72)	<0.4–54	13	11	90%
		Distribution System (56)	<0.4–77	15	15	91%
EPA/AMWA/CDHS [2] (1988–1989) Krasner et al., 1989b.	35 Water Utilities Nationwide.	Samples from Clearwell Effluent for 4 Quarters.			4.0–5.8 [3] 5.5	75% of Data was Below 15.3 µg/L DL = 0.6

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.
[3] Range of medians for individual quarters.

AMWA: Association of Metropolitan Water Agencies.
CDHS: California Department of Health Services.
EPA: Environmental Protection Agency.

No information is available concerning the occurrence of TCA in food and ambient or indoor air in the United States. The Food and Drug Administration (FDA) does not analyze for TCA in foods. However, there are several uses of chlorine in food production, such as the disinfection of chicken in poultry plants and the superchlorination of water at soda and beer bottling plants. Therefore, the possibility exists for dietary exposure from the by-products of chlorination in food products. Also, TCA has limited use as a herbicide. However, monitoring data are not available to characterize adequately the magnitude or frequency of potential TCA exposure from diet. Similarly, EPA's Office of Air and Radiation is not currently measuring for TCA in air (Borum, 1991). The exposure from air for TCA is probably not a large source since TCA is nonvolatile.

Since only a limited number of food groups are expected to contain chlorinated chemicals and no significant TCA levels are expected in ambient or indoor air, EPA assumes that drinking water is the predominant source of TCA intake. Characterization of potential exposures from food and air are issues currently under review. EPA is, therefore, proposing to regulate TCA in drinking water with a relative source contribution (RSC) value at the ceiling level of 80 percent. EPA requests any additional data on known concentrations of TCA in drinking water, food, and air.

Health Effects. The health effects information in this section is summarized from the Drinking Water Health Criteria Document for Chlorinated Acetic Acids, Alcohols, Aldehydes and Ketones (USEPA, 1994e). Studies mentioned in this section are summarized in the criteria document.

Estimates of acute and LD_{50} values for TCA range from 3.3 to 5 g/kg in rats to 4.97 g/kg in mice. Short-term studies, up to 30 days, in rats demonstrate few effects other than decreased weight gain after administration of 240–312 mg/kg/day.

Few studies on toxicokinetics of TCA were located; however, a human study and a dog study show TCA to respond pharmacokinetically similarly to DCA. The response indicates a rapid absorption, distribution to the liver and excretion primarily through the urine. The two studies indicate that TCA is readily absorbed from all sections of the intestine and that the urinary bladder may be significant in the absorption of TCA. TCA is also a major metabolite of trichloroethylene.

Longer-term studies in animals indicate that TCA affects the liver, kidney and spleen by altering weights, focal hepatocellular enlargement, intracellular swelling, glycogen accumulation, focal necrosis, an accumulation of lipofuscin, and ultimately tumor generation in mice.

In a study by Mather et al. (1990), male rats received TCA in their drinking water at 0, 4.1, 36.5 or 355 mg/kg/day. The high dose resulted in spleen weight reduction and increased relative liver and kidney weights. Hepatic peroxisomal B-oxidation activity was increased. Liver effects at the high dose included focal hepatocellular enlargement, intracellular swelling and glycogen accumulation. The NOAEL for this study was 36.5 mg/kg/day.

Parnell et al. (1988) exposed male rats to TCA in their drinking water at 2.89, 29.6 or 277 mg/kg/day for up to one year. No significant changes were detected in body weight, organ weight or histopathology over the study duration. This study identified a NOAEL as the highest dose tested, 277 mg/kg/day.

Bull et al. (1990) investigated the effects of TCA on liver lesions and tumor induction in male and female B6C3F$_1$ mice. Mice received TCA in their drinking water at 0, 1 or 2 g/L (164 or 329 mg/kg/day) for 37 or 52 weeks. Dose-related increases in relative and absolute liver weights were seen in

females and males exposed to 1 and 2 g/L for 52 weeks. Small increases in liver cell size, accumulation of lipofuscin and focal necrosis were also seen. A LOAEL of 164 mg/kg/day (1 g/L) was identified.

Several studies show that TCA can produce developmental malformations in fetal Long Evans rats, particularly in the cardiovascular system. Teratogenic effects were observed at the lowest dose tested, 330 mg/kg/day.

With regard to mutagenicity tests, TCA was negative in Ames mutagenicity tests using *Salmonella* strain TA100, but was positive for bone marrow chromosomal aberrations and sperm abnormalities in mice. It also induced single-strand DNA breaks in rats and mice exposed by gavage.

TCA has induced hepatocellular carcinomas in two tests with B6C3F$_1$ mice, one of 52 weeks and another of 104 weeks. In the Bull et al. (1990) study, a dose-related increase in the incidence of hepatoproliferative lesions was observed in male B6C3F$_1$ mice exposed to 1 or 2 g/L for 52 weeks. An increase in hepatocellular carcinomas was observed in males at both dose levels. Carcinomas were not found in females.

DeAngelo et al. (1991) administered mice and rats with TCA over their lifetime. Male and female B6C3F$_1$ mice were exposed to 4.5 g/L TCA for 104 weeks. Male mice at 4.5 g/L TCA had a tumor prevalence of 86.7%. Female mice appeared to be less sensitive to TCA than males: 60% prevalence over a 104-week exposure to 4.5 g/L. At 104 weeks, 0.5 g/L TCA did not result in a significant increase in tumors. In a preliminary study of 60 weeks exposure to 0.05, 0.5 and 5 g/L, no significant additional increase in tumors was seen at 0.05 g/L, but tumor prevalence was 37.9% and 55.2% at 0.5 and 5 g/L, respectively.

F344 male rats administered TCA over a lifetime at 0.05 to 5 g/L did not produce a significant increase in carcinogenicity.

EPA has placed TCA in Group C: possible human carcinogen. Group C is for those chemicals which show limited evidence of carcinogenicity in animals in the absence of human data.

EPA is following a Category II approach for setting an MCLG for TCA.. The developmental toxicity study by Smith et al. (1989) has been selected to serve as the basis for the RfD and MCLG. In this developmental study, pregnant Long-Evans rats (20/dose) were administered TCA at doses of 0, 330, 800, 1,200, or 1,800 mg/kg/d by gavage during gestation days 6–15. Maternal body weight was significantly reduced at doses of 800 mg/kg/d and above. Maternal spleen and kidney weights were increased significantly in a dose-dependent manner. Postimplantation loss was noted in the three highest dose groups with a significant decrease in the number of live fetuses per litter observed in the two highest dose groups. Other fetal effects included decreased fetal weight and crown-rump length, and malformations of the cardiovascular system, particularly the heart. The lowest dose tested, 330 mg/kg/d, was identified as a LOAEL. A NOAEL was not identified from this study.

An RfD of 0.1 mg/kg/day was derived using the LOAEL of 330 mg/kg/d and an uncertainty factor of 3,000 to account for use of a LOAEL and lack of a 2 generation reproductive study. Adjusting the RfD for a 70 kg adult drinking 2 L water per day, possible carcinogenicity and an RSC of 80%, an MCLG of 0.3 mg/L can be determined.

$$\text{MCLG} = \frac{(330\ \text{mg/kg/d}) \times 70\ \text{kg} \times 0.8}{3{,}000 \times 2\ \text{L/d} \times 10} = 0.3\ \text{mg/L}^{*}\ (\text{rounded})$$

EPA requests comments on the basis for the MCLG and the cancer classification for TCA.

11. Chloral Hydrate

Chlorination of water containing organic materials (humic, fulvic acids) results in the generation of organic compounds such as trichloroacetaldehyde monohydrate or chloral hydrate (CH) (CAS No. 302–17–0).

CH is used as a hypnotic or sedative drug (i.e., knockout drops) in humans, including neonates. CH is also used in the manufacture of DDT.

Occurrence and Human Exposure. CH has been found to occur as a disinfection by-product in public water systems that chlorinate water containing humic and fulvic acids.

Table V–12 presents occurrence information available for chloral hydrate in drinking water. Descriptions of these surveys and other data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," (USEPA, 1992a). Median concentrations of chloral hydrate in drinking water were found to range from 2.1 to 4.4 µg/L.

TABLE V–12.—SUMMARY OF OCCURRENCE DATA FOR CHLORAL HYDRATE

Occurrence of chloral hydrate in drinking water						
Survey (Year)[1]	Location	Sample information (No. of samples)	Concentration (µg/L)			
			Range	Mean	Median	Other
EPA, 1992b[2] (1987–1989).	Disinfection By-Products Field Studies.	Finished Water:	<0.2–25	5.0	2.5	Positive Detections:
		At the Plant (67)	<0.2–30	7.8	4.4	90%
		Distribution System ..... (53)				91%
EPA/AMWA/CDHS[2] (1988–1989) Krasner et al., 1989b.	35 Water Utilities Nationwide.	Samples from Clearwell Effluent for 4 Quarters.	Max. 22	.....	[3]1.7–3.0 2.1	75% of Data was below 4.1 µg/L[4]

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.
[3] Range of medians for individual quarters.
[4] Detection limit was 0.02 µg/L in the first quarter and 0.1 µg/L thereafter.

AMWA: Association of Metropolitan Water Agencies.

CDHS: California Department of Health Services.
EPA: Environmental Protection Agency.

Based on the available data sets, median exposures from CH due to drinking water would range from 3.4 to 8.8 µg/day, based on the consumption of 2 liters per day.

No information is available concerning the occurrence of CH in food and ambient or indoor air in the United States. The Food and Drug Administration (FDA) does not analyze for CH in foods since the analytical methods for such an evaluation have not been developed (Borum, 1991).

CH has been used as a sedative of hypnotic drug (see Health Effects Section). There are several uses of chlorine in food production, such as the disinfection of chicken in poultry plants and the superchlorination of water at soda and beer bottling plants. Therefore, the possibility exists for dietary exposure from the by-products of chlorination in food products. However, monitoring data are not available to adequately characterize the magnitude or frequency of potential CH exposure from the diet. Similarly, EPA's Office of Air and Radiation is not currently measuring for CH in air (Borum, 1991). However, CH from indoor air may contribute to exposure due to the volatilization from tap water.

Since only a limited number of food groups are expected to contain chlorinated chemicals and no significant levels are expected in ambient or indoor air, EPA believes that drinking water is the predominant source of CH intake. Characterization of potential food and air exposures are issues currently under review. EPA is therefore, proposing to regulate CH in drinking water with an RSC value at the ceiling level of 80 percent. EPA requests any additional data on known concentrations of CH in drinking water, food, and air.

Health Effects. The health effects information in this section is summarized from the draft Drinking Water Health Criteria Document for Chlorinated Acetic Acids, Alcohols, Aldehydes and Ketones (USEPA, 1994e). Studies mentioned in this section are summarized in the criteria document.

In its use as a sedative or hypnotic drug in humans, a history of adverse effects related to CH exposure have been recorded. The acute and toxic dose to humans is about 10 g (or 140 mg/kg), causing severe respiratory depression and hypertension. Adverse reactions such as central nervous system depression and gastrointestinal disturbances are seen between 0.5 and 1.0 g CH. Cardiac arrhythmias are seen when patients receive levels between 10 and 20 g (167–333 mg/kg). Chronic use of CH may result in development of tolerance, physical dependence, and addiction.

Estimates of acute oral LD_{50}s in mice range from 1,265 to 1,400 mg/kg with central nervous system depression and inhibition of respiration being the cause of death. Rats may be more sensitive than mice with acute oral LD_{50} values ranging from 285 mg/kg in newborn to 500 mg/kg in adults.

Short-term studies in mice indicate that the liver is the target of CH toxicity with changes in liver weight as the primary effect. NOAELs vary between 14 and 144 mg/kg/day.

Toxicokinetic studies of CH indicate that absorption is rapid and complete in dogs and humans. CH is metabolized to trichloroacetic acid (TCA) and trichloroethanol. CH is rapidly excreted primarily through the urine as trichloroethanol glucuronide and more slowly as TCA.

Three 90-day studies in mice were considered by EPA to derive the MCLG for CH. Each used the same dose levels (16 or 160 mg/kg/day) in mice. The first study (Kallman et al., 1984) exposed groups of 12 male mice to drinking water containing CH at concentrations of 70 and 700 mg/L for 90 days. These concentrations correspond to doses of 15.7 and 160 mg/kg/day. No treatment-related effects were observed for mortality, body weight, physical appearance, behavior, locomotor activity, learning in repetitive tests of coordination, response to painful stimuli, strength, endurance or passive avoidance learning. Both doses resulted in a decrease of about 1° in mean body temperature ($p < 0.05$). The biological significance of this hypothermic effect is uncertain.

In the second study, Sanders et al. (1982) supplied groups of 32 male and female CD–1 mice with CH in deionized drinking water (70 or 700 mg/L, corresponding to time-weighted average doses of approximately 16 mg/kg/day or 160 mg/kg/day, respectively). After 90 days, the liver appeared to be the tissue most affected. Males appeared to be more sensitive than females. In males, there was a dose-related hepatomegaly and microsome proliferation, accompanied by small changes in serum chemistry values for potassium, cholesterol, and glutathione. Females did not show hepatomegaly, but did display changed hepatic microsomal parameters. Based on hepatomegaly, this study identifies a LOAEL of 16 mg/kg/day for CH (the lowest dose tested).

In the third study, Kauffman et al. (1982) studied the effect of CH on the immune system. Groups of 13 to 18 male and female CD–1 mice were supplied with water containing 70 or 700 mg/L (corresponding to time-weighted average doses of approximately 16 or 160 mg/kg/day, respectively) for 90 days. In males, no effects were detected in either humoral or cell-mediated immunity at either dose level. In females, exposure to the high dose (160 mg/kg/day) resulted in decreased humoral immune function ($p < 0.05$), but no effects on cell-mediated immunity were noted. Based on this study, a NOAEL of 16 mg/kg/day and a LOAEL of 160 mg/kg/day were identified.

CH is weakly mutagenic in *Salmonella*, yeast and molds. It has also caused chromosomal aberration in yeast and nondisjunction of chromosomes during spermatogenesis.

One study has observed neurobehavioral effects on mice pups from female mice receiving CH at 205 mg/kg/day for three weeks prior to breeding. Exposure of females continued until pups were weaned at 21 days of age. Pups from the high dose group (205 mg/kg/day) showed impaired retention in passive avoidance learning tasks. This result can be construed as a developmental effect of CH.

Two studies on the carcinogenicity of CH indicate that CH produces mouse liver tumors. In the earlier study, Rijhsinghani et al. (1986), $B6C3F_1$ mice given a single oral dose of CH at 5 or 10 mg/kg developed a significant increase in liver tumors after 92 weeks.

In a later study, Daniel et al. (1992), reported that male mice, receiving 166 mg/kg/day CH for 104 weeks, showed a total liver tumor prevalence of 71 percent (17/24). Proliferative liver lesions recognized and tabulated in this study included hyperplastic nodules, hepatocellular adenomas and hepatocellular carcinomas. No other studies were located on the carcinogenicity of CH in other test species.

Based on the limited evidence of carcinogenicity in these two studies and the extensive mutagenicity of CH, EPA has classified CH in Group C: possible human carcinogen. The concentrations associated with a 10^{-4}, 10^{-5}, and 10^{-6}

excess cancer risk are 40 µg/L, 4 µg/L and 0.4 µg/L, respectively.

EPA is placing CH in Category II for setting an MCLG based on liver toxicity and limited evidence of carcinogenicity from drinking water. EPA believes the 90-day study by Sanders et al. (1982) is most appropriate to calculate the RfD and MCLG for CH because the liver effects observed in this study (i.e., change to hepatic microsomal parameters and hepatomegaly) appear to be more severe than the other studies have indicated at similar dose levels. From the mouse LOAEL of 16 mg/kg/day and an uncertainty factor of 10,000 for use of a LOAEL from a less than lifetime animal study, an MCLG of 0.04 mg/L is derived.

$$MCLG = \frac{(16\ mg/kg/d) \times 70\ kg \times 0.8}{10{,}000 \times 2\ l/day \times 1} = 0.04\ mg/L\ (rounded)$$

EPA is proposing to use an extra safety factor of 1 instead of 10 to account for possible carcinogenicity since an uncertainty factor of 10,000 has already been applied to the RfD. In addition, the proposed MCLG equals the 10^{-4} excess cancer risk. EPA requests comment on the Category II approach for setting an MCLG, the extra safety factor of 1 instead of 10 for a Category II contaminant, and whether the endpoint of liver weight increase and hepatomegaly is a LOAEL or NOAEL given the lack of histopathology.

12. Bromate

Bromate (CAS #7789–38–0 as sodium salt) is a white crystal that is very soluble in water. Bromate may be formed by the reaction of bromine with sodium carbonate. Sodium bromate can be used with sodium bromide to extract gold from gold ores. Bromate is also used to clean boilers and in the oxidation of sulfur and vat dyes. It is formed in water following disinfection via ozonation of water containing bromide ion. In laboratory studies, the rate and extent of bromate formation depends on the ozone concentration used in disinfection, pH and contact time.

Occurrence and Human Exposure. Bromide and organobromine compounds occur in raw waters from both natural and anthropogenic sources. Bromide can be oxidized to bromate or hypobromous acid; however, in the presence of excess ozone, bromate is the principal product.

Table V–13 presents occurrence information available for bromate in drinking water. Descriptions of this data are detailed in "Occurrence Assessment for Disinfectants and Disinfection By-Products (Phase 6a) in Public Drinking Water," (USEPA, 1992a__). Significant bromate concentrations may occur in ozonated water with bromide. More recent occurrence data on bromate and the influence of bromide concentration and ozone on bromate formation is discussed in Section VI of this preamble.

TABLE V–13.—SUMMARY OF OCCURRENCE DATA FOR BROMATE

Occurrence of bromate in drinking water						
Survey (year)[1]	Location	Sample information (No. of samples)	Concentration (µg/L)			
			Range	Mean	Median	Other
McGuire et al., 1990[2]	MWD Pilot Plant Studies.	Ozonation: Hydrogen Peroxide/Ozone.	Max. 60 Max. 90			
EPA, 1992b[2] (1987–1991).	Disinfection By-Products Field Studies.	Finished Water, Plants Not Using Ozone (33).	<10	.....	.....	Detection Limit of 5 µg/L

[1] Dates indicate period of sample collection.
[2] May not be representative of national occurrence.
EPA: Environmental Protection Agency.

Although bromate is used as a maturing agent in malted beverages, as a dough conditioner, and in confectionery products (Borum, 1991), monitoring data are not available to adequately characterize the magnitude or frequency of potential bromate exposure from the diet. Currently, the Food and Drug Administration does not have available data for bromate in foods, as bromate is not a part of their Total Diet Study program. Similarly, EPA's Office of Air and Radiation is not currently measuring for bromate in air (Borum 1991).

Since only a limited number of food groups are expected to contain bromate and no significant bromate levels are expected in ambient or indoor air, EPA believes that drinking water is the predominant source of intake for bromate, and contributions from air and food would be small. Characterization of potential exposures from food and air are issues currently under review. EPA requests any additional data on known concentrations of bromate in drinking water, food, and air.

Health Effects. The health effects information in this section is summarized from the Drinking Water Health Quantification of Toxicological Effects Document for Bromate (USEPA, 1993b). Studies mentioned in this section are summarized in the criteria document.

The noncancer effects of ingested bromate have not been well studied. Bromate is rapidly absorbed, in part unchanged, from the gastrointestinal tract following ingestion. It is distributed throughout the body, appearing in plasma and urine as bromate and in other tissues as bromide. Following exposure to bromate, bromide concentrations were significantly increased in kidney, pancreas, stomach, small intestine, red blood cells and plasma. Bromate is reduced in tissues probably by glutathione or by other sulfhydryl-containing compounds. Excretion occurs via urine and to a lesser extent feces.

Acute oral LD_{50} values range from 222 to 360 mg bromate/kg for mice and 500 mg/kg for rats. Acute symptoms of toxicity include decreased locomotion

and ataxia, tachypnea, hypothermia, hyperemia of the stomach mucosa, kidney damage and lung congestion. In subchronic drinking water studies, decreased body weight gain and marked kidney damage were observed in treated rodents. These effects were observed at the lowest doses tested (30 mg/kg/d).

Bromate was positive in a rat bone marrow assay to determine chromosomal aberrations. Positive findings for bromate were also reported in a mouse micronucleus assay. Bromate has also been found to be carcinogenic to rodents following long-term oral administration. In these studies, an increased incidence in kidney tumors was reported for male and female rats. Other tumors observed include thyroid follicular cell tumor and peritoneal mesothelioma. No carcinogenic effects have been seen in mice. Dose and time studies indicate that the minimum exposure time to produce tumors in rats is 13 weeks.

The available data are considered insufficient to calculate an RfD. Only one noncarcinogenic toxicity study (Nakano et al., 1989) was located in the literature. The study failed to provide dose response data and did not identify a NOAEL. Histopathological lesions in kidney tubules that coincided with decreased renal function were noted in rats exposed to 30 mg bromate/kg/d for 15 months. The available carcinogenicity studies also do not provide sufficient information on non-cancer related effects to determine an RfD.

In a cancer bioassay, Kurokawa et al. (1986a) supplied groups of 50 male and 50 female F344 rats (4–6 weeks old) with drinking water containing 0, 250 or 500 mg/L (the maximum tolerated dose) of potassium bromate ($KBrO_3$). The high dose (500 mg/L) caused a marked inhibition of weight gain in males, and so at week 60 this dose was reduced to 400 mg/L. Exposure was continued through week 110. The authors stated the average doses for low dose and high dose groups were 12.5 or 27.5 mg $KBrO_3$/kg/day in males (equivalent to 9.6 and 21.3 mg BrO_3/kg/day) and 12.5 or 25.5 mg $KBrO_3$ in females (equivalent to 9.6 and 21.3 mg BrO_3). The incidence of renal tumors in the three groups (control, low dose, high dose) was 6%, 60% and 88% in males and 0%, 56% and 80% in females. The effects were statistically significant ($p < 0.001$) in all exposed groups. The incidence of peritoneal mesotheliomas in males at three doses was 11% (control), 33% (250 mg/L, $p < 0.05$) AND 59% (500 mg/L, $p < 0.001$). The authors concluded that $KBrO_3$ was carcinogenic in rats of both sexes.

In a subsequent study, Kurokawa et al. (1986b) supplied F344 rats with water containing $KBrO_3$ at 0, 154, 30, 60, 125, 250 or 500 mg/L for 104 weeks. The authors reported that these exposures resulted in average doses of 0, 0.9, 1.7, 3.3, 7.3, 16.0 or 43.4 mg/kg/day of $KBrO_3$, equivalent to doses of 0, 0.7, 1.3, 2.5, 5.6, 12 or 33.4 mg/kg/day of BrO_3. The incidence of renal cell tumors in these dose groups was 0%, 0%, 4%, 21% ($p < 0.05$), 50% ($p < 0.001$), 95% ($p < 0.001$) and 95% ($p < 0.001$). Using the linearized multistage model, estimates of cancer risks were derived. Combining incidence of renal adenomas and adenocarcinomas in rats, and a daily water consumption for an adult, lifetime risks of 10^{-4}, 10^{5} and 10^{6} are associated with bromate concentrations in water at 5, 0.5 and 0.05 µg/L, respectively. Equivalent concentrations in terms of $KBrO_3$, lifetime risks would be 7, 0.7 and 0.07 µg/L, respectively.

The International Agency for Research on Cancer placed bromate in Group 2B, for agents that are probably carcinogenic to humans. EPA has performed a cancer weight of evidence evaluation, and has placed bromate in Group B2: probable human carcinogen since bromate has been shown to produce several types of tumors in both sexes of rats following drinking water exposures. In addition, positive mutagenicity studies which have been reported include indications of DNA interactions with bromate. As a result of bromate formation following disinfection, particularly with ozone, there is a potential for considerable exposure in drinking water. Thus, EPA is proposing an MCLG based on carcinogenicity and a Category I approach. The resulting MCLG is zero.

EPA is also interested in examining the mechanism of toxicity of bromate in rats in terms of whether renal tumor formation is due to direct action of bromate or indirectly through formation of specific adduct in kidney DNA of rats treated with bromate.

EPA requests comment on the MCLG of zero based on carcinogenic weight of evidence and the mechanism of action for carcinogenicity related to DNA adduct.

VI. Occurrence of TTHMs, HAA5, and other DBPs

A. Relationship of TTHMs, HAA5 to Disinfection and Source Water Quality

1. Primary and Residual Disinfectant Use Patterns in U.S. and Relationship to Formation of DBPs

A survey of 727 utilities nationwide was conducted for the American Water Works Association Research Foundation (AWWARF) in 1987 to determine the extent and cost of compliance with the 1979 maximum contaminant level (MCL) for trihalomethanes (THMs) (McGuire et al., 1988). The AWWARF survey reflected more than 67 percent of the population represented by water utilities serving more than 10,000 customers. The survey found that chlorine remained the most common disinfectant among water utilities. At the time of the survey, chlorine was used by 85 percent of the flowing stream and lake surface water systems and by 80 percent of the ground water systems. The median chlorine dose for flowing stream and lake systems was 2.2–2.3 mg/L and for ground water systems it was 1.2 mg/L. The range of chlorine doses was 0.1 to >20 mg/L.

Chloramines were used by 25 percent of the flowing stream systems and larger lake systems, but by only 13 percent of the smaller lake systems. Chloramines were rarely used by ground water systems reporting in the AWWARF THM survey. Typical chloramine doses for flowing stream systems was 2.7 mg/L, compared with 1.5 mg/L for lake systems. In addition, 10 percent of the flowing stream systems and 5 percent of the lake systems reported using chlorine dioxide. The latter systems typically served more than 25,000 customers. The typical chlorine dioxide doses ranged from 0.6 mg/L for the flowing stream systems to 1.0 mg/L for the lake systems. No ground water systems reported using this disinfectant. At the time of this survey, three utilities reported using ozone.

The AWWA Disinfection Committee also performed nationwide surveys on disinfectant use in 1978 (AWWA Disinfection Committee, 1983) and 1990 (AWWA Water Quality Division Disinfection Committee, 1992), principally among systems serving >10,000 persons (<3 percent of the surveyed systems served 10,000 persons or fewer). Chlorine has historically been applied early in the water treatment process (precoagulation) in order to utilize the benefit of chlorine as a disinfectant and an oxidant and to control biological growths in basins. In the 1978 survey, the vast majority (>85 percent) of those who relied on surface waters prechlorinated (AWWA Disinfection Committee, 1983). The 1990 survey found a significant reduction in the frequency of chlorine addition prior to coagulation, along with an increase in chlorine application after sedimentation (AWWA Water Quality Division Disinfection Committee, 1992). The AWWARF THM survey had found that 150 systems surveyed had changed the point of disinfection to comply with the 0.10-mg/L THM MCL (McGuire et

al., 1988). However, the 1990 AWWA survey (AWWA Water Quality Division Disinfection Committee, 1992) still found that 35 percent of the utilities reported chlorination before coagulation or sedimentation. The range and median chlorine doses in the 1990 AWWA survey were similar to the AWWARF THM survey.

In the 1990 AWWA survey, disinfection modifications to reduce THMs included (1) changes in prechlorination practices (24 percent of respondents moved the first point of chlorination, 23 percent ceased prechlorination, while 20 percent decreased the prechlorination dose), (2) implementation of ammonia addition (19 percent added ammonia after some free chlorine time, while nine percent added ammonia before chlorination), (3) or changed preoxidant (10 percent switched to potassium permanganate, five percent to chlorine dioxide, and 0.5 percent to ozone). A surprisingly large percentage of utilities reported operational problems with disinfection modifications used for THM reduction (e.g., 56 percent of utilities that implemented postammoniation reported such problems; as well as 44, 36, and 28 percent of those who moved the first point of chlorination downstream, ceased prechlorination, and decreased the prechlorination dose, respectively). Neither the exact nature of the problems noted, nor their duration, were defined in the survey. However, the Disinfection Committee believed that many of the reported problems were probably transitional and were alleviated after further experience.

The 1990 AWWA survey (Haas et al., 1990) found that disinfection modifications for THM minimization differed between ground and surface water utilities. For example, 13 percent of surface water systems changed their preoxidation practices, while this option was rarely used by ground water systems (which rarely preoxidize). Sixteen and 25 percent of surface and ground water utilities, respectively, reported adding ammonia after some free chlorine contact as their modification strategy to reduce THMs. Because 65 percent of the surveyed ground waters had a THM formation potential (THMFP) (a worst-case measure of the possible THM production rather than the amount actually produced in the distribution system) of <100 µg/l, most ground water systems probably did not require modifications to meet the 1979 TTHM rule.

AWWA established a Water Industry Data Base (WIDB) in 1990–91 (AWWA Water Industry Data Base, 1991). The WIDB contains information from about 500 utilities supplying water to more than 50,000 people and over 800 utilities supplying between 10,000 and 50,000 people. The utilities in the WIDB represent a combined population of 209 million people. In addition, a database for the Disinfectants/Disinfection By-Products (D/DBP) negotiated regulation ("reg neg" data base, RNDB) (JAMES M. MONTGOMERY, CONSULTING ENGINEERS, INC., 1992) was developed for AWWA. The RNDB comprises data on nationwide and regional DBP studies, including data on individual THMs and haloacetic acids (HAAs), chloral hydrate, and bromate, performed by EPA, water utilities, universities, and engineering consultants, as well as total THM (TTHM) data from the WIDB. The non-WIDB part of the RNDB (i.e., those studies on individual DBP occurrence and control) includes 166 utilities serving a combined population of about 72 million people. The majority of systems in the non-WIDB data occurrence part of the RNDB are also in the WIDB. Thus, the former data base represents a subset of the latter data base, in which specialized DBP studies were conducted. In addition, many of these studies attempted to select utilities that were representative of source water quality, treatment plant operations, disinfectant use, population served, and geographical locations throughout the United States (Krasner et al., 1989). Furthermore, the RNDB includes data on 48 utilities (serving a combined population of 37 million people) which have evaluated alternative treatments to comply with future DBP regulations.

Figure VI–1 shows a comparison of disinfectant/oxidant uses reported in the WIDB and the non-WIDB part of the RNDB. In general, the current usage of disinfectants/oxidants in both data bases are comparable, which indicates that the non-WIDB part of the RNDB is representative of nationwide disinfectant usage. Figure VI–2 shows disinfectants evaluated under alternative treatments in the RNDB. While ozone is the most prevalent alternative disinfectant under investigation in the RNDB, this data base is somewhat biased, as it does include two AWWARF studies involving ozonation. However, Figure VI–2 does demonstrate that ozone is an alternate disinfectant that is being widely evaluated. While most systems currently use chlorine only, the percentage drops when the data are population based. Figure VI–1 shows that chloramine use is higher on a population basis, probably due to its usage by some of the larger utilities.

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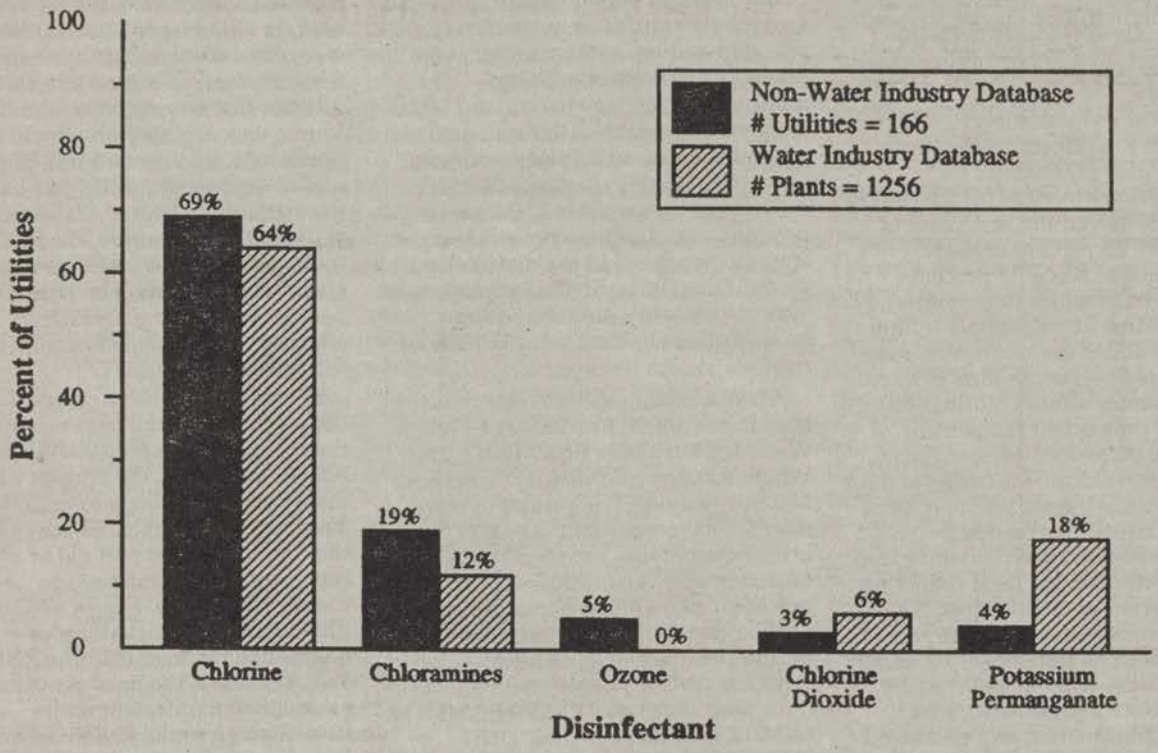
Figure VI-1
Comparison of Disinfectant Use Among Two Different Databases



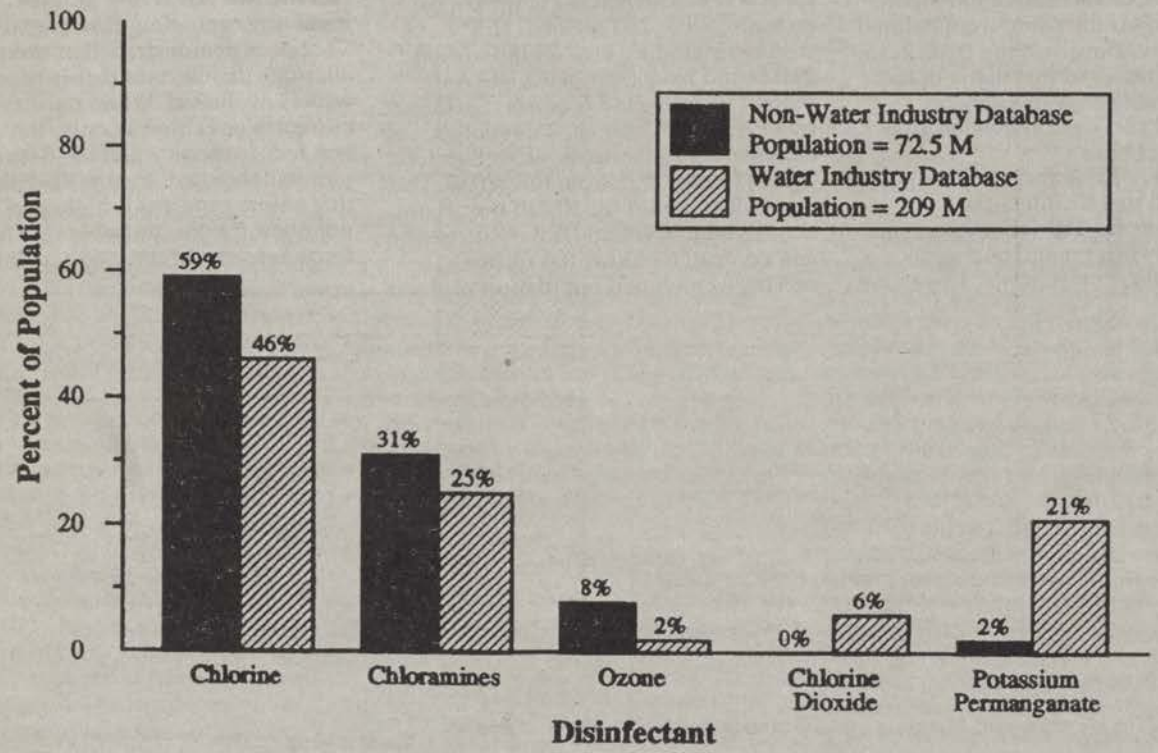
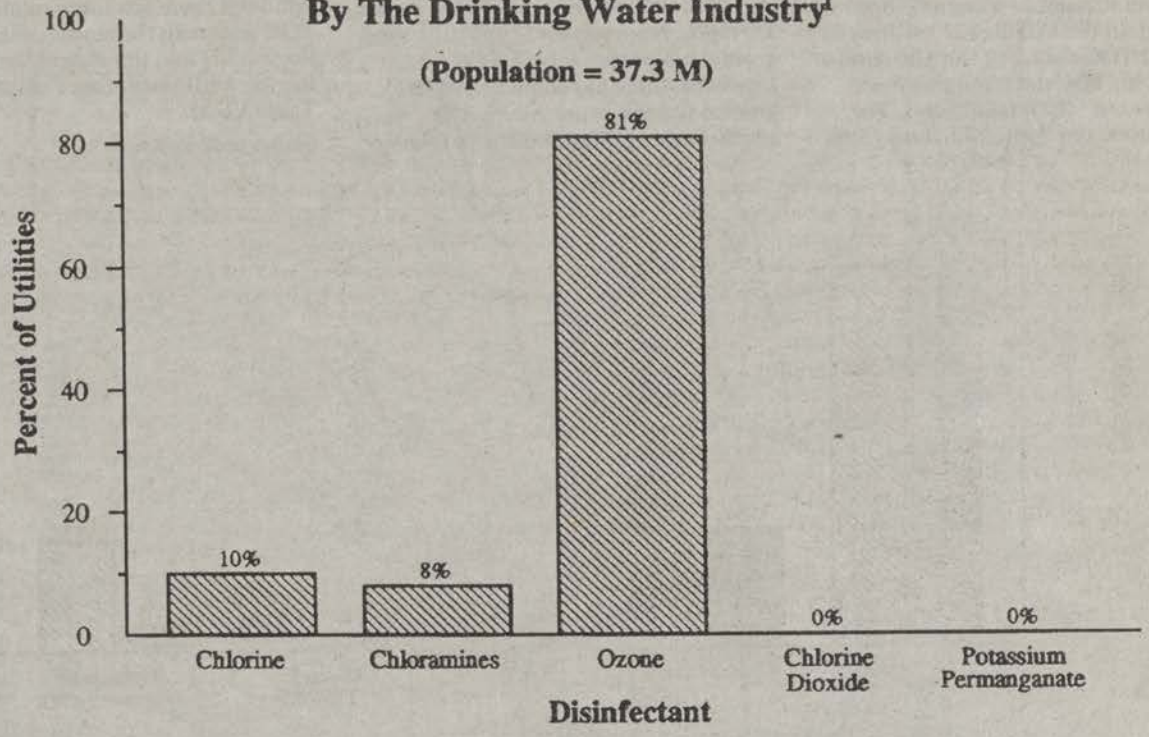
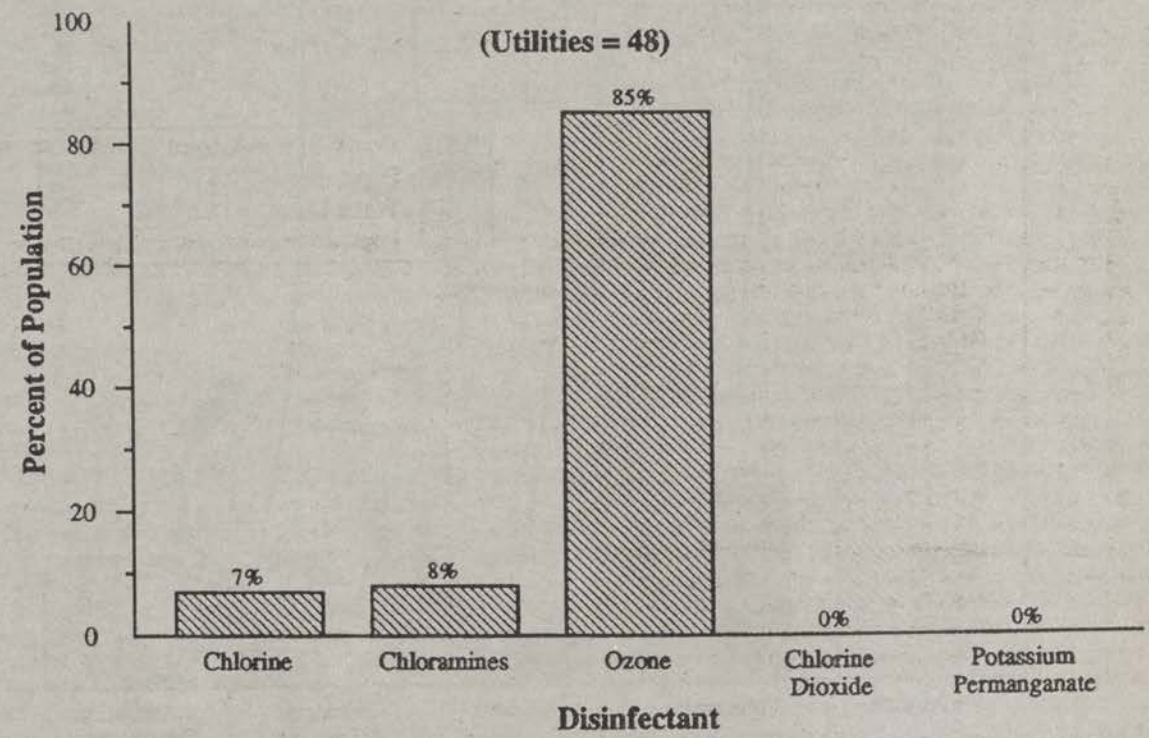


Figure VI-2

Alternative Disinfectants Under Evaluation By The Drinking Water Industry[1]





[1] Not a representation of changes expected to occur under this byproduct regulation.

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2. National Occurrence of TOC

The total organic carbon (TOC) level of a water is generally a good indication of the amount of THM and other DBP precursors present in a water (Singer et al., 1989). In the WIDB, 157 utilities provided TOC data. For the 100 surface waters with TOC data, the range was "not detected" (ND) to 30 mg/L. For these waters, the 25th, 50th, and 75th percentiles were 2.6, 4.0, and 6.0 mg/L, respectively. For the 57 ground waters with TOC data, the range was ND to 15 mg/L. For these waters, the 25th, 50th, and 75th percentiles were ND, 0.8, and 1.9 mg/L, respectively. Typically, most ground waters are low in TOC. However, there are some high-TOC ground waters, especially in the southeastern part of the United States (EPA Region IV; see Figure VI–3 and Table VI–1). For surface waters, the high-TOC waters also tend to be in the southeastern part of the United States, although there are some relatively high-TOC waters in the south central (EPA Region VI) and the mountain (EPA Region VIII) states (see Figure VI–3 and Table VI–2).

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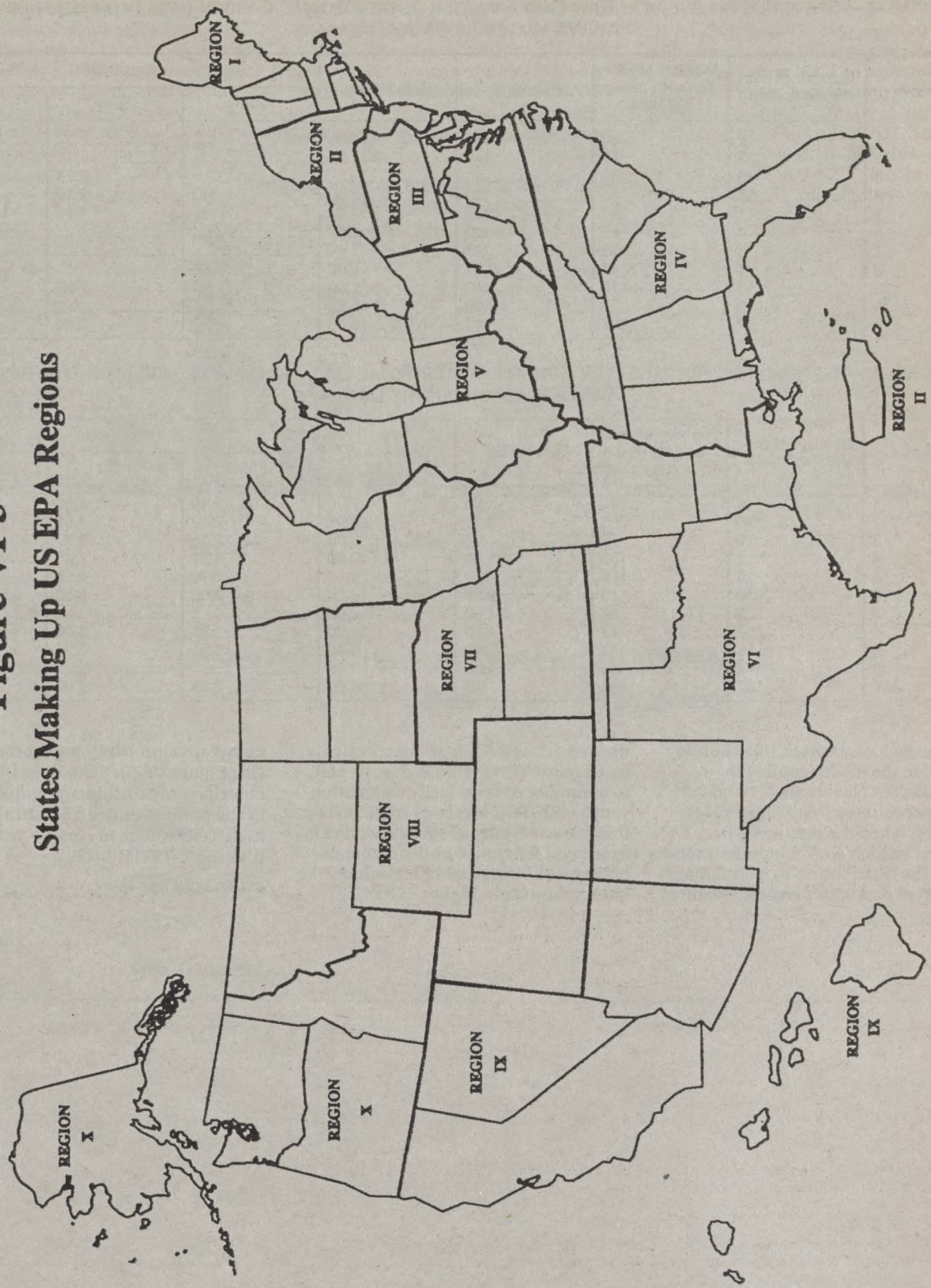

Figure VI-3
States Making Up US EPA Regions

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TABLE VI–1.—STATISTICS ON AVERAGE RAW GROUNDWATER TOTAL ORGANIC CARBON (MG/L) FOR UTILITIES IN THE AWWA WATER INDUSTRY DATABASE

EPA region	Number of utilities with data	Number of utilities with missing data	Min value	Max value	Percentile		
					25th	50th	75th
1	2	48	ND	1.38	.....	.....	.....
2	3	72	ND	1.91	.....	.....	.....
3	3	96	.....	.....	.....	2.74	.....
4	13	163	ND	15.00	ND	2.19	8.50
5	11	182	ND	4.00	0.63	1.45	1.92
6	4	82	ND	1.87	.....	.....	.....
7	5	53	ND	1.40	.....	.....	.....
8	4	46	0.71	2.00	.....	.....	.....
9	11	118	ND	1.00	ND	ND	0.30
10	1	37	0.80	0.80	.....	.....	.....
ALL	57	897	ND	15.00	ND	0.84	1.88

TABLE VI–2.—STATISTICS ON AVERAGE RAW SURFACE WATER TOTAL ORGANIC CARBON (MG/L) FOR UTILITIES IN THE AWWA WATER INDUSTRY DATABASE

EPA region	Number of utilities with data	Number of utilities with missing data	Min value	Max value	Percentile		
					25th	50th	75th
1	6	44	3.00	9.00	3.48	3.50	4.50
2	10	65	2.10	20.00	2.50	4.55	5.00
3	20	79	ND	25.00	2.15	2.87	4.80
4	11	165	1.60	30.00	5.27	7.40	12.60
5	14	179	ND	9.17	2.70	4.50	5.90
6	10	76	2.00	10.00	3.90	5.50	6.90
7	2	56	7.00	10.00	.....	.....	.....
8	7	43	1.00	14.00	1.75	3.30	8.50
9	16	113	ND	5.90	1.95	3.25	3.88
10	4	34	1.25	3.30	.....	.....	.....
ALL	100	854	ND	30.00	2.55	4.00	5.95

For surface waters that filter but do not soften, the median and 90th percentile TOC levels are 3.7 and 7.5 mg/L, respectively (see Figure VI–4). However, when the data are flow-weighted (which would represent more closely the distribution by population), the median and 90th percentile values drop to 2.7 and 5.1 mg/L, respectively (see Figure VI–4). This is due, in part, to a number of large facilities treating water with TOC levels <4 mg/L. When this same category of surface waters is examined for choice of disinfectants between chlorine and chloramines, the latter group has a higher TOC cumulative probability than the former (see Figure VI–5). Switching from free chlorine only to chloramination was one of the options utilized by utilities with high-TOC waters to comply with the 0.10 mg/L TTHM MCL.

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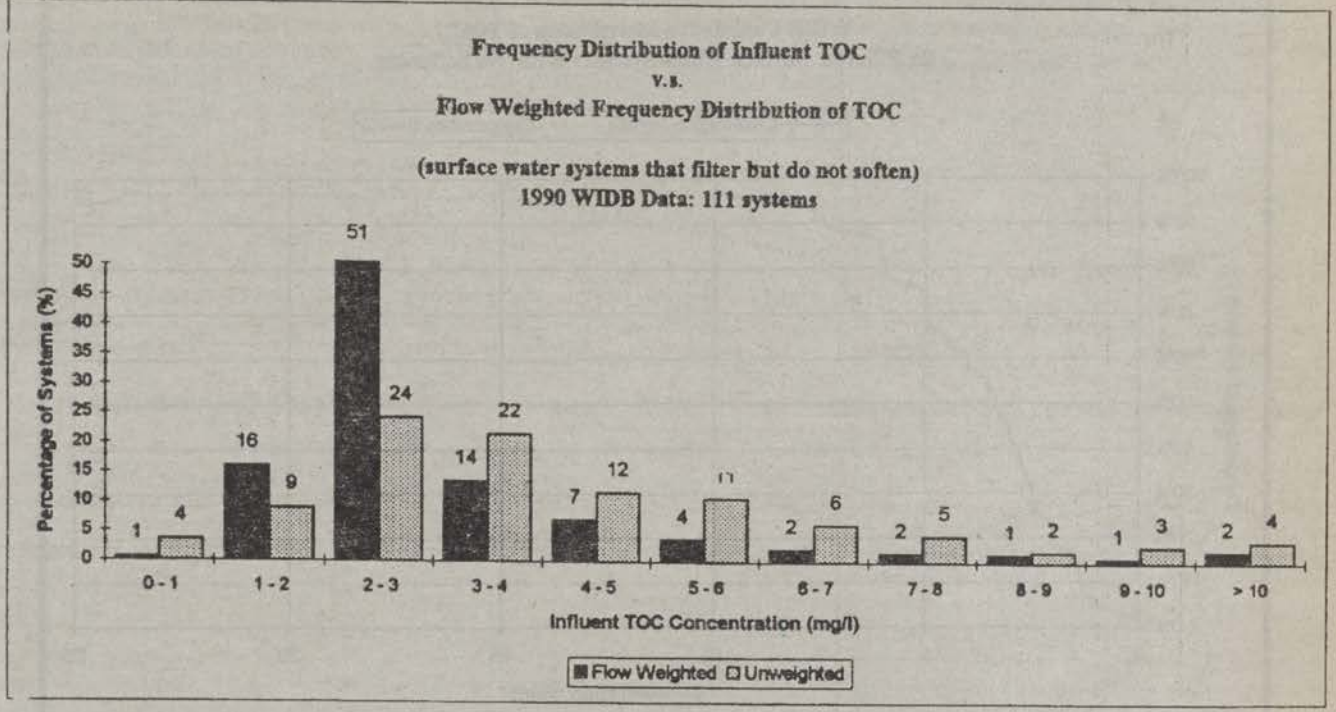
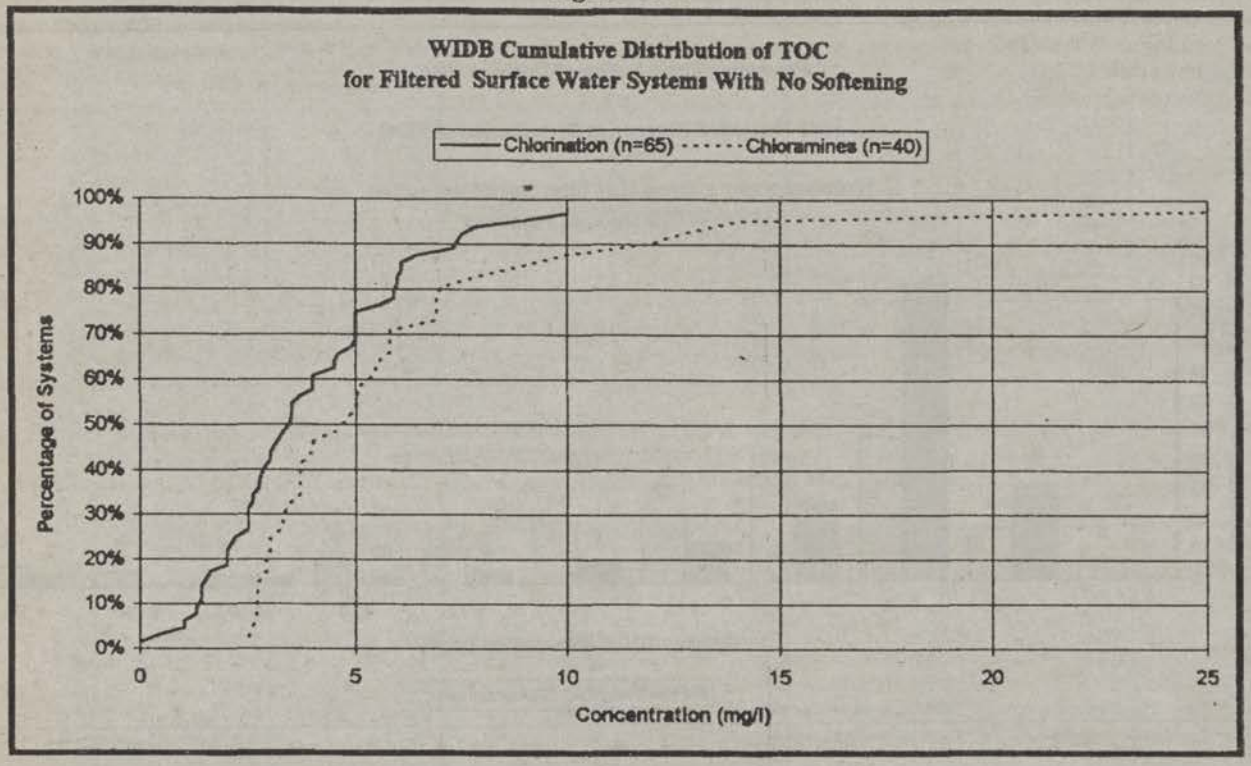
Figure VI-4



Summary Statistics of Influent TOC Distributions (1990 WIDB Data)

	Unweighted	*Flow Weighted*
Min	0.01	0.01
Max	25.0	25.0
Median	3.7	2.7
Mean	4.5	3.4
Std.Dev.	3.2	2.1
90th Percentile	7.5	5.1

Figure VI-5



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As part of a ground water supply survey (GWSS), TOC was measured at the point of entry into the distribution system (see Figure VI–6). Because most groundwater systems do not have precursor-removal technology as part of their treatment, these treated-water TOC levels provide a good indication of the range of raw-water TOC levels in ground waters. The median and 90th percentile TOC levels of systems without softening who chlorinate were 0.7 and 2.9 mg/L, respectively. However, the median and 90th percentile TOC levels of systems with softening who chlorinate were 1.7 and 6.8 mg/L, respectively.

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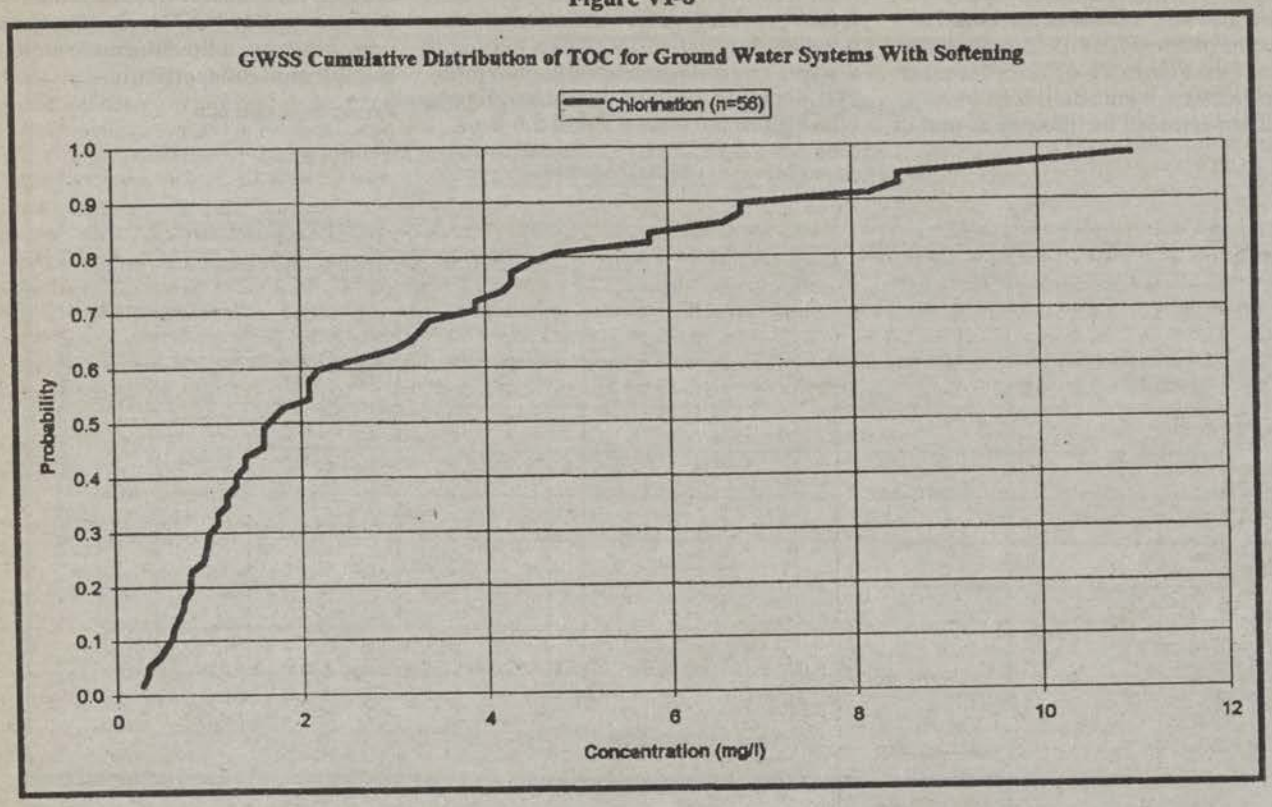
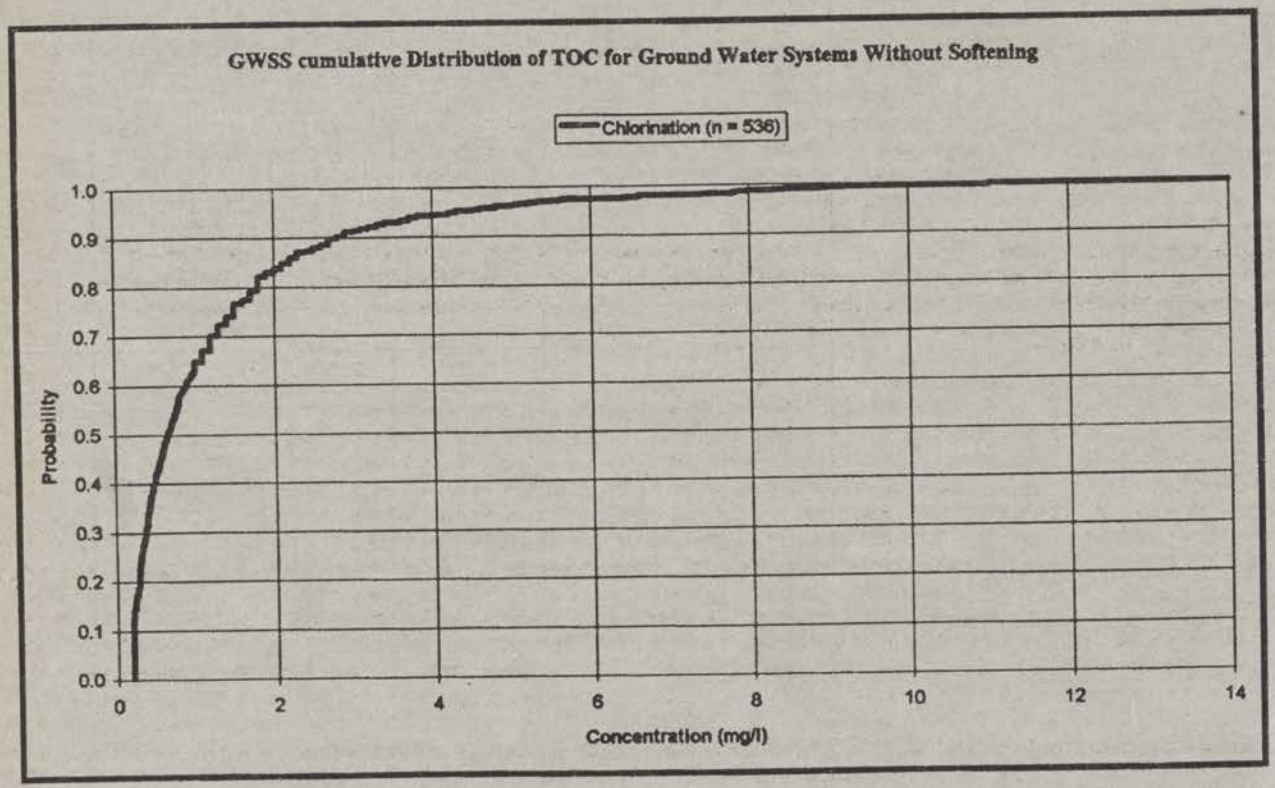
Figure VI-6


GWSS Cumulative Distribution of TOC for Ground Water Systems With Softening
Chlorination (n=58)
Probability
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
2
4
6
8
10
12
Concentration (mg/l)


GWSS cumulative Distribution of TOC for Ground Water Systems Without Softening
Chlorination (n = 536)
Probability
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
2
4
6
8
10
12
14
Concentration (mg/l)

In addition, the breakdown of treated-water TOC levels of ground waters was examined geographically (see Table VI–3). As indicated above (see Table VI–1), the southeastern part of the United States (i.e., EPA Region 4) has groundwaters with a relatively higher level of TOC (see Tables VI–3A and VI–3C). In addition, the mountain states (i.e., EPA Region 8) also tended to have a higher distribution of TOCs in the ground waters tested (see Tables VI–3A and VI–3C). Furthermore, these data are also broken down into those that chlorinate and those that do not (see Table VI–3). Typically, ground waters that are currently undisinfected tend to be ones with lower TOC levels. Thus, promulgation of the Ground Water Disinfection Rule will probably tend to have an impact on waters with a lower precursor level than are currently disinfecting.

TABLE VI–3A.—TOC VALUES FOR GWSS SYSTEMS THAT CHLORINATE

EPA region	Number of utilities with data	Max value	Percentile			
			25th	60th	75th	90th
1	19	4.3	0.4	0.5	0.95	2.3
2	59	4.6	0.3	0.5	0.9	1.5
3	62	4.2	0.3	0.5	0.7	1.2
4	185	14	0.8	0.7	2.1	5.3
5	90	8.9	0.7	1.1	1.8	2.6
6	46	8	0.6	1	1.7	2.4
7	103	7.8	0.8	0.8	1.8	3.7
8	26	11	0.6	1.9	3.1	6.6
9	39	11	<2	0.2	0.5	1.2
10	25	3.3	0.3	0.9	1.4	2.2
ALL	654	14	0.3	0.7	1.7	3.3

TABLE VI–3B.—TOC VALUES FOR GWSS SYSTEMS THAT DO NOT CHLORINATE

EPA region	Number of utilities with data	Max value	Percentile			
			25th	50th	75th	90th
1	27	3.6	0.3	0.5	0.8	1.3
2	14	0.8	<2	0.3	0.5	0.6
3	28	5.3	<2	0.3	0.6	1.5
4	34	3.2	0.3	0.5	0.8	1.7
5	41	18	0.7	1.3	2.2	3.4
6	26	5.6	0.2	0.6	1.5	2.9
7	18	2.9	0.6	0.9	1.1	2.2
8	14	5.9	0.3	0.4	1.8	2.7
9	49	3.4	<2	0.3	0.4	0.9
10	40	5	0.2	0.4	0.8	2
ALL	291	18	0.3	0.5	1.1	2.2

TABLE VI–3C.—TOC VALUES FOR ALL GWSS SYSTEMS

EPA region	Number of utilities with data	Max value	Percentile			
			25th	50th	75th	90th
1	46	4.3	0.3	0.5	0.8	1.6
2	73	4.6	0.3	0.5	0.8	1.3
3	90	5.3	0.3	0.4	0.7	1.2
4	219	14	0.3	0.7	1.9	4.8
5	131	18	0.7	1.2	1.9	3.2
6	72	8	0.4	0.9	1.7	2.4
7	121	7.8	0.4	0.9	1.7	3.2
8	40	11	0.3	1.8	2.7	5.9
9	88	11	<2	0.2	0.5	1
10	65	5	0.2	0.5	1.2	2.2
ALL	945	18	0.3	0.6	1.4	2.9

3. National Occurrence of Bromide

Bromide is a concern in both chlorinated and ozonated supplies. In chlorinated supplies, while the organic precursor level of a source water has an impact on the amount of DBPs formed, the bromide concentration has an impact on the speciation as well as the overall yield (Symons et al., 1993). Typically, regardless of the organic content in water, bromate can be formed when waters containing sufficient levels of bromide are ozonated (Krasner et al., Jan. 1993).

In a 35-utility nationwide DBP study, bromide ranged from <0.01 to 3.0 mg/L and the median bromide level was 0.1 mg/L (Krasner et al., 1989). Some

utilities have bromide in their source water due to saltwater intrusion (one utility had as much as 0.4 to 0.8 mg/L bromide due to this phenomenon) (Krasner et al., 1989). However, some non-coastal communities can have moderate-to-high levels of bromide due to connate waters (ancient seawater that was trapped in sedimentary deposits at the time of geological formation) or industrial and oil-field brine discharges. The highest bromide detected in the latter study (2.8–3.0 mg/L) (Krasner et al., 1989) was from a water in the midsouthern part of the U.S.

Currently, a nationwide bromide survey of 70 utilities has found bromide levels ranging from <0.005 to >3.0 mg/L (Amy et al., 1992–3). Some waters have been sampled more than once (up to three seasonal samples to date) in order to determine the variability in bromide occurrence. The average raw-water bromide level per water, though, provides an indication of the typical occurrence of bromide in each water. Table VI–4 provides some preliminary insight into the geographical occurrence of bromide. Ideally, more data per region are needed; however, sufficient data are available for general trends. Regions 6 (which includes Texas) and 9 (which includes California) have the highest occurrence of bromide. While some California communities have problems with saltwater intrusion, some Texas communities may have bromide from connate waters or oil-field brines. However, most geographical regions have at least one high-bromide water in their area, except for the systems surveyed in the Pacific Northwest (EPA Region 10) and the northeast (EPA Regions 1 and 2).

TABLE VI–4.—STATISTICS ON AVERAGE RAW-WATER BROMIDE (MG/L) FOR UTILITIES IN THE NATIONWIDE BROMIDE SURVEY

EPA region	Number of utilities with data	Min value	Max value	Percentile			
				25th	50th	75th	90th
1	8	0.005	0.089	0.02	0.03	0.05	0.05
2	4	0.023	0.093	0.03	0.05	0.08	NA
3	8	0.005	0.276	0.03	0.06	0.07	0.08
4	7	0.010	0.190	0.02	0.04	0.05	0.05
5	6	0.012	0.322	0.05	0.09	0.12	0.14
6	7	0.014	>3.00	0.02	0.03	0.25	0.37
7	6	0.042	0.206	0.06	0.08	0.09	0.10
8	7	0.006	0.368	0.02	0.02	0.06	0.09
9	11	0.008	0.429	0.05	0.08	0.33	0.36
10	6	<0.005	0.015	<0.005	0.006	0.009	0.012

NA=Not applicable; insufficient number of utilities to determine.

Figures VI–7 and VI–8 show the cumulative probability distribution of average raw-water bromide levels in surface and ground waters, respectively, in the nationwide bromide survey. In surface waters in this survey, the median, 75th, 90th, and 95th percentile bromide level were 0.04, 0.08, 0.2, and 0.35 mg/L, respectively. In ground waters in this survey, the median, 75th, 90th, and 95th percentile bromide level were 0.06, 0.1, 0.25, and 0.35 mg/L, respectively. Overall, ground waters appear to have a somewhat higher probability of bromide occurrence than in surface waters. In the 35-utility DBP study, one midwest utility pumped ground water into a lake to augment a low-lake level during a drought period. Bromide rose from 0.19 to 0.68 mg/L during this period of time.

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Figure VI-7
Cumulative Probability Distribution of
Average Raw Water Bromide Concentration in Surface Waters

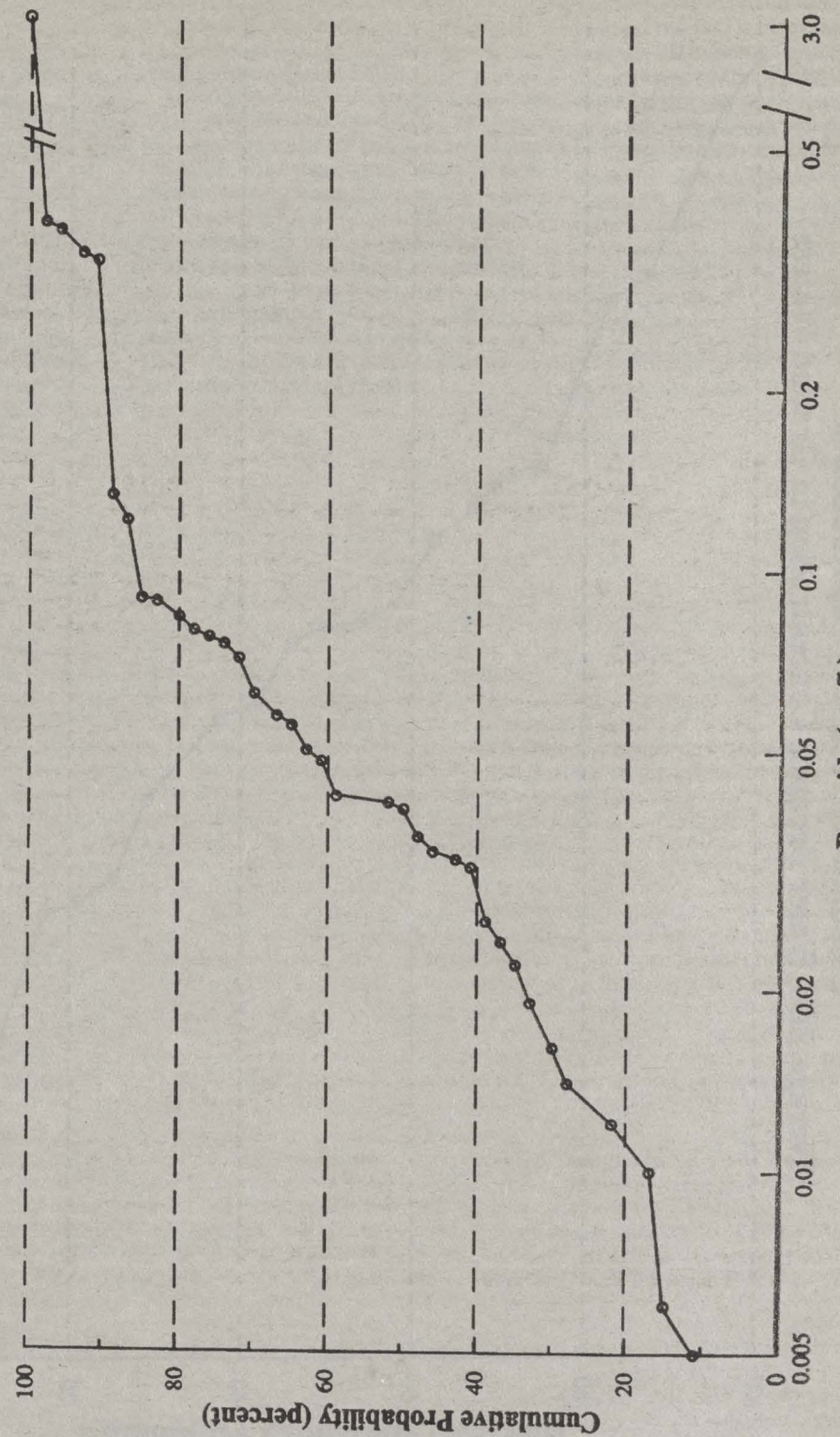
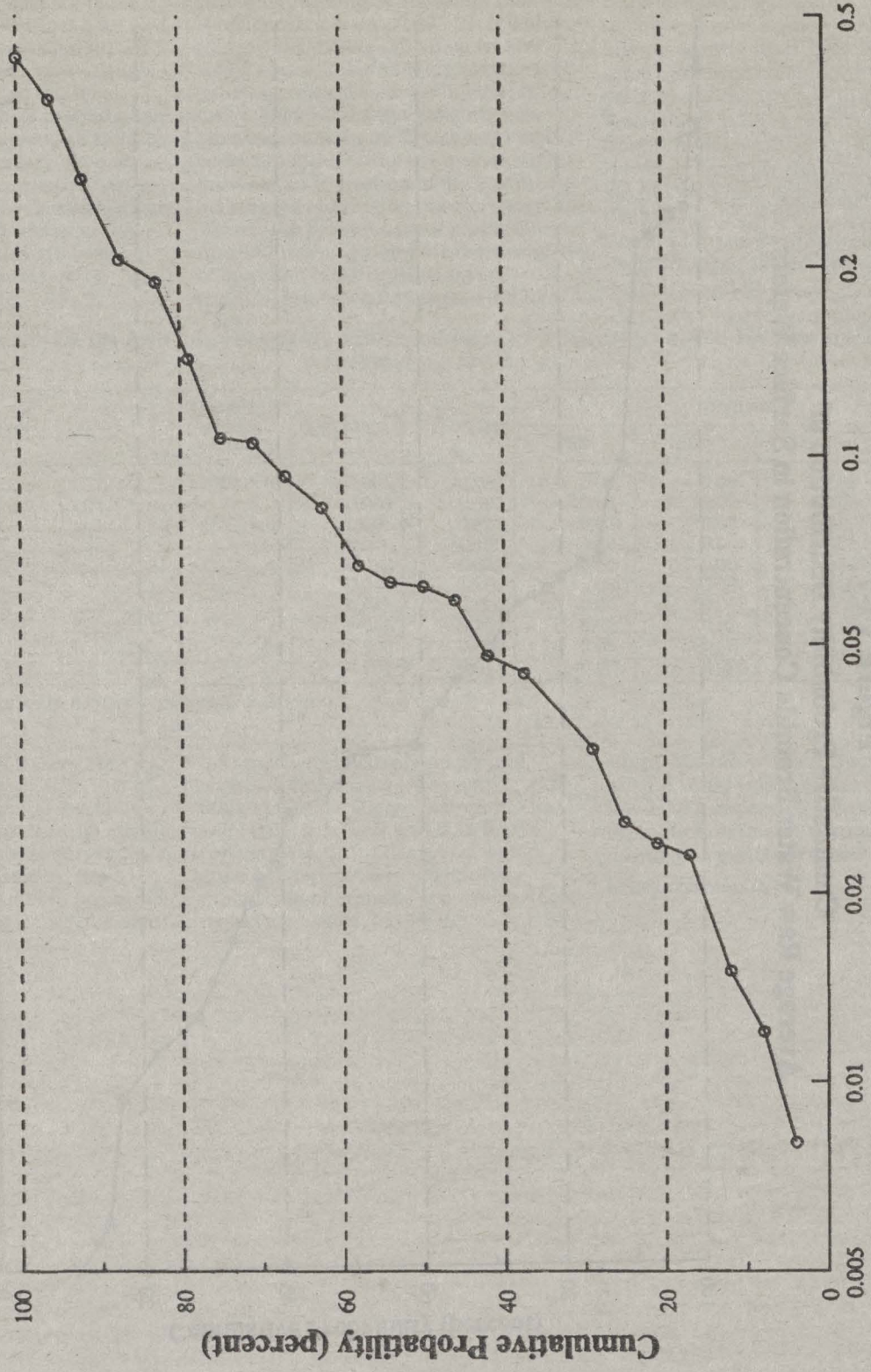


Figure VI-8
Cumulative Probability Distribution of Average Raw Water Bromide Concentration in Ground Waters



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B. Chlorination Byproducts

1. TTHMs—Occurrence Studies

Prior to the promulgation of an MCL of 0.10 mg/L TTHMs in 1979, EPA performed two surveys to obtain information on the occurrence of THMs and other organic compounds: the National Organics Reconnaissance Survey (NORS) in 1975 (Symons et al., 1975) and the National Organic Monitoring Survey (NOMS) in 1976–77 (Brass et al., 1977 and The National Organics Monitoring Survey, unpubl.). NORS and NOMS were conducted primarily to determine the extent of THM occurrence in the United States. These data were used, in part, in determining the 1979 THM regulation. Surveys in the 1980s were performed to provide data for assessing a new MCL for THMs, as well as to develop regulations for other DBPs.

The AWWARF THM survey used data from 1984–86, and these THM values reflected the result of compliance with the 1979 THM regulation. Mean TTHM values were computed for each of the utilities in the AWWARF THM survey; these means, as well as data from the NORS and NOMS surveys, are plotted (see Figure VI–9) on a frequency distribution curve. The AWWARF survey's overall TTHM average was 42 µg/L, which was a 40–50 percent reduction in national THM concentrations as compared to the averages of the NORS and NOMS (all phases) results. It is important to note that the disinfection practices of some of the utilities in the AWWARF survey (such as the use of chloramines as a primary disinfectant) were employed to meet the 1979 TTHM MCL, and not to meet the requirements of the recently promulgated Surface Water Treatment Rule (SWTR). Thus, THM and DBP levels at some utilities would most likely be different if their current treatment practices required modification in order to meet the new disinfection requirements of the SWTR.

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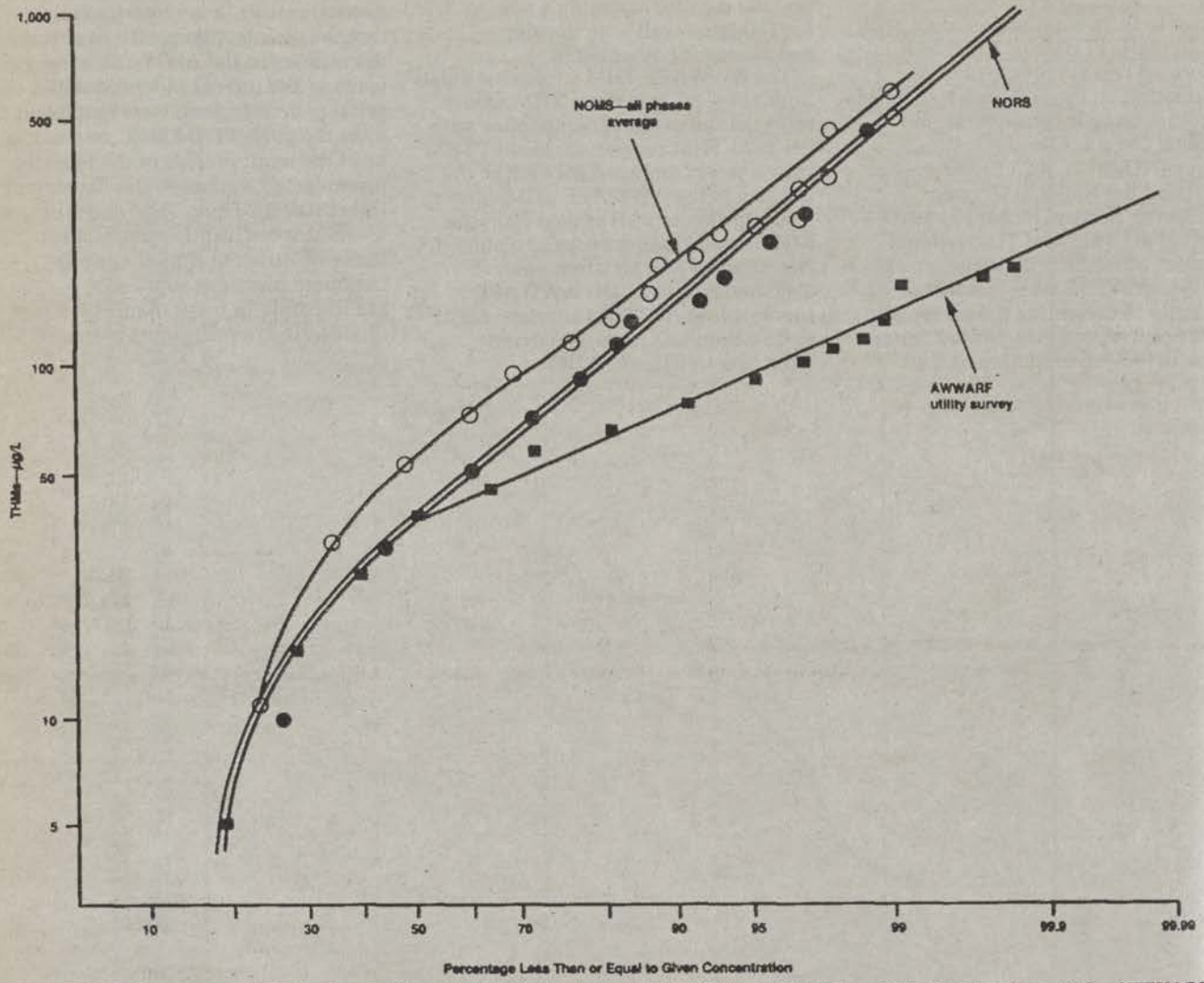

Figure VI-9. Frequency distributions of national THM survey data (From: McGuire, M.J. & Meadow, R.G. AWWARF Trihalomethane Survey, *Jour. AWWA*, 80:1:61 [Jan. 1988])

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Median TTHM concentrations in the AWWARF survey for the spring, summer, fall, and winter seasons were 40, 44, 36, and 30 µg/L, respectively. THM levels were highest in the summer and lowest in the winter, due primarily to the faster formation rates in warmer water temperatures. In the 35-utility DBP study, the second highest THM levels were in the fall (Krasner et al., 1989). For many utilities in California and the southern United States, fall can be almost as warm as summer. However, seasonal impacts may be due to changes in the nature of naturally occurring organics or bromide levels as well. Compliance with the THM regulation is based on a running annual average to reflect these types of seasonal variations.

Because the 1979 regulation did not apply to systems that serve <10,000 people, the running annual average TTHM distribution for small systems is expected to be different. In the AWWARF THM survey, TTHM data for small systems from 12 states were obtained (McGuire et al., 1988). While the number of utilities (677) for which TTHM data were received represents only a small percentage of the total number serving fewer than 10,000 customers (55,449), some important observations can be made. The range of TTHMs was from ND to 313 µg/L, with a mean of 36 µg/L and a median of 18 µg/L (McGuire et al., 1988). The cumulative probability distribution differs significantly from the NORS and NOMS data (see Figure VI–10). This lack of agreement is probably due to many of the small systems using ground water sources, which are generally much lower in THM precursors than surface water sources. In addition, the overall statistics of the AWWARF survey (for 677 cities) were markedly affected by the low TTHM results (range of ND to 42 µg/L with a mean of 2 µg/L) of the 204 systems sampled in Wisconsin. Although McGuire does not identify a reason for low TTHMs in Wisconsin, EPA data indicate that over 90 percent of Wisconsin systems use ground water (probably with low precursor levels) as a primary source. Since 30 percent of the systems in the survey were from Wisconsin, this would bias the results.

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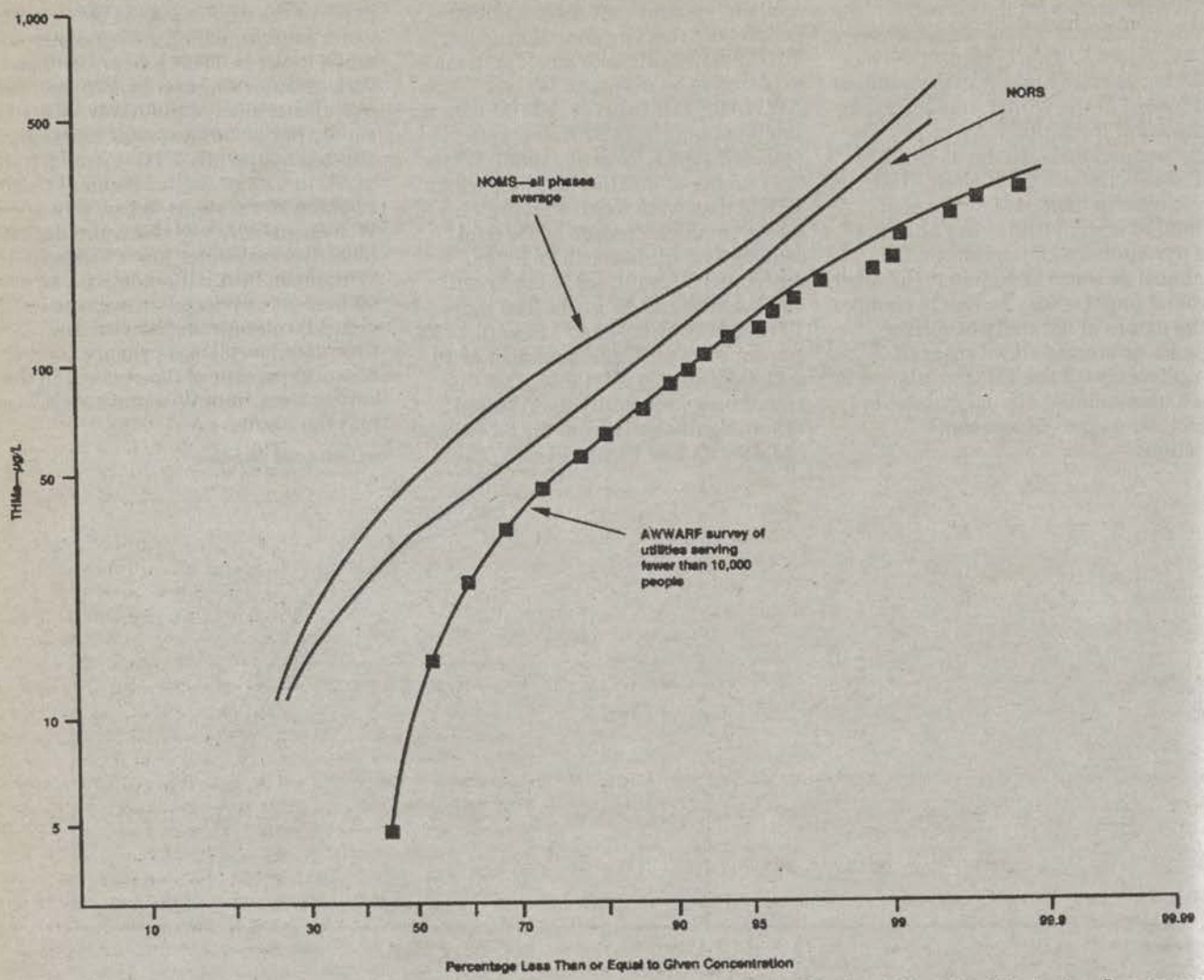

Figure VI-10. Frequency distributions of National Organics Reconnaissance Survey, National Organics Monitoring Survey, and AWWA Research Foundation data from surveys of smaller utilities (From: McGuire, M.J. & Meadow, R.G. AWWARF Trihalomethane Survey, *Jour. AWWA*, 80:1:61 [Jan. 1988])

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Since the AWWARF THM survey, EPA measured DBP data in a number of small systems. These data represent part of the non-WIDB data in the RNDB. Figure VI–11 compares the TTHM frequency distribution for the WIDB (large systems only) with that of the non-WIDB data on both large and small systems. For the small systems, there is essentially a biomodal distribution of TTHM levels: 50 percent of the small systems have ≤10 µg/L TTHMs, while the remaining utilities have TTHM levels of 20 to 430 µg/L. Most likely, many of the very low THM levels are associated with treatment of low-TOC, low-bromide ground waters. For community water, non-purchased systems serving <10,000 people, 4562 systems treat surface water, while 17941 disinfect ground water. For systems serving >10,000 people, 1395 treat surface water and 1117 disinfect ground water. Thus, small systems are utilizing ground water more than surface water.

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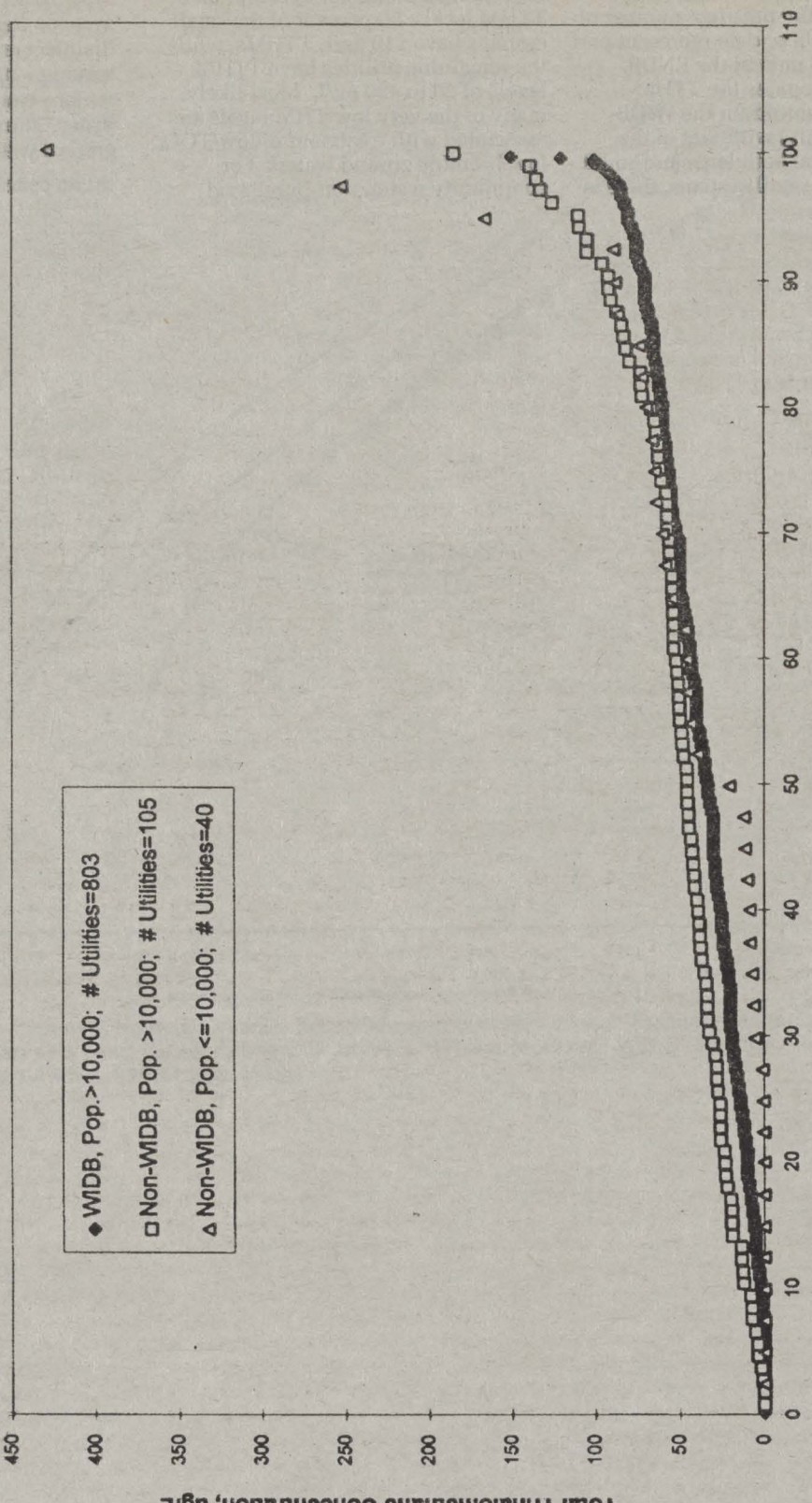
Figure VI.11

Distribution of Average Total Trihalomethane Concentrations for Utilities in the AWWA Regulation Negotiations Database with AWWA Water Industry Database (WIDB) and Non-WIDB Datasources



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In the WIDB (which only includes large systems), 482 utilities that treat surface water or a mix of surface and ground waters had TTHM median, 75th, and 90th percentile values of 43, 59, and 74 µg/L, respectively. In the WIDB, 277 utilities that treat ground water only had TTHM median, 75th, and 90th percentile values of 13, 34, and 60 µg/L, respectively. However, systems using both types of source waters had TTHM levels in the neighborhood of 100 µg/L. Thus, while ground waters in general tend to form less THMs than surface waters, there are some ground waters with sufficient precursor levels to form significant amounts of THMs.

2. HAAs and Other Chlorination DBPs—Occurrence Studies

a. *Discovery of Additional Chlorination By-Products.* In 1985, EPA determined chlorination DBPs at 10 operating utilities, using both target-compound and broad-screen analyses (Stevens et al., 1989). A total of 196 compounds that can be attributed to the chlorination process were found in one or more of the 10 utilities' finished waters. Approximately half of the compounds contained chlorine and many were structurally identified; however, 128 compounds were of unknown chemical structure. The compounds which were quantifiable represented from 30 to 60 percent of the total organic halide (TOX) of those supplies. That study served to significantly reduce the list of compounds that EPA considered most significant for further work.

b. *Available Data on Chlorination By-Products.* Taken as an example of subsequent survey results where quantifiable target-compound analyses were used, Figure VI–12 shows the occurrence of DBPs in the 35-utility study (Metropolitan Water District of So. Calif et al., 1989). The figure presents an overview of the results of four seasonal sampling quarters combined. In addition, all sampling was performed at treatment-plant clearwell effluents. It is important to note that these survey results do not reflect any impacts of the SWTR under which a substantial number of systems could be expected to modify disinfection practice to achieve compliance. On a weight basis, THMs were the largest class of DBPs detected in this study; the second largest fraction was haloacetic acids (HAAs). At the time of this study, commercial standards were only available for five of the nine theoretical species: monochloro-, dichloro-, trichloro-, monobromo-, and dibromoacetic acid. The data indicate that the median level of THMs (i.e., 36 µg/L) was approximately twice that of HAAs (i.e., 17 µg/L). The third largest fraction was the aldehydes (i.e., formaldehyde and acetaldehyde). These two low-molecular-weight aldehydes were initially discovered as by-products of ozonation, but they also appear to be by-products of chlorination. Every target-compound DBP was detected at some time in some utility's water during the study; however, 2,4,6-trichlorophenol was only detected at low levels at a few utilities during the first sampling quarter and was not detected in subsequent samplings.

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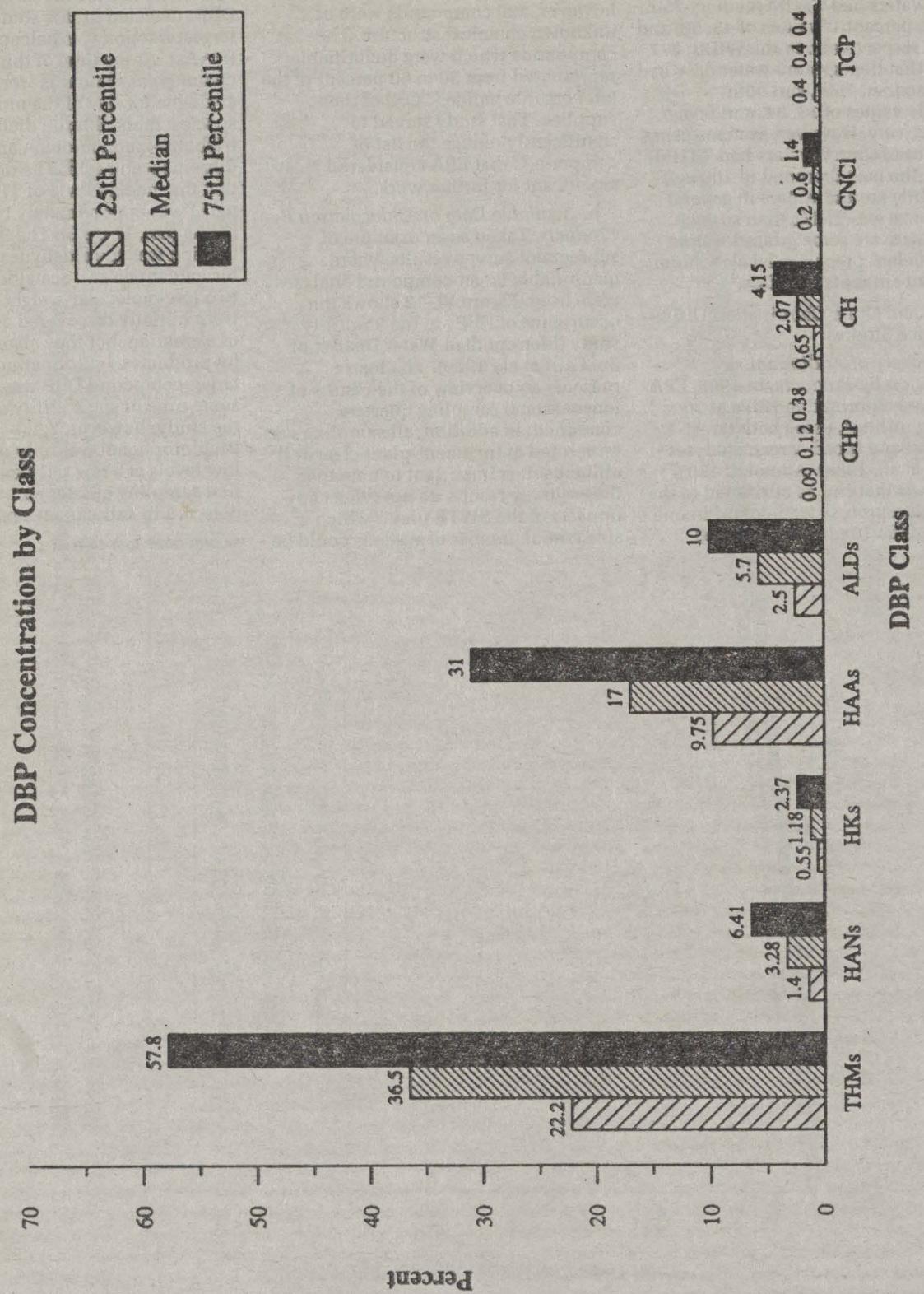

Figure VI-12
DBP Concentration by Class

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The 35-utility DBP study assessed systems using a range of disinfectants, a number of which used chloramines as a residual disinfectant. In a study (in 1987–89) by EPA, primarily chlorine-only systems were evaluated at the plant and in the distribution system (typically a terminal location). The range of total HAAs (THAAs) (a sum of the five aforementioned species) at the plant effluent was <1 to 86 μg/L (representing 73 samples), with a median value of 28 μg/L (Fair, 1992). In the distribution system (56 samples collected), the range and median THAAs were <1–136 and 35 μg/L, respectively.

In a six-utility DBP survey in North Carolina (Grenier et al., 1992), the sum of four measured HAAs—dibromoacetic acid was not included in this study, as these waters are all low in bromide—ranged from 14 to 141 μg/L in the distributed waters (with utility annual averages of 51 to 97 μg/l). In this survey, HAA concentrations consistently exceeded the concentration of TTHMs (which ranged from 13 to 114 μg/l, with utility annual averages of 34 to 72 μg/l). The prevalence of the HAAs may be due, in part, to chlorination of settled and finished waters with pH levels of 5.9 to 7.8. Chlorination at lower pH levels results in lower THM formation but higher HAA concentrations (Stevens et al., 1989).

Recently, a commercial standard for bromochloroacetic acid (BCAA) has become available. Studies to date suggest that the other mixed bromochloroacetic acids may be unstable (Pourmoghaddas et al., 1992). The RNDB includes the occurrence of BCAA for 25 utilities. The median, 75th and 90th percentile occurrence were 3, 5, and 8 μg/L, respectively. In the chlorinated distribution system of a water containing from 0.04 to 0.31 mg/L bromide (i.e., an average- and a high-bromide source water were being treated), BCAA was present from 6 to 17 μg/L and accounted for 25 percent of the concentration of the sum of the six measured HAA species (D/DBP Regulations Negotiation Data Base (RNDB), 1992). Thus, most DBP studies which measured only five of the HAA species will have some level of underestimation of total HAAs present, although that should be a small error in low bromide waters.

The RNDB includes HAA data, including from the 35-utility, EPA, and North Carolina DBP studies. When a utility was sampled more than once in time and space, a "quasi" running annual average value was determined (RNDB). Figure VI–13 shows the cumulative probability occurrence of THAAs (the four- to six-species sums) for large and small systems. The median THAA for either population group is 30 μg/L, although the small systems have 30 percent of the utilities with ≤7 μg/L THAAs. The difference at the low THAA levels was probably due to treatment of low-precursor source waters in small systems. The high end of the THAA occurrence was not significantly different, most likely due to a lack of a HAA regulation and the fact that pH of chlorination impacts THM and HAA formation in opposite ways. In the RNDB, 121 of the utilities treated surface water or a ground water/surface water mix. For those systems treating some percentage of surface water, the median, 75th, 90th percentile, and maximum values were 28, 50, 73, and 155 μg/L, respectively. In the RNDB, 13 of the utilities treated ground water only. For this limited ground water data set, the median, 90th percentile, and maximum values were 4, 13, and 37 μg/L, respectively.

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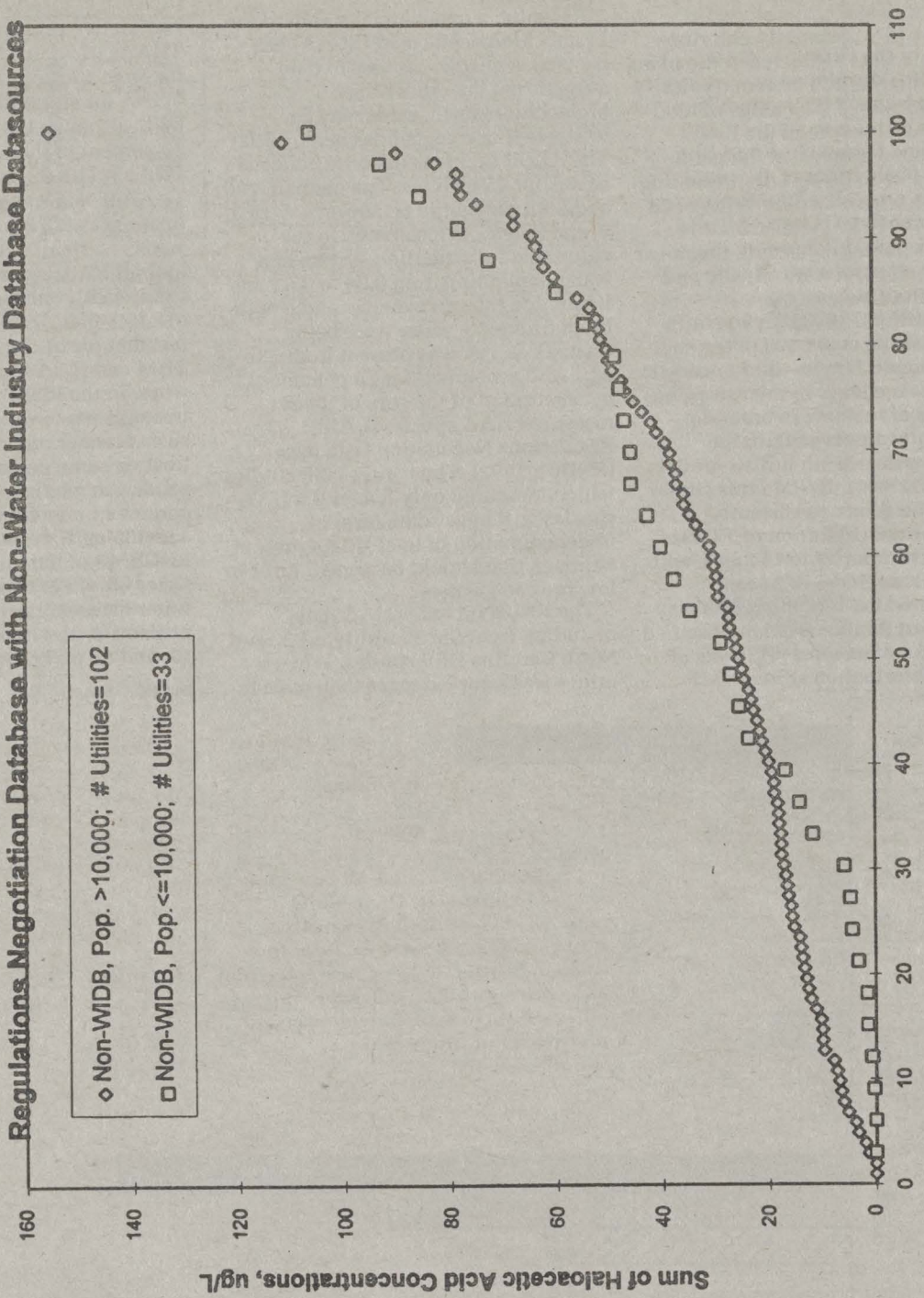
Figure VI.13



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3. Modeling (DBPRAM) Formation TTHMs, HAA5 and Extrapolation to National Occurrence and Effects of SWTR

As part of the D/DBP rulemaking process, EPA developed regulatory impact assessments of technologies that will allow utilities to comply with possible new disinfection and DBP standards (Gelderloos et al., 1992). As part of this process, a DBP Regulatory Assessment Model (DBPRAM) was developed. The DBPRAM included predictive equations to estimate DBP concentrations during water treatment (Harringon et al., 1992). However, because reliable equations for predicting individual DBP formation in a wide range of waters (e.g., those containing high levels of bromide) were not available, the regulatory impact assessments emphasized TTHM (Amy et al., 1987) and total HAA5 formation. Because BCAA was not commercially available when HAAs were measured during the development of the HAA predictive equations, those equations only included the formation of five HAA species (Mallon et al., 1992). However, for a low-bromide water, the error from not including mixed bromochloro HAA species was probably low.

The DBPRAM predicted the removal of TOC during alum coagulation, granular activated carbon (GAC) adsorption, and nanofiltration (Harrington et al., 1992 and Harrington et al., 1991). These equations were developed based upon a number of bench-, pilot-, and full-scale studies. The removal of TOC during precipitative softening, though, has not been modeled to date. However, systems that soften represent a small percentage of the surface-water treatment plants (about 10 percent). The DBPRAM also predicted the alkalinity and pH changes resulting from chemical addition (Harrington et al., 1992), as well as the decay of residual chlorine and chloramines in the plant and distribution system (Dharmarajah et al., 1991).

In developing regulatory impact assessments, the first step was to estimate the occurrence of relevant source-water parameters (Letkiewicz et al., 1992). TOC data from the WIDB and bromide data from the nationwide bromide survey formed the basis for determining the DBP precursor levels (Wade Miller Associates, 1992). Actual water quality data were used to simulate predicted occurrence values based upon a statistical function such as a log-normal distribution (Letkiewicz et al., 1992 and Wade Miller Associates, 1992). In running the DBPRAM, the production of DBPs was restricted to surface-water plants that filtered but did not soften. Surface waters typically have higher disinfection criteria—and thus a greater likelihood to produce more DBPs—than ground waters (i.e., *Giardia* in surface waters is more difficult to inactivate than viruses in ground waters). As mentioned before, an equation to predict TOC removal during softening was not available. However, the surface water systems which were modeled represented water treated and distributed to approximately 103 million people (Letkiewicz et al., 1992). Another mechanism was developed for accounting for DBP occurrence in other water systems (see below).

The second step in the regulatory impact assessment was to prepare a probability distribution of nationwide THM and HAA occurrence if all surface water plants that filter but do not soften used a particular technology for DBP control (i.e., enhanced coagulation, GAC, nanofiltration, or alternative disinfectants). Even though individual utilities will consider a range of technologies to meet disinfection and D/DBP rules, the DBPRAM can only predict the performance of one technology at a time. Subsequently, a decision-making process was employed to examine the predicted compliance choices that systems will make (Gelderloos et al., 1992). As part of the DBPRAM, compliance with the SWTR, a potential enhanced SWTR, the total coliform rule, and the lead-corrosion rule were modeled. Thus, while nationwide DBP studies typically measured DBP occurrence prior to implementation of these new microbial and corrosion rules, the DBPRAM allowed one to assess the impacts of meeting a multitude of rules simultaneously.

During the D/DBP negotiated rulemaking, a Technology Workgroup (TWG) of engineers and scientists was formed. The TWG reviewed the DBPRAM and regulatory impact assessments, and provided input to ensure that the predicted output was consistent with real-world data. Prior validation of the model in Southern California (where bromide occurrence was relatively high) indicated that the central tendency was to underpredict TTHMs by 20–30 percent (Harrington et al., 1992). In addition, evaluation of the model in low-bromide North Carolina waters also found that the model tended to underpredict both THM and HAA concentrations and resulted in absolute median deviations of approximately 25–30 percent (Grenier et al., 1992). Neither Harrington nor Grenier were able to identify reasons for the underpredictions. Therefore, the TWG adjusted the DBPRAM output to correct for the underpredictions; the resultant data were confirmed against full-scale data from throughout the United States.

Prior validation of the alum coagulation part of the model was performed in several eastern states, as well as in Southern California. The overall central tendency was to overpredict TOC removal by 5–10 percent. The TWG believed that utilities would implement an overdesign factor to ensure that precursor removal technologies could consistently meet water quality objectives. A 15 percent overdesign factor for TOC removal compensated for a typical overprediction in TOC removal by alum. For plants that do not filter or filter with softening, case studies on a number of systems through the nation were used to assess compliance choices and predicted water qualities. For ground waters, data from the WIDB and GWSS on TOC and THM levels were used in developing regulatory impact analyses (RIAs) for those systems.

With the revised DBPRAM output, the proposed stage 1 D/DBP rule—i.e., MCLs of 80 µg/L TTHMs and 60 µg/L THAAs, as well as a performance criteria for DBP precursor removal—would affect large systems that filter but do not soften as follows: TTHMs would drop on a median basis from 45 to 32 µg/L, while the 95th percentile would drop from 104 to 58 µg/L; THAAs would drop on a median basis from 27 to 20 µg/L, and the 95th percentile would drop from 86 to 43 µg/L.

C. Other Disinfection Byproducts

1. Ozonation Byproducts

a. *Identification of Ozonation Byproducts.* Ozone can convert organic matter in water to aldehydes (e.g., formaldehyde) (Glaze et al., 1989) and assimilable organic carbon (AOC) (Van der Kooij et al., 1982). Recent research optimized the aldehyde method in order to quantitatively recover additional carbonyls of interest (e.g., dialdehydes such as glyoxal and aldo-ketones such as methyl-glyoxal (Sclimenti et al., 1990)). AOC is the fraction of organic carbon that can be metabolized by microorganisms; it also represents a potential for biological regrowth in distribution systems. Polyfunctional ozone DBPs such as ketoacids have been detected at higher levels than the low-molecular-weight aldehydes and have been shown to correlate well with AOC (Xie et al., 1992). Using resin columns to accumulate organics from ozonated waters, Glaze and co-workers detected

aldehydes, carboxylic acids, aliphatic and alicyclic ketones, and hydrocarbons (Glaze et al., August 1989). Ozone is known to produce other organic oxygenated DBPs, such as peroxides and epoxides (Glaze et al., 1989). Analytical methods for low-level detection are currently not available for epoxides, but progress in detecting peroxides (inorganic and organic) has recently been made (Weinberg et al., 1991). As with chlorine, occurrence data for ozone DBPs are limited to compounds that can be detected by current methods.

Although most ozone by-products are oxygenated species, the presence of bromide will result in the formation of brominated DBPs (Haag et al., 1983 and Dore et al., 1988). When bromide is present in a source water, it may be oxidized by ozone to hypobromous acid (HOBr). At common drinking-water pH levels, HOBr is in equilibrium with the hypobromite ion, OBr^-. Once produced, HOBr can react with organic THM/DBP precursors to form bromoform and other brominated organic by-products (Dore et al., 1988 and Glaze et al., Jan. 1993). OBr^- (but not HOBr) can be oxidized by ozone to bromate (BrO_3^-) (Krasner et al., Jan 1993 and Haag et al., 1983). Krasner and colleagues found that ozonation of bromide-containing waters can form a number of brominated organic DBPs that are analogous to chlorinated DBPs (e.g., bromoform, dibromoacetic acid, tribromonitromethane [bromopicrin], and cyanogen bromide) (Krasner et al., 1990 and Krasner et al., 1991). Similarly, Glaze and co-workers studied the formation of bromo-organic DBPs formed during ozone (e.g., bromoform; dibromoacetonitrile; mono-, di-, and tribromoacetic acid; and monobromoacetone) (Glaze et al., Jan. 1993). However, only a fraction of the dissolved organic bromide was found as targeted brominated organic DBPs (Glaze et al., Jan. 1993). As with chlorination, not all of the halogenated DBPs can be accounted for with existing analytical methodologies. However, researchers are continuing to try to uncover new DBPs all the time, such as the bromine-substituted analogues of chloral hydrate (trichloroacetaldehyde) formed during chlorination and/or ozonation (Xie et al., 1993, in press).

b. *National Occurrence—Trends*—i. Ozone use in U.S., pre vs. post SWTR. While ozone technology in drinking-water treatment has been in use for more than 80 years in Europe, applications in the United States (U.S.) have been much more limited. However, the use of this disinfectant/oxidant is growing rapidly in the U.S. as utilities are working to meet the requirements of the SWTR, anticipation of a D/DBP Rule, regulations for volatile and synthetic organic chemicals, and for taste-and-odor control (Ferguson et al., 1991 and Tate, 1991). Virtually every surface water system use of ozone was intended to accomplish multiple water quality objectives, such as disinfection, DBP control, taste and odor, or any combination of these (Tate, 1991). Ground water plants in Florida have used ozone for controlling DBPs, color, and odor (Tate, 1991).

The first U.S. ozone plant was on-line in 1978. The number increased to 18 by June 1990 (Tate, 1991). A recent survey has identified an additional 11 facilities under construction, as well as at least 37 U.S. ozone pilot-plant studies underway (Rice, Aug.–Sept. 1992). As part of the D/DBP negotiated regulation, the TWG has evaluated compliance choices for meeting stage 1 and possible stage 2 criteria. For example, the TWG predicted that six percent of surface water systems will use ozone/chloramines in addition to enhanced coagulation to achieve compliance with Stage 1 requirements. Depending on the role of precursor-removal criteria in a stage 2 Rule, it is predicted that from 8 to 27 percent of large surface-water systems would use ozone/chloramines as part of the treatment process. The current and projected ozone usage is based on an existing SWTR and the anticipation of a DBP Rule, both of which have led to the choice of ozone, a powerful disinfectant that typically produces limited DBPs.

ii. *AWWARF bromide/bromate survey and studies.* In order to comply with new and more stringent regulations, alternative treatments are being studied. A 2-year study of ozone treatment at 10 North American utilities was conducted at pilot and full scale (Glaze et al., 1993 in press). For four of the six surveyed utilities where the bromide level was ≤0.06 mg/L, bromate was not detected with minimum reporting level (MRL) values of 5–10 µg/L at the ozone dosages investigated (Krasner et al., Jan. 1993). For the other two low-bromide utilities, bromate at 5–8 µg/L was detected inconsistently over time and space. For three of the four tested waters in which the ambient bromide level was 0.18–0.33 mg/L, bromate was typically detected at levels of 9–18 µg/L. No bromate was detected at one utility where the very high level of TOC (i.e., 26 mg/L) may have produced an ozone demand that overwhelmed the production of bromate. In another study, using a special, labor-intensive concentration method at an EPA research facility, bromate was detected in seven of the nine ozonated waters tested at an MRL of 0.4 µg/L or higher (Sorrell et al., 1992). In one instance, bromate was detected in the source water at this MRL value.

Utilizing these data, as well as that of other EPA and AWWARF investigators (Krasner et al., Jan 1993, Amy et al., 1992–93, Sorrell et al., 1992, Hautman, 1992, and Miltner, Jan. 1993). The nationwide distribution of bromate occurrence if all surface water plants switched to ozone for predisinfection was estimated (Krasner et al., 1993). It was estimated that the 20th, median, and 80th percentile for bromate occurrence in surface waters using ozone for predisinfection might be 0.5–0.8, 1–2, and 3–5 µg/L, respectively.

The 90th to 95th percentile occurrence of bromate could be in the range of 5 to 20 µg/L (Krasner et al., 1993). However, the proposed regulation for bromate would result in either (1) some utilities choosing not to employ ozonation or (2) other utilities operating the ozonation process in a manner which would reduce bromate formation. For example, demonstration-scale tests of the ozonation of a surface water containing bromide at approximately the 90th to 95th percentile level of occurrence (i.e., 0.17 to 0.49 mg/L) at an ambient pH of 8 produced from <3 to 25 µg/L bromate, depending on the amount of ozone added (Gramith et al., 1993). In the latter tests, *Giardia* inactivations from ozonation of from 0.5 to 3 logs were achieved. When the pH of ozonation was reduced to about 6, bromate formation in this water was consistently below 10 µg/L and often below 5 µg/L. In addition, *Giardia* inactivations of up to 4 logs were achieved at this pH.

c. *Potential DBPs not regulated at this time.*—i. *Aldehydes, ketones, peroxides, and formation of precursors for other DBPs—national occurrence.* Miltner and co-workers ozonated a surface water with 1.4 mg/L TOC at various ozone doses up to an ozone-to-TOC ratio of 2.8:1 mg/mg (Miltner et al., Nov. 1992). They found that the formation of the three most-prevalent aldehydes (formaldehyde, glyoxal, and methylglyoxal) continued to increase as the ozone dose increased, and that these three aldehydes had not reached maximum yields before the highest ozone-to-TOC ratio was tested. Weinberg and colleagues studied the formation of aldehydes at 10 North American utilities at pilot- and full-scale plants (Weinberg et al., 1993) . The interquartile range (i.e., 25th to 75th percentile occurrence) of formaldehyde was 11 to 20 µg/L, while the sum of aldehydes tested had an interquartile range of 23 to 47 µg/L. The utility with

the highest TOC in the 10-utility study (8.1 mg/L in the ozonator influent) represented a maximum outlier in aldehyde production (i.e., about 70 µg/L formaldehyde and up to 150 µg/L of summed aldehydes). The minimum outlier was the summer testing of a low-TOC water (1.0 mg/L) which received an applied ozone dose of 1.0 mg/L. When the occurrence data were normalized to TOC level, the interquartile ranges were 3.9 to 8.4 µg formaldehyde per mg TOC and 9 to 20 µg of summed aldehydes per mg TOC. This normalization brought the water with the highest TOC into the interquartile range. When the aldehyde formation was further normalized for the ozone dose, the interquartile ranges per unit TOC and per ozone dose were 1.2 to 4.2 µg formaldehyde/(mg * mg/L) and 2.9 to 11 µg summed aldehydes/(mg * mg/L). With this latter normalization, the high-TOC water dropped to almost the minimum outlier. Because the ozone demand of the latter water exceeded the dose, it is possible that more aldehydes could have been produced with a higher dose. These limited data suggest that either TOC or ozone dose can be the limiting factor in aldehyde production (i.e., for the low-TOC water in the summer testing and the high-TOC water, respectively).

While ozonation can produce significant levels of aldehydes, the presence of these ozone by-products in the distribution system are highly dependent on whether the filters downstream of ozone are operated biologically (i.e., no secondary disinfectant is applied before the filters), as well as the choice of filter media and filtration rate (or more exactly, the empty bed contact time [EBCT] in the filter media) (Miltner et al., Nov. 1992, Weinberg et al., 1993, and Krasner et al., May 1993).

Using a bioreactor, many aldehydes can be quantitatively removed (Miltner et al., Nov. 1992). In pilot- and full-scale studies, formaldehyde tended to be the most biodegradable of the aldehydes tested, while the glyoxals, in some instances, were somewhat recalcitrant (Weinberg et al., 1993, and Krasner et al., May 1993). These aldehydes (including the glyoxals) were typically best removed at utilities in which granular activated carbon (GAC) contactors or filters were employed, even when the GAC was removing little or no TOC (Weinberg et al., 1993, and Krasner et al., May 1993). When anthracite coal/sand filters were used without a secondary disinfectant before filtration, these aldehydes could be removed to varying degrees with the best results at low filtration rates (or high EBCTs) (Weinberg et al., 1993, and Krasner et al., May 1993). Because part of the proposed D/DBP Rule sets criteria for biological filtration following ozonation of raw water, it is anticipated that the occurrence of aldehydes, while not directly regulated, can be minimized in the finished water.

Other oxygenated organic ozone by-products (e.g., ketoacids (Xie et al., 1992) and organic peroxides (Weinberg et al., 1991) can also be reduced during biological filtration. The use of biological treatment for drinking water treatment in the United States is currently very limited, while in Europe such processes are more common. However, research into the incorporation of biological filtration in the United States is now being extensively studied and its implementation is becoming more common (Weinberg et al., 1993). In addition, some ozone by-products are relatively unstable (e.g., peroxides and epoxides) and may not persist in the finished water. Furthermore, because hydrogen peroxide can reduce chlorine to chloride ions (Connick, 1947), the addition of free chlorine should destroy a peroxide residual (Weinberg et al., 1991). Finally, because GAC can reduce oxidant residuals, GAC downstream of ozone should be able to destroy hydrogen peroxide.

While ozone can partially destroy the precursors of some THMs and HAAs (Miltner et al., 1992), it can increase the formation potential of other DBPs (e.g., chloropicrin (Miltner et al., Nov. 1992 and Hoigné et al., 1988) and chloral hydrate (Mcknight et al., 1992)). However, Miltner and co-workers found that ozonation followed by biotreatment reduced chloropicrin formation potential (Miltner et al., 1992). McKnight and Reckhow found that if acetaldehyde—an ozone by-product—undergoes an initial chlorine substitution, then the reaction should rapidly proceed to form the trichlorinated product chloral hydrate (Mcknight et al., 1992). Because acetaldehyde can be reduced during biological filtration (Miltner et al., Nov. 1992 and Weinberg et al., May 1993), this should minimize subsequent formation during postchlorination. Jacangelo and colleagues found that when biological filtration was not practiced, preozonation increased chloral hydrate formation in postchlorinated waters (Jacangelo et al., 1989). However, these researchers also observed that chloral hydrate production for systems using preozonation/postchloramination was lower than that for systems using chlorination only (Jacangelo et al., 1989). To avoid by-products of secondary disinfection, more research into the relative merits of biological filtration and/or postchloramination for systems using preozonation must be pursued.

d. *Concerns with AOC in high TOC source waters.* Typically a high-TOC water will have a high oxidant demand. Thus, ozonating a high-TOC water has the potential to form a higher level of ozone by-products, such as aldehydes (see Section VI.C.1.c. above). In addition, there are concerns that more AOC can be formed in such a water.

Amy and colleagues found that biodegradable organic carbon (BDOC) correlated well (r^2=0.92) with the TOC level of ozonated waters (Amy et al., 1992). On the average, 28 percent of the TOC was present as BDOC after ozonation (typical ozone dose of 1:1 mg ozone/mg TOC). However, the correlation between BDOC and AOC for the six waters studied was poor, suggesting that individual source waters may have a unique relationship between these constituents.

While there is a concern over forming AOC, BDOC, aldehydes, etc., during ozonation, current research is examining the ability of the treatment plant to remove significant portions of the biodegradable organic matter (e.g., through biological filtration). A question remains as to what level AOC needs to be reduced to minimize biological regrowth.

e. *Removal of by-products.* Ozonated waters may require GAC treatment or other biological processes for removal of aldehydes, AOC, other DBPs. There are concerns that switching to ozone may increase the availability of AOC and potentially increase bacterial populations in distribution systems. In addition, some ozone by-products (e.g., certain aldehydes and organic peroxides) may be regulated at a future date when more data become available (USEPA, 1991).

During the 35-utility DBP study performed in 1988–1989, two utilities switched to ozonation as the primary disinfectant (Metropolitan Water District of So. Calif et al., 1989 and Jacangelo et al., 1989). Both utilities applied a secondary disinfectant (chlorine or chloramines) before the filtration step. At both plants, ozonation produced formaldehyde and acetaldehyde (aldehydes for which analytical methodology was being used), the levels of which were undiminished in passing through the filters and distribution system. Subsequently, a North American study of 10 utilities that used ozonation at a pilot- and/or full-scale in 1990–1991 (Glaze et al.,

1993, in press; and Weinberg et al., 1993) indicated the following:

- Aldehydes and aldo-ketones—especially formaldehyde, glyoxal, and methyl-glyoxal—were ubiquitous ozone DBPs, formed in all the surveyed utilities.
- These compounds were removed to varying extents by filters which were allowed to operate in a biological mode (i.e., secondary disinfection was postponed until after filtration).
- In studies where formaldehyde and acetaldehyde were efficiently removed, glyoxals were sometimes removed to a lesser extent.
- These aldehydes were typically best removed at utilities in which GAC contactors or filters were employed, even when the GAC was removing little or no TOC.
- However, GAC filters in this survey were almost always operated at lower filtration rates (1.0 to 5.0 gpm/sf), whereas anthracite coal filters were typically operated at higher filtration rates (3.8 to 13.5 gpm/sf).
- In addition, secondary disinfection, which was sometimes applied before the anthracite filters, was never applied before the GAC filters in this survey.

Because surveys provide a "snapshot" of treatment practices in use, other investigators have performed studies to better assess individual parameters that impact the efficacy of biological filtration. Merlet and co-workers (Merlet et al., 1991) evaluated biological activated carbon (BAC) for the reduction in BDOC produced by ozonation. As the EBCT of the BAC was varied up to 25 min, BDOC removal increased up to a point, at which its efficacy plateaued out. LeChevallier and colleagues (LeChevallier et al., 1992) also observed that increased EBCTs increased AOC removal; however, AOC levels of <100 µg/L could be achieved with a 5- to 10-min EBCT. In addition, the latter researchers found that the application of free chlorine to GAC filters did not inhibit AOC removal, whereas the application of chloramines showed a slight inhibitory effect. Furthermore, LeChevallier and colleagues found that GAC filter media supported larger bacterial populations and provided better removal of AOC than conventional filter media (LeChevallier et al., 1992).

Miltner and co-workers (Miltner et al., 1992) found that biological activity was established within approximately one week, as evidenced by 90-percent removal of certain aldehydes. However, approximately 80 days of filter use were required before half of the AOC could be removed. Price and colleagues (Price et al., 1992) found that dual-media filters (anthracite coal/sand) performed as well as GAC after time, especially as the water temperature went up. The latter researchers also observed that GAC/sand filters operating at 1, 3, and 5 gpm/sf provided similar removals of AOC. Reckhow and co-workers (Reckhow et al., 1992) found that GAC/sand filters removed less AOC and aldehydes when backwashed with chlorinated water. As the filtration rate increased, filters backwashed with chlorinated water achieved lower removals, whereas filters backwashed with non-chlorinated waters were less impacted by filtration rate.

Clearly, many researchers are investigating means of optimizing the removal of AOC, BDOC, and aldehydes produced by ozonation through biologically active filtration. Because many plants that are switching to ozonation are retrofitting existing treatment plants, it is desirable to achieve biological filtration with the same filters used for turbidity removal. In pilot-plant testing of ozonation at Metropolitan Water District of Southern California (Metropolitan Water District of So. Calif. et al., 1991), dual-media (anthracite/sand) filters operating at 3 gpm/sf were evaluated, as these were representative of the operation at some of Metropolitan's full-scale facilities. When secondary disinfection was delayed until after filtration, these filters were able to remove AOC, formaldehyde, and acetaldehyde (Paszko-Kolva et al., 1992 and Metropolitan Water District of So. Calif. et al., 1991). However, when the aldehyde analysis was expanded to include glyoxals at the end of the project, limited testing indicated that glyoxals were not well removed by these filters (Metropolitan Water District of So. Calif. et al., 1991). In addition, there were concerns that because some of Metropolitan's facilities operate with higher filtration rates (up to 9 gpm/sf), this could impact the biological filtration process.

A new pilot-plant study was initiated to evaluate biological filtration for the removal of AOC and aldehydes, including the glyoxals . Analyzing for a wide range of aldehydes (i.e., monoaldehydes, such as formaldehyde; the dialdehyde glyoxal; and the aldo-ketone methyl-glyoxal) allowed for a more thorough investigation into the efficacy of biological filtration. Not only may these individual carbonyls pose different health concerns (USEPA, June 1991), but they also have the potential to represent organic matter which is relatively biodegradable (i.e., formaldehyde) and which is potentially somewhat recalcitrant to biological filtration (i.e., the glyoxals).

The latter pilot testing indicated that biological activity was established sooner on slow-filtration-rate filters with a 4.2-min EBCT, but the high-filtration-rate filters with 2.1- and 1.4-min EBCTs eventually were able to achieve comparable capabilities for the removal of AOC and most aldehydes (Krasner et al., May 1993 and Paszko-Kolva et al., 1992). However, even 111 days of operation did not allow the anthracite coal filter operating with a 1.4-min EBCT an opportunity to demonstrate consistently high removal (80 percent) of the glyoxals. The latter filter, though, did remove significant amounts of AOC and formaldehyde. Glyoxals were well removed on the anthracite filter operated at a low filtration rate (with a 4.2-min EBCT) or the GAC filters operated at either low or high filtration rates (with 4.2- and 1.4-min EBCTs, respectively). Note that these filters were able to remove aldehydes and AOC efficiently at relatively short EBCTs and that the higher EBCTs associated with GAC contactors were not required.

Use of a biological filter can produce a more biologically stable water and can minimize the presence of aldehydes and other ozone by-products (e.g., ketoacids (Xie et al., 1992) and peroxides (Weinberg et al., 1991)) of potential health and regulatory concern. As the studies to date demonstrate, the appropriate choice of media and filtration rate can ensure that AOC and specific organic ozone by-products can be significantly reduced in concentration.

2. Chlorine Dioxide Byproducts

Chlorine dioxide is used as an alternative disinfectant to chlorine to treat drinking water for THM control, taste-and-odor control, oxidation of iron and manganese, and oxidant-enhanced coagulation-sedimentation (Aieta et al., 1986). In 1977, 103 facilities in the U.S. were using or had used chlorine dioxide (Symons et al., 1979). Currently, 500 to 900 municipalities in the U.S. use chlorine dioxide, although some use was only seasonal (Private communication with Chemical Manufacturers' Association, 1993). In Europe, several thousand utilities have used chlorine dioxide, mostly to maintain a disinfectant residual in the distribution system (Aieta et al., 1986).

Chlorine-free chlorine dioxide does not react with natural organic matter such as humic and fulvic acids to form THMs (Symons et al., 1981). Studies show that the TOX formed with chlorine dioxide is from 1 to 25 percent

of the TOX formed with chlorine under the same reaction conditions (Aieta et al., 1986 and Symons et al., 1981). Before the introduction of high-yield chlorine dioxide systems that were capable of producing nearly chlorine-free chlorine dioxide solutions, significant amounts of chlorine could be present in the chlorine dioxide solutions used in water treatment. Chlorine dioxide has been used effectively by many utilities in order to comply with the 1979 THM Rule (Aieta et al., 1986 and Lykins et al., 1986).

However, when chlorine dioxide is used, the inorganic by-products chlorite and chlorate are produced. During water treatment, approximately 50–70 percent of the chlorine dioxide reacted will immediately appear as chlorite and the remainder as chlorate (Aieta et al., 1984). The residual chlorite continues to degrade in the water distribution system in reactions with oxidizable material in the finished water or in the distribution system. In a study of five U.S. utilities employing chlorine dioxide, median chlorite and chlorate concentrations in the distribution systems tested typically ranged from 0.4 to 0.8 mg/L and between 0.1 to 0.2 mg/L, respectively (Gallagher et al., 1993, in press). For the latter systems, the 75th percentiles for chlorite concentrations ranged from 0.4 to 1.4 mg/L.

Data for up to 17 utilities in EPA Region 6 who employ chlorine dioxide were obtained (Personal communication, Novatek 1993). In many instances, data for chlorite occurrence on a monthly basis were available. As an example, for June 1992 chlorite ranged from 0.4 to 1.2 mg/L, while in January 1993 chlorite was at values of 0.2 to 0.8 mg/L. The higher values in June may have been due, in part, to the need for more chlorine dioxide in warmer months to meet the oxidant demand of the water. When the data are examined quarterly (e.g., quarter 1 is January through March), Figure VI–14 shows that the highest occurrence for chlorite in the systems sampled in EPA Region 6 was during the spring and summer seasons.

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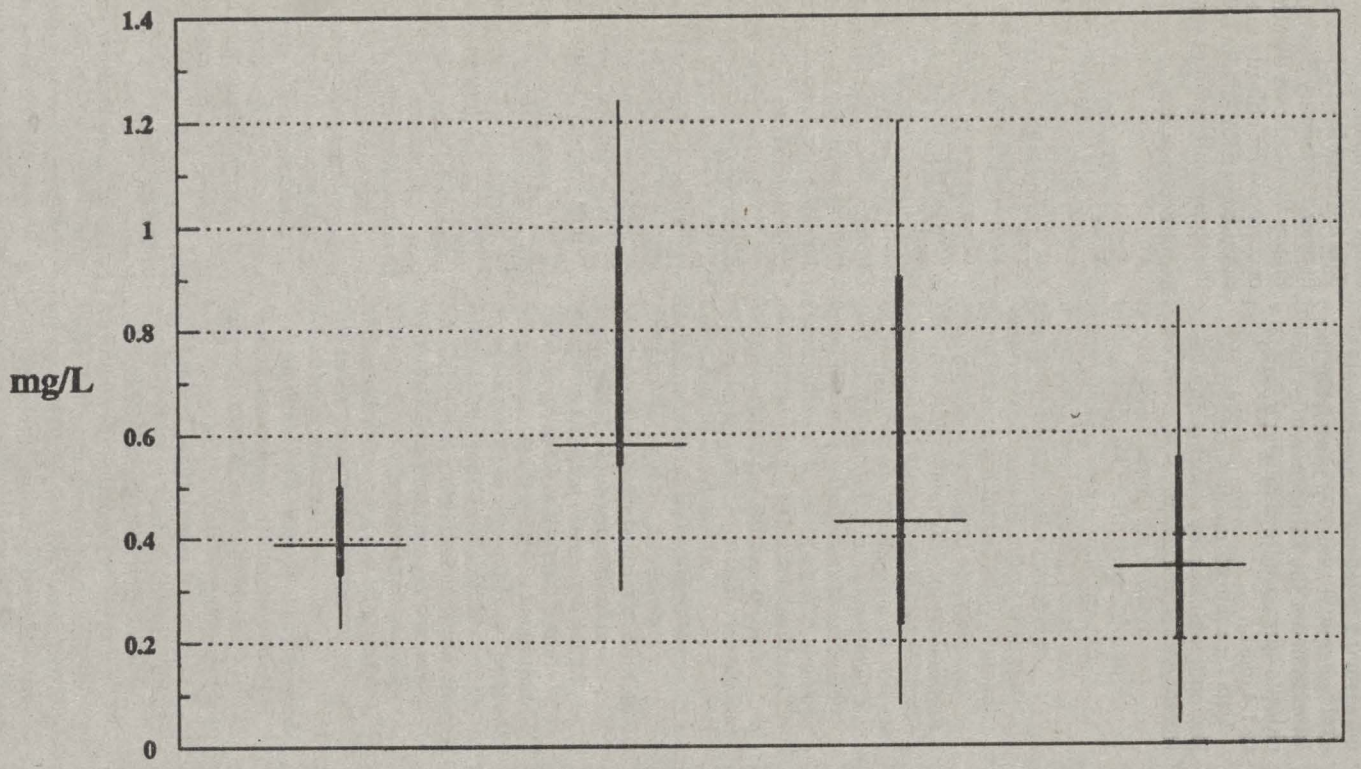
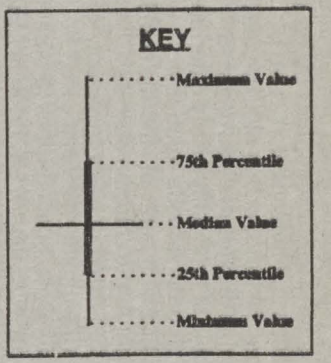
Figure VI-14

Chlorite Occurrence in 1992 for 13 Utilities in US EPA Region VI



	Quarter 1	Quarter 2	Quarter 3	Quarter 4
No. of Points	6	11	19	20
Mean	0.40	0.69	0.52	0.39
Inter-Quartile Range	0.17	0.42	0.67	0.365



a. *Potential chlorine dioxide DBPs not regulated at this time.* This proposed regulation will not include an MCLG or MCL for chlorate. Insufficient data exist at this time to develop an MCLG for chlorate (Orme-Zavaleta, 1992). If chlorate is regulated in the future, systems which use hypochlorination will also need to monitor for this by-product (Bolyard et al., August 1992). Limited testing shows that chlorine dioxide can form low concentrations of aldehydes (Weinberg et al., 1993). However, studies also demonstrate that chlorine can produce aldehydes (Krasner et al., August 1989 and Jacangelo et al., 1989).

3. Chloramination Byproducts

a. *Cyanogen chloride.* Typically, chloramines do not react to form significant levels of THMs and other chlorinated DBPs. Because monochloramine (the predominant form of chloramines in most drinking-water applications) is a much less potent oxidant or chlorinating agent than chlorine, the by-products of monochloramine reactions with organic substances are much less extensively oxidized or chlorinated (Scully, 1990). Nevertheless, chloramines appear to chlorinate natural organic matter sufficient to produce low levels of TOX.

During the 35-utility DBP study, 14 of the 35 utilities surveyed were utilizing chloramines (Krasner et al., 1989). Ten of these had free-chlorine contact time prior to ammonia addition, and the remaining four added chlorine and ammonia concurrently. The median value of cyanogen chloride in utilities that used only free chlorine was 0.4 µg/L. Utilities that pre-chlorinated and postammoniated had a cyanogen chloride median of 2.2 µg/L. The 95-percent confidence intervals around the medians indicated that these two disinfection schemes were statistically different with regard to the cyanogen chloride levels detected in the clearwell effluents. Krasner and co-workers found that a number of parameters affect the formation of cyanogen chloride during chloramination (Krasner et al., 1991).

b. *Potential other chloramination DBPs not regulated at this time.* Studies have demonstrated the formation of organochloramines by the use of inorganic chloramines in the disinfection of water (Scully, 1982). Recently, an analytical method has been developed to distinguish organic chloramines from the inorganic species (Jersy et al., 1991). Monochloramine has been shown to react with aldehydes to yield nitriles (Le Cloirec et al., 1985). The presence of cyanogen chloride and low concentrations of TOX in chloraminated waters indicate a need to further identify chloramine by-products.

VII. General Basis for Criteria of Proposed Rule

A. Goals of Regulatory Negotiation

In the **Federal Register** "Notice of Intent to Form an Advisory Commitee to Negotiate the Disinfection Byproducts Rule and Announcement of Public Meeting" (USEPA, 1992), EPA identified key issues to be addressed and resolved during the conduct of the negotiation. They were:

—What disinfectants and disinfection byproducts present the greatest risks, and how should they be grouped for regulation?
—Which categories of public water suppliers should be regulated?
—Should the regulation establish Maximum Contaminant Levels or be technology driven?
—How effective are advanced technologies and alternative disinfectants in the removal of disinfectants, disinfection byproducts, and microbial risks?
—How should disinfectants, disinfection byproducts, and microbial risks be compared, given differences in the type and certainty of their effects?
—What levels of disinfectant, disinfection byproduct, and microbial risks are acceptable, and at what cost?
—How should the achievement of acceptable levels of risks be defined?
—How might risk-risk models be used, if at all, in the development of Maximum Contaminant levels within the current regulatory schedule?
—How should the needs of sensitive populations be taken into account in the rule?
—How should Best Available Technology be defined for the removal of disinfectants and disinfection byproducts?
—Should a comprehensive disinfectant/disinfection byproduct regulation be issued in 1995, or should the control of certain disinfectants/disinfection byproducts be deferred until research confirms the safety of alternative treatment methods?
—How should affordability be factored into judgements regarding feasibility of treatment techniques?
—How should monitoring requirements be defined?
—How can the rule be drafted to be most easily understood by both State regulators and small system operators?

In addition to the issues identified in the **Federal Register** that needed to be resolved, potential negotiating committee members identified the following additional issues (RESOLVE, 1992a):

—How can the rule be drafted to be most easily accepted and understandable by the general public?
—Is there a need for further regulation of DBPs?
—How should the rule account for differences in size of a system (i.e., number of people served) or a system's water source?
—How should the rule account for differences in type of disinfection technology and quality of source water?
—How should the rule account for the particular characteristics of some water distribution systems that complicate efforts to minimize DBP formation?
—How should the rule account for the cross-media environmental impacts and ecological risks associated with DBP control technologies?
—Will the DBP rule be compatible with other EPA regulations (e.g., groundwater, lead, surface water)? Will current exposure and occurrence data change with implementation of other rules? Are EPA's models good enough to predict the effects of other regulations on the occurrence of various DBPs in drinking water?
—To what extent are watershed protection and maintenance of source water quality useful strategies to achieve risk reduction?
—How should analytic methods be defined? Should DBP content be monitored at the treatment plant, within the distribution system, or at the tap?
—How much has already been achieved by the THM rule? How can this be taken into account in the assumptions for this rule?
—What types of research on DBP effects and controls are presently being or should be conducted in the future?
—What are the assumptions that underlie EPA's description of acceptable risk from exposure to microbes and DBPs in drinking water? Is there a safe level for human exposure to DBPs? How certain are EPA's models? Should EPA's cancer risk assessment policies be reopened in this forum?
—How can the rule be most easily implemented?

B. Concerns for Downside Microbial Risks and Unknown Risks From DBPs of Different Technologies

This rule is intended to limit concentrations of disinfectants and their byproducts in public water systems. However, there is the possibility that

reducing the level of disinfection without adequately addressing microbial risk may result in increasing microbial exposure. The Negotiating Committee wanted to ensure that drinking water utilities can effectively provide treatment that controls both disinfectants and their byproducts and microbial contaminants. The Negotiating Committee believes it accomplished this goal by developing an additional proposed rule (Enhanced Surface Water Treatment Rule, proposed elsewhere in today's **Federal Register**) to control the level of microbial risk.

If disinfection is decreased to reduce byproduct formation, there is the possibility that risk from pathogenic organisms could increase. This relationship is not well understood, particularly as it applies to the many different source waters and the various disinfectants that may be used. To better understand and characterize this risk-risk relationship, EPA proposed an Information Collection Rule [59 *FR* 6332] to gather needed information.

In addition to concerns about increasing microbial risk, the Negotiating Committee had concerns about large numbers of systems switching from chlorine to an alternative disinfectant (e.g., ozone, chlorine dioxide, chloramines) whose disinfection efficacy and byproducts (both occurrence and health effects) are not as well understood as those of chlorine. Chlorine has been studied far more than the alternative disinfectants; this additional study may account for some or all of the differences in known health risks. Chlorine has proved to be an effective disinfectant under a wide range of conditions. For conditions where chlorine was not adequate as a disinfectant (e.g., high TTHM formation potential or high pH), systems have changed to other disinfectants. However, the Committee does not want to force large numbers of additional systems to switch disinfectants before more information is available, since research has indicated that health risks from alternative disinfectants may be significant (e.g., bromate formation from ozonation).

C. Ecological Concerns

In addition to concerns about risk-risk tradeoffs and risks from alternative disinfectants, the Technologies Working Group (TWG) identified ecological risks that could result from a change in technology. These concerns included:

—Moving the point of chlorination may result in problems with zebra mussel infestation in the intake pipe.
—Increasing addition of coagulants may result in increased sludge production and attendent disposal problems.
—Changing to ozone may require large amounts of additional energy (electricity) for ozone generation.
—Adding GAC makes construction of on- or off-site GAC regeneration facilities necessary.
—Adding membranes may require large amounts of additional energy (electricity) for pressure, may cause problems in disposing of brine in some areas, and may not be feasible in water-short areas.

D. Watershed Protection

One issue that the Negotiating Committee considered throughout the negotiation process was the relationship and role of watershed protection to these proposed regulations. The Committee desired to promote watershed protection and to provide incentives to establish new watershed protection programs and to improve existing ones. These desires were prompted by the benefits that watershed protection provides not only for disinfectant byproduct control, but for a wide range of potential drinking water contaminants and related water supply and environmental issues.

Watershed protection reduces microbial contamination in water sources, and hence the amount of disinfectant needed to reduce microbial risk to a specified level in a finished water supply. It also reduces the level of turbidity, pesticides, volatile organic compounds, and other synthetic organic drinking water contaminants found in some water sources. Precursor (material that reacts with disinfectants to form disinfection byproducts) levels can be lowered, which may lower the levels of DBPs formed. Watershed protection results in economic benefits for water supply systems by minimizing reservoir sedimentation and eutrophication and reducing water treatment operation and maintenance costs. Moreover, adequate watershed protection in many cases will reduce overall organic matter (TOC) in source water and therefore reduce DBP formation. Watershed protection also provides other environmental benefits through improvements in fisheries and ecosystem protection.

The types of watershed programs that the Committee wished to encourage are those that consider agricultural controls, silvicultural controls, urban non-point controls, point discharge controls, and land use protections which are tailored to the environmental and human characteristics of the individual watershed. These characteristics include the hydrology and geology of the watershed, the nature of human sources of contaminants, and the legal, financial and political constraints surrounding entities which have control of aspects of the watershed.

The Committee considered options for providing incentives for watershed protection programs directly within these proposed regulations through such things as reduced monitoring or reduced requirements based on the existence of a watershed program. However, unlike other potential contaminants whose introduction can be directly prevented by watershed protection, disinfectant byproducts do not directly enter the water source, but are formed in the water treatment process.

Because of general agreement that watershed protection had qualitative benefits, the Committee agreed that watershed protection was desirable and included several indirect incentives for watershed protection within these proposed regulations. The TOC levels which trigger enhanced coagulation requirements under the proposed Disinfectant Byproducts Rule and which trigger pilot studies under the proposed Information Collection Rule are those that are typically achieved in water supplies with protected watersheds. Systems which meet the source water criteria for unfiltered systems under the Surface Water Treatment Rule do not have to conduct virus monitoring under the proposed Information Collection Rule [59 *FR* 6332], whether the system is filtered or unfiltered. These systems are likely to have watershed protection programs. The proposed Enhanced Surface Water Treatment Rule (proposed elsewhere in today's *FR*) contains proposed options which require less water treatment for water sources with lower levels of microbial contamination. Such sources can achieve those levels through watershed protection programs. The Negotiating Committee believes that these indirect incentives will result in enhancements to watershed protection efforts in many systems.

E. Narrowing of Regulatory Options Through Reg-Neg Process

The Negotiating Committee considered a wide range of regulatory options during the development process. The initial approach was to come up with several straw regulation outlines. These could generally be classified as being either (1) MCL regulations (in which compliance would be determined by meeting MCLs for specified disinfectants and DBPs) or (2) treatment technique regulations (in which compliance would be determined by meeting specified treatment

parameters or surrogate compound maximum levels).

The Negotiating Committee considered two categories of MCL options. The first was MCLs for groups of related DBPs, such as TTHMs and HAA5. Advantages of this approach included regulatory simplicity, avoidance of tinkering with disinfection operations to address minor exceedances of MCLs of individual DBPs, and the complex, not-well-understood production relationships among related DBPs. MCLs for individual compounds were also considered. Some members of the Negotiating Committee felt that individual MCLs approach best met the intent of the SDWA by regulating specific, measurable chemicals.

The Negotiating Committee also considered treatment technique options. The first would have required systems to reduce the levels of DBP precursors (DBPP)—compounds that react with disinfectants to form DBPs, such as total organic carbon—to less than some specified level before adding any disinfectant. This approach may be inappropriate for two reasons. First, systems have different levels and types of precursors; using a surrogate such as TOC as a trigger may result in tremendous variation in DBP levels from system to system due to the disinfectant used, composition and reactivity of the DBPP, and presence of other DBPPs such as bromide. Also, many systems must add a disinfectant as an oxidant immediately at the source water intake to control water quality problems (e.g., zebra mussels, iron).

The second treatment technique option was enhanced coagulation, which is the addition of higher levels of coagulant than required to meet turbidity limits for the purpose of removing higher levels of DBPPs. However, enhanced coagulation is practical only in systems that operate conventional filtration treatment. Systems using other filtration technologies (e.g., direct filtration, slow sand filtration) or that do not filter (such as most ground water systems) cannot operate enhanced coagulation without addition of conventional filtration treatment. Also, some systems have water that cannot be effectively treated by enhanced coagulation.

A final option considered was a "risk bubble". Under this option, systems would be required to keep the sum of estimated risks from levels of specified DBPs under a certain risk level. However, this option was quickly dropped because of many problems, including failure to account for potential synergisms and antagonisms between DBPs, data gaps, and the evolving nature of risk assessment.

VIII. Summary of the Proposed National Primary Drinking Water Regulation for Disinfectants and Disinfection Byproducts

The Disinfectants and Disinfection Byproducts Rule (D/DBPR) proposal addresses a number of complex and interrelated drinking water issues. EPA must balance the health risks from microbial organisms (such as *Giardia, Cryptosporydium*, bacteria, and viruses) against risks from compounds formed during water disinfection. Most of the DBPs that have been measured in drinking water are byproducts from the use of chlorine. While there is some occurrence information on even these DBPs, the extent of exposure for systems that have not reported DBP levels can only be estimated using available information on TOC levels and the available models. A subset of DBPs has been studied to determine whether long-term exposure to them presents a risk to public health. The current lack of data on certain relatively unstudied DBPs and on the effectiveness of certain treatment techniques has made regulatory decisions more difficult. Water treatment facilities and their customers potentially face significant changes to treatment operations in response to the proposed regulations and will have to pay more for water treatment. For these reasons, EPA is proposing the D/DBPR in two stages. The two-stage process allows the best use of information available during the regulatory development.

The Stage 1 D/DBPR, which will be proposed, promulgated, and implemented concurrently with the Interim Enhanced Surface Water Treatment Rule, will:

—Lower the maximum contaminant level (MCL) for total trihalomethanes (the only DBPs currently regulated);
—Add new disinfectants and DBPs for regulation; and
—Extend regulations to include all system sizes.

For the Stage 2 D/DBPR, EPA will collect data on parameters that influence DBP formation and occurrence of DBPs in drinking water through an Information Collection Rule for large community water systems (59 FR 6332). Based on this information and new data generated through research, EPA will reevaluate the Stage 2 regulations and repropose, as appropriate, depending on criteria agreed on in a second regulatory negotiation (or similar rule development process). In addition, Stage 2 D/DBPR MCLs for TTHMs and HAA5 are being proposed in this Federal Register notice.

A. Schedule and Coverage

The requirements of this rule will apply to community water systems (CWSs) and nontransient noncommunity water systems (NTNCWSs) that treat their water with a chemical disinfectant for either primary or residual treatment. In addition, MRDL and monitoring requirements for chlorine dioxide will also apply to transient noncommunity water systems because of the short-term health effects from high levels of chlorine dioxide (see section V. for a detailed discussion of health effects).

The effective dates for compliance with these requirements will be staggered based on system size and raw water source. The schedule is summarized in Table VIII–1. Members of the Negotiating Commitee reserved the right to comment on the timetable for promulgation of the final rule and on the compliance dates of the rule.

—Subpart H systems (systems that use surface water or ground water under the direct influence of surface water, in whole or in part) serving 10,000 or more persons must comply with the Stage 1 requirements beginning 18 months from promulgation.
—Subpart H systems serving fewer than 10,000 persons must comply with the Stage 1 requirements beginning 42 months from promulgation.
—A CWS or NTNCWS using only ground water not under the direct influence of surface water serving 10,000 or more persons must comply with the Stage 1 requirements beginning 42 months from promulgation.
—A CWS or NTNCWS using only ground water not under the direct influence of surface water serving fewer than 10,000 persons must comply with the Stage 1 requirements beginning 60 months from promulgation.

TABLE VIII–1.—COMPLIANCE DATE OF STAGE 1 REGULATIONS FOR CWSS OR NTNCWSS

Raw water source	Number of people served	Following promulgation, regulations become effective after
Surface	≥10,000	18 Months.
Surface	<10,000	42 Months.
Ground	≥10,000	42 Months.
Ground	<10,000	60 Months.

In this proposal, EPA has not specified how monitoring and compliance requirements should be split among wholesalers and retailers of water. The Agency believes that § 141.29 (consecutive systems) provides the State adequate flexibility and authority to address individual situations. EPA solicits comment on whether any specific federal regulatory requirements are necessary to handle such situations. If so, what are they?

B. Summary of DBP MCLs, BATs, and Monitoring and Compliance Requirements

EPA is proposing to amend Subpart G, Maximum Contaminant Levels, by adding § 141.64, Maximum Contaminant Levels for Disinfection Byproducts. Section 141.64 lists the proposed MCLs for total trihalomethanes (TTHMs—i.e., the sum of the concentrations of chloroform, bromodichloromethane, dibromochloromethane, and bromoform), haloacetic acids (five) (HAA5—i.e., the sum of the concentrations of mono-, di-, and trichloroacetic acids and mono- and dibromoacetic acids), bromate, and chlorite. Routine monitoring requirements for all DBPs and residual disinfectants are summarized in Table VIII–2. Reduced monitoring requirements for all DBPs and residual disinfectants are summarized in Table VIII–3. Members of the Negotiating Committee reserved the right to comment on the question of whether compliance monitoring is defined as an average of several samples across the distribution system and over time or whether it will be based upon monitoring at points of maximum residence time. See Section IX of this notice for further discussion and EPA's solicitation of comments on this issue.

TABLE VIII–2.—ROUTINE MONITORING REQUIREMENTS [7]

Requirement (reference)	Location for sampling	Large surface systems [1]	Small surface systems [1]	Large ground water systems [2]	Small ground water systems [2]
TOC (141.133(b)(3)) ...	Paired samples[3]—Only required for plants with conventional filtration treatment.	1 paired sample/ month/ plant [3].	1 paired sample/ month/plant [3].	NA	NA.
TTHMs (141 133(b)(1)(i)).	25% in dist sys at max res time, 75% at dist sys representative locations.	4/plant/ quarter	1/plant/quarter [6] at maximum residence time if pop. <500, then 1/plant/ yr [8].	1/plant/quarter [6] at maximum residence time.	1/plant/year [6,8] at maximum residence time during warmest month.
THAAs (141.133(b)(1)(i)).	25% in dist sys at max res time, 75% at dist sys representative locations.	4/plant/ quarter	1/plant/quarter [6] at maximum residence time if pop. <500, then 1/plant/ yr [8].	1/plant/quarter [6] at maximum residence time.	1/plant/year [6,8] at maximum residence time during warmest month.
Bromate [4] (141 133(b)(1)(iii)).	Dist sys entrance point.	1/month/trt plant using O_3.	1/month/trt plant using O_3.	1/month/trt plant using O_3.	1/month/trt plant using O_3.
Chlorite [5] (141 133(b)(1)(ii)).	1 near first cust, 1 in dist sys middle, 1 at max res time.	3/month	3/month	3/month	3/month.
Chlorine (141.133(b)(2)(i)).	Same points as coliform in TCR.	Same times as coliform in TCR.	Same times as coliform in TCR.	Same times as coliform in TCR.	Same times as coliform in TCR.
Chlorine dioxide [5] (141 133(b)(2)(ii)).	Entrance to dist sys ..	Daily/trt plant using ClO_2.	Daily/trt plant using ClO_2.	Daily/trt plant using ClO_2.	Daily/trt plant using ClO_2.
Chloramines (141.133(b)(2)(i)).	Same points as coliform in TCR.	Same times as coliform in TCR.	Same times as coliform in TCR.	Same times as coliform in TCR.	Same times as coliform in TCR.

[1] Large surface (Subpart H) systems serve 10,000 or more persons. Small surface (Subpart H) systems serving fewer than 10,000 persons.

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

[3] Subpart H systems which use conventional filtration treatment (defined in Section 141.2) must monitor 1) source water TOC prior to any treatment and 2) treated TOC before continuous disinfection (except that systems using ozone followed by biological filtration may sample after biological filtration) at the same time; these two samples are called paired samples.

[4] Only required for systems using ozone for oxidation or disinfection.

[5] Only required for systems using chlorine dioxide for oxidation or disinfection. Additional chlorine dioxide monitoring requirements apply if any chlorine dioxide sample exceeds the MRDL.

[6] Multiple wells drawing water from a single aquifer may, with State approval, be considered one treatment plant for determining the minimum number of samples.

[7] Samples must be taken during representative operating conditions. Provisions for reduced monitoring shown elsewhere.
[8] If the annual monitoring result exceeds the MCL, the system must increase monitoring frequency to 1/plant/quarter. Compliance determinations will be based on the running annual average of quarterly monitoring results.

TABLE VIII–3.—REDUCED MONITORING REQUIREMENTS[2]

Requirement (reference)	Location for reduced sampling	Reduced monitoring frequency and prerequisites[1]
TOC (141.133(c)(3))	Paired samples[3]	Subpart H systems-reduced to 1 paired sample/plant/quarter if 1) avg TOC <2.0mg/l for 2 years or 2) avg TOC <1.0mg/l for 1 year. Monitoring cannot be reduced if source water TOC >4.0mg/l.
TTHMs and THAAs (141 133(c)(1))	In dist sys at point with max res time.	Subpart H systems serving 10,000 or more-reduced to 1/plant/qtr if 1) system has completed at least 1 yr of routine monitoring and 2) *both* TTHM and THAA running annual averages are no more than 40 µg/l and 30 µg/l, respectively. Subpart H systems serving <10,000 and ground water systems[6] serving 10,000 or more-reduced to 1/plant/yr if 1) system has completed at least 1 yr of routine monitoring and 2) *both* TTHM and THAA running annual averages are no more than 40 µg/l and 30 µg/l, respectively. Samples must be taken during month of warmest water temperature. Subpart H systems serving <500 may not reduce monitoring to less than 1/plant/yr. Groundwater systems[6] serving <10,000-reduced to 1/plant/3yr if 1) system has completed at least 2 yr of routine monitoring and *both* TTHM and THAA running annual averages are no more than 40 µg/l and 30 µg/l, respectively or 2) system has completed at least 1 yr of routine monitoring and *both* TTHM and THAA annual samples are no more than 20 µg/l and 15 µg/l, respectively. Samples must be taken during month of warmest water temperature.
Bromate[4] (141.133(c)(1))	Dist sys entrance point	1/qtr/trt plant using O_3, if system demonstrates 1) avg raw water bromide <0.05 mg/l (based on annual avg of monthly samples).
Chlorite[5] (141.133(c)(1))	NA	Monitoring may not be reduced.
Chlorine, chlorine dioxide[5], chloramines (141.133(c)(2)).	NA	Monitoring may not be reduced.

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

1. Maximum Contaminant Levels for Total Trihalomethanes and Total Haloacetic Acids

The formation rate of DBPs is affected by type and amount of disinfectant used, water temperature, pH, amount and type of precursor material in the water, and the length of time that water remains in the treatment and distribution systems. For this reason, the proposed rule specifies the point in the distribution system (and in some cases, the time) where samples must be taken.

In this action today, EPA proposes to lower the MCL for TTHMs from 0.10 mg/l to 0.080 mg/l. In addition, EPA proposes to set the Stage 1 MCL for HAA5 at 0.060 mg/l. EPA believes that by meeting MCLs for TTHMs and HAA5, water suppliers will also control the formation of other DBPs not currently regulated that may also adversely affect human health.

a. *Subpart H Systems Serving 10,000 or More People.*

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

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure VIII–1). Systems eligible for reduced monitoring may reduce the monitoring frequency for TTHMs and HAA5 to one sample per quarter. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year is no more than 75 percent of each MCL. Systems that do not meet these levels revert to routine monitoring.

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

FIGURE VIII–1.—ELIGIBILITY FOR REDUCED MONITORING: ALL SYSTEMS SERVING 10,000 OR MORE PEOPLE AND SURFACE WATER SYSTEMS SERVING 500 OR MORE PEOPLE

All systems serving 10,000 or more people, and surface water systems serving 500 or more people, may reduce monitoring of TTHMs and HAA5 if they meet all of the following conditions:

FIGURE VIII–1.—ELIGIBILITY FOR REDUCED MONITORING: ALL SYSTEMS SERVING 10,000 OR MORE PEOPLE AND SURFACE WATER SYSTEMS SERVING 500 OR MORE PEOPLE—Continued

—The annual average for TTHMs is no more than 0.040 mg/l.
—The annual average for HAA5 is no more than 0.030 mg/l.
—At least one year of routine monitoring has been completed.
—Annual average source water Total Organic Carbon (TOC) level is no more than 4.0 mg/l prior to treatment.

b. *Ground Water Systems Serving 10,000 or More People.*

Routine Monitoring: CWSs and NTNCWSs using only ground water sources not under the direct influence of surface water that treat their water with a chemical disinfectant and serve 10,000 or more people are required to take one water sample each quarter for each treatment plant in the system. Samples must be taken at points that represent the maximum residence time in the distribution system. For purposes of this regulation, multiple wells drawing raw water from a single aquifer may, with State approval, be considered one plant for determining the minimum number of samples. Systems may take additional samples if they desire. If additional samples are taken, at least 25 percent of the total number of samples must be taken at the point of maximum residence time in the distribution system. The remaining samples must be taken at representative points in the distribution system.

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure VIII–1). Systems eligible for reduced monitoring may reduce the monitoring frequency to one sample per treatment plant per year. Systems that are on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year is no more than 75 percent of the MCLs. Systems that do not meet these levels must revert to routine monitoring.

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

c. *Subpart H Systems Serving 500 to 9,999 People.*

Routine Monitoring: Systems are required to take one water sample each quarter for each treatment plant in the system. All samples must be taken at the point of maximum residence time in the distribution system.

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure VIII–1). Systems eligible for reduced monitoring may reduce the monitoring frequency for TTHMs and HAA5 to one sample per year per treatment plant. Systems that are on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year is no more than 75 percent of the MCLs. Systems that do not meet these levels must revert to routine monitoring.

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

d. *Subpart H Systems Serving Fewer than 500 People.*

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

Reduced Monitoring: These systems may not reduce monitoring. Systems on increased monitoring may return to routine monitoring if the annual average of quarterly samples is no more than 75 percent of the TTHM and HAA5 MCLs.

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

e. *Ground Water Systems Serving Fewer than 10,000 People.*

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

Reduced Monitoring: To qualify for reduced monitoring, systems must meet certain prerequisites (see Figure VIII–2). Systems eligible for reduced monitoring may reduce the monitoring frequency for TTHMs and HAA5 to one sample per three-year monitoring cycle. Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year is no more than 75 percent of the MCLs. Systems that do not meet these levels must resume routine monitoring. Systems on increased monitoring may return to routine monitoring if the annual average of quarterly samples is no more than 75 percent of the TTHM and HAA5 MCLs.

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

Systems using ground water not under the direct influence of surface water that serve fewer than 10,000 people may reduce monitoring for TTHMs and HAA5 if they meet either of the following conditions:
1. The average of two consecutive annual samples for TTHMs is no more than 0.040 mg/l, the average of two consecutive annual samples for HAA5 is no more than 0.030 mg/l, at least two years of routine monitoring has been completed, and the annual average source water Total Organic Carbon (TOC) level is no more than 4.0 mg/l prior to treatment.
2. The annual sample for TTHMs is no more than 0.020 mg/l, the annual sample for HAA5 is no more than 0.015 mg/l, at least one year of routine monitoring has been completed, and the annual average source water Total Organic Carbon (TOC) level is no more than 4.0 mg/l prior to treatment.

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

f. *Best Available Technology.*

EPA has identified the best technology available for achieving compliance with the MCLs for both TTHMs and HAA5 as enhanced coagulation or treatment with granular activated carbon with a ten minute empty bed contact time and 180 day reactivation frequency (GAC10), with

chlorine as the primary and residual disinfectant. Enhanced coagulation means the addition of excess coagulant for improved removal of disinfection byproduct precursors by conventional filtration treatment.

2. Maximum Contaminant Level for Bromate

Bromate is one of the principal byproducts of ozonation in bromide-containing source waters. The proposed MCL for bromate is 0.010 mg/l.

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

Reduced Monitoring: If a system's monthly measurements for one year indicate that the average raw water bromide concentration is less than 0.05 mg/l, the system may reduce the monitoring frequency to once per quarter.

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

Best Available Technology: EPA has identified the best technology available for achieving compliance with the MCL for bromate as control of ozone treatment process to reduce production of bromate.

3. Maximum Contaminant Level for Chlorite

Chlorite is an inorganic DBP formed when drinking water is treated with chlorine dioxide. The proposed MCL for chlorite is 1.0 mg/l.

Routine Monitoring: CWSs and NTNCWSs using chlorine dioxide for disinfection or oxidation are required to take three samples each month in the distribution system. One sample must be taken at each of the following locations: as close as possible to the first customer, in a location representative of average residence time, and as close as possible to the end of the distribution system (reflecting maximum residence time in the distribution system).

Reduced monitoring: Systems required to monitor for chlorite may not reduce monitoring.

Compliance Determination: A PWS is in compliance if the monthly average of samples is less than or equal to the MCL.

Best Available Technology: EPA has identified as the best means available for achieving compliance with the chlorite MCL as control of treatment processes to reduce disinfectant demand, and control of disinfection treatment processes to reduce disinfectant levels.

C. Summary of Disinfectant MRDLs, BATs, and Monitoring and Compliance Requirements

Disinfectants are added during water treatment to control waterborne microbial contaminants. Some residual disinfectants will remain in water after treatment. MRDLs protect public health by setting limits on the level of residual disinfectants in drinking water. MRDLs are similar in concept to MCLs—MCLs set limits on contaminants and MRDLs set limits on residual disinfectants. MRDLs, like MCLs, are enforceable.

1. MRDL for Chlorine

Chlorine is a widely used and highly effective water disinfectant. The proposed MRDL for chlorine is 4.0 mg/l.

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

Reduced monitoring: Monitoring for chlorine may not be reduced.

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

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

2. MRDL for Chloramines

Chloramines are formed when ammonia is added during chlorination. The proposed MRDL for chloramines is 4.0 mg/l (as total chlorine).

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

Reduced monitoring: Monitoring for chloramines may not be reduced.

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

Compliance Determination: A PWS is in compliance with the MRDL when the running annual average of samples, computed quarterly, is less than or equal to the MRDL. EPA recognizes that it may be appropriate to increase residual disinfectant levels in the distribution system of chloramines significantly above the MRDL for short periods of time to address specific microbiological contamination problems (e.g., distribution line breaks, storm runoff events, source water contamination, or cross-connections).

Best Available Technology: EPA identifies the best means available for achieving compliance with the MRDL for chloramines as control of treatment processes to reduce disinfectant demand, and control of disinfection treatment processes to reduce disinfectant levels.

3. MRDL for Chlorine Dioxide

Chlorine dioxide is used primarily for the oxidation of taste and odor-causing organic compounds in water. It can also be used for the oxidation of reduced iron and manganese and color, and is also a powerful disinfectant and algicide. Chlorine dioxide reacts with impurities in water very rapidly, and is dissipated very quickly. EPA is proposing an MRDL of 0.80 mg/l for chlorine dioxide.

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

distribution system. If the MRDL is exceeded, the system must go to increased monitoring.

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

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

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

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

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

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

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

Monitoring for CT credit: Subpart H systems required to operate enhanced coagulation or enhanced softening may receive credit for compliance with CT requirements in Subpart H if the following monitoring is completed and the required operational standards are met.

—For each chlorine dioxide generator, the system must demonstrate that the generator is achieving at least 95 percent yield and producing no more than five percent free chlorine by testing a minimum of once per week.

—On any day that a generator fails to achieve at least 95 percent yield, and on subsequent days until at least 95 percent yield is achieved, and/or any day that the generator produces more than five percent free chlorine and on subsequent days until no more than five percent free chlorine is produced, the system may not receive credit for compliance with CT requirements.

—On any day that a generator achieves at least 90 percent, but less than 95 percent, yield, and/or any day that a generator produces more than five percent, but less than 10 percent, free chlorine, the system may take immediate corrective action to achieve a minimum of 95 percent yield and no more than five percent free chlorine. If subsequent testing conducted on the same day demonstrates at least 95 percent yield and no more than five percent free chlorine, the system may receive credit for compliance with CT requirements on that day. If the generator continues to fail to demonstrate at least 95 percent yield and/or continues to produce more than five percent free chlorine, the system may not receive credit for compliance with CT requirements on that day.

—Measurements must be made at least every seven days. If, in the interim, the system changes generator conditions (e.g., change in chlorine dose, change conditions to match changing plant flow rate), it shall remeasure for chlorine dioxide yield and free chlorine.

To calculate compliance with § 141.133(b)(2)(ii)(C) in order to receive credit for CT compliance, Method 4500–ClO_2 E (Standard Methods for the Examination of Water and Wastewater, 18th Ed. 1992) must be used to determine concentrations of chlorine dioxide, chlorine, and related species in the generator effluent. Calculations are performed as demonstrated below.

1. Perform titration on generator sample aliquots as required by Method 4500–ClO_2 E. Record the titration readings for A through E below, the normality (N) of the titrant used, and the sample dilution.

—A (ml titrant/ml sample) for titration of chlorine and one-fifth of ClO_2.

—B (ml titrant/ml sample) for titration of four-fifths of ClO_2 and of chlorite.

—C (ml titrant/ml sample) for titration of nonvolatilized chlorine.

—D (ml titrant/ml sample) for titration of chlorite.

—E (ml titrant/ml sample) for titration of chlorine, ClO_2, chlorate, and chlorite.

—N (normality of the titrant used in equivalents per liter).

2. Determine chlorine dioxide generator performance (yield). The calculations in a. through c. below must be corrected for the sample dilution.

a. Calculate chlorine dioxide concentration.

$$[ClO_2\ (mg/l)] = 13490 \times 5/4 \times (B - D) \times N$$

b. Calculate chlorite concentration.

$$[ClO_2\ (mg/l)] = 16863 \times D \times N$$

c. Calculate chlorate concentration.

$$[ClO_3\ (mg/l)] = 13909 \times [E - (A+B)] \times N$$

d. Calculate yield (in %).

$$\%\,\text{Yield} = \frac{[ClO_2\ (mg/l)] \times 100}{[ClO_2\ (mg/l)] + [ClO_2\ (mg/l)] + (67.5/83.5)[ClO_3\ (mg/l)]}$$

3. Determine excess chlorine. This calculation must be corrected for sample dilution.

a. Calculate chlorine concentration.

$$[Cl_2\ (mg/l)] = \{A - [(B - D)/4]\} \times N \times 35453$$

b. Using the concentrations of chlorine dioxide, chlorite, and chlorate calculated above (2.a.–c.), calculate excess chlorine.

$$\text{Excess chlorine (in \%)} = \frac{[ClO_2\ (mg/l)] \times 100}{\left\{[ClO_2\ (mg/l)] + [ClO_2\ (mg/l)] + \frac{67.5}{83.5}[ClO_3\ (mg/l)]\right\} \times \frac{70.9}{2 \times 67.5}}$$

4. Determine whether CT credit can be taken.

a. If % Yield ≥ 95% and % Excess Chlorine ≤ 5%, CT credit may be taken.

b. If % Yield ≥ 90% but < 95%, and/or % Excess chlorine > 5% but < 10%, the system may take immediate corrective action and then remeasure. CT credit may be taken if a subsequent measurement performed on the same day shows a yield ≥ 95% and % Excess Chlorine ≤ 5%.

c. If % Yield < 90% or excess chlorine > 10%, the system may not take CT credit for that day and for any subsequent days until a subsequent measurement shows a yield ≥ 95% and % Excess Chlorine ≤ 5%.

Best Available Technology: EPA identifies the best means available for achieving compliance with the MRDL for chlorine dioxide as control of treatment processes to reduce disinfectant demand, and control of disinfection treatment processes to reduce disinfectant levels.

D. Enhanced Coagulation and Enhanced Softening Requirements

In addition to meeting MCLs and MRDLs, some water suppliers must also meet treatment requirements to control the organic material (disinfection byproduct precursors (DBPPs)) in the raw water that combines with disinfectant residuals to form DBPs. Subpart H systems using conventional treatment are required to control for DBPPs (measured as total organic carbon (TOC)) by using enhanced coagulation or enhanced softening. A system must remove a certain percentage of TOC (based on raw water quality) prior to the point of continuous disinfection. Systems using ozone followed by biologically active filtration or chlorine dioxide which meets specific criteria would be required to meet the TOC removal requirements prior to addition of a residual disinfectant. Systems able to reduce TOC by a specified percentage level have met the DBPP treatment technique requirement. If the system does not meet the percent reduction, it must determine its alternative minimum TOC removal level, which is further explained in Section IX. The State approves the alternative minimum TOC removal possible for the system on the basis of the relationship between coagulant dose and TOC in the system.

1. Applicability

Subpart H systems using conventional treatment must use enhanced coagulation or enhanced softening to remove TOC unless they meet one of the criteria in a. through d. below. Systems using chlorine dioxide that achieve a 95 percent yield of chlorine dioxide and have no more than five percent excess chlorine would be required to meet the TOC removal requirements prior to the addition of another residual disinfectant.

a. The system's treated water TOC level, prior to the point of continuous disinfection, is less than 2.0 mg/l.

b. The system's source water TOC level, prior to any treatment, is less than 4.0 mg/l; the alkalinity is greater than 60 mg/l; and not later than the effective dates for compliance for the system, either the TTHM annual average is no more than 0.040 mg/l and the THAA annual average is no more than 0.030 mg/l, or the system has made a clear and irrevocable financial commitment not later than the effective date for compliance for Stage 1 to technologies that will limit the levels of TTHMs and THAAs to no more than 0.040 mg/l and 0.030 mg/l, respectively. Systems must submit evidence of the clear and irrevocable financial commitment, in addition to a schedule containing milestones and periodic progress reports for installation and operation of appropriate technologies, to the State for approval not later than the effective date for compliance for Stage 1. These technologies must be installed and operating not later than the effective date for Stage 2.

c. The system's TTHM annual average is no more than 0.040 mg/l and the THAA annual average is no more than 0.030 mg/l and the system uses only chlorine for disinfection.

d. Systems practicing softening and removing at least 10 mg/l of magnesium hardness (as $CaCO_3$), except those that use ion exchange, are not subject to performance criteria for the removal of TOC.

2. Enhanced Coagulation Performance Requirements

Systems Not Practicing Softening. Systems that use either (1) ozone followed by biological filtration or (2) chlorine dioxide and meet the performance requirements for CT credit must reduce TOC by the amount specified in Table VIII–4 before the addition of a residual disinfectant. All other systems must reduce the percentage of TOC in the raw water by the amount specified in Table VIII–4 prior to continuous disinfection, unless the State approves a system's request for an alternative minimum TOC removal level.

Required TOC reductions for Subpart H systems, indicated in Table VIII–4, are based upon the specified source water parameters.

Systems Practicing Softening. Systems that use either (1) ozone followed by biological filtration or (2) chlorine dioxide and meet the performance requirements for CT credit must reduce TOC by the amount specified in the far-right column of Table VIII–4 (Source Water Alkalinity >120 mg/l) for the specified source water TOC before the addition of a residual disinfectant. All other systems practicing softening are required to meet the percent reductions in the far-right column of Table VIII–4 (Source Water Alkalinity >120 mg/l) for the specified source water TOC prior to continuous disinfection, unless the State approves a system's request for an alternative minimum TOC removal level. Systems removing more than 10 mg/l of magnesium hardness (as $CaCo_3$) are considered to be practicing enhanced softening, and are not subject to performance criteria for the removal of TOC (see paragraph D.1.(d) above).

TABLE VIII–4.—REQUIRED REMOVAL OF TOC BY ENHANCED COAGULATION FOR SUBPART H SYSTEMS USING CONVENTIONAL TREATMENT [1]
[In percent]

Source water total organic carbon (mg/l)	Source water alkalinity (mg/l)		
	0–60	>60–120	>120 [2]
>2.0–4.0	40.0	30.0	20.0
>4.0–8.0	45.0	35.0	25.0
>8.0	50.0	40.0	30.0

[1] Systems meeting at least one of the conditions in § 141.135(a)(1)(i)–(iv) are not required to operate with enhanced coagulation.
[2] Systems practicing softening must meet the TOC removal requirements in this column.

3. Alternative Performance Criteria

a. *Non-softening systems.* Non-softening Subpart H conventional treatment systems that cannot achieve the TOC removals required above due to unique water quality parameters or operating conditions must apply to the State for alternative performance criteria. The system's application to the State must include, as a minimum, results of bench- or pilot-scale testing for alternate performance criteria. Alternative TOC removal criteria may be determined as follows:

(1) bench- or pilot-scale testing used to determine alternative TOC removal criteria must be based on quarterly measurements and must be conducted at pH levels no greater than those indicated in Table VIII–5, dependent on the alkalinity of the water,

(2) the alternative TOC removal criteria will be no less than the percent removal determined by the alternative enhanced coagulation level (AECL), where an incremental addition of 10 mg/l of alum (or an equivalent amount of ferric salt) results in a TOC removal of 0.3 mg/l (determined as a slope),

(3) once approved by the State, this new requirement (alternative TOC removal criteria) supersedes the minimum TOC removal required in Table VIII–4 and remains effective until the State approves a new value, and

(4) if the TOC removal is consistently less than 0.3 mg/l of TOC per 10 mg/l of incremental alum dose at all dosages of alum, the water is deemed to contain TOC not amenable to enhanced coagulation and the system may then apply to the State for a waiver of enhanced coagulation requirements.

TABLE VIII–5.—ALTERNATE ENHANCED COAGULATION LEVEL MAXIMUM pH

Alkalinity (mg/l as $CaCO_3$)	Maximum pH
0–60	5.5
60–120	6.3
>120–240	7.0
>240	7.5

The system may then operate at any coagulant dose or pH necessary to achieve the minimum TOC removal determined under the testing. For example, a system may choose to use lower levels of alum and depress the pH further instead of adding higher levels of alum at the higher pH.

b. *Softening systems.* During the negotiation, the Committee was not able to develop alternative performance criteria for Subpart H softening systems. In Section IX of this Notice, EPA solicits comments on what these criteria should include.

4. Compliance Determinations

Compliance for systems required to operate with enhanced coagulation or enhanced softening is based on a running annual average, computed quarterly, of normalized monthly TOC percent reductions. A system is in compliance if the normalized running annual average is at least 1.00. For Subpart H systems using conventional treatment but not required to operate enhanced coagulation or enhanced softening, compliance with the DBPP treatment technique is based on continuing to meet the avoidance criteria in paragraph 1 above. Example VIII–1 below shows how to determine compliance with the enhanced coagulation (or enhanced softening) requirements for systems that do not require alternative TOC removal requirements.

Example VIII–1

The system conducts the required monitoring for 12 months. Complete data are included only for the most recent quarter of monitoring.

(1) Using the procedure explained in § 141.135(b), the system determines the percent TOC removal, which is equal to:

(1 − (treated water TOC/source water TOC)) × 100

(2) Determine the required monthly TOC percent removal (from either the table in § 141.135(a)(2)(i) or from § 141.135(a)(3). Note that seasonal water quality variations may require systems to determine required TOC removals from both sections (i.e., both Step 1 and Step 2 levels) during any one year.

(3) Divide 1) by 2).

(4) Add together the results of 3) for the last 12 months and divide by 12.

(5) If 4) <1.00, the system is not in compliance.

In the report below, the system is in compliance with the TOC removal requirements.

Month	Treated TOC(mg/l) a.	Source TOC(mg/l) b.	(1 − a./b.) × 100 c.	Source water alkalinity	Reqd. TOC removal (%) d.	c./d. e.
January						1.10
February						0.94
March						1.03
April						1.07
May						0.98
June						1.24
July						1.10
August						1.07
September						1.02

Month	Treated TOC(mg/l) a.	Source TOC(mg/l) b.	(1 − a./b.) × 100 c.	Source water alkalinity	Reqd. TOC removal (%) d.	c./d. e.
October	4.6	8.2	44	70	40	1.10
November	4.0	6.1	34	75	35	0.98
December	4.4	6.2	29	85	35	0.83
Last 12 mos.	N/A	N/A	N/A	N/A	N/A	Σ= 12.48÷(=f.)

f./12 = 1.04 (=g.)
If g ≥ 1.00, the system is in compliance.

EPA solicits comment on how the following situations should be handled in compliance determinations.

—when the monthly source water TOC is less than 2.0 mg/l and enhanced coagulation is not required.
—when seasonal variations cause the system to determine that TOC is not amenable to any level of enhanced coagulation and the system would be eligible for a waiver of enhanced coagulation requirements.

EPA believes that assigning a value of 1.00 for these months is a reasonable approach.

5. CT Credit.

Systems required to operate with enhanced coagulation or enhanced softening may not take credit for compliance with CT requirements prior to sedimentation unless they meet one of the following criteria:

a. Systems may include CT credit during periods when the water temperature is below 5°C and the TTHM and HAA5 quarterly averages are no greater than 40 µg/l and 30 µg/l, respectively.

b. Systems receiving disinfected water from a separate entity as their source water shall be allowed to include credit for this disinfectant in determining compliance with the CT requirements. If the TTHM and HAA5 quarterly averages are no greater than 40 µg/l and 30 µg/l, respectively, systems may use the measured "C" (residual disinfectant concentration) and the actual contact time (as T_{10}). If the TTHM and HAA5 quarterly averages are greater than 40 µg/l and 30 µg/l, respectively, systems must use a "C" (residual disinfectant concentration) of 0.2 mg/l or the measured value, whichever is lower; and the actual contact time (as T_{10}). This credit shall be allowed from the disinfection feed point, through a closed conduit only, and ending at the delivery point to the treatment plant.

c. Systems using chlorine dioxide as an oxidant or disinfectant may include CT credit for its use prior to enhanced coagulation or enhanced softening if the following standards are met: the chlorine dioxide generator must generate chlorine dioxide on-site at a minimum 95 percent yield from sodium chlorite; and the generated chlorine dioxide feed stream applied from the chlorine dioxide generator must contain less than five percent (by weight) chlorine, measured as the weight ratio of chlorine to chlorine dioxide, chlorite, and chlorate in such feed stream. Compliance with these standards must be demonstrated by monitoring.

E. Requirement for Systems to Use Qualified Operators

Under the proposed rule, each PWS must be operated by qualified personnel who meet the requirements specified by the State. This proposed requirement is similar to the requirement in the Surface Water Treatment Rule. States must develop operator qualifications if they do not already have them and they must require that systems be operated by personnel who meet these qualifications. In addition, the State must maintain a register of qualified operators. The appropriate criteria for determining if an operator is qualified depend upon the type and size of the system.

F. Analytical Method Requirements

Disinfection By-Products. Disinfection by-products must be measured by the methods listed in Table VIII–6:

TABLE VIII–6.—PROPOSED METHODS FOR DISINFECTION BY-PRODUCTS

Contaminant	Methods
Trihalomethanes (4)	[1] 502.2, [2] 524.2, [3] 551.
Haloacetic Acids (5)	[2] 552.1, [4] 6233 B.
Bromate, Chlorite	[5] 300.0.

[1] EPA Method 502.2 is in the manual "Methods for the Determination of Organic Compounds in Drinking Water", EPA/600/4–88/039, July 1991, NTIS publication PB91–231480.

[2] EPA Methods 524.2 and 552.1 are in the manual "Methods for the Determination of Organic Compounds in Drinking Water—Supplement II", EPA/600/R–92/129, August 1992, NTIS PB92–207703.

[3] EPA Method 551 is in the manual "Methods for the Determination of Organic Compounds in Drinking Water—Supplement I", EPA/600/4–90/020, July 1990, NTIS PB91–146027.

[4] Standard Method 6233 B is in "Standard Methods for the Examination of Water and Wastewater," 18th Edition, American Public Health Association, American Water Works Association, and Water Environment Federation, 1992.

[5] EPA Method 300.0 is in the manual "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R/93/100, August 1993, with revisions. See Section IX for revisions.

All measurements listed in this section must be conducted by a laboratory certified by EPA or the State. To receive certification, the laboratory must:

(1) Use the promulgated method(s).

(2) On an annual basis, successfully analyze appropriate performance evaluation (PE) samples provided by EPA or the State.

Disinfectant Residuals. The three disinfectant residuals are measured and reported as follows: chlorine as free or total chlorine; chloramines as combined or total chlorine; and chlorine dioxide as chlorine dioxide. Residual disinfectant concentrations must be measured by the methods listed in Table VIII–7.

TABLE VIII–7.—PROPOSED METHODS FOR DISINFECTANTS

Disinfectant measurement	Proposed methods[1]
Chlorine as free or total residual chlorine, chloramines as combined or total residual chlorine.	4500–Cl D Amperometric Titration. 4500–Cl F DPD Ferrous Titrimetric. 4500–Cl G DPD Colorimetric.
Chlorine as free residual chlorine.	4500–Cl H Syringaldazine (FACTS).
Chlorine or Chloramines as total residual chlorine.	4500–Cl E Low-Level Amperometric. 4500–Cl I Iodometric Electrode.

TABLE VIII–7.—PROPOSED METHODS FOR DISINFECTANTS—Continued

Disinfectant measurement	Proposed methods[1]
Chlorine Dioxide as residual chlorine dioxide.	4500–ClO_2 C Amperometric Titration. 4500–ClO_2 D DPD. 4500–ClO_2 E Amperometric Titration.

[1] Proposed methods are in "Standard Methods for the Examination of Water and Wastewater," 18th Edition, American Public Health Association, American Water Works Association, and Water Environment Federation, 1992.

Residual disinfectant concentrations for chlorine and chloramines may also be measured by using DPD colorimetric test kits if their use is approved by the State. Measurement for disinfectant residual concentration must be conducted by a party approved by the State.

Other Parameters—Total Organic Carbon, Alkalinity and Bromide. Other parameters that are monitored to meet treatment technique requirements must be measured using the methods listed in Table VIII–8.

TABLE VIII–8.—PROPOSED ANALYTICAL METHODS FOR OTHER PARAMETERS

Parameter	Method
Total Organic Carbon	5310 C Persulfate-Ultraviolet Oxidation[1] 5310 D Wet Oxidation[1]
Alkalinity	2320 B[1], 310.1[2], D–1067–88B Titrimetric[3] I–1030–85 Electrometric[4]
Bromide	300.0 Ion Chromatography[5]

[1] Standard Methods 2320 B, 5310 B and 5310 C are in Standard Methods for the Examination of Water and Wastewater, 18th Edition, American Public Health Association, American Water Works Association, and Water Environment Federation, 1992.

[2] EPA Method 310.1 is in the manual "Methods for Chemical Analysis of Water and Wastes", EPA/600/4–79–020, March 1983, NTIS PB84–128677.

[3] Method D–1067–88B is in the "Annual Book of ASTM Standards", Vol. 11.01, American Society for Testing and Materials, 1993.

[4] Method I–1030–85 is in Techniques of Water Resources Investigations of the U.S. Geological Survey, Book 5, Chapter A–1, 3rd ed., U.S. Government Printing Office, 1989.

[5] EPA Method 300.0 is in the manual "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R/93/100—Draft, June 1993.

Measurement for these parameters must be conducted by a party approved by the State.

G. Public Notice Requirements

Standard provisions for public notice apply to this rule. These provisions are explained in Section XIV of this preamble. There is only one acute violation, which occurs when the chlorine dioxide MRDL is exceeded in the distribution system (or if the system fails to take the required samples in the distribution system).

H. Variances and Exemptions

Standard provisions for variances and exemptions apply to this rule. These provisions are explained in Section XI of this preamble.

I. Reporting and Recordkeeping Requirements for PWSs

Reporting: EPA has proposed reporting requirements designed to document compliance with the treatment and monitoring requirements described above. These requirements are specified in § 141.134(b) of the proposed rule. Systems required to sample quarterly or more frequently must report monitoring information to the State within 10 days after the end of each quarter in which samples were collected. Systems required to sample less frequently than quarterly must report monitoring information to the State within 10 days after the end of each required monitoring period in which samples were collected.

Recordkeeping: There are no additional recordkeeping requirements for systems.

J. State Implementation Requirements

Records Kept by States: EPA is proposing to add several requirements to § 142.14, Records Kept by States. These include records of the currently applicable or most recent State determinations, including supporting information and an explanation of the technical basis for each decision.

—Records of systems that are installing GAC or membrane technology.
—Records of systems that are required, by the State, to meet alternative TOC performance criteria (alternate enhanced coagulation level).
—Records of Subpart H systems using conventional treatment meeting any of the enhanced coagulation or enhanced softening exemption criteria.
—Register of qualified operators.
—Records of systems with multiple wells considered to be one treatment plant.

Reports by States: EPA is proposing to add several requirements to § 142.15, Reports by States. These requirements include:

—Reports of systems that must meet alternative minimum TOC removal levels.
—Reports of extensions granted for compliance with MCLs in § 141.64 and the date by which compliance must be achieved.
—A list of systems required to monitor for various disinfectants and disinfection byproducts.
—A list of all systems using multiple ground water wells which draw from the same aquifer and are considered a single source for monitoring purposes.

Special Primacy Requirements: EPA is proposing to add several requirements to § 142.16, Special Primacy Requirements. These requirements include how the State will:

—Determine the interim treatment requirements for those systems electing to install GAC or membrane filtration.
—Qualify operators of community and nontransient-noncommunity public water systems subject to this regulation.
—Approve alternative TOC minimum removal levels.
—Approve parties to conduct pH, alkalinity, temperature and residual disinfectant concentration measurements.
—Approve DPD colorimetric test kits for free and total chlorine measurements.
—Define the criteria to use to determine if multiple wells are being drawn from a single aquifer and therefore be considered a single source for compliance with monitoring requirements.

IX. Basis for Key Specific Criteria of Proposed Rule

A. 80/60 TTHM/HAA5 MCLs, Enhanced Coagulation Requirements, and BAT

1. Basis for Umbrella Concept vs. Individual MCLs

The proposed rule would establish limits for two DBP class sums (i.e., TTHMs and the sum of five HAA species [HAA5]) rather than individual DBPs. In performing the regulatory impact analysis (RIA), TTHM and HAA5 data were generated that were believed to represent occurrence data with conventional drinking water treatment as well as that achievable with the use of advanced technologies. However, individual DBPs could not be reliably predicted over the range of TOC and bromide levels that are found in surface waters before and after treatment.

In addition to the inability to characterize individual DBP formation, the Negotiating Committee was concerned that individual DBPs cannot all be controlled simultaneously without adverse impacts. While precursor removal processes (i.e., coagulation, precipitative softening, GAC, and nanofiltration) can remove TOC, they do not remove bromide (except for nanofiltration to a limited extent). Such processes are best for controlling the formation of chloroform and least effective for controlling the formation of bromoform (Summers et al., 1993). Amy and colleagues found that increasing the bromide-to-TOC ratio (e.g., by reducing TOC with a precursor-removal technology) yielded a higher percentage of brominated THM species (Amy et al., 1991). Symons and colleagues speculated that this phenomenon is due to the following: (1) after treatment to lower TOC, a water may be "precursor-limited"; (2) THM formation kinetics favor bromine incorporation; (3) thus bromine consumes most of the active precursor sites, leaving few for chlorine substitution (Symons et al., 1993).

In an enhanced coagulation study of 16 waters nationwide, the median reduction in TTHMs was 50 percent (JAMES M. MONTGOMERY, CONSULTING ENGINEERS, INC., 1991 and Means et al., 1993). Because this technology removed TOC but not bromide, chloroform levels were well reduced (median of 65 percent), while bromodichloromethane values were not as well reduced (for 15 of the waters the median reduction was 28 percent; this THM level, though, went up six percent in the sixteenth water). For the more brominated species (dibromochloromethane and bromoform), the THM levels decreased in some waters and increased in others. Again, the increase in formation of these brominated THMs was attributed to the change in bromide-to-TOC ratio and/or competition between bromine and chlorine for precursors. For the raw waters in this study (median TOC of 4.3 mg/L and bromide of 0.09 mg/L), chlorination (at 20 °C for 16 hr) yielded median values of 77 µg/L chloroform, 17 µg/L bromodichloromethane, 6 µg/L dibromochloromethane, 0.2 µg/L bromoform, and 124 µg/L TTHMs. For the coagulated/settled waters, chlorination yielded median values of 26 µg/L chloroform, 12 µg/L bromodichloromethane, 6 µg/L dibromochloromethane, 0.3 µg/L bromoform, and 56 µg/L TTHMs. These data demonstrate that enhanced coagulation can reduce TTHMs, with varying impacts on individual species. While not all chemical species were significantly reduced, the overall theoretical cancer risk from THMs is lower. This may also apply to HAA5 and other byproducts.

In the aforementioned coagulation study, the median raw- and settled-water DCAA levels were 28 and 14 µg/L, respectively (JAMES M. MONTGOMERY, CONSULTING ENGINEERS, INC., 1991 and Means et al., 1993). For the waters tested, the median reduction in DCAA was 61 percent, which was comparable to the reduction in chloroform. For dibromoacetic acid (DBAA), the median raw- and settled-water levels were 1.2 and 1.6 µg/L, respectively (JAMES M. MONTGOMERY, CONSULTING ENGINEERS, INC., 1991). For the three waters in this study with very high bromide levels, DBAA was reduced from a range of 16 to 52 µg/L in the chlorinated raw waters to a range of 11 to 30 µg/L in the chlorinated coagulated/ settled waters.

These types of data indicate that while it is feasible for systems utilizing enhanced coagulation to reduce TTHM and HAA5 levels, it is not possible to reduce all of the individual THMs and HAAs to the same extent. Using precursor control technologies, which can remove TOC but not bromide, there is a feasible limit on being able to minimize the formation of each individual THM or HAA. Alternatively, using alternative disinfectants (e.g., ozone/chloramines), one can significantly reduce the formation of all THMs and HAAs. However, as discussed in Section VI.C., there are concerns with the byproducts of alternative disinfectants.

Utilizing the DBP class sums, though, the Technologies Working Group (TWG) was able to evaluate the benefits of enhanced coagulation with the DBPRAM. For surface waters that filter but do not soften, using conventional filtration treatment and chlorine, it was determined that the median, 75th, and 90th percentile TTHMs are 46, 68, and 90 µg/L, respectively. With enhanced coagulation for all surface water systems that filter but do not soften, it was predicted that median, 75th, and 90th percentile TTHMs would drop to 29, 41, and 58 µg/L, respectively. Similarly, using conventional treatment and chlorine, it was determined that the median, 75th, and 90th percentile HAA5 levels are 28, 47, and 65 µg/L, respectively. With enhanced coagulation, it was predicted that median, 75th and 90th percentile HAA5 levels would drop to 17, 26, and 37 µg/L, respectively.

In order to comply with MCLs of 80 µg/L TTHMs and 60 µg/L HAA5, the TWG assumed that a utility would design the treatment process to achieve levels less than 80 percent of the MCL values (i.e., 64 µg/L TTHMs and 48 µg/L HAA5) as an operating margin of safety. Such TTHM and HAA5 levels should be attainable for approximately 90 percent of the systems when using enhanced coagulation with chlorine, based upon the predicted 90th percentile levels above. Similarly, GAC10 with chlorine was predicted to result in comparable levels of TTHMs and HAA5. Note, though, that for some waters the HAA levels may exceed the THM concentrations (Grenier et al., 1992) and that compliance with both sets of DBP classes may require additional treatment changes. For example, the DBPRAM predicted that for these surface-water systems using enhanced coagulation, the maximum TTHM would be 80 µg/L while the maximum HAA5 level would be 81 µg/L.

Enhanced coagulation can be used to remove the precursors for other DBPs as well as those associated with THMs and HAAs. Reckhow and Singer demonstrated that the formation potential (a measure of precursor levels) of THMs, di-, and trichloroacetic acid, dichloroacetonitrile, 1,1,1-trichloropropanone, and TOX could all be reduced with enhanced coagulation (Reckhow et al., 1990). Thus, enhanced coagulation can be used to control other DBPs as well, even though they are not part of this proposed D/DBP Rule.

In a full-scale evaluation of enhanced coagulation performed during the 35-utility DBP study, the alum dose was raised from 10 to 40 mg/L (Metropolitan Water District of So. Calif. et al, 1989). Removal of TOC (raw water TOC of 3 mg/L—a low-alkalinity water) through coagulation and settling increased from 25 to 50 percent. Chlorination (at 25 °C for 24 hr) of settled/filtered water during the low-alum-dose test yielded 86 µg/L TTHMs, 50 µg/L HAA5, and 9.4 µg/L chloral hydrate. Chlorination of settled/filtered water during the high-alum-dose test yielded 55 µg/L TTHMs, 29 µg/L HAA5, and 6.0 µg/L chloral hydrate. By enhancing the coagulation process at this utility, the levels of TTHMs, HAA5, and chloral hydrate were all reduced (compared to the low-alum-dose test) by 36–42 percent. In the 35-utility study, the overall correlation between the occurrence of chloral hydrate and chloroform in the treatment plant effluents of all the systems was good (correlation coefficient of 0.85) (Metropolitan Water District of So. Calif. et al., 1989). Chloral hydrate has been

postulated to form as an intermediate in the conversion of ethanol to chloroform (Beibar et al., 1973). By removing THM and HAA precursors during enhanced coagulation, chloral hydrate should be controlled as well.

2. Basis for Level of Stringency in MCLs, BAT, and Concurrent Enhanced Coagulation Requirements

The Safe Drinking Water Act directs EPA to set the MCL as close to the MCLG as is technically and economically feasible to achieve and to specify in the rule such best available technology (BAT). Systems unable to meet the MCL after application of BAT can get a variance (see Section XI for a discussion of variances). Systems that obtain a variance must meet a schedule approved by the State for coming into compliance. Systems are not required to use BAT in order to comply with the MCL but can use other technologies as long as they meet all drinking water standards and are approved by the State.

For chemicals classified as B2 carcinogens, EPA must set standards as close to zero (the MCLG) as is technically and economically feasible to achieve by the BAT. EPA has classified three THMs (chloroform, bromodichloromethane, and bromoform) and one of the HAAs (dichloroacetic acid) as probable human carcinogens (i.e., B2 carcinogens) based on evidence of carcinogenicity in animals. EPA is also concerned with the potential risks of chlorination byproducts other than THMs or HAAs, indicated in part by the presence of THMs and HAAs. A TTHM MCL and HAA MCL would limit exposure from different THMs and HAAs as well as other chlorinated DBPs.

EPA is proposing a combined limit for only five of the HAAs (HAA5)—monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid—because currently available data enable EPA to predict only their combined occurrence.

How BAT is defined determines the level at which MCLs are set for TTHMs and HAA5. Per agreement with the Negotiating Committee, EPA is proposing either enhanced coagulation or shallow bed GAC (GAC10) with chlorine as the primary and residual disinfectant. The TWG considered GAC10 as roughly equivalent to enhanced coagulation in removing organic precursors to DBPs. The Negotiating Committee considered it appropriate to define chlorination for primary and residual disinfection within the BAT definition because 1) chlorine is an effective disinfectant for inactivating most microbial pathogens originating in the source water and for limiting contamination in the distribution system, and 2) health risks from DBPs from use of alternate disinfectants are not as yet as well characterized as they are for DBPs of chlorination. However, as noted above, alternate disinfectants (such as ozone) may be used to achieve D/DBPR compliance.

As discussed previously, based on model predictions by the DBPRAM, most systems in the U.S. would be able to achieve a TTHM level of 80 µg/l or an HAA5 level of 60 µg/l if they were to apply the proposed BATs. The Negotiating Committee agreed to propose the MCLs accordingly. Alternative BATs and corresponding MCLs were considered but not included for the reasons discussed below.

Including a more effective precursor removal technology such as GAC20 or membrane filtration in the BAT would result in significantly lower MCLs. Setting such MCLs would probably result in much greater use of alternative disinfectants, such as ozone and chloramines because these technologies would be significantly less expensive than the BAT for achieving the MCL. While much greater use of such technology may be appropriate, some members of the Negotiating Committee did not consider this increased use desirable, at least until more was known concerning health risk associated with DBPs formed from use of alternative disinfectants. For the same reasons, alternative disinfectants were not included in the BAT definition(s).

Setting the MCLs for TTHMs and HAA5 at 80 and 60 µg/l, respectively, should lead to substantially lower TTHM and HAA levels than those being achieved under the existing TTHM MCL. The TWG estimated that, for surface water systems serving over 10,000 people that do not soften, the median concentration for TTHMs and HAA5 would drop from about 46 µg/l to 31 µg/l and 28 µg/l to 20 µg/l, respectively, as a result of such regulations. As part of today's proposal, EPA is also proposing that all systems using surface water sources which use sedimentation and filtration must operate with either enhanced coagulation or enhanced softening unless they meet certain water quality conditions (discussed in the following section of the preamble). This requirement was set in conjunction with the MCLs for TTHMs and HAA5 for the following reasons:

(1) A substantial amount of precursors to disinfection DBPs could be removed at low cost and within a short period of time, regardless of which disinfectants were used. Thus, any health effects associated with DBPs that might otherwise be formed would be reduced quickly and at low costs.

(2) Reducing precursors would lead to lower TTHM and HAA5 levels and thereby diminish the incentive for many systems to shift toward use of alternative disinfectants in order to comply with the new MCLs, thereby limiting concerns from any potential associated health risks.

(3) Enhanced coagulation and enhanced softening will also significantly reduce disinfectant demand, thereby allowing utilities to use less disinfectant while still maintaining a residual in the distribution system. Maintaining a residual is important for identifying when contamination occurs into the distribution system (indicated by the absence of a residual) and for limiting bacterial growth.

While lowering DBP precursors and disinfectant demand can provide obvious benefits, there are also associated potential downside risks. Since water treatment plant operators often apply disinfectant dosages in order to maintain a residual in the distribution system, if the disinfectant demand is lowered, lower disinfectant dosages could inadvertently lead to lower levels of inactivation of pathogens originating in the source water and increased microbial risk. To prevent such risks, compensating treatment must be provided where appropriate. EPA is therefore concurrently proposing possible amendments to the SWTR to address such concerns in today's Federal Register.

Another concern with precursor removal is that, in waters with high bromide concentrations, it is possible (as previously discussed) to increase the concentrations of certain brominated DBPs even though the group concentrations of the TTHMs and HAA5 may decrease. Since the health risks associated with many of the brominated DBPs are currently unknown, it remains unclear whether the benefits of lowering the concentrations of chlorinated DBPs outweigh the possible downside risks of increasing certain brominated DBPs. Nevertheless, since only a small percentage of systems may experience increased concentrations of certain brominated DBPs from enhanced coagulation, the Negotiating Committee reached a consensus that setting a national requirement for precursor removal by enhanced coagulation or enhanced softening would be appropriate.

The Committee could not reach consensus on whether to require systems to use technologies such as GAC20 or membrane technology in conjunction with setting lower MCLs, as was done for enhanced coagulation with the proposed Stage 1 MCLs. Some members did not consider it appropriate without a better understanding of the impacts of such a requirement. Installation and use of GAC20 or membrane technology involve greater costs and time to begin implementing than enhanced coagulation. Some Committee members believed that, depending on source water quality, use of alternative disinfectants may be significantly more cost-effective for reducing health risks from DBP levels than GAC20 or membrane technology. Also, these members believed that use of alternative disinfectants instead of GAC20 or membranes may pose fewer ecological impacts. However, other members believed that GAC20 or membranes would substantially improve water quality and should be required. The Committee did not reach consensus.

If GAC20 or membrane technology were required under Stage 1, bench- and pilot-scale studies would need to be conducted prior to design and installation. Such studies would probably require at least several years to complete for most systems. Under the ICR (59 FR 6332), large systems with high TOC levels will be required to conduct bench- or pilot-scale studies to evaluate the treatment effectiveness of GAC or membrane technology. These studies will enable systems to design and install GAC or membrane technologies, if required by the Stage 2 D/DBPR, in a shorter time than otherwise would be possible under the Stage 2 rule. Bench- or pilot-scale studies initiated under the ICR will in part simulate the same initial actions that many utilities will take in the future and reduce the time needed to come into compliance if GAC20 or membrane technology are required.

3. Basis for enhanced coagulation and softening criteria

a. *Enhanced coagulation.* Removal of organic carbon in conventional drinking water treatment by the addition of alum or iron salts has been demonstrated by laboratory research, pilot-scale, demonstration plant, and full-scale studies. Until recently, there have been limited data available on the removal of organic carbon (measured as TOC) using natural organic carbon matrices. Much of the developmental work for the removal of TOC by coagulation and sedimentation has been done in the laboratory using synthetic mixtures of humic materials. Researchers have demonstrated that natural TOC exhibits a wide range of responses to treatment with high doses of alum and iron salts. A key indication of the ability of TOC to be removed by coagulation is the molecular weight distribution of the organic carbon. A large proportion of high molecular weight organic carbon is much easier to remove than an organic carbon that is predominantly low molecular weight material. Unfortunately, the procedure to determine TOC molecular weight distribution is cumbersome, is only being used in research applications, and is not generally available in water treatment plants or to consulting firms.

Even though TOC removal has been practiced for some time at conventional, full-scale plants, there has not been a standard method to evaluate the potential for a water treatment plant to remove TOC during the coagulation/sedimentation process. As a result of the work of the TWG of the Negotiating Committee, a number of alternatives for defining enhanced coagulation have been evaluated. The term optimized coagulation was not used to describe the process of incremental removal of TOC by coagulants to avoid confusion with optimized coagulation for particle removal practiced by many water utilities.

The majority of the data for removal of TOC in drinking water treatment has been developed with the use of aluminum sulfate ($AlSO_4 \bullet 14H_2O$). Iron salts are also effective for removing TOC and equivalent dosages for iron salts were developed on the basis of TOC removal by alum. Research has demonstrated that polyaluminum chloride and cationic polymers are not effective for removing the same degree of TOC as either alum or iron salts. Cationic polymers (as well as anionic and nonionic polymers) have been proven to be valuable in creating settlable floc when high dosages of alum or iron salts are used. Specific organic polymers have been shown to remove color in water treatment applications, but significant TOC removal by organic polymers has not been demonstrated on a widespread basis. Other coagulation process arrangements that result in the required removals for enhanced coagulation are acceptable. For example, sludge blanket clarifiers with or without powdered activated carbon have been shown to remove significant levels of TOC.

The TWG attempted to define what percent TOC removals could be achieved by most systems treating surface water and using coagulation/sedimentation processes using elevated, but not unreasonable, amounts of coagulant dose. The intent was to define enhanced coagulation in such a manner that (a) significant TOC reductions would be achieved and (b) the criteria could easily be enforced with minimal State transactional costs. A TOC-based performance standard was therefore desirable. It was not considered appropriate to base a performance standard on what all systems would be expected to be able to achieve since some waters are especially difficult to treat. Under such a standard many systems with easier to treat waters might not be motivated to reduce their TOC to the extent that was reasonably achievable. On the other hand, setting a standard based on what many systems would not be able to readily achieve would introduce large transactional costs to States enforcing the rule. To address these concerns the TWG developed a two-step standard for enhanced coagulation. The first step includes performance criteria which, if achieved, would define compliance. The second step would allow systems that have difficult to treat waters to demonstrate to the State, through a specific protocol, alternative performance criteria for achieving compliance.

The TWG examined case histories of TOC removal with alum and developed the 4X3 matrix shown below (Table IX–1) as the initial step for defining enhanced coagulation. The TWG members and other experts consulted during this process attempted to specify criteria by which about 90 percent of the water utilities employing conventional treatment and required to operate enhanced coagulation would be able to meet the TOC removal percentages listed, without unreasonable addition of alum. While limited empirical data were used to develop these criteria, the 90 percent compliance objective with the step 1 criteria is not statistically based. Establishing criteria at the anticipated 90 percent level, versus (for example) a 50 percent level with more stringent percent TOC removal requirements, was expected to result in much lower transactional costs to the State (because fewer evaluations of experimental data to establish alternative criteria would be required) without significantly higher TOC levels in treated waters nationally.

Systems not practicing conventional treatment were excluded from enhanced coagulation requirements because they were generally expected to (a) have higher quality source waters with lower TOC levels than waters treated by conventional water treatment plants, and (b) not have treatment that could be

expected to achieve significant TOC reduction (e.g., most ground water supplies, direct filtration, diatomaceous earth filtration, and slow sand filtration).

TABLE IX–1.—REQUIRED REMOVAL OF TOC BY ENHANCED COAGULATION FOR SUBPART H SYSTEMS USING CONVENTIONAL TREATMENT [2]

[In percent]

Source Water Total Organic Carbon (mg/l)	Source Water Alkalinity(mg/l)		
	0–60	>60–120	>120 [1]
>2.0–4.0	40.0	30.0	20.0
>4.0–8.0	45.0	35.0	25.0
>8.0	50.0	40.0	30.0

[1] Systems practicing softening must meet the TOC removal requirements in this column.
[2] Systems meeting at least one of the conditions in § 141.135(a)(1)(i)–(iv) are not required to operate with enhanced coagulation.

The percent removals required as part of the initial compliance determination were developed in recognition of the general trends in TOC coagulation research that removals of TOC were more difficult the higher the alkalinity (due to the difficulty of reaching the optimum coagulation pH for TOC, usually between 5.5 and 6.5). It is also fairly well established that TOC removal by coagulation is generally easier the higher the initial TOC in the water. More information on the practice of removing TOC in a wide variety of source waters would have been helpful for developing the proposed criteria. EPA solicits comment on whether the TOC percent removal levels in Table IX–1 indicated above are representative of what 90 percent could be expected to achieve with elevated, but not unreasonable, coagulant addition.

About 10 percent of the utilities required to operate enhanced coagulation are not expected to achieve the percent removals in Table IX–1. The purpose of the second step in the definition of enhanced coagulation is to determine the point of diminishing returns for the addition of coagulant for TOC removal.

Some waters contain TOC composed mostly of highly mineralized organic carbon with most of the molecular weight fraction in the low range. It is known that this kind of TOC can be very difficult to remove. It is not the intent of this rule to require the addition of very high concentrations of coagulants with little removal of TOC. Therefore, the second step in the definition of enhanced coagulation allows utilities to avoid such a situation. It requires the evaluation of incremental addition of coagulant in a bench- or pilot-scale test and measurement of the amount of TOC removed by 10 mg/L increments of coagulant. Per recommendation of the TWG, EPA is proposing that the point of diminishing returns for coagulant addition be defined as the alternate enhanced coagulation level (AECL) at 0.3 mg/L of TOC removed per 10 mg/L of alum added or equivalent addition of iron coagulant, and that the percent TOC removal achieved at this point be defined, if approved by the State, as the alternative minimum TOC removal level (to that indicated in Table IX–1) that could be met for demonstrating compliance.

TABLE IX–1a.—COAGULANT DOSE EQUIVALENTS

[mg/l]

Coagulant	Dose
Aluminum sulfate• $14H_2O$	10
Ferric chloride• $6H_2O$	9.1
Ferric chloride	5.5
Ferric sulfate• $9H_2O$	9.5

The guidance manual contains a bench-scale method for demonstrating alternative performance criteria under step 2 of the enhanced coagulation definition (EPA, 1994). The method described therein is patterned after the ASTM D 2035–80 method for "Standard Practice for Coagulation-Flocculation Jar Test of Water."

The bench-/pilot-scale procedure for determining alternative percent TOC removal requirements does not require the use of a laboratory filtration step. Experience has shown that most TOC is removed during coagulation/sedimentation. Also, not requiring laboratory filtration eliminates a point of possible contamination. TOC is known to leach from some commercially available filters. Not specifying laboratory filtration also avoids the issue of requiring a particular type of filter for the bench-scale studies. During the development of this proposed rule, no consensus could be reached on the use of membrane filters with various pore diameters versus glass fiber filters.

If a utility wishes to include the TOC removal in the filtration process as part of compliance with enhanced coagulation, under step 2, filtration would then have to be part of the bench-/pilot-scale study. Using filtration in the treatment plant as part of compliance with enhanced coagulation TOC removal would also require that continuous disinfection for CT credit would not be allowed until after the filters.

EPA solicits comment on whether filtration should be required as part of the bench-/pilot-scale procedure for determination of Step 2 enhanced coagulation. If so, what type of filter should be specified for bench-scale studies?

Figure IX–1 shows three examples of the types of curves anticipated to result from a step 2 analysis and are based on actual data collected during the TWG evaluation. Curve A represents a water containing a TOC highly susceptible to removal by coagulation/sedimentation. Step 2 is met at an alum dosage of 40 mg/L. Note that due to its low alkalinity (<60 mg/L), the percent removal of TOC at this point (57%) is actually more than is required under step 1 (45%). In this case, the utility is only required to remove TOC to the level specified in step 1, 45%, although removal of higher levels of easily removed TOC is encouraged.

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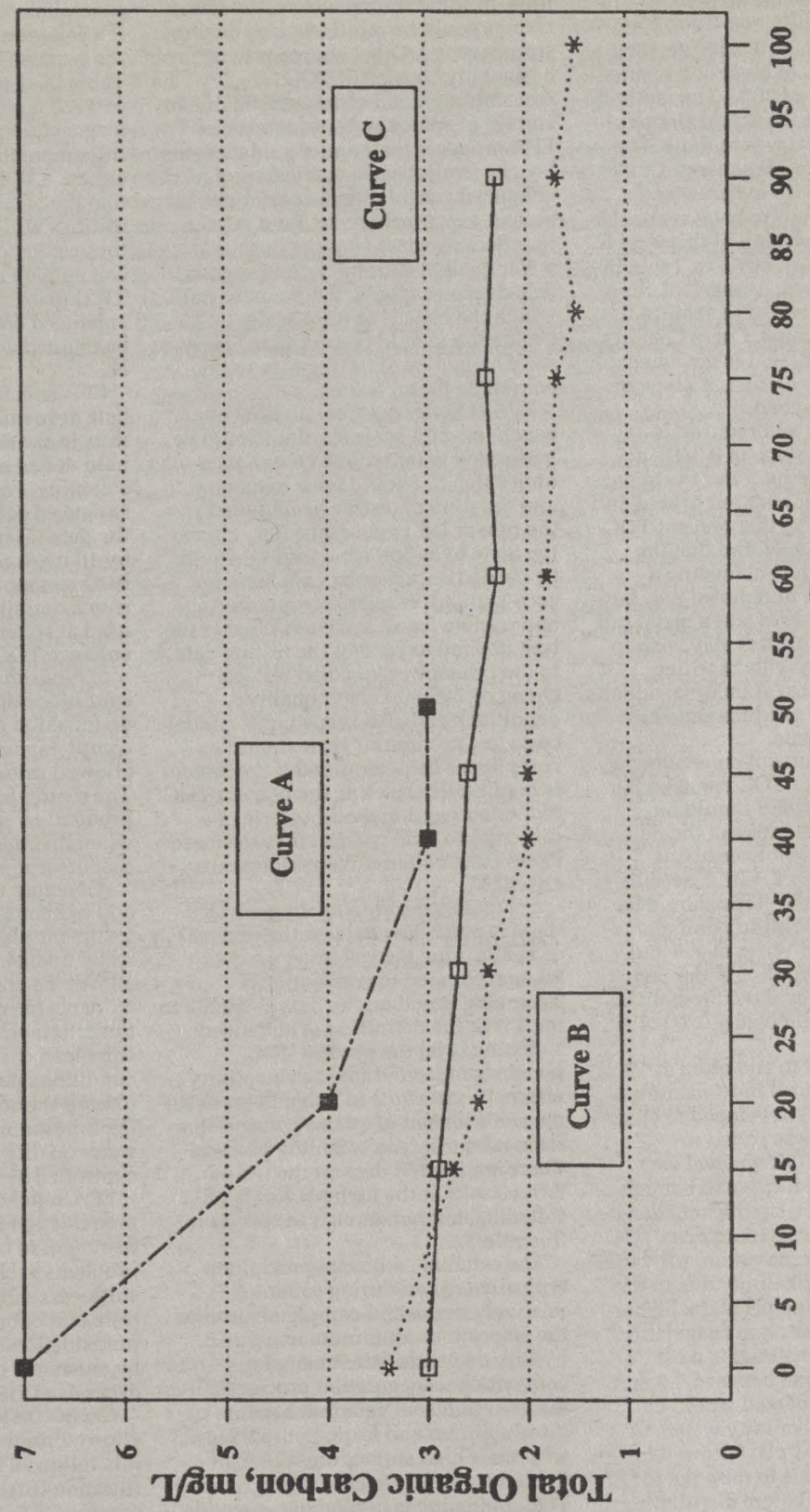
Figure IX-1
Bench-Scale Test Results
Enhanced Coagulation Step 2



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Curve B is probably more typical of waters that fall into the step 2 evaluation (alkalinity ≥60–120). Note that the slope of 0.3/10 is located at a dosage of 25 mg/L of alum and results in a TOC removal of 26%. The method used to determine the actual slopes of portions of Curve B was to draw it on graph paper and count squares. Curve fitting programs with instantaneous slope determinations may be available to improve the precision of this task. If the specified TOC removal in Table IX–1 had been followed, 31 mg/L of alum would have been added to achieve the required 30% removal. Curve C shows a water with a TOC that is not amenable to removal by coagulation. A slope of 0.3/10 is never reached.

Once a TOC percent removal is established at the slope of 0.3/10, a utility may operate its water treatment plant with any combination of acid and coagulant to achieve that percent TOC removal. Utilities may find that the least-cost approach to achieving a specific TOC percent removal may be with both sulfuric acid and a metal salt coagulant. Other utilities may wish to avoid the concerns with handling sulfuric acid and use alum or ferric salts to depress pH and produce a metal hydroxide precipitate.

EPA solicits comment on whether a slope of 0.3 mg/L of TOC removed per 10 mg/L of alum added should be considered representative of the point of diminishing returns for coagulant addition under Step 2. EPA also solicits comment on how the slope should be determined (e.g., point-to point, curve-fitting). If the slope varies above and below 0.3/10, where should the Step 2 alternate TOC removal requirement be set—at the first point below 0.3/10? At some other point?

The requirement to add alum at 10 mg/L increments until the "maximum pH" is reached was developed to ensure that enough alum was added to adequately test if TOC removal was feasible and to add it in small enough increments to notice significant changes in the slope of the coagulant dose-TOC removal curve. The maximum pH varies depending on the alkalinity due to the difficulty in changing pH at the higher alkalinities. Because alum coagulation of natural organic material is most effective at a pH level between 5.5 and 6.5, large amounts of acid would be required for high alkalinity waters to achieve this optimal pH, followed by large amounts of base to raise the pH of the water up to 8.0 before distributing to ensure compliance with the lead/copper rule.

It is well demonstrated that the concentrations and characteristics of TOC in source waters will change over time. In some source waters, the rate of change could be rapid (such as during storm events). Other source waters have a generally consistent TOC concentration and characteristic due to storage of source water in reservoirs. EPA proposes that, under guidance, the bench- or pilot-scale evaluation of enhanced coagulation be performed on at least a quarterly basis, for one year, to reflect seasonal changes in source water quality. Currently, the proposed rule does not specify the frequency at which the bench- or pilot-scale evaluation should be conducted because such frequency of testing may not be warranted for all waters.

EPA solicits comment on how often bench- or pilot-scale studies should be performed to determine compliance under step 2. Should such frequency and duration of testing be included in the rule or left to guidance (i.e., allow the State to define what testing would be needed on a case by case basis for each system)? Is quarterly monitoring appropriate for all systems? What is the best method to present the testing data to the primacy agency that reflects changing influent water quality conditions and also keeps transactional costs to a minimum? How should compliance be determined if the system is not initially meeting the percent TOC reduction requirements because of a difficulty to treat waters and a desire to demonstrate alternative performance criteria?

b. *Enhanced softening.* In general, there is much less data on the removal of TOC during the softening process when compared to conventional treatment. Based on the data available to the TWG, the definition of enhanced softening is (a) the percent TOC removals indicated for high alkalinity waters (> 120 mg/l) in Table IX–1, or (b) the achievement of 10 mg/L magnesium removal during the softening process. There are limited data on the use of ferrous salts at the high pH levels of softening, but not enough to specify in this rule.

The calcium carbonate precipitate typically created during softening is relatively dense and completely unlike the amorphous aluminum and ferric hydroxide precipitates created in conventional coagulation processes. It is the amorphous or gelatinous nature of the aluminum and ferric hydroxides with their high surface areas that give them their ability to absorb and remove TOC. Softening is carried out at a wide range of pH levels, generally between 9.5 and 11.0. Above a pH of about 10.5, magnesium precipitates as magnesium hydroxide (which has very similar characteristics to alum and ferric precipitates). The TWG determined that if a softening process could not achieve the percent TOC removals shown in Table IX–1 under the alkalinity column of >120 mg/L and it was practicing magnesium precipitation, there was little more that could be done to enhance TOC removal. It is anticipated that the vast majority of softening utilities will be able to comply with these enhanced softening requirements. Not enough data were available to the TWG to determine whether alternative enhanced coagulation criteria needed to be defined and, if so, what they should be.

EPA solicits comment on whether data are available on the use of ferrous salts in the softening process which can help define a step 2 for enhanced softening. For softening plants, is enhanced softening properly defined by the percent removals in Table IX–1 or by 10 mg/L removal of magnesium hardness reported as $CaCO_3$? Is there a step 2 definition? Can ferrous salts be used at softening pH levels to further enhance TOC removals?

c. *Preoxidation credit.* Except for the conditions described below, disinfection credit for the purpose of complying with the ESWTR is not allowed prior to enhanced coagulation. The reason for these limitations is the production of higher levels of DBPs when disinfectants are used prior to the precursor removal step.

A number of water treatment plants add oxidants to the influent to the treatment plant to control a variety of water quality problems. The regulation allows the continuous addition of oxidants to control these problems. The limitation on disinfection credit prior to enhanced coagulation, except for the conditions described below, is expected to keep the addition of disinfectants to the minimum necessary to control the water quality problems that can be controlled by oxidation.

EPA solicits comments on whether preoxidation is necessary in water treatment to control water quality problems such as iron, manganese, sulfides, zebra mussels, Asiatic clams, taste and odor. Will allowing preoxidation before precursor removal by enhanced coagulation generate excessive DBP levels?

Ozone. Disinfection credit for ozone is allowed prior to enhanced coagulation if it is followed by biologically active filtration (BAF) because many of the organic DBPs formed by ozone are generally removed by a biological process. In order to maintain a filter in a biologically active mode, virtually no chlorine, chlorine dioxide, or

chloramines can be added to the filter influent.

EPA solicits comments on whether biologically active filtration following ozonation is sufficient to remove most byproducts believed to result from ozonation. What parameters, if any, should be measured in and/or out of the filter to demonstrate a biologically active filter, or alternatively, that ozone byproducts are adequately being removed? For example, would it be sufficient to demonstrate greater than 90 percent removal of formaldehyde to establish that a filter is biologically active and that predisinfection credit could therefore be given?

Chlorine dioxide. Due to the wide variation in the application of chlorine dioxide generation technology, it is common for water treatment plants to apply chlorine dioxide along with an excess of free chlorine. Technologies do exist to produce high purity chlorine dioxide, but these technologies are not universally used. EPA is proposing to allow disinfection credit for chlorine dioxide prior to enhanced coagulation in the same manner as for ozone and BAF if the system can demonstrate the generation of high purity chlorine dioxide.

Under the proposal, a system using chlorine dioxide could get disinfection credit if the following standards are met: the chlorine dioxide generator must generate chlorine dioxide on-site at a minimum 95 percent conversion efficiency (yield) from sodium chlorite; and the generated chlorine dioxide feed stream applied from the chlorine dioxide generator must contain less than five percent (by weight) free chlorine residual, measured as the weight ratio of free residual chlorine (i.e., hypochlorous acid) to chlorine dioxide in such feed stream. Compliance with these standards must be demonstrated on an ongoing basis for each generator in use. By meeting these standards, chlorite and chlorate (chlorine dioxide generation byproducts) will be limited and free residual chlorine will not be available to react with the organic precursors prior to TOC removal and the potential for halogenated organic DBP production is limited.

EPA solicits comments on whether disinfection credit should be allowed for chlorine dioxide used prior to enhanced coagulation if virtually no halogenated organic DBPs are formed. Should some other limit, in addition to or in lieu of that proposed, be set (e.g., 5 µg/L TTHMs) on DBPs formed by high purity chlorine dioxide to ensure sufficient control for the production of excessive halogenated organic DBPs if disinfection credit were to be allowed with chlorine dioxide prior to enhanced coagulation?

Disinfection credit during cold water months. It is well established that temperature plays a critical role in the production of DBPs and that DBP concentrations are the lowest in winter months. The cold water temperature months are also the most difficult time for utilities to meet CT requirements, because longer contact times with a disinfectant are needed to overcome the poorer inactivation efficiencies.

Figure IX–2 plots the required CT values for inactivation of Giardia cysts for free chlorine at various pH and log inactivation levels. The family of curves clearly indicates a significant change in slope below a temperature of 5° C indicating that it is much more difficult to achieve a log inactivation of Giardia cysts in water below this temperature.

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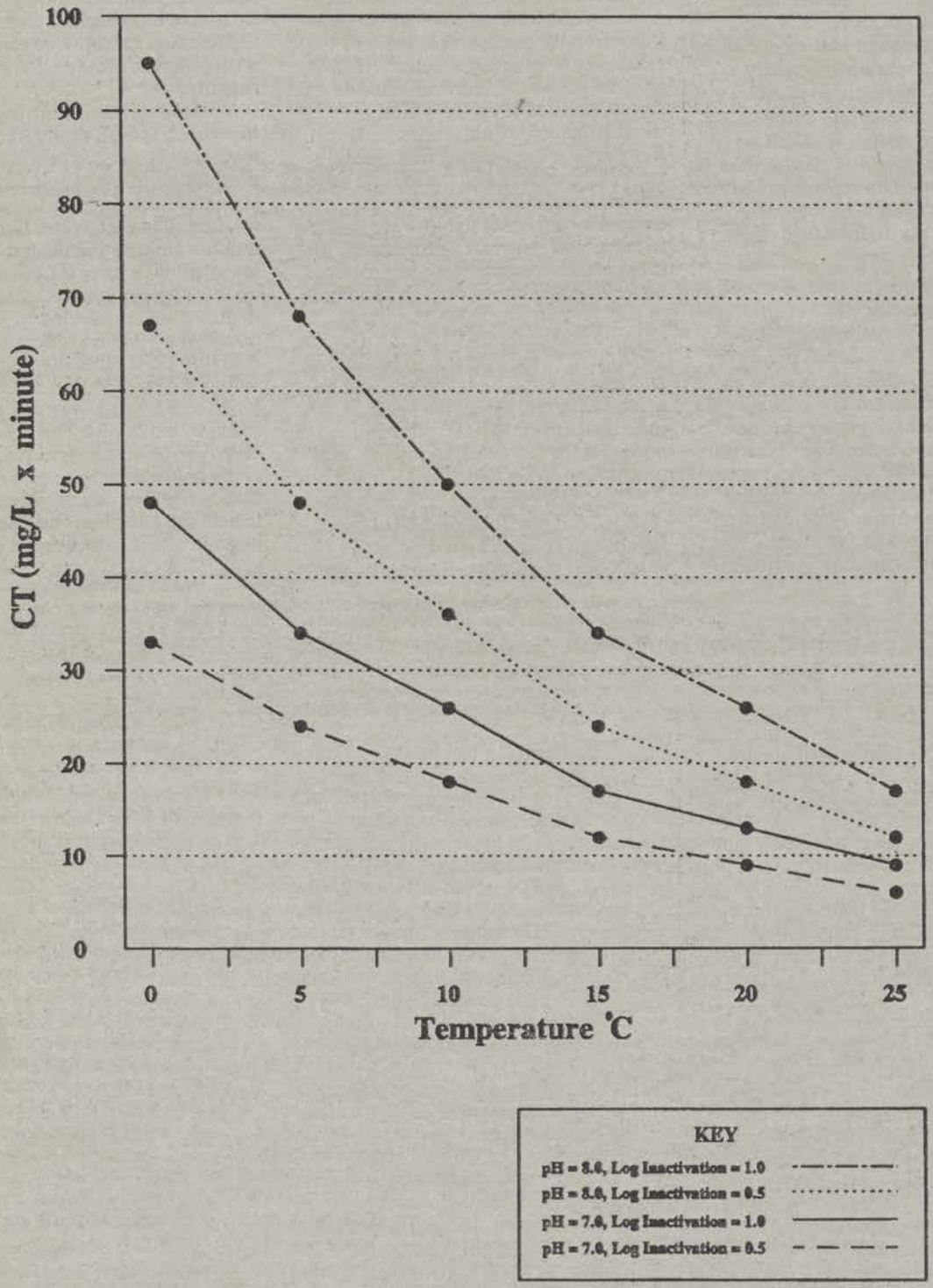
Figure IX-2

CT Values - Inactivation of Giardia Cysts by Free Chlorine (Residual = 0.6 mg/L)



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NSERT FIGURE IX–2 HERE.

EPA is proposing that systems be allowed to add a disinfectant before enhanced coagulation when water temperatures are less than or equal to 5°C. In order to ensure that excessive DBPs are not produced by this special case and to more cost effectively balance chemical and microbial risks, exercise of this provision would only be allowed if the TTHM and HAA5 winter quarterly averages in the distribution system served by the treatment plant are less than 40 and 30 ug/l, respectively.

EPA solicits comment on the appropriateness of this provision or alternative means for addressing this issue.

d. *Basis for Avoiding Enhanced Coagulation or Enhanced Softening Requirements.* The purpose of the treatment technique for control of disinfection byproduct precursors (DBPPs) is to remove one of the factors which result in the production of DBPs upon subsequent disinfection. Criteria have been established which allow systems to forgo the requirement to implement enhanced coagulation for control of DBPPs. These criteria were generally established to either recognize low potential of certain waters to produce DBPs or to account for types of water which contain TOC that is difficult to remove by enhanced coagulation. Implementation of enhanced coagulation in difficult to treat waters generally costs much more than the average case used to develop the national costs for this rule, and may introduce other water quality problems.

TOC <2.0 mg/L. If a water contains less than 2.0 mg/L TOC before continuous disinfection, it does not have to implement enhanced coagulation. This level is calculated each quarter as a running annual average, based on monthly (or quarterly, if the system has qualified for reduced monitoring) treated water (i.e., prior to continuous disinfection) TOC measurements. The basis for this criterion is related to the purpose of the enhanced coagulation requirement (which is to reduce the presence of organic matter when chlorine or other disinfectants are added to the water). A TOC of less than 2.0 mg/L would be expected, in general, to produce TTHM and HAA5 levels upon chlorination that are less than 40 and 30 µg/L, respectively. This criterion would apply to high quality source waters and to systems with water treatment plants which have installed a precursor removal process other than enhanced coagulation prior to continuous disinfection. High quality surface waters with TOC levels less than 2.0 mg/L account for less than 20 percent of the total number of utilities using surface water in the U.S.

Systems with other installed precursor removal technologies include a water treatment plant with granular activated carbon in a post-filter adsorber configuration, e.g., Cincinnati, Ohio. As long as the TOC is less than 2.0 mg/L before continuous disinfection, it is not important which precursor removal technology is employed.

40/30/<4/>60. It is harder to remove organic matter by enhanced coagulation in waters with alkalinities greater than 60 mg/L as $CaCO_3$ and TOC levels less than 4.0 mg/L. To compensate for this phenomenon, systems with these water quality characteristics are permitted to apply alternate disinfectants before any precursor removal step and, if the TTHM and HAA5 levels produced are less than 40 and 30 µg/L, respectively, the utility would not have to implement enhanced coagulation. Source water TOC, source water alkalinity and TTHM and HAA5 levels are calculated each quarter as running annual averages, based on monthly measurements.

In addition to allowing systems that already meet these criteria to avoid enhanced coagulation, the Committee also agreed to allow systems that were installing alternative disinfection technology that would allow the system to meet these criteria to avoid enhanced coagulation. The technology must be installed prior to the compliance date for Stage 2 D/DBPR. For example, a system that already had a TOC of less than 4.0 mg/l and an alkalinity of greater than 60 mg/l would be allowed to avoid enhanced coagulation if the system committed to installation of ozonation. This commitment must include a clear and irrevocable financial commitment not later than the effective date for compliance with Stage 1 D/DBPR to technologies that will limit the levels of TTHMs and HAA5 to no more than 0.040 mg/l and 0.030 mg/l, respectively. Systems must submit evidence of the financial commitment, in addition to a schedule containing milestones for installation and operation of appropriate technologies, to the State for approval. Violation of the approved schedule will constitute a violation of the National Primary Drinking Water Regulation.

The schedule must be enforceable, but should only contain significant milestones. Types of schedule items that should be included as enforceable include award contract, begin construction, end construction, pilot operations, and full compliance. The schedule should allow for minor slippage, but must require compliance by the compliance date for Stage 2. The State may also require periodic progress reports, but EPA recommends that these not be part of the enforceable schedule (and thus be a basis for finding the system in violation for late submission or failure to submit).

The cost of employing enhanced coagulation to waters of this type is higher than the base case examined as part of the regulatory impact analysis for this rule. It is assumed that systems with this type of water quality will, in general, achieve more cost effective reduction of DBPs by use of alternative treatment strategies than by use of enhanced coagulation. The overall purpose of this rule is to reduce the levels of both DBPs that are known and DBPs which are not known. The criterion in this section is expected to accomplish these goals.

40/30 with Chlorine. It is possible that some types of TOC do not produce significant levels of DBPs upon chlorination. To account for this fact, systems which use chlorine (and meet the CT requirements under the SWTR or ESWTR) and which achieve running annual averages of less than 40 and 30 µg/L for TTHM and HAA5, respectively, do not have to employ enhanced coagulation. The type of precursors normally encountered in surface waters will produce TTHMs and THAAs higher than the concentrations of 40 and 30 µg/L if the TOC level is greater than 2.0 mg/L and CT requirements are met. It is expected that this criterion will not be applicable to many surface water systems.

4. Basis for GAC Definitions

Treatment with granular activated carbon (GAC) has been found by many researchers to remove organic DBP precursors. For water treatment applications, GAC is typically placed in a gravity filter, not unlike granular media filters for particle removal, and operated in a downflow mode. The design parameters most often specified for the use of GAC are empty bed contact time (EBCT) and regeneration frequency (or equivalently, carbon use rate). During the development of this proposed rule, GAC was defined at two levels of treatment to facilitate the development of national cost data as well as project expected national DBP levels resulting from the use of GAC treatment.

GAC10 means granular activated carbon filter beds with an empty-bed contact time of 10 minutes based on average daily flow and a carbon regeneration frequency of every 180 days. The GAC10 definition, which was recommended by the TWG, was meant

to specify the design and operating conditions of GAC that would be necessary to remove approximately the same amount of DBP precursors (measured as TOC) as that achieved by enhanced coagulation. As discussed previously, the Negotiating Committee agreed that enhanced coagulation or GAC10, used in conjunction with chlorine as the sole disinfectant, should be the BATs corresponding to the Stage 1 MCLs of 80 and 60 μg/l for TTHMs and HAA5, respectively.

GAC20 means granular activated carbon filter beds with an empty-bed contact time of 20 minutes based on average daily flow and a carbon regeneration frequency of every 60 days. The GAC20 definition, recommended by the TWG, was meant to specify the conditions by which at least 90% of the systems in the U.S. would be able to use this technology, with chlorine as the sole disinfectant, and comply with the Stage 2 MCLs of 40 and 30 μg/l for TTHMs and HAA5, respectively. The ability of systems to use GAC20 and achieve such performance was tested and confirmed by the TWG using national TOC occurrence data obtained from the Water Industry Data Base (WIDB) and the Water Treatment Plant Simulation Model (USEPA 1992; USEPA, 1994).

The Water Treatment Plant Simulation Model predicts the production of TTHMs and HAA5 based on water quality and treatment conditions. GAC performance in the model is based on equation parameters developed as part of a TOC removal study at Jefferson Parish, Louisiana. Jefferson Parish is proposed as representative of the "general case" for TOC removal. TOC removal has been demonstrated to be higher at Jefferson Parish than at Manchester, NH; Miami, FL; and the Metropolitan Water District of Southern California. TOC removal was lower at Jefferson Parish than at Philadelphia, PA; Cincinnati, OH; and Shreveport, LA.

The TWG participants who developed these definitions also thought that it would be conceivable for GAC10 to be employed in a filter media replacement mode. GAC20 was clearly not compatible in a filter media replacement mode and would have to be applied as post-filter adsorbers.

EPA solicits comment on whether GAC10 and GAC20 are reasonable definitions of GAC performance? Do they span the expected level of GAC applications in drinking water treatment for the control of TTHMs and HAA5? Is it appropriate to consider Jefferson Parish, Louisiana, TOC removal by GAC representative of the "general case" of TOC removal?

5. Basis for Monitoring Requirements

Monitoring for disinfection byproducts, disinfectant residuals, and total organic carbon must be conducted during normal operating conditions. Systems may not change their operating conditions for the sole purpose of meeting an MCL or MRDL and then change back to an operating regime that would not meet limits. For example, a system may not reduce disinfectant feed temporarily to meet the chlorine MRDL and the TTHM and HAA5 MCLs (or chlorine dioxide MRDL and chlorite MCL) and then immediately revert to a higher feed. However, systems are allowed to modify operations to address changing conditions and to protect human health. For example, systems must modify operations to address changes in source water quality or emergency conditions (such as earthquakes and floods). Such modifications have been made for legitimate reasons and are included as "normal operations".

Failure to monitor in accordance with the monitoring plan is a monitoring violation. Where compliance is based on a running annual average of monthly or quarterly samples or averages and the system's failure to monitor makes it impossible to determine compliance with MCLs or MRDLs, this failure to monitor will be treated as a violation for the entire period covered by the annual average. Systems whose monitoring is substantially complete will not be in violation for the entire period covered by the annual average. Substantially complete means that the State is able to determine MCL/MRDL compliance. For example, a system that missed a few percent of its MRDL compliance samples due to inability to sample at required locations (or took all necessary samples, but had minor deviations from its monitoring plan) would be able to determine compliance. These systems would be in violation of monitoring requirements, but only for the month or quarter (depending on the particular requirement). A system that did not take samples or took samples at locations that would be expected to produce results that are not representative (e.g., not taking TTHM samples at the point of maximum residence time) is in violation for the entire period covered by the annual average.

a. *TTHMs and HAA5.* In general, monitoring requirements for TTHMs and HAA5 follow closely the requirements contained in the 1979 TTHM rule. In that rule, there were provisions for routine and reduced monitoring. In this proposal, the Agency has included the same frequency of monitoring for routine monitoring for Subpart H systems serving at least 10,000 people as in the 1979 TTHM rule, although the Committee did not reach consensus on these specific requirements. See below for (1) further discussion and (2) requests for comment on the monitoring requirements. Subpart H systems serving 10,000 or more persons must take four water samples each quarter for each treatment plant in the system, with at least 25 percent of the samples taken at locations within the distribution system that represent the maximum residence time of the water in the system. The remaining samples must be taken at locations within the distribution system that represent the entire system, taking into account the number of persons served, different sources of water, and different treatment methods employed.

Initial monitoring for ground water systems serving at least 10,000 people will be less than what is required under the 1979 TTHM rule, because of the generally lower byproduct formation shown over the life of the 1979 rule. Systems that use a chemical disinfectant must take one water sample each quarter for each treatment plant in the system, taken at locations within the distribution system that represent the maximum residence time of the water in the system. Routine samples must be taken at locations meant to reflect the highest possible TTHM and HAA5 levels (i.e., at the maximum residence time in the distribution system). If those samples are below the MCL, the Agency believes that the system should be considered in compliance.

The Agency is also requiring systems not regulated under the 1979 TTHM rule to meet the requirements of this proposed rule. Community water systems serving fewer than 10,000 people will be covered, as will nontransient noncommunity water systems, a category that did not exist in 1979. Nontransient noncommunity water systems must sample at the same frequency and location as community water systems of the same size.

Routine samples for these systems must be taken at locations meant to reflect the highest TTHM and HAA5 levels (i.e., at the maximum residence time in the distribution system). If those samples are below the MCL, the Agency believes that the system should be considered in compliance. Subpart H systems serving from 500 to 9,999 persons must take one water sample each quarter for each treatment plant in the system, taken at a point in the distribution system that represents the

maximum residence time in the distribution system.

Subpart H systems serving fewer than 500 persons must take one sample per year for each treatment plant in the system, taken at a point in the distribution system reflecting the maximum residence time in the distribution system and during the month of warmest water temperature, when the formation rate of TTHMs and HAA5 is the fastest. This monitoring requirement will allow for a worst case sample, but will limit the monitoring burden for these very small systems.

Systems using only ground water sources not under the direct influence of surface water that use a chemical disinfectant and serve less than 10,000 persons must sample once per year for each treatment plant in the system, taken at a point in the distribution system reflecting the maximum residence time in the distribution system and during the month of warmest water temperature, as with very small Subpart H systems.

All ground water systems may, with State approval, consider multiple wells drawing water from the same aquifer as one plant for the purposes of determining monitoring frequency. This provision is the same as was in the 1979 TTHM rule. EPA requests comment on whether any additional regulatory requirements, guidance, or explanation is required to define "multiple wells". It was the intention of the Committee that multiple wells include both individual wells and well groups. This was done because many ground water systems are extremely decentralized, with multiple entry points to the distribution system, unlike most Subpart H systems with only one or several entry points. Also, EPA requests comment on whether there should be an upper limit of sampling frequency for systems that either cannot determine that they are drawing water from a single aquifer or are drawing water from multiple aquifers. For example, should a system that must draw water from many aquifers to satisfy demand be allowed to limit monitoring as if they were drawing from no more than four aquifers (routine sampling would thus be limited to four samples per quarter from systems serving at least 10,000 people or to four samples per year for systems serving fewer than 10,000 people)? Does EPA need to develop any additional guidance for any other aspect of this requirement?

Systems monitoring less frequently than one sample per quarter per plant must increase monitoring to one sample per treatment plant per quarter until the system meets criteria for reduced sampling if the sample (or the average of the annual samples, when more than one sample is taken) exceeds the MCL.

Systems may sample more frequently than one sample per quarter and more frequently than required, but must take at least 25 percent of the samples at a location reflecting the maximum residence time in the distribution system. The remaining samples must be taken at locations representative of at least average residence time in the distribution system. Any public water system that samples once per quarter or less, but more frequently than the frequency required in this section, must take all of its samples at a location reflecting the maximum residence time in the distribution system.

Taken together, these requirements attempt to balance TTHM and HAA5 formation, system size and source characteristics, and system monitoring costs. As the number of required samples decreases, the system is required to take samples at locations (and times, in some cases) where the highest levels would be expected.

Reduced TTHM and HAA5 Monitoring. Some systems are not able to reduce monitoring. Any Subpart H system which has a source water TOC level, before any treatment, of greater than 4.0 mg/l may not reduce its monitoring. Subpart H systems serving fewer than 500 people may not reduce their monitoring to less than one sample per plant per year. Should there be any exceptions that would allow systems with a TOC> 4.0 mg/l to reduce monitoring (e.g., the system has installed nanofiltration)?

Systems may reduce monitoring (1) if they have a running annual averages for TTHMs and HAA5 that are no more than 0.040 mg/l and 0.030 mg/l, respectively, or (2) for systems using ground water not under the direct influence of surface water that serve fewer than 10,000 persons and are required to take only one sample per year, if either (a) the average of two consecutive annual samples is no more than 0.040 mg/l and 0.030 mg/l, respectively, for TTHMs and HAA5 or (b) any annual sample is less than 0.020 mg/l and 0.015 mg/l, respectively, for TTHMs and HAA5. Systems must meet these requirements for both TTHMs and HAA5 to qualify for reduced monitoring. The system may reduce monitoring only after the system has completed at least one year of monitoring. This standard is more stringent than that in the TTHM rule, in which the system had only to demonstrate that the TTHM concentrations would be "consistently below" the MCL. The Negotiating Committee felt that a more objective set of criteria were necessary.

Reduced monitoring frequency. Subpart H systems serving 10,000 persons or more that are eligible for reduced monitoring may reduce the monitoring frequency for TTHMs and HAA5 to one sample per quarter per treatment plant, with samples taken at a point in the distribution system reflecting the maximum residence time in the distribution system. Subpart H systems serving between 500 to 9,999 persons that are eligible for reduced monitoring may reduce the monitoring frequency for TTHMs and HAA5 to one sample per year per treatment plant, with samples taken at a point in the distribution system reflecting the maximum residence time in the distribution system and during the month of warmest water temperature.

Systems using only ground water not under the direct influence of surface water and serving 10,000 persons or more that are eligible for reduced monitoring may reduce the monitoring frequency for TTHMs and HAA5 to one sample per year per treatment plant, with samples taken at a point in the distribution system reflecting the maximum residence time in the distribution system and during the month of warmest water temperature. Systems using only ground water sources not under the direct influence of surface water and serving fewer than 10,000 persons may reduce the monitoring frequency for TTHMs and HAA5 to one sample per three-year monitoring cycle, with samples taken at a point in the distribution system reflecting the maximum residence time in the distribution system and during the month of warmest water temperature.

EPA believes that this procedure of taking worst-case samples less frequently will adequately identify systems with TTHM and HAA5 problems, since systems have to meet relatively stringent criteria to be eligible for reduced monitoring. Systems which are on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year (for systems which must monitor quarterly) or the result of the sample (for systems which must monitor no more frequently than annually) is no more than 75 percent of the MCLs. Systems that do not meet these levels must resume monitoring at routine frequency. Also, the State may return a system to routine monitoring at the State's discretion.

During the negotiated rulemaking, the Association of State Drinking Water Administrators (ASDWA) expressed the

opinion that the reduced monitoring for ground water systems serving fewer than 10,000 people could be expanded beyond what is in the proposal. These are the systems usually having multiple ground water sources, whose quality is unlikely to change with respect to DBP precursors and are most likely to benefit from reduced monitoring. The additional options presented below both have as a basis the demonstration that the ground water source in question has a minimal likelihood of having precursor material that could combine with chlorine to form any significant concentrations of THMs or HAA5s. Each option would rely on having each entry point of the system go through three years of routine monitoring to qualify for reduced monitoring. After this period, if the entry points meet additional criteria, then the entry points would be subject to minimal additional monitoring. Option one would reduce the monitoring to once every nine years for THMs and HAA5s in the distribution system. This option would minimize the expense of THM and HAA5 monitoring for these systems. Option two, which specifies even more restrictive criteria, would exempt systems from any additional THM and HAA5 monitoring as long as the TOC criteria are met. This option offers the largest cost savings and eliminates the need for tracking and enforcing monitoring requirements on those systems that have historically had the poorest monitoring compliance records and are least likely to have significant levels of DBPs. The Agency would like to receive comments on the following two options.

Option One: Any ground water system serving fewer than 10,000 people that has a raw water TOC of less than 1.0 mg/l, and has both TTHM and HAA5 values less than 25 percent of the MCLs (20 µg/l and 15 µg/l, respectively) after three years of routine and reduced monitoring, can reduce the monitoring for TTHMs and HAA5s to one sample every nine years, taken at the maximum distribution system residence time during the warmest month.

Option Two: Any ground water system serving fewer than 10,000 people that has a raw water TOC of less than 0.5 mg/l, and has both TTHM and HAA5 values less than 25 percent of the MCLs (20 µg/l and 15 µg/l, respectively) after three years of routine and reduced monitoring, is exempt from the distribution system monitoring requirements for TTHMs and HAA5s for as long as TOC monitoring is conducted once every three years and the raw water TOC remains less than 0.5 mg/l.

These options are not mutually exclusive, that is, both could be used simultaneously or some hybrid could be developed. The Agency seeks comment on whether either or both of these options are reasonable in adequately protecting the public health and should therefore be considered as criteria for reduced monitoring. Are there other options for reduced monitoring that should be considered? What are they?

Consensus was not reached on certain key aspects of monitoring and compliance determination. Some members of the Negotiating Committee expressed concerns about the following issues, especially (but not solely) as related to TTHMs and HAA5 monitoring:

—Is the monitoring frequent enough to adequately determine variations in sample results caused by time and/or location in the distribution system? If not, what is a more appropriate monitoring schedule? Should requirements differ for systems based on population served, raw water source, or other factors? If so, should the proposed requirements be changed? How should they be changed? If requirements should not be based on these factors, what should the requirements be?

—Does averaging of sample results taken in various locations and averaging over the course of a year to determine compliance adequately protect individuals that are in locations that may regularly have higher than average levels? If it does not, how should the proposed requirements be changed?

EPA solicits comment on the above issues.

b. *Basis for TOC Monitoring Requirements With Enhanced Coagulation or Enhanced Softening.* In order to demonstrate that the necessary DBPP removal is accomplished (either the percentage specified in Table IX–1 or the alternative minimum TOC removal level determined by the AECL), systems must monitor TOC on a monthly basis, with both source water and treated water (prior to continuous disinfection) samples taken. At the same time, systems must monitor for source water alkalinity. Compliance is based on a running annual average, computed quarterly. Specifics on compliance calculations are included in Section VIII.

B. Bromate MCL and BAT

During the D/DBP negotiated regulation, ozone was evaluated as an alternative disinfectant to chlorine. In particular, the use of ozone for primary disinfection and chloramines for residual disinfection were considered as a disinfection scenario to significantly minimize the formation of THMs, HAAs, and TOX (Metropolitan Water District of So. Calif. et al., 1989; Ferguson et al., 1991; Glaze et al., 1993, in press; Miltner, 1993; and Jacangelo et al., 1989). In addition, when a "cancer-risk bubble" was evaluated by examining the theoretical risks contributed by five compounds that have been classified as B2 (i.e., "probable human") carcinogens (i.e., chloroform, bromodichloromethane, bromoform, dichloroacetic acid [DCAA], and bromate), it was shown that the production of bromate during ozonation may present less of a theoretical cancer risk than the sum of the risks from the individual chlorination DBPs. However such a determination largely depended upon the risk attributed to DCAA (which had not been finally established by EPA). Also, the ability to detect bromate at risk levels equivalent to risk levels for chlorinated DBPs greatly obscures this analysis.

As part of the TWG evaluation of different technologies that might be used to comply with the D/DBP Rule, ozone/chloramines were evaluated under a possible enhanced SWTR scenario for large systems using surface waters that filter but do not soften. It was predicted that TTHMs would range from 4 to 62 µg/L, with median, 75th, and 90th percentile values of 15, 23, and 30 µg/L, respectively. In addition, it was predicted that HAA5 would range from 2 to 133 µg/L, with median, 75th, and 90th percentile values of 16, 26, and 41 µg/L, respectively. The TWG believed that use of alternative disinfectants would provide a feasible means of not only achieving the Stage 1 criteria of 80 µg/L TTHMs and 60 µg/L HAA5 but also allow some systems the means of complying with a proposed Stage 2 criteria of 40 µg/L TTHMs and 30 µg/L HAA5. As discussed previously (Section VI.C.1.b.ii), the TWG also conducted an analysis of bromate occurrence with use of ozone technology and determined that most systems, allowing for modifications in treatment if necessary such as lowering of pH, could achieve a bromate level of 10 µg/L (Krasner et al., 1993).

A major issue, however, is the ability to determine low levels of bromate during compliance monitoring and concern that the risk from bromate could exceed the risk from chlorinated DBPs for which risk estimates are available. While Haag and Hoigné discussed the theoretical basis for the formation of bromate in their 1983 paper (Haag et al., 1983), an analytical method sensitive enough to determine if bromate was indeed formed in ozonated

drinking water was not available until a few years ago (Pfaff et al., 1990). In addition, the initial ion chromatography (IC) method was unable to adequately resolve low levels of bromate from very high amounts of chloride. Because most waters high in bromide can have very high levels of chloride (Metropolitan Water District of So. Calif. et al., 1989), Kuo and colleagues developed a modification to the IC method in order to remove chloride prior to bromate analysis (Kuo et al., 1990). This modification permitted quantitation of bromate down to a concentration of 10 µg/L; subsequently quantitation has been lowered in several research laboratories to 3 or 5 µg/L (Gramith et al., 1993). Using two different labor-intensive concentration methods prior to IC analysis at EPA research facilities, quantitation for bromate was lowered to less than 1.0 µg/L (Sorrell et al., 1992 and Hautman, 1992).

Currently, though, a minimum quantitation level for bromate by conventional IC is probably about 10 µg/L in laboratories that might perform compliance monitoring. During the D/DBP negotiated rulemaking, some members of the Negotiating Committee expressed concern that setting an MCL at 10 µg/L would exceed the theoretical 10^{-4} risk level for bromate of 5 µg/L. The regulation of bromate, at this time, represents an unresolved issue. However, the Negotiating Committee was willing to propose an MCL for bromate of 10 µg/L with the following qualifications and reservations:

1. EPA is seeking data to show that a lower quantitation level (at least down to 5 µg/L) can be obtained by those laboratories that will perform compliance monitoring for bromate in natural drinking water matrices. Whether this improvement in sensitivity is accomplished by improvements to the official EPA method 300.0 (USEPA, 1993) or an alternative analytical method, such data would need to demonstrate appropriate precision and accuracy, including a linear calibration curve for the range of values to be measured, quantitative and precise measurements at the MCL (U.S. Office of the Federal Register, 1987), intra- and interlaboratory reproducibility, as well as freedom from potential interferences in natural matrices (e.g., other anions in water such as chloride, and other ozone byproducts such as organic acids). In addition, this methodology would need to be demonstrated in a number of ozonated drinking water matrices and tested in several laboratories nationwide. If the improved methodology uses equipment and/or reagents that are not currently required for EPA method 300.0, data to indicate the commercial availability and costs of these items would also need to be presented.

2. In addition, EPA is soliciting comments on a treatment technique that could ensure that bromate can be kept below 5 µg/L, even if quantitation at 5 µg/l is not achievable under routine laboratory conditions. A possible treatment technique that could ensure that all systems be able to produce ≤5 µg/L bromate (the theoretical 10^{-4} risk level), would be to construct a matrix of predicted bromate concentration as a function of bromide concentration levels, ozone disinfection conditions (CT), and pH levels under which ozonation occurs. As the bromide and/or inactivation criterion increased, the pH of ozonation might need to be decreased to ensure that the bromate concentration was kept below 5 µg/l. Under a treatment requirement, if a system used ozone, it would be required to operate within the specified matrix conditions for bromide, CT, and pH levels to achieve compliance. This matrix would need to consider ozone residuals sufficient to meet CT criteria for a possible ESWTR.

Other treatment techniques which allow ozone to meet disinfection and oxidation requirements while minimizing bromate formation are also solicited. In addition, any proposed treatment technique must be field-tested in a number of representative natural water matrices. A number of parameters which can affect bromate formation and must be evaluated in establishing a treatment technique include TOC, bromide, alkalinity, pH, ammonia, and hydrogen peroxide levels of the water, as well as the temperature and ozone contact time (Krasner et al., Jan. 1993; Amy et al., 1992–3; Haag et al., 1983; Glaze et al., Jan. 1993; Krasner et al., 1991; Miltner, Jan. 1993; Krasner et al., 1993; Gramith et al., 1993; Miltner et al., 1992; Siddiqui et al., 1993; and Von Gunten et al., 1992). Because the hydrodynamics of the ozone contactor can significantly affect bromate formation (Krasner et al., Jan. 1993; Krasner et al., 1991; and Gramith et al., 1993), the treatment technique may need to be evaluated at pilot-, demonstration-, and/or full-scale. (Bench-scale testing can be used in preliminary evaluations of ozone/bromide/bromate chemistry, but such experiments cannot provide the sole basis for determining an appropriate treatment technique.)

Evaluation of the treatment technique will also require quantitation of bromate concentrations that are ≤5 µg/L. Thus, appropriate quality assurance and control will be required to ensure that the data are precise and accurate.

3. Because the proposed bromate MCL of 10 µg/L was determined to be feasible based upon studies performed to date, if sufficient data are presented to EPA to indicate that a lower MCL and/or an appropriate treatment technique can be obtained, the feasibility and nationwide regulatory impact would need to be considered. For example, the cost of chemical addition to lower the pH of water before ozonation and to raise the pH prior to distribution was not considered in developing the national cost data for systems using ozone to meet the D/DBP Rule. This cost for pH adjustment could be significant for systems with high alkalinity. EPA requests comment on the cost impact that this requirement would have on systems with both high alkalinity and high bromide levels. The effect of a treatment technique would also need to be evaluated in terms of other water quality impacts. Therefore, if a treatment technique is developed, EPA would revise the regulatory impact analysis to reflect new costs and other water quality impacts. EPA requests comment on the relative costs of adjusting pH to reduce bromate formation versus the costs of other technologies to meet the MCLs in this proposed rule.

The following limited data suggest that a significant increase in sensitivity of the method for measuring bromate may indicate that other disinfectant/oxidants produce bromate, and/or that bromate may be a contaminant in some source waters. In a study conducted to test a more sensitive method for measuring bromate (Hautman, 1992), a bromate concentration of 0.4 µg/L was measured in one of the nine source waters tested (i.e., before the point of disinfection/oxidation). However, the researcher did not rule out the possibility of sample contamination of this source water. Theoretical and limited data suggest that chlorine dioxide can react with bromide in the presence of sunlight to form brominated DBPs, including possibly bromate (Cooper, 1990 and Kruithof, 1992). Likewise, under alkaline conditions, bromide reacts with hypochlorite to form hypobromite which then disproportionates to bromate (Bailar et al, 1973). When the hypochlorite solutions from 14 drinking water utilities were surveyed for the presence of oxyhalides (Bolyard et al., 1992), bromate was measured in nine of the hypochlorite solutions, at levels of 4 to 51 mg/L. However, the chlorinated drinking water samples did not contain bromate at concentrations above the 10

µg/L quantitation level. Based on this information, if the MCL for bromate is lowered, analyses for the occurrence of bromate may need to be extended to sources other than ozonated water.

4. EPA plans to convene a second meeting of interested parties to develop a consensus on the second stage of the D/DBP Rule in 1998. It is anticipated that by that time, measurement for bromate at concentrations <10 µg/L may be practical, more health effects data on this DBP will be available, and the treatment to control bromate formation will be appropriately developed and field tested. EPA solicits comments on the feasibility of developing a treatment technique requirement for bromate, lowering the MCL based upon improved analytical techniques, and the time frame under which such alternative standards could be developed.

In the proposed D/DBP Rule, bromate compliance will be based on a running annual average value. This schedule is analogous to that used for THMs and HAAs. Because carcinogens represent a risk based upon a lifetime exposure, temporary peaks in exposure should not affect the lifetime cancer risk. Unlike THMs and HAAs, though, bromate will be measured monthly rather than quarterly and at the entry point to the distribution system rather than in the distribution system. THMs and HAAs can increase in a distribution system as DBP precursors continue to react with the residual disinfectant, especially if free chlorine is used. Because ozone and other active oxidant residuals (e.g., hydroxyl radicals) are short-lived, bromate formation should be complete within the treatment plant. Once in the distribution system, bromate should be stable (Glaze et al., 1993, in press), so analyzing samples in the distribution system will provide no additional information. Because there are many water quality parameters and treatment plant operations that can affect bromate formation, it was not clear whether quarterly monitoring would be adequate to capture the variability in bromate formation (Krasner et al., Jan. 1993, Miltner, Jan. 1993, and Gramith et al., 1993). However, EPA is proposing reduced bromate monitoring where a utility's average raw water bromide level is less than 0.05 mg/L. This reduction is based on limited data to date to suggest that under typical drinking water ozonation conditions of water with ≤0.05 mg/L bromide (based on pilot- and full-scale data) that bromate will typically not be formed at levels of 5 to 10 µg/L or higher (Krasner et al., 1993).

C. Chlorite MCL and BAT

Chlorite is formed as a result of treating source water with chlorine dioxide. Many utilities use chlorine dioxide because of specific water quality characteristics that make the water difficult to treat. These characteristics include high hardness, TOC, and bromide concentrations. For example, at high pHs (above 9.0), chlorine is much less effective as a disinfectant and ozone residuals cannot be maintained in solution long enough for effective disinfection. Systems now using chlorine dioxide may not be able to meet the standards proposed in this regulation, since in some cases, even expensive precursor removal technologies such as GAC or membrane technology may not be able to remove precursors adequately to meet DBP MCLs and, in other cases, systems may not be able to use the technologies due to site restrictions (e.g., membranes not feasible due to water limits—system cannot afford loss of significant amounts of water as membrane reject).

While research is underway on how to reduce chlorite residuals at the treatment plant, e.g., using ferrous iron (Griese et al., 1992), additional work is required. At this time, the only means for reducing chlorite levels is to control the use of chlorine dioxide.

During the negotiations, EPA had not yet established a reference dose for chlorite and, therefore, no MCLG was considered at that time. However, EPA's Office of Water staff stated that they interpreted the available health effects data to indicate the toxicological endpoint of concern as oxidative stress to red blood cells. This effect is considered reversible, lasting a matter of a few weeks or months.

Based on considerations that the health effect was of relatively short duration, and that some systems might require chlorine dioxide, the Negotiating Committee agreed to propose a conditional MCL of 1.0 mg/l. This MCL was selected based on a recommendation from the TWG that 1.0 mg/l is the lowest level achievable by typical systems using chlorine dioxide, and taking into consideration the monitoring requirements to determine compliance.

In agreeing to propose 1.0 mg/l as the MCL for chlorite, the Negotiating Committee set certain qualifications and reservations:

(1) If EPA proposed a MCLG for chlorite of 1.0 mg/l or higher, the proposed MCL would be set at the MCLG value. If EPA proposed a MCLG for chlorite of less than 1.0 mg/l based on EPA's reference dose, the proposed MCL would be set at 1.0 mg/l based on technological feasibility considerations.

(2) Additional research would be conducted including a two-generation reproductive effects study in animals and a clinical study of humans exposed to chlorite to determine what minimum levels of exposure can be considered safe. It was agreed that these studies would be completed in time for consideration of possible changes to the MCL under the final Stage 1 rule. If the studies indicate that a level of 1.0 mg/l of chlorite is safe, the MCL would remain at 1.0 mg/l. If the studies indicate that a level of 1.0 mg/l of chlorite is not safe or, if such a study is not conducted, the MCL would be reevaluated.

Based on a consideration that the health effect is reversible and relatively short term in duration, the Negotiating Committee agreed that systems would determine compliance by monitoring for chlorite three times per month. Samples would be taken at the following locations: one near the first customer, one in a location representative of average residence time, and one near the end of the distribution system reflecting maximum residence time. Monitoring would be conducted in the distribution system since the concentration of chlorite is likely to increase in the distribution system. If the monthly average of the three distribution system samples exceeded the MCL, the system would be in violation for that month. In agreeing to propose these requirements, the Negotiating Committee assumed that, if a system were out of compliance during one month but achieved compliance during the following month, that any health effects that might occur from the short term exposure would cease once the system achieved compliance.

After the Negotiating Committee agreed to propose the above MCL and monitoring requirements at its last meeting in June, 1993, EPA's Reference Dose Committee met and determined a different toxicological endpoint for chlorite. The Reference Dose Committee determined that chlorite poses an acute developmental heath effect, which is a neurobehavioral effect: depressed exploratory behavior. Based on the new reference dose, the MCLG for chlorite would be 0.08 mg/l (see section V of this preamble). The derivation of the MCLG includes a 1,000-fold uncertainty factor to account for use of a LOAEL instead of a NOAEL from an animal study. EPA does not believe that the proposed MCL of 1.0 mg/l and monitoring requirements agreed to by the Negotiating Committee are adequate to protect the public from

the acute developmental health effect, unless new data indicate otherwise.

EPA is concerned about proposing an MCL significantly above the MCLG, especially since the MCLG is based on acute health risks. EPA is proposing this level to honor the agreement of the Negotiating Committee. However, EPA solicits comment on the following approaches for promulgating a final rule.

(1) EPA could promulgate an MCL at the MCLG. Based on currently available information, an MCL of 0.08 mg/l would probably rule out the use of chlorine dioxide as a disinfectant, since it does not appear possible for systems to meet simultaneously disinfection requirements and the resultant chlorite MCL. If new data become available indicating a NOAEL of 1 mg/kg/day, the highest resultant MCLG and corresponding MCL would likely be no more than 0.3 mg/l. An MCL of 0.3 mg/l for chlorite ion would allow some systems to be able to use chlorine dioxide. However, other water systems, because of water quality parameters that affect chlorine dioxide demand and chlorite ion control, will not be able to find a feasible operating region to use chlorine dioxide, at least on a year-round basis. EPA would be concluding that other technologies besides chlorine dioxide are feasible for those systems for meeting the Stage 1 D/DBPR and SWTR (or ESWTR, if such a rule is necessary), taking cost into consideration for systems currently using chlorine dioxide. A regulatory impact analysis will have to be prepared to evaluate technical feasibility, production of other DBPs based on a different disinfectant, and cost considerations.

(2) EPA could promulgate an MCL lower than the proposed MCL of 1.0 mg/l, but above the MCLG, depending upon all data that became available in the near term. In doing so, EPA would be concluding that risks from other alternatives are commensurate at this level, or that other technologies, taking costs into consideration, are not available at the 0.08 mg/l level, but are available at a higher level. EPA would thus be indicating that some systems must use chlorine dioxide to meet disinfection requirements, but can maintain compliance by making operational modifications that are not available to all systems. This approach would more narrowly limit the use of chlorine dioxide to systems with very specific source water or other characteristics if use of chlorine dioxide were considered essential versus use of other disinfectants.

(3) Depending on new data that become available, EPA could promulgate an MCL at the proposed MCL of 1.0 mg/l if the Agency determined that the systems currently using chlorine dioxide could not meet disinfection requirements in any other feasible manner, taking cost into consideration.

As part of any of the above approaches, EPA could accelerate the promulgation of NPDWRs for chlorine dioxide and chlorite if the Agency believed it necessary to avoid acute health effects. Also, as part of the final rule, EPA would consider the appropriateness of the proposed monitoring requirements and public notification language in light of the acute health effect. Monitoring changes could include increasing the sampling frequency, changing the location of monitoring, and/or changing the determination of compliance. These changes may result in requirements similar to those for chlorine dioxide (e.g., daily measurements within the distribution system to determine compliance).

In making its final decision, EPA will consider a number of factors: the risk which would be posed from chlorite and chlorine dioxide compared to the risk from other contaminants if chlorine dioxide were not used, the uncertainty in those risk estimates, the feasibility of using other means of control, and the cost of those other control mechanisms.

EPA requests comments on the above approaches for regulating chlorite. Specifically, EPA requests comment on the following:

—Is the basis for EPA's MCLG and concern for acute health effects appropriate? See Section V. for a complete discussion.

—In light of the proposed MCLG and concern for acute health risks that were not apparent during the negotiations, should EPA accelerate the promulgation of NPDWRs for chlorine dioxide and chlorite? If so, should EPA set the MCL at the proposed MCLG? Should EPA wait until more data become available, as agreed upon during the negotiations, before promulgating an MCL? Such data will be available through CMA. CMA is conducting health effects studies to fill data gaps for chlorine dioxide and chlorite. EPA will evaluate these data (which are scheduled to be available prior to rule promulgation) to help determine what changes to the MRDLG and MRDL may be warranted.

—Are there any particular water quality characteristics for systems currently using chlorine dioxide which make it ineffective to use any other disinfection technology? What are the lowest chlorite levels these systems can achieve? What technologies would need to be adopted and at what costs if such systems with these particular water quality characteristics would no longer use chlorine dioxide to meet the other regulatory criteria proposed herein?

—Should EPA set the chlorite MCL at a level so that chlorine dioxide remains a viable disinfection alternative for some systems even if this level is above the MCLG? If so, what would be the rationale for doing so?

—Is 1.0 mg/l the lowest level that systems needing chlorine dioxide can reliably achieve?

—How should EPA change the compliance monitoring requirements for chlorite to reflect concern about acute effects? Should such changes include increasing the frequency or changing the location of monitoring to be similar to those for chlorine dioxide? How would the MCL be affected by changes in the monitoring requirements?

—How should EPA change the public notification requirements for chlorite to reflect concern about acute effects?

D. Chlorine MRDL and BAT

The chlorine MRDL has been set at the MRDLG of 4.0 mg/l, with compliance being based on a running annual average of monthly averages of samples taken in the distribution system. A running annual average was used as the basis for compliance because health effects are long term (see Section V.).

There will be no additional monitoring required by Subpart H systems to comply with this requirement, since samples that are already required to be taken by systems to comply with the Surface Water Treatment Rule (see 40 CFR 141.74) may be used to demonstrate compliance with the MRDL. The samples required under the SWTR are used to demonstrate compliance with the requirement for maintenance of a residual in the distribution system (in effect, a floor or minimum); the samples required under this rule would set a maximum or ceiling for chlorine levels.

Additional monitoring is required for systems that use only ground water not under the direct influence of surface water to comply with this requirement, since samples are not already required to be taken by these systems. However, this sampling may be required to comply with the forthcoming Ground Water Disinfection Rule (GWDR) to be proposed at a later date. If such monitoring is required by the GWDR,

one set of samples will be allowed to be used to demonstrate compliance with both the MRDL in this rule and the distribution system monitoring requirements in the GWDR.

Since compliance is based on an annual average, the MRDL does not apply to individual samples, which are allowed to be higher than the MRDL. In addition, allowing individual samples to exceed the MRDL gives the system operator the flexibility to address short-term microbiological problems caused by distribution system line breaks, storm runoff events, source water contamination, or cross connections.

EPA believes that it is essential that system operators are aware of the flexibility that this rule gives them in addressing specific microbiological threats without worrying about violating an MRDL. For this reason, the definition of "maximum residual disinfectant level" proposed today in § 141.2 specifically allows higher disinfectant levels for the two disinfectants with long-term, but not short-term, effects (chlorine and chloramines), while pointing out that increasing levels of chlorine dioxide to address short-term problems is not allowed (because of the short-term health effects—see Section V.). The Agency believes that even if systems must increase disinfectant levels to address specific contamination problems, they will be able to meet the MRDL on an annual basis.

E. Chloramine MRDL and BAT

The chloramine MRDL has been set at the MRDLG of 4.0 mg/l, with compliance based on a running annual average of monthly averages of samples taken in the distribution system. A running annual average was used as the basis for compliance because health effects are long term (see Section V.). The Negotiating Committee considered a range of 4 to 6 mg/l and chose 4 mg/l. This decision was based on compliance being determined by a running annual average rather than by individual samples. Also, 4 mg/l was thought to be the lowest feasible MRDL for some systems that would not compromise microbial protection. Residual disinfectant demand could be reduced by additional precursor removal, but the Negotiating Committee agreed that precursor removal beyond that achieved by enhanced coagulation or enhanced softening should not be required in Stage 1. EPA requests comment on what level would be feasible to achieve by most systems without increasing microbial risk.

There will be no additional monitoring required by Subpart H systems to comply with this requirement, since samples that are already required to be taken by systems to comply with the Surface Water Treatment Rule (see 40 CFR 141.74) may be used to demonstrate compliance with the MRDL. The samples required under the SWTR are used to demonstrate compliance with the requirement for maintenance of a residual in the distribution system (in effect, a floor or minimum); the samples required under this rule would set a maximum or ceiling for chloramine levels.

Additional monitoring is required for systems that use only ground water not under the direct influence of surface water to comply with this requirement, since samples are not already required to be taken by these systems. However, this sampling may be required to comply with the forthcoming Ground Water Disinfection Rule (GWDR) to be proposed at a later date. If such monitoring is required by the GWDR, one set of samples will be allowed to be used to demonstrate compliance with both the MRDL in this rule and the distribution system monitoring requirements in the GWDR.

Since compliance is based on an annual average, the MRDL does not apply to individual samples, which are allowed to be higher than the MRDL. In addition, allowing individual samples to exceed the MRDL gives the system operator the flexibility to address short-term microbiological problems caused by distribution system line breaks, storm runoff events, source water contamination, or cross connections.

EPA believes that it is essential that system operators are aware of the flexibility that this rule gives them in addressing specific microbiological threats without worrying about violating an MRDL. For this reason, the definition of "maximum residual disinfectant level" proposed today in § 141.2 specifically allows higher disinfectant levels for the two disinfectants with long-term, but not short-term, effects (chlorine and chloramines), while pointing out that increasing levels of chlorine dioxide to address short-term problems is not allowed (because of the short-term health effects—see Section V.). The Agency believes that even if systems must increase disinfectant levels to address specific contamination problems, they will be able to meet the MRDL on an annual basis.

F. Chlorine Dioxide MRDL and BAT

EPA has proposed the MRDLG for chlorine dioxide at 0.3 mg/L (see section V of this preamble). The derivation of the MRDLG includes an uncertainty factor of three to address one data gap (i.e., lack of a 2-generation reproduction study). In the near future, it is tentatively planned that health effects studies on the impact of chlorine dioxide in drinking water will be performed to resolve the data gap concerning reproductive effects.

Chlorine dioxide is used in Europe as a residual disinfectant, while in the U.S. it is used for disinfection or oxidation within the treatment plant. Because chlorine dioxide residuals are short-lived, they are typically not detected in distribution systems. When chlorine dioxide residuals are analyzed, the presence of other oxidants (e.g., chlorine, chlorite, and chlorate) must be subtracted out from a total oxidant measurement. In a method where the value is obtained by difference, there is a limit to how low a quantitative measurement can be made. The PQL for chlorine dioxide residuals is probably in the range of 0.5 to 1.0 mg/L.

Systems must monitor for chlorine dioxide daily since there are acute health effects. Monitoring must be conducted at the entrance to the distribution system, since the concentration of chlorine dioxide will not increase in the distribution system. If monitoring indicates that the concentration of chlorine dioxide exceeds the MRDL, the system is then required to conduct additional monitoring in the distribution system. This monitoring consists of three samples taken the day following an exceedance of the MRDL at specific locations within the distribution system considered to be those most likely to have the highest levels and depend on the type and location of residual disinfection. For systems that use chlorine dioxide or chloramines to maintain a residual in the distribution system, or that use chlorine with no booster chlorination after the water enters the distribution system, three samples must be taken as close as possible to the first customer at intervals of at least six hours. For systems that use chlorine to maintain a disinfectant residual in the distribution system, and have one or more locations within the distribution system where additional chlorine is added (i.e., booster chlorination), samples must be taken at the following locations: One as close as possible to the first customer, one in a location representative of average residence time, and one near the end of the distribution system reflecting maximum residence time. These additional samples must be taken each day following any sample taken at the entrance to the distribution system that exceeds the MRDL.

Compliance is based on samples taken both at the entrance to the distribution

system and in the distribution system. If one or more of the samples taken in the distribution system exceed the MRDL, the system has an acute violation and must take immediate corrective action to lower the level of chlorine dioxide and make appropriate public notification. If two consecutive samples taken at the entrance to the distribution system exceed the MRDL (and none of the required samples taken in the distribution system exceed the MRDL), the system has a nonacute violation and must take corrective action to lower the level of chlorine dioxide and make appropriate public notification. If a required sample is not taken, the system must treat it as if the sample had been taken and exceeded the MRDL. Therefore, failure to take one or more of the additional distribution system samples the day following a sample taken at the entrance to the distribution system that exceeds the MRDL is considered an acute violation. Failure to take a sample at the entrance to the distribution system the day following a sample taken at the entrance to the distribution system that exceeds the MRDL is considered a nonacute violation.

The Negotiating Committee agreed to propose 0.8 mg/L as the MRDL for chlorine dioxide with certain qualifications and reservations:

(1) A two-generation reproductive study would be completed for consideration in the final Stage 1 rule. If this study indicates there is no concern from reproductive effects at the proposed MRDL, unless public comments otherwise influence the Agency, then the proposed MRDL would remain the same as proposed (0.8 mg/l).

(2) If no new health effects studies become available on reproductive effects, the chlorine dioxide MRDL will be reassessed. It will be necessary to re-examine the tradeoffs and regulatory impacts of a lower chlorine dioxide MRDL in light of the positive aspects of chlorine dioxide disinfection and control of chlorination DBPs. EPA would probably promulgate a final MRDL that is the higher of the MRDLG or the detection level because the health effects are acute. Issues that would be considered include new information on health effects of other disinfectants.

As part of the above approaches, EPA could accelerate the promulgation of an NPDWRs for chlorine dioxide if the Agency believed it necessary to avoid acute health effects. In making its final decision, EPA will consider a number of factors: The risk which would be posed from chlorite and chlorine dioxide compared to the risk from other contaminants if chlorine dioxide were not used, the uncertainty in those risk estimates, the feasibility of using other means of control, and the cost of those other control mechanisms.

EPA requests comments on the above approaches for regulating chlorite. Specifically, EPA requests comment on the issues identified earlier in the chlorite subsection.

Regardless of the final MRDL value, the Negotiating Committee agreed on the following monitoring program to protect against the risk of a reproductive endpoint due to short-term exposure to a high dose of chlorine dioxide: the entry point to the distribution system will be measured daily. If any day's value exceeds the MRDL, sampling will be initiated in the distribution system. If the second-day plant effluent is also above the MRDL, but distribution system samples are less than the MRDL, then the utility will be in violation (but this would not be considered an acute violation); the lower concentration of chlorine dioxide in the distribution system will minimize the risk to consumers due to the lower level of exposure. If chlorine dioxide is detected at a level greater than the MRDL in the distribution system, then the utility would be considered in acute violation because the risk to susceptible consumers (i.e., pregnant women) is higher. By monitoring chlorine dioxide residuals daily in the treatment plant, utilities can work best at minimizing exposure in the distribution system.

G. Basis for Analytical Method Requirements

The SDWA directs EPA to set an MCL for a contaminant "if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems." [SDWA section 1401(1)(c)(ii)] To make this threshold determination for the disinfectants and disinfection by-products (DBPs) proposed today, EPA evaluated the availability, costs, and performance of analytical techniques which measure these disinfectants and DBPs. This evaluation is discussed below. EPA also considered the ability of laboratories to measure consistently and accurately at the maximum residual disinfectant level (MRDL) or the maximum contaminant level (MCL) of each contaminant. The ability to measure consistently and accurately at 25 and 50 percent of the total trihalomethane (TTHM) and haloacetic acid (HAA5) MCLs was also evaluated in order to ensure that measurements for allowing reduced monitoring can be made reliably.

The reliability of analytical methods is critical at the MRDL or MCL and at levels which allow reduced monitoring. Therefore, each analytical method was evaluated for lack of bias (i.e. accuracy or recovery) and precision (good reproducibility) at these concentrations for each contaminant. The primary purpose of the evaluation was to determine: (1) Whether analytical methods exist to measure disinfectants and DBPs; (2) reasonable expectations of technical performance by analytical laboratories at the MRDL or MCL levels and at the levels which allow reduced monitoring for TTHMs and HAA5; and (3) analytical costs.

In selecting analytical methods, EPA considered the following factors:

(a) Reliability (i.e., precision/accuracy) of the analytical results;

(b) Specificity in the presence of interferences;

(c) Availability of enough equipment and trained personnel to implement a national monitoring program (i.e., laboratory availability);

(d) Rapidity of analysis to permit routine use; and

(e) Cost of analysis to water supply systems.

Several analytical methods are described and discussed below. EPA refers readers to the published methods for additional information on the precision, accuracy and quality control requirements of the proposed analytical methods.

1. Disinfectants

Today's rule proposes monitoring requirements to ensure compliance with proposed maximum residual disinfectant levels for chlorine, chloramines, and chlorine dioxide. Analytical methods, most of which have been in use for years, exist to measure these residuals. There are additional analytical techniques available for measuring disinfectant residuals (AWWARF, 1992) that are not proposed in today's rule because they are not written in a standard format that is readily available to the public. Nine disinfectant methods are proposed in today's rule (Table IX–2). Most of the proposed methods are in use, because they were promulgated with the Surface Water Treatment Rule (SWTR). (54 FR 27486, June 29, 1989)

TABLE IX–2.—PROPOSED METHODS FOR DISINFECTANTS

Disinfectant measurement	Proposed methods
Chlorine as free or total residual chlorine, chloramines as combined or total residual chlorine.	4500–Cl D Amperometric Titration. 4500–Cl F DPD Ferrous Titrimetric. 4500–Cl G DPD Colorimetric.
Chlorine as free residual chlorine.	4500–Cl H Syringaldazine (FACTS).
Chlorine or Chloramines as total residual chlorine.	4500–Cl E Low-Level Amperometric. 4500–Cl I Iodometric Electrode.
Chlorine Dioxide as residual chlorine dioxide.	4500–ClO_2 C Amperometric Titration. 4500–ClO_2 D DPD. 4500–ClO_2 E Amperometric Titration.

Proposed methods are in "Standard Methods for the Examination of Water and Wastewater," 18th Edition, American Public Health Association, American Water Works Association, and Water Environment Federation, 1992.

The disinfectant residual methods proposed in today's rule were selected based on evaluations that included the results of an evaluation made for the methods that were promulgated with the SWTR. In today's rule, EPA proposes to withdraw Standard Method 408F, which was promulgated for measurement of chlorine residual under the SWTR. EPA is also proposing two methods (Standard Methods 4500–Cl H and 4500–Cl I) that were inadvertently omitted from the SWTR. Methods 4500–Cl H and I would be approved for compliance monitoring under the SWTR and the D/DBP rule. In addition, EPA proposes to update all of the disinfectant methods, which were promulgated in 1989 with the SWTR, to the versions that will be promulgated with the D/DBP rule. This update will allow laboratories to use the most recent versions of these methods for all compliance monitoring of disinfectant residuals.

Standard Method 408F was dropped from the 17th and subsequent editions of Standard Methods because it is difficult to use, and because there are several other available methods that are superior to it. Since EPA believes few, if any, laboratories use Method 408F, withdrawal should have little effect on the regulated community.

In evaluating disinfectant residual methods for use under the SWTR EPA considered, but did not promulgate, five EPA and two Standard Methods. The seven methods were rejected for the following reasons. EPA methods 330.1 to 330.5 for free and total chlorine measurement were not promulgated because equivalent methods published by Standard Methods, which contained more up-to-date and complete descriptions of required analytical procedures, were available. The five EPA methods have not been updated since 1979, while new editions of Standard Methods are issued periodically to include all applicable improvements made to the methods during the interim. Standard Method 4500–Cl B (Iodometric I) was not promulgated with the SWTR because it cannot measure chlorine accurately at concentrations of less than 1 mg/L. Standard Method 4500–Cl C (Iodometric II) was not promulgated because it is not sensitive enough for drinking water analyses. For these same reasons, EPA is not proposing these seven methods in today's rule.

EPA is aware that all of the disinfectant methods proposed today are subject to interferences, especially when used to measure low concentrations of disinfectant residuals. However, when procedures specified in the methods are followed, the methods can be used to indicate compliance with the minimum disinfectant residual concentrations proposed in today's rule (AWWARF, 1992). EPA is soliciting information on improvements which may have been made to these methods, but that are not reflected in the 18th edition of Standard Methods. EPA is also seeking information on new methodology that may be applicable for compliance monitoring. New methods must provide demonstrated advantages over the current methods and have the potential for being distributed in a standard format in the time frame of this regulation.

EPA is aware that several vendors manufacture or may manufacture test kits that are based on DPD colorimetric Standard Methods 4500–Cl G and 4500–ClO_2 D. If Methods 4500–Cl G and 4500–ClO_2 D are promulgated under the D/DBP rule, EPA proposes that kits using the same chemistry as these methods be approved for compliance monitoring for chlorine and chlorine dioxide, respectively, provided the State also approves of their use.

EPA believes that the analytical methods being proposed today are within the technical and economic capability of many laboratories. For example, utility laboratories are currently using the proposed disinfectant methods to measure disinfectant residuals under the SWTR. The analytical cost is estimated at $10 to $20 per sample. Costs will vary with the laboratory, analytical technique selected, number of samples, and other factors. EPA believes these costs are affordable.

Below is a description of the analytical methods proposed for compliance with the proposed MRDLs. The three disinfectant residuals are measured and reported as follows: chlorine as free or total chlorine; chloramines as combined or total chlorine; and chlorine dioxide as chlorine dioxide. For information on the precision and accuracy of these methods, EPA refers the readers to the written methods and to AWWARF, 1992. EPA requests public comments on the technical adequacy of these proposed analytical techniques.

a. Amperometric Titration Method (SM 4500–Cl D) for chlorine and chloramines. Free residual chlorine is measured by adjusting the pH of the sample to between 6.5 and 7.5 followed by titration to the endpoint with a phenylarsine oxide reducing solution. Total residual chlorine is measured by adding potassium iodide to the sample, adjusting the pH to between 3.5 and 4.5, and titrating with phenylarsine oxide to the endpoint. Chloramines, as combined chlorine, are determined by subtracting the result of the free residual chlorine measurement from the total residual chlorine measurement in the same sample. A microammeter is used to detect the endpoints in each titration. Commercial titrators are considered to have detection limits as low as 20 µg/L (as Cl_2), but the limit of detection depends on the type of water sample (AWWARF, 1992). Since interferences may account for a high percentage of the instrument response at low concentrations, results in samples with low concentrations of free or total chlorine should be used with caution (AWWARF, 1992). EPA believes the working range for this method adequately covers the proposed MRDLs for free, combined, and total chlorine residuals.

b. Low Level Amperometric Titration Method (SM 4500–Cl E) for chlorine and chloramines measured as total residual chlorine. This method utilizes the same principle as the amperometric titration method listed above. This method modifies SM 4500–Cl D by using a more dilute concentration of phenylarsine oxide titrant and a graphical procedure to determine the endpoint. Use of this method is recommended when the total chlorine residual is less than or equal to 0.2 mg/L as Cl_2. This method will show a positive bias if other oxidizing reagents are present in the water sample. Since SM 4500–Cl E is only

applicable to measuring total residual chlorine, it cannot be used to differentiate between free and combined residual chlorine.

c. DPD Ferrous Titrimetric Method (SM 4500–Cl F) for chlorine and chloramines. When the proper sample pH is chosen, this method can differentiate between free chlorine, monochloramine, dichloramine, and total chlorine. The color produced by the reaction of the chlorine species with the DPD dye slowly disappears as the sample is titrated with ferrous ammonium sulfate. The amount of titrant corresponds to the concentration of chlorine species being measured. This method is proposed for the determination of free, combined, and total residual chlorine.

d. DPD Colorimetric Method (SM 4500–Cl G) for chlorine and chloramines. The method utilizes the same principle as SM4500–Cl F except that the color produced is read by a colorimeter and the concentrations of free and total chlorine are calculated after standardization. Combined residual chlorine is the sum of the monochloramine and dichloramine measurements. Total residual chlorine is the sum of free and combined residual chlorine. This method is proposed for the determination of free, combined, and total residual chlorine.

e. Syringaldazine (FACTS) Method (SM 4500–Cl H) for chlorine. The reagent, syringaldazine, is oxidized by free chlorine on a 1:1 basis to produce a color which is determined colorimetrically. The pH of the sample must be maintained at approximately 6.7 to stabilize the color formed. This method is proposed for the determination of free residual chlorine.

f. Iodometric Electrode Technique (SM 4500–Cl I) for chlorine and chloramines. This method involves the direct potentiometric (electrode) measurement of iodine released when potassium iodide is added to an acidified sample containing chlorine. A platinum-iodide electrode pair is used in combination to measure the liberated iodine. This method is proposed for the determination of total residual chlorine.

g. Amperometric Method I (SM 4500–ClO_2 C) for chlorine dioxide residuals. This titration method is an extension of SM 4500–Cl D (which measures chlorine). By sequentially performing four titrations at different sample pH with phenylarsine oxide, four chemicals (free chlorine, monochloramine, chlorite, and chlorine dioxide) may be determined by a method of differences. This method is proposed for the determination of chlorine dioxide residuals.

h. DPD Method (SM 4500–ClO_2 D) for chlorine dioxide. This method is an extension of the DPD method for chlorine (SM 4500–Cl F). Chlorine dioxide appears in the first step of this procedure, but only to the extent of one-fifth of its available oxidation/reduction potential. This potential arises from the reduction of chlorine dioxide in the sample to chlorite. After a pH adjustment and the addition of a buffer, a color is produced which corresponds to the chlorine dioxide content of the sample. This method is proposed for the determination of chlorine dioxide residuals.

i. Amperometric Method II (4500–ClO_2 E) for chlorine dioxide. This titration method is similar to SM 4500–ClO_2 C which is described above. The method can measure chlorine dioxide in samples which contain free chlorine and other interfering compounds. The method can measure a wide range of chlorine dioxide concentrations in drinking water samples. Dilute (0.1 to 10 mg/L) and concentrated (10 to 100 mg/L) concentrations of chlorine dioxide are measured by varying the size of the drinking water sample and the concentration of the titrating solution. This method is proposed for the determination of chlorine dioxide residuals.

2. By-Products

Six analytical methods for measurement of inorganic and organic disinfection by-products (Table IX–3) are proposed and discussed in parts 3 and 4.

TABLE IX–3.—PROPOSED METHODS FOR DISINFECTION BY-PRODUCTS

Contaminant	Methods[1]
Trihalomethanes	502.2, 524.2, 551.
Haloacetic Acids	552.1, 6233 B.
Bromate, Chlorite	300.0.

[1] EPA Method 502.2 is in the manual "Methods for the Determination of Organic Compounds in Drinking Water", EPA/600/4– 88/039, July 1991, NTIS publication PB91–231480. EPA Method 551 is in the manual "Methods for the Determination of Organic Compounds in Drinking Water—Supplement I", EPA/600/4–90/020, July 1990, NTIS PB91–146027. EPA Methods 524.2 and 552.1 are in the manual "Methods for the Determination of Organic Compounds in Drinking Water—Supplement II", EPA/600/R–92/129, August 1992, NTIS PB92–207703. EPA Method 300.0 is in the manual "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R/93/100—Draft, June 1993. Standard Method 6233 B is in "Standard Methods for the Examination of Water and Wastewater," 18th Edition, American Public Health Association, American Water Works Association, and Water Environment Federation, 1992.

3. Organic By-Product Methods

EPA is proposing five methods (Table IX–3) for the analysis of two classes of organic disinfection by-products—total trihalomethanes (TTHMs) and haloacetic acids (five) (HAA5). Compliance with the 0.08 mg/L TTHM MCL will be determined by summing the concentration of each of four trihalomethanes (bromoform, chloroform, dibromochloromethane and bromodichloromethane) as measured in a drinking water sample by EPA Methods 502.2 or 524.2 or 551. EPA is also proposing to withdraw approval of two EPA methods which use older technology and have been superseded by Methods 502.2 and 551.

Compliance with the HAA5 MCL of 0.060 mg/L will be determined by summing the concentration of each of five haloacetic acids (mono-, di-, and trichloroacetic acids; mono- and dibromoacetic acids) as measured in a drinking water sample with EPA Method 552.1 or Standard Method 6233 B. The haloacetic analytical methods can also measure a sixth haloacetic (bromochloroacetic) acid. Since this acid may be considered in a future disinfection by-product control regulation, EPA encourages, but does not require, water systems to measure and report occurrences of bromochloroacetic acid in samples analyzed for HAA5 MCL compliance monitoring.

EPA believes the analytical methods being proposed today are within the technical capability of many laboratories and within the economic capability of the regulated community. The analytical cost for trihalomethane (THM) analysis is estimated to be from $50 to $100 per sample. There is generally no additional cost for THM measurements if Method 502.2 or 524.2 is used to measure volatile organic compounds (VOCs) in the same sample. The analytical cost for haloacetic acid analysis is estimated at $150 to $250 per sample; adding bromochloroacetic acid to the analysis should not significantly change the cost. Actual costs may vary with the laboratory, analytical technique selected, the total number of samples, and other factors.

Today's proposed requirements would impose little or no extra trihalomethane monitoring on community water systems serving populations of 10,000 or more because most of these systems must routinely monitor for THMs under the Trihalomethane rule [44 FR 68264, November 29, 1979]. Monitoring for haloacetic acids will increase each

system's analytical costs but EPA believes these costs are affordable.

With the exception of EPA Method 551, the proposed methods for measuring trihalomethanes are in widespread use. More than 700 laboratories are presently certified to measure THMs. Many of these laboratories use Methods 502.2 and 524.2 to comply with VOC and THM monitoring requirements and MCLs. EPA believes there is adequate laboratory capacity for trihalomethane analysis. EPA expects that many of these laboratories will become certified to conduct analysis of haloacetic acids in drinking water samples.

The methods for measuring haloacetic acids are new and not in widespread use. These compounds have been included in several of EPA's Water Supply (WS) performance evaluation (PE) studies, and the number of participants has increased with each successive study. In the WS 31 study, twenty-five laboratories reported data for all five of the haloacetic acids covered in today's proposed rule, compared to sixteen laboratories in the WS 29 study. These data were produced using a liquid-liquid extraction method. Based on the available PE data, EPA believes the haloacetic acid methods can provide reliable data at the proposed MCLs. EPA is aware that many utility laboratories are developing analytical capability for haloacetic acids, and commercial laboratories are receiving requests from utilities for haloacetic acid analyses. Therefore, EPA believes there will be adequate laboratory capability by the time compliance monitoring for haloacetic acids is required.

a. Trihalomethane Methods. Presently EPA Methods 501.1, 501.2, 502.2, and 524.2 are approved for compliance with total trihalomethane monitoring requirements under 40 CFR 141.30. For reasons discussed below, EPA proposes to withdraw Methods 501.1 and 501.2, and to approve a new method (EPA Method 551) for trihalomethane compliance measurements.

Method 502.2, Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series, and Method 524.2, Measurement of Purgeable Organic Compounds in Water by Capillary Column Purge and Trap Capilláry Column Gas Chromatography/ Mass Spectrometry, are widely used for THM and VOC analyses. Readers are referred to previous notices, 52 FR 25690 (July 8, 1987) and 56 FR 3548 (January 30, 1991), for discussions and descriptions of these methods. Method 502.2 requires a photoionization detector and an electrolytic conductivity detector, configured in series, to measure aromatic or unsaturated VOCs by photoionization, and other VOCs and THMs by electrolytic conductivity. If only THMs are to be determined in a sample, Method 502.2 may be used without the photoionization detector.

EPA proposes to withdraw approval of EPA Methods 501.2 and 501.1 for TTHM compliance monitoring. Method 501.2, which uses a liquid-liquid extraction technique, and Method 501.1, which uses a purge-and-trap sparging technique, have not been updated since 1979. Both methods use packed column technology. Packed columns have less resolving power than capillary columns, which often limits their use to very simple analyses. This is one of the reasons that Methods 501.1 and 501.2 are only promulgated for trihalomethane monitoring.

Packed column technology is becoming obsolete, and capillary columns are required in most modern gas chromatographic methods that have been developed for compliance monitoring. In a rule which was published on August 3, 1993 (58 FR 41344), EPA encourages the use of capillary column methods for THM analysis, and announces discontinuance of technical support for packed column methods. As laboratories replace their gas chromatographs over the next few years, EPA believes most, if not all, laboratories will acquire capillary column instruments because they offer greater flexibility in the number of analytes that can be measured [W.L. Budde, 1992].

The Agency has promulgated (58 FR 41344) two capillary column methods (EPA Methods 502.2 and 524.2) that can replace Method 501.1. Today EPA is proposing a capillary column method (EPA Method 551) for trihalomethane monitoring that can replace Method 501.2. Withdrawal of EPA Methods 501.1 and 501.2 would not become effective until 18 months after today's rule is promulgated, so laboratories would be able to use these methods for several more years. EPA does not believe that withdrawal of the methods will adversely affect laboratories over this time frame.

EPA Method 551, Determination of Chlorination Disinfection Byproducts and Chlorinated Solvents in Drinking Water by Liquid- Liquid Extraction and Gas Chromatography with Electron Capture Detection, is proposed for THM compliance measurements. It is a liquid-liquid extraction method applicable to the determination of a variety of halogenated organic compounds.

In Method 551 the ionic strength of a 35-mL drinking water sample aliquot is adjusted using sodium chloride, and the sample is extracted with 2-mL of methyl-tert-butyl ether. If only THMs are to be measured, pentane can be used as the extracting solvent provided the quality control requirements specified in Method 551 are met. When pentane is used, Method 551 is very similar to liquid-liquid extraction Method 501.2. EPA believes laboratories wishing to use liquid-liquid extraction to measure THMs will prefer Method 551 to Method 501.2.

b. THM-Sample Dechlorination. All of the promulgated and proposed methods for THM compliance analysis require that the THM formation reaction be halted by addition of a reagent that removes all free chlorine from the sample. EPA provides the following guidance to help laboratories correctly preserve samples for compliance with proposed and existing (40 CFR 141.30 and 141.133) THM monitoring requirements. The Agency believes that this guidance is warranted because many preservation procedures are available, depending on the method, and because laboratories may wish to measure VOCs and THMs in a single analysis.

Laboratories must carefully follow the preservation procedure described in each method, especially the order in which reagents are added to the sample. The methods allow analysts to choose among four reagents (ammonium chloride, ascorbic acid, sodium sulfite, or sodium thiosulfate) to dechlorinate a water sample. These reagents remain available for use but, with one exception, EPA strongly recommends the use of sodium thiosulfate for the analyses of THMs, since EPA has the most performance data with this chemical. The exception is that ascorbic acid should be used when sulfur dioxide will interfere with analyses that are performed using a mass spectrometer. Samples dechlorinated with ascorbic acid must be acidified immediately, as directed in the method.

c. Haloacetic Acid Methods. Standard Method 6233 B and EPA Method 552.1 are relatively new, use capillary columns, and are proposed today for measurement of five haloacetic (monochloroacetic, dichloroacetic, trichloroacetic, monobromoacetic and dibromoacetic) acids. As discussed above, EPA recommends that bromochloroacetic acid also be measured with these methods.

Standard Method 6233 B, Micro Liquid-Liquid Extraction Gas Chromatographic Method for Haloacetic Acids, was developed by several

laboratories, including EPA. The analytical procedures used in Method 6233 B are equivalent and very similar to those used in the 30-mL extraction option, which is described in EPA Method 552, Determination of Haloacetic Acids in Drinking Water by Liquid-Liquid Extraction, Derivatization, and Gas Chromatography with Electron Capture Detection. EPA considered proposing both methods; however, Method 552 contains a 30-mL and a 100-mL extraction option. EPA believes that the 100-mL extraction option uses a quantitation and calibration procedure that will not produce acceptable results for compliance with today's monitoring requirements. Also, the performance data for the 30-mL extraction option is more completely presented in Method 6233 B. For purposes of today's rule, EPA believes that Method 6233 B is more complete and easier to use than Method 552. Laboratories, which have been using the 30-mL extraction option in Method 552, will have no trouble switching to Method 6233 B. If EPA revises Method 552, it may be approved in the final rule.

In Method 6233 B, the pH of a 30-mL drinking water sample is adjusted to 0.5 or less, and the ionic strength of the sample is increased by adding sodium sulfate. The acids are extracted into 3-mL of methyl-tert-butyl ether (MTBE). Exactly 2-mL of the extract is transferred to a volumetric flask and the volume is reduced to approximately 1.7-mL.

The haloacetic acids, which have been concentrated in the MTBE extract, are converted to methyl esters using a dilute solution of diazomethane in MTBE. The extract, which now contains the methyl esters of the haloacetic acids, is analyzed using capillary column gas chromatography with electron capture detection.

The analytical method is calibrated and the haloacetic acids are quantitated using standards with a known concentration of each haloacetic acid. These standards are called aqueous procedural standards because they are prepared in reagent water and treated exactly like a drinking water sample. This means that the standards are carried through the extraction, derivatization, and chromatographic steps of the method. Aqueous standards which are analyzed in this way automatically correct for the method bias that occurs when any of the haloacetic acids are not completely extracted from the drinking water sample with the solvent MTBE.

EPA Method 552.1, Determination of Haloacetic Acids and Dalapon in Drinking Water by Ion-Exchange Liquid-Solid Extraction and Gas Chromatography with an Electron Capture Detector, is a liquid-solid extraction method which does not require the use of diazomethane. It is proposed today for five haloacetic acids.

In Method 552.1, a 100-mL sample aliquot is adjusted to pH 5.0 and extracted with a preconditioned miniature anion exchange column. The haloacetic acids are eluted from the column with small aliquots of acidic methanol. After the addition of a small volume of MTBE as a co-solvent, the acids are converted to their methyl esters directly in the acidic methanol. The methyl esters are partitioned into the MTBE phase and identified and measured by capillary column gas chromatography with electron capture detection.

4. Inorganic By-Product Method

EPA is proposing Method 300.0, Determination of Inorganic Anions by Ion Chromatography, for analysis of the inorganic disinfection by-products covered in today's proposed rule—bromate and chlorite (Table IX–3). Method 300.0 must be modified as specified below to adequately measure bromate at the MCL proposed in today's rule. This method is presently approved for the analysis of nitrate and nitrite in drinking water under 40 CFR 141.23. The method is described below; additional information may be found in the May 22, 1989 notice [54 FR 22097].

Method 300.0 requires an ion chromatograph and an ion chromatographic column. Ion chromatography is conducted in many laboratories because it can simultaneously measure many anions of interest—bromide, chloride, fluoride, nitrate, nitrite, orthophosphate, sulfate, bromate, chlorite, and chlorate. Method 300.0 specifies the two columns that are required to separate and measure the ions of interest. The AS9 column is used to measure chlorite, chlorate, and bromate. This column has the advantage that it separates the chlorate ion from the nitrate ion.

EPA believes that Method 300.0 is within the technical capability of many laboratories and within the economic capability of the regulated community. The analytical cost of bromate and chlorite analysis is estimated to range from $50 to $100 per sample. Actual costs may vary with the laboratory, the total number of samples, and other factors. EPA believes the analytical costs for bromate and chlorite ion monitoring are affordable.

Under the requirements set forth in this proposed rule, monitoring for the bromate ion would apply to water systems using ozone in the treatment train. Monitoring for the chlorite ion would apply to systems using chlorine dioxide. Since utilities rarely use both ozone and chlorine dioxide, most systems will use Method 300.0 to measure only bromate or only chlorite for compliance with the MCLs proposed in today's rule.

EPA WS PE studies indicate that an increasing number of laboratories have the capability to measure bromate and chlorite. The lowest concentration of the bromate ion in a PE sample to date was 30 µg/L in WS 31. Twenty-three laboratories reported data and 65% of them were within ±50% of the true value. Chlorite ion concentrations have ranged from 100 to 460 µg/L in studies WS 29 through WS 31. The percentage of laboratories successfully meeting ±50% of the true value acceptance criteria ranged from 85 to 96%. These data indicate that adequate laboratory capacity will be available by the time the compliance monitoring requirements proposed in this rule become effective.

EPA has evaluated Method 300.0, modifications to the method, and the results from PE studies to determine the feasibility of obtaining reliable measurements at the MCLs proposed in today's rule for chlorite and bromate. Based on this evaluation, EPA believes that Method 300.0 can easily provide reliable data at the proposed MCL for chlorite. To reliably measure bromate at the proposed MCL, Method 300.0 must be modified to improve the sensitivity of the analysis. The modifications, which are discussed below, involve changes to the injection volume and to the eluent.

a. Bromate Ion. EPA is aware that the current version of Method 300.0 is not sensitive enough to measure bromate ion concentrations at the proposed MCL. Method 300.0 is more sensitive to bromate if a weaker ion chromatographic eluent is used. In a recent EPA study, Hautman & Bolyard [1992] successfully used a borate, rather than a carbonate, eluent to chromatographically measure bromate ion concentrations in drinking water. This alternate eluent reduced baseline noise, thereby increasing the method sensitivity. The detection limit for bromate can be further reduced by increasing the volume of sample that is injected into the ion chromatograph (from 50 to 200 µL) and by further decreasing the concentration of the borate eluent to 18mM NaOH/72 mM H_3BO_3 [Hautman, 1993]. These are acceptable modifications to Method 300.0. The quality control requirements, which must be met when a weaker

eluent or a larger sample injection volume is used, are specified in the method.

A few utility, university, and commercial laboratories are analyzing ozonated drinking water for low concentrations of the bromate ion. According to verbal communications with EPA, some of these laboratories are able to quantitate bromate down to concentrations of 5 to 10 µg/L, and they can detect bromate down to concentrations of 1 to 2 µg/L. In order to achieve this sensitivity, the laboratories are using the modifications mentioned above and, in some cases, the laboratories are also treating the samples to remove a chloride interference [Kuo et al., 1990].

Based on the information presented above, EPA believes that Method 300.0 with the appropriate modifications can be used to reliably determine compliance with the proposed MCL for bromate. Whether laboratories are able to reliably measure bromate ion concentrations at levels below the proposed MCL under routine operating conditions is presently unknown. Laboratory performance data will be collected as part of the proposed Information Collection Rule (ICR) (59 *FR* 6332) so EPA will be able to more accurately determine laboratory capabilities for measuring bromate prior to promulgation of today's proposed rule.

EPA is aware of efforts to develop more sensitive techniques for measuring bromate ion concentrations in drinking water. Two studies have demonstrated the capability to measure bromate levels of <1 µg/L using sample concentration techniques prior to injection into the ion chromatograph [Hautman, 1992; Sorrell & Hautman, 1992]. However, these techniques are labor-intensive and not generally available to laboratories that do routine analyses using ion chromatography. Efforts are underway to develop an automated sample concentration technology which may be applicable to routine analyses [Joyce & Dhillon, 1993]. EPA solicits comments on whether use of a sample concentration technology prior to ion chromatographic analysis should be considered as a new methodolgy or a modification to Method 300.0 under today's rule. EPA also solicits comments on the applicability of sample concentration technology to today's proposed MCL for bromate.

EPA is aware that high concentrations of the chloride ion interfere with the measurement of the bromate ion. There are currently two solutions to this interference problem. The first solution is based on a recent study [Hautman & Bolyard, 1992] that successfully used a borate eluent to chromatographically separate bromate and chloride. The study demonstrated that these conditions can be used to measure other anions for which ion chromatography is an approved compliance monitoring technique. The second solution to the chloride interference is to remove chloride from the sample by filtering it through a silver filter before injecting it into the ion chromatograph [Kuo et al., 1990]. Both of these solutions are permitted as part of EPA Method 300.0 provided the quality control requirements, which are specified in the method, are met.

EPA prefers the first solution (borate as eluent) to the chloride interference problem, because it lowers the baseline noise, thereby increasing the method's sensitivity for all anions in the analytical scope of the method. However, in some waters, chloride ion concentrations are too high, and a silver filter must be used to remove excess chloride. EPA cautions that silver will leach from the filters into the sample. If the leachate is not removed from the sample, it will contaminate the ion chromatographic column. Since a contaminated column cannot be used to measure chloride or bromide ion concentrations, the leachate must be removed by filtering the sample through an ion chromatographic chelate cartridge prior to injection into the ion chromatograph [Hautman, 1992]. Another alternative is to dedicate an ion chromatographic column to bromate analysis, since silver interferes only with the analysis of chloride and bromide, not bromate, ions.

Compliance with the bromate MCL under today's rule is determined by analyzing samples collected at the entrance point to the distribution system. EPA does not believe an ozone residual will exist at this sampling point, so the reactions that cause bromate formation should be complete. Bromate does not decompose after it is produced. As a result, Method 300.0 does not require the use of a preservative for bromate samples. EPA is soliciting any data that demonstrate the need for a preservative in samples collected at this sampling point for measurement of bromate.

b. Chlorite Ion. EPA considered other available methods for the measurement of the chlorite ion. For example, chlorite ion, chlorate ion, and the disinfectant chlorine dioxide can be measured by amperometric or potentiometric measurements of iodine, which is formed from the reaction of these chemicals with iodide ion. EPA recognizes that these methods may be useful to utility operators for routine operational monitoring of unit processes. Their use is encouraged for such work when an ion chromatograph is not available at the treatment plant. However, EPA does not believe that these methods are suitable for compliance monitoring, because chlorite is determined by a method of differences rather than direct measurement. EPA believes that the ion chromatography method is the compliance technique of choice, because it provides a direct measurement of each inorganic DBP anion. Method 300.0 is also a very versatile method with an analytical scope that includes several other ions that are commonly present in drinking water samples. Therefore, Method 300.0 is the only method proposed for chlorite ion monitoring in today's rule.

Utilities using chlorine dioxide as a disinfectant or oxidant will have the ions, chlorite and chlorate, in the treated water. Using Method 300.0, chlorate can be measured along with chlorite at little or no extra cost. Since chlorate may be considered in a future disinfection by-product control regulation, utilities are encouraged, but not required, to obtain data on chlorate concentrations in their water.

Since the chlorite ion reacts with free residual chlorine and with metal ions such as nickel and iron, it is not stable in some drinking water matrices [Hautman & Bolyard, 1992]. Method 300.0 addresses this problem by requiring the addition of ethylenediamine (EDA) as a preservative, if samples cannot be analyzed for the chlorite ion within 10 minutes of sample collection. If the chlorite ion is measured in samples with a chlorine dioxide residual, the sample must also be sparged with nitrogen at the time of collection to remove the chlorine dioxide residual. EPA is interested in learning whether there are vendors who are willing, or would be willing in the future, to sell high purity chlorite standards to laboratories performing analyses for chlorite.

. Other Parameters—Total Organic Carbon, Alkalinity and Bromide

TABLE IX–4.—PROPOSED ANALYTICAL METHODS FOR OTHER PARAMETERS

Parameter	Method[1]
Total Organic Carbon	5310 C Persulfate-Ultraviolet Oxidation. 5310 D Wet Oxidation

TABLE IX–4.—PROPOSED ANALYTICAL METHODS FOR OTHER PARAMETERS—Continued

Parameter	Method[1]
Alkalinity	2320 B, 310.1, D–1067–88B Titrimetric. I–1030–85 Electrometric.
Bromide	300.0 Ion Chromatography.

[1] EPA Method 300.0 is in the manual "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R/93/100—Draft, June 1993. EPA Method 310.1 is in the manual "Methods for Chemical Analysis of Water and Wastes", EPA/600/4–79–020, March 1983, NTIS PB84–128677. Standard Methods 2320B, 5310B and 5310C are in Standard Methods for the Examination of Water and Wastewater, 18th Edition, American Public Health Association, American Water Works Association, and Water Environment Federation, 1992. Method D–1067–88B is in the "Annual Book of ASTM Standards", Vol. 11.01, American Society for Testing and Materials, 1993. Method I–1030–85 is in Techniques of Water Resources Investigations of the U.S. Geological Survey, Book 5, Chapter A–1, 3rd ed., U.S. Government Printing Office, 1989.

Total organic carbon, alkalinity, and bromide are not covered by proposed MRDLs or MCLs in today's rule. As explained in Sections VIII and IX of this notice, EPA is proposing monitoring requirements for some or all of these parameters at systems that need to use the results to comply with certain treatment requirements. To ensure accurate measurement of these parameters, EPA proposes the following analytical methods.

a. *Total organic carbon (TOC) methods.* Several analytical methods exist to measure total organic carbon; two Standard Methods are proposed in today's rule (Table IX–4). TOC measurements are conducted in many laboratories. In a recent EPA Water Pollution PE study (WP 30), 541 laboratories reported TOC data. EPA believes this response indicates an adequate potential laboratory capability to comply with the requirements of today's rule. EPA believes these methods are within the technical and economic capability of many laboratories. The analytical cost for TOC analyses is estimated to range from $50 to $75 per sample. Actual costs may vary with the laboratory, analytical technique selected, the total number of samples, and other factors. EPA believes that the costs for TOC monitoring are affordable.

Today's rule proposes monitoring for TOC, not dissolved organic carbon (DOC). TOC is the sum of the undissolved and dissolved organic carbon in the water sample. DOC is differentiated from TOC by filtering the sample with a very fine (0.45-μm) filter. Today's rule specifies that TOC samples are not to be filtered except to remove turbidity, which is known to interfere with accurate TOC measurement when the sample turbidity is greater than 1 NTU. A TOC sample can be filtered to remove turbidity provided a prewashed, glass-fiber filter with a large (5- to 10-μm) pore size is used. As an alternative to filtering, the TOC sample can be diluted with organic-free reagent water in order to reduce the turbidity interference. EPA solicits comments on the proposed turbidity threshold, and on the sample filtration procedure as described above and in the proposed methods.

EPA has evaluated several methods to determine the feasibility of obtaining reliable TOC measurements. To meet today's proposed requirements, a TOC method must have a detection limit of at least 0.5 mg/L, and more importantly achieve a reproducibility of ±0.1 mg/L over a range of approximately 2 to 5 mg/L. This reproducibility is required because some systems will have to reliably measure 0.3 mg/L differences in TOC removal in several jar test samples to which progressively greater amounts of coagulant have been added [R. Miltner, 1993]. Reliable measurement of 0.3 mg/L differences requires that the error bars on the analysis approach ±0.1 mg/L. When calculated as a percent, this precision requirement becomes ±5% at 2 mg/L of TOC, and ±2% at 5 mg/L of TOC. Data presented in Standard Method 5310 C indicate that this is feasible, and Standard Method 5310 D is close to this level of performance.

In a PE sample prepared for EPA's Water Pollution WP 27 study, 26 EPA and State laboratories achieved a precision of ±0.33 mg/L on a TOC sample spiked at about 5 mg/L. In WP 30, a mean value of 8.74 ±0.79 mg/L was measured by the 541 laboratories that reported results. A subset of 27 EPA and State laboratories in WP 30 reported a precision of ±0.4 mg/L on the same sample. EPA solicits comment on what precision can be routinely expected on differential TOC measurements of jar test samples. EPA is also interested in new methods or modifications to the methods proposed today that would improve the reproducibility of TOC measurement.

EPA considered, but is not proposing, Standard Method 5310 B because the stated detection limit is 1 mg/L, which is 0.5 mg/L greater than the required TOC detection limit. EPA is aware that the instrumentation used in Method 5310 B is being improved. If this work is successful, EPA will consider the next version of Method 5310 B (or its equivalent) for promulgation in the final rule. The two methods proposed today for TOC measurements are described below.

Persulfate-Ultraviolet Oxidation Method (SM 5310 C) measures organic carbon via infrared absorption of the carbon dioxide gas that is produced when the organic carbon in the sample is simultaneously reacted with a persulfate solution and irradiated with ultraviolet light. Inorganic carbon is removed from the sample prior to analysis by acidification with phosphoric or sulfuric acid. Chloride and low sample pH can impede the analysis; precautions are specified in the method. The lower limit of detection of the method is 0.05 mg/L.

Wet-Oxidation Method (SM 5310 D) has a detection limit of 0.10 mg/L and is subject to the same interferences as the persulfate-ultraviolet method. Persulfate and phosphoric acid are added to the sample; the sample is then purged with pure oxygen to remove inorganic carbon. The purged sample is sealed in an ampule and combusted for four hours in an oven at a temperature that causes persulfate to oxidize organic carbon to carbon dioxide. The ampule is opened inside a TOC-analyzer, and TOC is measured via infrared absorption of carbon dioxide.

b. *Alkalinity Methods.* With two minor exceptions, EPA is proposing all of the methods (Table IX–4) which are currently approved under 40 CFR 141.89 for measurement of alkalinity. The exceptions are that EPA is proposing more recent versions of the alkalinity methods, which are published by Standard Methods and the American Society of Testing and Materials (ASTM). In today's rule, EPA is proposing Method 2320 B, which is in the 18th edition of Standard Methods, and Method D1067–88B, which is in the 1993 Annual Book of ASTM Standards, in lieu of the versions cited at 40 CFR 141.89. There are no technical difference between the proposed versions and the currently approved versions.

EPA is also aware that EPA Method 310.1, which uses the same technology as Methods 2320 B and D1067–88B, has not been updated since 1983. The references in the EPA method are becoming obsolete, and the equivalent methods from ASTM and Standard Methods are updated more regularly. To allow laboratories the use of only the most current versions of equivalent methods, EPA may not promulgate Method 310.1 with the final D/DBP rule,

and EPA also may withdraw approval of it under 40 CFR 141.89.

To accurately measure alkalinity, the sample pH at the source where the sample was collected must be recorded. It is important to accurately measure carbon dioxide gas, which is dissolved in the sample and is a major contributor to the alkalinity of the sample. To minimize loss of carbon dioxide, the sample is collected in an air tight container, and agitation of the sample is kept to a minimum.

EPA believes that the proposed alkalinity methods, which have been used for years, are within the technical and economic capability of many laboratories. The analytical cost of alkalinity analysis is estimated to range from $5 to $10 per sample. Actual costs may vary with the laboratory, analytical technique selected, the total number of samples and other factors. EPA believes the analytical costs for alkalinity monitoring are affordable.

EPA believes the working range for each method adequately covers the requirements proposed for alkalinity monitoring in today's rule. All procedures and precautions listed below and in the methods must be followed carefully. Descriptions and more information on the methods are in the notices of August 18, 1988 [53 FR 31516] and October 19, 1990 [55 FR 42409].

c. *Bromide Method.* EPA Method 300.0, Determination of Inorganic Anions by Ion Chromatography, is proposed for measurement of bromide ion. This method is described above under inorganic by-product methods for chlorite and bromate. EPA believes the working range for this method adequately covers the requirements proposed for bromide monitoring in today's rule.

EPA believes that Method 300.0 is within the technical and economic capability of many laboratories. The analytical cost of bromide analysis is estimated to range from $50 to $100 per sample. However, if other anions, such as fluoride or chloride, are measured in the same sample, the additional cost for bromide analysis should be minimal. Actual costs may vary with the laboratory, analytical technique selected, the total number of samples, and other factors. EPA believes the analytical costs for bromide ion monitoring are affordable.

6. Sources and Scope of Future Analytical Methods

The Standard Methods proposed in today's rule are published in the 18th edition of *Standard Methods*. EPA is aware that these methods will be updated when the 19th edition is published. EPA is also gathering additional performance data on several EPA methods which are proposed in today's rule. EPA will obtain these data from occurrence studies, from laboratory certification performance evaluation sample analyses and from other sources. To support pollution prevention goals and to generally improve the safety and efficiency of analytical methods, EPA is working to reduce the volume of solvents and the amounts of potentially hazardous reagents in EPA methods. Thus, EPA may revise, improve, or expand several EPA methods prior to promulgation of the D/DBP rule. Examples of methods that EPA or other organizations might change are discussed below.

EPA may refine the solvent extraction and sample preservation procedures in Method 551, which is proposed today for trihalomethanes. EPA may also extend approval of EPA Method 551 to compliance measurements of six chemicals currently regulated under 40 CFR 141.24. The six contaminants are: carbon tetrachloride, trichloroethylene, tetrachloroethylene, 1,2-dibromoethane (EDB), 1,2-dibromo-3-chloropropane (DBCP), and 1,1,1-trichloroethane. EPA may revise Method 552, merge it with Method 552.1, and approve it for the analysis of haloacetic acids. EPA may revise Method 300.0 to improve the detection limits for bromate and to further eliminate some of the interference problems in the method. The Standard Methods organization may incorporate more sensitive instrumentation in later versions of TOC method 5310 B.

To accommodate future improvements in analytical methods, EPA proposes that the methods in the then current editions of books published by Standard Methods and ASTM and the then current versions of EPA methods be cited in the final D/DBP rule provided no unacceptable changes are in the later versions of these methods.

H. Basis for Compliance Schedule and Applicability to Different Groups of Systems, Timing With Other Regulations

Under the negotiated rulemaking the Negotiating Committee agreed to propose three rules: (a) an information collection requirements rule (ICR) (59 *FR* 6332), (b) an "interim" enhanced surface water treatment rule (ESWTR) (proposed in today's **Federal Register**), and c) Disinfection/Disinfection By-products (D/DBP) regulations, proposed herein today. Table IX–5 indicates the schedule agreed to by the Negotiating Committee by which these rules would be proposed, promulgated, and become effective. Compliance dates for the ICR are indicated under the columns of the Stage 2 D/DBP rule and ESWTR to reflect the relationship between these rules.

The Negotiating Committee agreed that more data, especially monitoring data, should be collected under the ICR to assess possible shortcomings of the SWTR and develop appropriate remedies, if needed, to prevent increased risk from microbial disease when systems began complying with the Stage 1 D/DBP regulations. It was also agreed that EPA would propose an interim ESWTR (proposed elsewhere in today's **Federal Register**) pertaining to systems serving greater than 10,000 people, including a wide range of regulatory options. Data gathered under the ICR would form the basis for (a) promulgating the most appropriate criteria among the options presented in the proposed interim ESWTR, and (b) proposing at a later date a long-term ESWTR pertaining to all system sizes. Both of these rules, if needed, would be proposed and promulgated so as to be in effect at the same time that systems of the respective size categories would be required to comply with new regulations for D/DBPs.

The Negotiating Committee also agreed that additional data on the occurrence of disinfectants, disinfection byproducts (DBPs), potential surrogates for DBPs, source water and within treatment conditions affecting the formation of DBPs, and bench-pilot scale information on the treatability for removal of DBP precursors would be beneficial for developing the Stage 2 D/DBP regulatory criteria.

Prior to promulgating the interim ESWTR, EPA intends to issue a Notice of Availability to: (a) discuss the pertinent data collected under the ICR rule, (b) discuss additional research that would influence determination of appropriate regulatory criteria, (c) discuss criteria EPA considered appropriate to promulgate in the interim ESWTR (which would be among the regulatory options of the proposed interim ESWTR) and (d) solicit public comment on the intended criteria to be promulgated.

The Negotiating Committee believed that the December 1996 scheduled date for promulgating the Stage 1 D/DBP Rule was within the shortest time possible by which the interim ESWTR, if necessary, could also be promulgated. EPA is proposing that the Stage 1 D/DBP regulations and the interim ESWTR (if necessary) become effective on the same date of June 30, 1998 for systems using surface water and serving greater than 10,000 people.

TABLE IX–5.—PROPOSED D/DBP, ESWTR, ICR RULE DEVELOPMENT SCHEDULE

Time line	Stage 1 DBP rule	Stage 2 DBP rule	ESWTR
12/93		Propose information collection requirements for systems >100k.	Propose information collection requirements for systems >10k.
3/94	Propose required enhanced coagulation for systems with conventional treatment. MCLs-TTHMs (80µg/l), HAA5 (60µg/l), bromate, chlorite. Disinfectant limits.	Propose Stage 2. MCLs for TTHMs (40 µg/l), HAA5 (30 µg/l), BAT is precursor removal with chlorination.	Propose interim ESWTR for systems >10k.
6/94		Promulgate ICR	Promulgate ICR.
8/94	Close of public comment period		Public comment period for proposed ESWTR closes.
10/94		Systems >100k begin ICR monitoring	Systems >100k begin ICR monitoring.
1/95			Systems 10–100k begin source water monitoring.
10/95		SW systems >100k, GW systems >50k begin bench/pilot studies unless source water quality criteria met.	
11/95			NOA for monitoring data, direction of interim ESWTR.
1/96			Systems >10k complete ICR monitoring. End NOA public comment period.
3/96		Systems complete ICR monitoring	Systems >100k complete ICR monitoring.
12/96	Promulgate Stage 1		Promulgate interim ESWTR for systems >10k.
6/97		Notice of availability for Stage 2 reproposal.	Propose long-term ESWTR for systems <10k, possible changes for systems >10k.
10/97		Complete and submit results of bench/pilot studies.	
12/97		Initiate reproposal—begin with 3/94 proposal.	
6/98	Effective. Effective for SW systems serving greater >10k, extended compliance date for GAC or membrane technology.	Close of public comment period	Interim ESWTR effective for systems >10k. 1994–6 monitoring data used to determine treatment level.
12/98		Propose for CWSs, NTNCWSs	Publish long-term ESWTR.
6/00	Stage 1 limits effective for surface water systems <10k, GW systems <10k.	Promulgate Stage 2 for all CWSs, NTNCWSs.	Long-term ESWTR effective for all system sizes.
1/02	Stage 1 limits effective for GW systems >10k unless Stage 2 criteria supersede.	Stage 2 effective, compliance for GAC/membranes by 2004.	

Although the Agency anticipates that the ICR will be promulgated later than the date indicated in Table IX–5, EPA believes that the long-term schedule will be adhered to and the final D/DBPR will be promulgated in December, 1996.

EPA is proposing that systems using surface water and serving fewer than 10,000 people comply with the Stage 1 D/DBP regulations by June 30, 2000 to allow such systems to also come into compliance with the final ESWTR. EPA believes that the June 30, 2000 compliance date reflects the shortest time possible that would allow for the final ESWTR to be proposed, promulgated, and become effective; thereby providing the necessary protection from any downside microbial risk that might otherwise result when systems of this size attempt to achieve compliance with the Stage 1 D/DBP rule.

EPA is also proposing that systems using ground water and serving greater than 10,000 people would be required to achieve compliance with the Stage 1 D/DBP rule by June 30, 2000. EPA believes this is the earliest date possible by which all ground water systems of this size could be expected to achieve compliance with both the GWDR and the Stage 1 D/DBP rule. Many ground water systems would be expected to be able to achieve compliance by an earlier date but others, due to recently installing or upgrading disinfection to meet the GWDR, would require some period of monitoring for DBPs in order to adjust their treatment processes to also meet the Stage 1 D/DBP standards.

For the same reasons as stated above, EPA is proposing that systems using ground water and serving 10,000 or less people be required to meet the Stage 1 D/DBP rule beginning January 1, 2002. The delayed date for the ground water systems serving 10,000 or less people is because of the much large number of such systems in this size category, and the time necessary for States and systems to implement the GWDR.

I. Basis for Qualified Operator Requirements and Monitoring Plans

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

programs for Subpart H systems may be modified to account for the differences between Subpart H systems and ground water systems. Also, States must maintain a register of qualified operators.

EPA encourages States which do not already have operator license certification programs in effect to develop such programs. The Negotiating Committee and Technologies Working Group believed that properly trained personnel were an essential first step in ensuring safer drinking water.

Also, systems are required to develop and follow monitoring plans for monitoring required under this proposed rule. Systems may update these plans for reasons including changes to the distribution system or changes in treatment.

J. Basis for Stage 2 Proposed MCLs

EPA is proposing lower MCLs for TTHMs and total haloacetic acids (THAAs) for Stage 2 to indicate the desire to further decrease exposure from these chemicals but also to lower the exposure from other byproducts resulting from chlorine reacting with naturally occurring organics. Systems which lower the levels of TTHMs and THAAs are also likely to lower the levels of many other chlorination byproducts, some of which may pose additional health risks.

The proposed 40/30 MCL is based on what would be achievable by most systems if they were to use the "best available technology" (BAT) proposed for Stage 2. The Negotiating Committee agreed that the BAT in Stage 2 for controlling TTHMs and THAAs include either enhanced coagulation and shallow bed granular activated carbon (GAC10) or deep bed granular activated carbon (GAC20) and chlorine as the primary and residual disinfectant.

One of the major reasons for defining BAT as including chlorine versus, for example, defining BAT as including alternative disinfectants, is to recognize the many benefits of chlorine as a disinfectant, especially in preventing microbial disease. In addition to being a strong primary disinfectant, a chlorine residual in the distribution system helps prevent bacterial growth and is an excellent marker (when there is an absence of chlorine) for indicating potential contamination from outside sources into the distribution system. EPA believes that chlorine should be included in the BAT definition at least until there is more health effects information on byproducts formed by use of alternative disinfectants.

Currently it is not clear whether risks from chlorination byproducts are more significant than those formed from use of alternative disinfectants. The Negotiating Committee agreed that EPA would repropose Stage 2 requirements in 1998 to consider new information that would become available, especially data on the health effects of alternative disinfectants.

X. Laboratory Certification and Approval

EPA recognizes that the effectiveness of today's proposed regulations depends on the ability of laboratories to reliably analyze the regulated disinfectants and disinfection byproducts at the proposed MRDL or MCL, respectively. Laboratories must also be able to measure the trihalomethanes and haloacetic acids at the proposed monitoring trigger levels, which are between 25 and 50 percent of the proposed MCLs for these compound classes. EPA has established a drinking water laboratory certification program that States must adopt as a part of primacy. (40 CFR 142.10(b)). EPA has also specified laboratory requirements for analyses, such as alkalinity and disinfectant residuals, that must be conducted by approved parties. (40 CFR 141.89 and 141.74). EPA's "Manual for the Certification of Laboratories Analyzing Drinking Water", EPA/570/9–90/008, specifies the criteria which EPA uses to implement the drinking water laboratory certification program.

Today EPA is proposing MCLs for total trihalomethanes, total haloacetic acids (HAA5), bromate, and chlorite. EPA is proposing that only certified laboratories be allowed to analyze samples for compliance with the proposed MCLs. For the disinfectants and other parameters in today's rule, which have MRDLs or monitoring requirements, EPA is requiring that analyses be conducted by a party acceptable to the State.

Performance evaluation (PE) samples, which are an important tool in EPA's laboratory certification program, are provided by EPA or the States to laboratories seeking certification. To obtain and maintain certification, a laboratory must use a promulgated method and at least once a year successfully analyze an appropriate PE sample. In the drinking water PE studies, EPA has samples for bromate, chlorite, five haloacetic acids, four trihalomethanes, free chlorine, and alkalinity. EPA has total chlorine and total organic carbon samples in the wastewater PE studies and has the potential to provide these samples for drinking water studies. Due to the lability of chlorine dioxide, EPA does not expect a suitable PE sample can be designed for chlorine dioxide measurements.

A. PE-Sample Acceptance Limits for Laboratory Certification

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

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

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

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

in order for the laboratory to be certified.

B. Approval Criteria for Disinfectants and Other Parameters

Today's rule proposes MRDLs for the three disinfectants—chlorine, chloramines, and chlorine dioxide. In addition, monitoring requirements (under conditions explained in sections VIII and IX of this notice) are being proposed for total organic carbon (TOC), alkalinity, and bromide; there are no MCLs proposed for these parameters. In previous rules (40 CFR 141.28, .74, and .89), EPA has required that measurements of alkalinity, disinfectant residuals, pH, temperature, and turbidity be made with an approved method and conducted by a party approved (not certified) by the State. In today's rule, EPA proposes that samples collected for compliance with today's requirements for alkalinity, bromide, residual disinfectant, and TOC only be conducted with approved methods and by a party approved by the State.

C. Other Laboratory Performance Criteria

For all contaminants and parameters proposed for monitoring in today's rule, the States may impose other requirements for a laboratory to be certified or a party to be approved to conduct compliance analyses. EPA solicits suggestions for other optional or mandatory performance criteria that EPA or the States should consider for certification or approval of laboratories.

XI. Variances and Exemptions

A. Variances

Under section 1415(a)(1)(A) of the SDWA, a State which has primary enforcement responsibility (primacy), or EPA as the primacy agent, may grant variances from MCLs to those public water systems that cannot comply with the MCLs because of characteristics of the water sources that are reasonably available. At the time a variance is granted, the State must prescribe a compliance schedule and may require the system to implement additional control measures. The SDWA requires that variances only be granted to those systems that have installed BAT (as identified by EPA in the regulations). Furthermore, before EPA or the State may grant a variance, it must find that the variance will not result in an unreasonable risk to health (URTH) to the public served by the public water system. The levels representing an URTH for each of the contaminants and disinfectants in this proposal will be addressed in subsequent guidance. In general, the URTH level would reflect acute and subchronic toxicity for shorter term exposures and high carcinogenic risks for long-term exposures (as calculated using the linearized multistage model in accordance with the Agency's risk assessment guidelines; see URTH Guidance, 55 FR 40205, October 2, 1990).

Under section 1413(a)(4), States that choose to issue variances must do so under conditions, and in a manner, that are no less stringent than EPA allows in section 1415. Of course, a State may adopt standards that are more stringent than the EPA standards. Before a State may issue a variance, it must find that the system is unable to (1) Join another water system or (2) develop another source of water and thus comply fully with all applicable drinking water regulations.

EPA specifies BATs for variance purposes. EPA may identify as BAT different treatments under section 1415 for variances than BAT under section 1412 for MCLs. EPA's section 1415 BAT findings may vary depending on a number of factors, including the number of persons served by the public water system, physical conditions related to engineering feasibility, and the costs of compliance with MCLs. In this proposal, EPA is not proposing a different BAT for variances under section 1415.

B. Exemptions

Under section 1416(a), EPA or a State may exempt a public water system from any requirements related to an MCL or treatment technique of an NPDWR, if it finds that (1) Due to compelling factors (which may include economic factors), the PWS is unable to comply with the requirement; (2) the exemption will not result in an unreasonable risk to health; and (3) the PWS was in operation on the effective date of the NPWDR, or for a system that was not in operation by that date, only if no reasonable alternative source of drinking water is not available to the new system.

If EPA or the State grants an exemption to a public water system, it must at the same time prescribe a schedule for compliance (including increments of progress) and implementation of appropriate control measures that the State requires the system to meet while the exemption is in effect. Under section 1416(a)(2), the schedule must require compliance within one year after the date of issuance of the exemption. However, section 1416(b)(2)(B) states that EPA or the State may extend the final date for compliance provided in any schedule for a period not to exceed three years, if the public water system is taking all practicable steps to meet the standard and one of the following conditions applies: (1) The system cannot meet the standard without capital improvements that cannot be completed within the period of the exemption; (2) in the case of a system that needs financial assistance for the necessary implementation, the system has entered into an agreement to obtain financial assistance; or (3) the system has entered into an enforceable agreement to become part of a regional public water system. For public water systems which serve less than 500 service connections and which need financial assistance for the necessary improvements, EPA or the State may renew an exemption for one or more additional two-year periods if the system establishes that it is taking all practicable steps to meet the requirements above.

Under section 1416(d), EPA is required to review State-issued exemptions at least every three years and, if the Administrator finds that a State has, in a substantial number of instances, abused its discretion in granting exemptions or failed to prescribe schedules in accordance with the statute, the Administrator, after following established procedures, may revoke or modify those exemptions and schedules. EPA will use these procedures to scrutinize exemptions granted by States and, if appropriate, may revoke or modify exemptions.

In addition to the conditions stated above, EPA solicits comment on whether exemptions to this rule should be granted if a system could demonstrate to the State, that due to unique water quality characteristics, it could not avoid through the use of BAT the possibility of increasing its total health risk by complying with the Stage 1 regulations. EPA solicits comment on when such situations might occur. For example, such situations might occur for systems with elevated bromide levels in raw water. In this case, it is possible that the use of BAT could result in the increase of total risk due to increased concentrations of brominated byproducts in the finished water. EPA also solicits comment on what specific conditions, if any, should be met for a system to be granted an exemption under such a provision. What provisions should EPA require of States to grant these exemptions? Should such exemptions be granted for a limited period but be renewable by the State if no new health risk information became available?

XII State Implementation

The Safe Drinking Water Act provides that States may assume primary implementation and enforcement responsibilities. Fifty-five out of 57 jurisdictions have applied for and received primary enforcement responsibility (primacy) under the Act. To implement the federal drinking water regulations, States must adopt their own regulations which are at least as stringent as the federal regulations. This section describes the regulations and other procedures and policies that States must adopt to implement this proposed rule.

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

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

In addition to adopting regulations no less stringent than the federal regulations, EPA is proposing that States adopt certain requirements related to this regulation in order to have their program revision applications approved by EPA. In several instances, the proposed NPDWRs provide flexibility to States in implementing of the monitoring requirements of this rule.

EPA is also proposing changes to State recordkeeping and reporting requirements. EPA's proposed changes are discussed below.

A. Special Primacy Requirements

To ensure that a State program includes all the elements necessary for an effective and enforceable program, a State application for program revision approval must include a description of how the State will:

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

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

(3) Approve percentage reduction of TOC levels lower than those required in § 141.135(a)(3) (i.e., how the State will approve alternate enhanced coagulation levels).

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

(5) Approve alternate analytical methods for measuring residual disinfectant concentrations for chlorine and chloramines. State approval granted under Subpart H (§ 141.74(a)(5)) for the use of DPD colorimetric test kits for free chlorine testing would be considered acceptable approval for the use of DPD test kits in measuring free chlorine residuals as required in Subpart L.

(6) Define criteria to use in determining if multiple wells are to be considered as a single source. Such criteria will be used in determining the monitoring frequency for systems using only ground water not under the direct influence of surface water.

B. State Recordkeeping

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; sanitary surveys; State approvals; enforcement actions; and the issuance of variances and exemptions. In this rule, States would be required to keep additional records of the following, including all supporting information and an explanation of the technical basis for each decision:

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

(2) Records of systems that apply for alternative TOC performance criteria (alternate enhanced coagulation levels). These records must include the results of testing to determine alternative limits.

(3) Records of systems that are required to meet alternative TOC performance criteria (alternate enhanced coagulation levels). These records must include the alternative limits and rationale for establishing the alternative limits.

(4) Records of Subpart H systems using conventional treatment meeting any of the enhanced coagulation or enhanced softening exemption criteria.

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

(6) Register of qualified operators.

Pursuant to § 141.133(d), Subpart H systems serving more than 3,300 people are required to submit monitoring plans to the State. EPA solicits comment on whether the State should be required to keep this plan on file at the State after submission to make it available for public review.

C. State Reporting

EPA currently requires in § 142.15 that States report to EPA information such as violations, variance and exemption status, and enforcement actions. In addition to the current reporting requirements, EPA is proposing under § 142.15(c) that States also report:

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

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

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

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

(5) A list of all Subpart H systems using conventional treatment which are not required to operate with enhanced coagulation, and the reason why enhanced coagulation is not required for each system, as listed in § 141.135(a)(1)(A)–(D); and

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

EPA believes that the State reporting requirements contained in this proposal are necessary to ensure effective oversight of State programs. Public comments on these proposed reporting requirements are requested. EPA particularly requests comment from the States on whether the proposed reporting requirements are reasonable.

XIII. System Reporting and Recordkeeping Requirements

The current system reporting regulations, 40 CFR 141.31, require public water systems to report

monitoring data to States within ten days after the end of the compliance period. No changes are proposed to those requirements.

Specific data required by this rule to be reported by public water systems are included in § 141.134. These data are required to be submitted quarterly for any monitoring conducted quarterly or more frequently, and within 10 days of the end of the monitoring period for less frequent monitoring. Systems that are required to do extra monitoring because of the disinfectant used have additional reporting requirements specified. This applies to systems that use chlorine dioxide (must report chlorine dioxide and chlorite results) and ozone (must report bromate results).

Subpart H systems that use conventional treatment are required to report either compliance/noncompliance with disinfection byproduct precursor (TOC) removal requirements or report which of the enhanced coagulation/enhanced softening exemptions they are meeting. There are additional requirements for systems that cannot meet the required TOC removals and must apply for an alternate enhanced coagulant level. These requirements are included in § 141.134(b)(6).

Calculation of compliance with the TOC removal requirements is based on normalizing the percent removals over the most recent four quarters, since compliance is based on that period. Normalization is necessary since source water quality changes will change the percent removal requirements. To illustrate this process, EPA has developed a sample reporting and compliance calculation sheet that will be included in the (to be developed) guidance manual. An example of calculations using the sheet is included in Section VIII (Description of the Proposed D/DBP Rule).

XIV. Public Notice Requirements

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

The 1986 Amendments required that EPA amend its current public notification regulations to provide for different types and frequencies of notice based on the differences between violations which are intermittent or infrequent and violations which are continuous or frequent, taking into account the seriousness of any potential adverse health effects which may be involved. EPA promulgated regulations to revise the public notification requirements on October 28, 1987 (52 FR 41534). The regulations state that violations of an MCL, treatment technique, or variance or exemption schedule ("Tier 1 violations") contain health effects language specified by EPA which concisely and in non-technical terms conveys to the public the adverse health effects that may occur as a result of the violation. States and water utilities remain free to add additional information to each notice, as deemed appropriate for specific situations. Today's proposed rule contains specific health effects language for the contaminants which are in today's proposed rulemaking. EPA believes that the mandatory health effects language is the most appropriate way to inform the affected public of the health implications of violating a particular EPA standard. The proposed mandatory health effects language in § 141.32(e) describes in non-technical terms the health effects associated with the proposed contaminants.

Under this rule, § 141.135 prescribes treatment technique requirements. Violations of these requirements are considered Tier 1 violations. Tier 2 violations include monitoring violations, failure to comply with an analytical requirement specified by an NPDWR, and operating under a variance or exemption.

EPA requests comment on its proposed rule language. Of particular interest is the acute violation language in § 141.32(e)(85) for violations of the chlorine dioxide MCL. Also of interest is the language in § 141.32(e)(86) for violations of the TTHM and HAA5 MCLs and the enhanced coagulation treatment technique requirement.

XV. Economic Analysis

A. Executive Order 12866

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

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

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

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

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

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

B. Predicted Cost Impacts On Public Water Systems

1. Compliance Treatment Cost Forecasts

Compliance treatment cost forecasts were estimated by the TWG. The basis for these estimates presented herein are described in the Regulatory Impact Analysis (USEPA, 1994). Tables XV–1 through XV–3 present summaries of the estimated total national costs of installing and operating treatment to comply with both Stage I and Stage II requirements. Table XV–1 is a summary of estimated cost impacts for all public water supplies affected (i.e., community and nontransient noncommunity systems) and represents a combination of the estimates indicated in Table XV–2 for community systems and Table XV–3 for nontransient noncommunity systems.

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Table XV-1: Disinfection By-Product Compliance Treatment Cost Forecast (for Community & Non-Transient Non-Community Water Systems)

		Ground Water Systems			Surface Water Systems			All Water Systems		
		Small	Large	Total	Small	Large	Total	Small	Large	Total
Population Served Per System (persons)		<= 10K	> 10K		<= 10K	> 10K		<= 10K	> 10K	
Total #. of Non-Purchased Water Systems*		68,171	1,320	69,491	5,165	1,395	6,560	73,336	2,715	76,051
Stage I	Systems Affected	8,324	198	8,521	3,611	1,009	4,620	11,935	1,206	13,141
	Total Capital ($B)	1.1	0.7	1.8	0.6	2.0	2.6	1.7	2.7	4.4
	Annualized Capital ($M)	167	78	245	93	207	301	261	285	546
	Annual O&M ($M)	88	56	144	50	295	345	138	351	489
	Total Annual Cost ($M)	255	135	389	143	502	645	398	637	1,035
Stage II (as proposed) **	Systems Affected	8,324	198	8,521	3,611	1,108	4,719	11,935	1,305	13,240
	Total Capital ($B)	1.1	0.7	1.8	0.6	5.5	6.1	1.7	6.2	7.9
	Annualized Capital ($M)	167	78	245	93	582	675	261	660	920
	Annual O&M ($M)	88	56	144	50	657	707	138	713	851
	Total Annual Cost ($M)	255	135	389	143	1,238	1,382	398	1,373	1,771
Stage II (extended) ***	Systems Affected	16,151	412	16,563	4,094	1,108	5,202	20,245	1,520	21,765
	Total Capital ($B)	1.8	1.7	3.6	2.2	5.5	7.7	4.0	7.2	11.2
	Annualized Capital ($M)	321	182	503	342	582	923	662	764	1,427
	Annual O&M ($M)	159	141	300	176	657	833	335	797	1,132
	Total Annual Cost ($M)	479	323	803	518	1,238	1,756	997	1,561	2,559

* Community and non-transient non-community water systems

** Stage II (as proposed: 40/30 for large surface water systems), cumulative costs for Stage II

*** Stage II (extended: 40/30 for all water systems), cumulative costs for Stage II

Notes:

(1) Total Capital Cost (1991 June dollars) is the cost of inst ing required equipment, the amount to be financed.

(2) Annualized Capital is the annual debt service payment (or carrying cost) resulting from the capital expenditure, computed on the basis of a range of interest rate assumptions based on system size and ownership.

(3) Annual O&M is the annual cost of operating and maintaining the treatment.

(4) Total Annual Cost is the sum of annual debt service payments and annual operation and maintenance costs.

Table XV-2: Disinfection By-Product Compliance Treatment Cost Forecast (for Community Water Systems)

		Ground Water Systems			Surface Water Systems			All Water Systems		
		Small	Large	Total	Small	Large	Total	Small	Large	Total
Population Served Per System (persons)		<= 10K	> 10K		<= 10K	> 10K		<= 10K	> 10K	
Total #. of Community Non-Purchased Sys.		44,310	1,316	45,626	4,562	1,395	5,957	48,872	2,711	51,583
Stage I	Systems Affected	5,481	197	5,677	3,196	1,009	4,205	8,677	1,206	9,882
	Total Capital ($B)	0.9	0.7	1.7	0.6	2.0	2.5	1.5	2.7	4.2
	Annualized Capital ($M)	144	78	222	90	207	297	234	285	520
	Annual O&M ($M)	76	56	132	48	295	343	124	351	475
	Total Annual Cost ($M)	220	134	356	138	502	640	358	636	995
Stage II (as proposed) *	Systems Affected	5,481	197	5,677	3,196	1,108	4,304	8,677	1,305	9,981
	Total Capital ($B)	0.9	0.7	1.7	0.6	5.5	6.1	1.5	6.2	7.8
	Annualized Capital ($M)	144	78	222	90	582	672	234	660	894
	Annual O&M ($M)	76	56	132	48	657	705	124	713	837
	Total Annual Cost ($M)	220	134	356	138	1,238	1,376	358	1,373	1,731
Stage II (extended) **	Systems Affected	10,636	411	11,047	3,617	1,108	4,725	14,253	1,519	15,772
	Total Capital ($B)	1.6	1.7	3.3	2.1	5.5	7.6	3.7	7.2	10.9
	Annualized Capital ($M)	271	182	453	331	582	913	602	764	1,366
	Annual O&M ($M)	137	141	278	171	657	828	308	797	1,105
	Total Annual Cost ($M)	408	323	731	502	1,238	1,740	910	1,561	2,471

* Stage II (as proposed: 40/30 for large surface water systems), cumulative costs for Stage II

** Stage II (extended: 40/30 for all water systems), cumulative costs for Stage II

Notes:

(1) Total Capital Cost (1991 June dollars) is the cost of installing required equipment, the amount to be financed.

(2) Annualized Capital is the annual debt service payment (or carrying cost) resulting from the capital expenditure, computed on the basis of a range of interest rate assumptions based on system size and ownership.

(3) Annual O&M is the annual cost of operating and maintaining the treatment.

(4) Total Annual Cost is the sum of annual debt service payments and annual operation and maintenance costs.

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Table XV-3: Disinfection By-Product Compliance Treatment Cost Forecast (for Non-Transient Non-Community Water Systems)

		Ground Water Systems			Surface Water Systems			All Water Systems		
		Small	Large	Total	Small	Large	Total	Small	Large	Total
Population Served Per System (persons)		<= 10K	> 10K		<= 10K	> 10K		<= 10K	> 10K	
Total #. of NTNCWS Non-Purchased Sys.*		23,861	4	23,865	603	0	603	24,464	4	24,468
Stage I	Systems Affected	2,843	1	2,844	415	0	415	3,259	1	3,259
	Total Capital ($B)	0.15	0.001	0.15	0.02	0	0.02	0.17	0.001	0.2
	Annualized Capital ($M)	23	0.1	23	3	0	3	26	0.1	26
	Annual O&M ($M)	12	0.1	12	2	0	2	14	0.1	14
	Total Annual Cost ($M)	35	0.2	35	5	0	5	40	0.2	40
Stage II (as proposed) **	Systems Affected	2,843	1	2,844	415	0	415	3,259	1	3,259
	Total Capital ($B)	0.15	0.001	0.15	0.02	0	0.02	0.17	0.001	0.2
	Annualized Capital ($M)	23	0.1	23	3	0	3	26	0.1	26
	Annual O&M ($M)	12	0.1	12	2	0	2	14	0.1	14
	Total Annual Cost ($M)	35	0.2	35	5	0	5	40	0.2	40
Stage II (extended) ***	Systems Affected	5,515	1	5,516	477	0	477	5,992	1	5,993
	Total Capital ($B)	0.27	0.003	0.27	0.06	0	0.06	0.33	0.003	0.3
	Annualized Capital ($M)	50	0.3	50	11	0	11	60	0.3	61
	Annual O&M ($M)	22	0.2	22	5	0	5	27	0.2	27
	Total Annual Cost ($M)	71	0.5	72	16	0	16	87	0.5	87

* Non-transient non-community water systems (NTNCWS)

** Stage II (as proposed: 40/30 for large surface water systems), cumulative costs for Stage II

*** Stage II (extended: 40/30 for all water systems), cumulative costs for Stage II

Notes:

(1) Total Capital Cost (1991 June dollars) is the cost of installing required equipment; the amount to be financed.

(2) Annualized Capital is the annual debt service payment (or carrying cost) resulting from the capital expenditure, computed on the basis of a range of interest rate assumptions based on system size and ownership.

(3) Annual O&M is the annual cost of operating and maintaining the treatment.

(4) Total Annual Cost is the sum of annual debt service payments and annual operation and maintenance costs.

The rule would affect about 51,500 "non-purchased" community water systems and 24,500 "non-purchased" nontransient noncommunity water systems. Non-purchased water systems are those that produce and/or treat water for distribution. Of the affected community water systems, about 95% serve fewer than 10,000 persons. It is estimated that all but four of the affected nontransient noncommunity water systems serve fewer than 10,000 persons. As a group, the systems serving fewer than 10,000 persons are projected to account for about 40 percent of the total annual cost of installing and operating treatment to comply with the rule and about 55 percent of the total cost of monitoring and reporting to comply with the rule. In terms of the Regulatory Flexibility Act, this rule will have a significant impact on a substantial number of small systems. Following EPA guidance, the Regulatory Flexibility Act Analysis will be presented within the Regulatory Impact Analysis.

The Stage II DBP Rule—as proposed—would apply only to non-purchased community and NTNC surface water systems serving more than 10,000 persons. The impact of the Stage II requirements on these systems will result in a combined total annual cost (Stage I + Stage II) for installing and operating treatment facilities of $1.77 billion per year. If the Stage II requirements were extended to cover all systems, the result would be a combined total annual cost (Stage I + Stage II) for installing and operating treatment facilities of $2.56 billion per year. Monitoring and state implementation costs have not been estimated for Stage II. Under this extended Stage II scenario, systems serving fewer than 10,000 persons would account for nearly 40 percent of the total annual cost of installing and operating treatment. In terms of the total annual cost of installing and operating treatment, the Stage II extended scenario would be about one-and-one-half times as expensive as Stage I. The same ratio applies to both size categories of systems, i.e., those serving greater or fewer than 10,000 people.

2. Compliance Treatment Forecast

Tables XV–4 and XV–5 present summaries of the national forecasts of treatment choices that were made to support the development of the national treatment cost estimates. The DBPRAM, a Monte Carlo simulation model of influent variability combined with a treatment model to predict treatment performance, was used to seed this analysis. Initially, the DBPRAM provided a default set of most likely compliance choices based on a least cost algorithm based on estimated costs of different unit processes (Gelderloos et al., 1992; Cromwell et al., 1992; USEPA, 1992). These choices were then adjusted via a consensus process reflecting the combined judgement of the TWG (USEPA, 1994). While some technologies, such as chlorine dioxide, were recognized as possible means for achieving compliance, insufficient data were available to predict such compliance choices. However, the TWG believed that failure to consider compliance choices other than those listed in Tables XV–4 and XV–5 would not significantly affect the total national cost compliance cost estimates.

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Table XV-4: Surface Water Systems Disinfection By-Product Compliance Forecast (for Community & Non-Transient Non-Community Water Systems)

Treatments	Stage I						Stage II					
	Small Systems (Pop. per Sys. <=10K)		Large Systems (Pop. per Sys. >10K)		All Systems		Small Systems (Pop. per Sys. <=10K)		Large Systems (Pop. per Sys. >10K)		All Systems	
	#.	%	#.	%	#.	%	#.	%	#.	%	#.	%
(No Further Treatment)	1,554	30%	386	28%	1,940	30%	1,071	21%	287	21%	1,358	21%
CL2/NH2CL	146	3%	41	3%	187	3%	299	6%	82	6%	381	6%
Enhanced Coag.	2,147	42%	600	43%	2,747	42%	732	14%	204	15%	936	14%
Enhanced Coag. & CL2/NH2CL	488	9%	136	10%	624	10%	1,171	23%	327	23%	1,499	23%
Oz/NH2CL	244	5%	68	5%	312	5%	40	1%	72	5%	112	2%
Enhanced Coag. & Oz/NH2CL	293	6%	82	6%	375	6%	0	0%	232	17%	232	4%
GAC10	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
GAC10 & CL2/NH2CL	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Enhanced Coag. & GAC10	0	0%	41	3%	41	1%	0	0%	0	0%	0	0%
Enhanced Coag. & GAC10 & CL2/NH2CL	0	0%	0	0%	0	0%	0	0%	14	1%	14	0.2%
GAC10 & Oz/NH2CL	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Enhanced Coag. & GAC10 & Oz/NH2CL	0	0%	0	0%	0	0%	0	0%	82	6%	82	1%
GAC20	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
GAC20 & CL2/NH2CL	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Enhanced Coag. & GAC20	0	0%	41	3%	41	1%	0	0%	55	4%	55	1%
Enhanced Coag. & GAC20 & CL2/NH2CL	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
GAC20 & Oz/NH2CL	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Enhanced Coag. & GAC20 & Oz/NH2CL	0	0%	0	0%	0	0%	0	0%	27	2%	27	0.4%
Membrane	293	6%	0	0%	293	4%	1,706	33%	0	0%	1,706	26%
Membrane & CL2/NH2CL	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Enhanced Coag. & Memb.	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
NH2CL	0	0%	0	0%	0	0%	96	2%	8	1%	104	2%
Oz/CL2	0	0%	0	0%	0	0%	23	0.4%	2	0.1%	25	0.4%
Oz,DE Filt.	0	0%	0	0%	0	0%	17	0.3%	2	0.1%	19	0.3%
Oz/Dir. Filt./NH2CL	0	0%	0	0%	0	0%	10	0.2%	1	0.1%	10	0.2%
Total	5,165	100%	1,395	100%	6,560	100%	5,165	100%	1,395	100%	6,560	100%

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Table XV-5: Ground Water Systems Disinfection By-Product Compliance Forecast (for Community & Non-Transient Non-Community Water Systems)

Treatments	Stage I						Stage II					
	Small Systems (Pop. per Sys. <=10K)		Large Systems (Pop. per Sys. >10K)		All Systems		Small Systems (Pop. per Sys. <=10K)		Large Systems (Pop. per Sys. >10K)		All Systems	
	#.	%	#.	%	#.	%	#.	%	#.	%	#.	%
(No Further Treatment)	59,847	88%	1,123	85%	60,970	88%	52,020	76%	908	69%	52,928	76%
CL2/NH2CL	5,403	8%	126	9%	5,529	8%	10,310	15%	215	16%	10,525	15%
Enh.Coag.	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Enhanced Softening	0	0%	0	0%	0	0%	0	0%	17	1%	17	0.02%
Oz/NH2CL	0	0%	25	2%	25	0.04%	0	0%	17	1%	17	0.02%
GAC10	0	0%	0	0%	0	0%	438	1%	17	1%	455	0.7%
GAC20	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Membrane	2,921	4%	47	4%	2,968	4%	5,403	8%	78	6%	5,481	8%
Oz/Dir. Filt./NH2CL	0	0%	0	0%	0	0%	0	0%	68	5%	68	0.1%
Total	68,171	100%	1,320	100%	69,491	100%	68,171	100%	1,320	100%	69,491	100%

Regarding Table XV–4, the DBPRAM predicted that 60 percent of all systems using surface water would at least use enhanced coagulation to comply with the Stage 1 requirements. Among the systems using enhanced coagulation, 10% would also use chloramines as their residual disinfectant (with chlorine used as the primary disinfectant), 6% would also use ozone as their primary disinfectant and chloramines as their residual disinfectant, 1% would also use GAC10, and 1% would also use GAC20. Among the systems not using enhanced coagulation, 3% would use chloramines as a residual disinfectant (with chlorine as the primary disinfectant), 5% would use ozone as their primary disinfectant and chloramines as their residual disinfectant, and 4% would use membrane technology. The predicted compliance choices for systems serving 10,000 people or less are almost the same as those for systems serving greater than 10,000 people. One notable difference is that because of large economies of scale for GAC20, no systems serving 10,000 people or less are predicted to use GAC20; rather all such systems (6%) requiring substantial precursor removal are predicted to use membrane technology.

Regarding Table XV–5, the DBPRAM predicted that for systems using ground water and seeking to comply with the Stage 1 requirements, 8% would use chloramines as their residual disinfectant (with chlorine as the primary disinfectant), 4% would use membrane technology, and 0.04% would use ozone for primary disinfection with chloramines for residual disinfection. While 2% of systems serving greater than 10,000 people were predicted to use ozone and chloramines, no systems serving 10,000 people or less were predicted to use this technology (for these sized systems membranes were considered a preferred option to ozone and chloramines because of the likely lower system level cost and ease of use).

Unlike for surface water supplies, all large ground water systems with high DBP precursor levels are predicted to use membrane technology in lieu of GAC. This is because large ground water systems are assumed to use multiple wells, each being of small enough size to be more cost effectively treated with membrane technology than by GAC.

The percentage of systems affected by the DBP regulations is markedly less among those using ground waters than those using surface waters. This is because (1) Most ground waters have much lower levels of DBP precursors than surface waters, and (2) most ground waters (i.e., those not under the direct influence of surface water as assumed in this analysis) are not considered vulnerable to contamination by protozoa and therefore require much less disinfection. Also, some ground water systems which are adequately protected will be able to avoid disinfection altogether and thereby avoid needing to meet any regulatory requirements pertaining to DBPs.

3. DBP Exposure Estimates

Table XV–6 presents three computer generated profiles of exposure reflecting the baseline condition, the Stage I rule, and the Stage II rule. The change in exposure is characterized in terms of TOC, TTHMs, and HAA5. These data are applicable only to large systems (>10,000 population) which filter but do not soften. The median and 95th percentile values for effluent TOC are shown to be reduced from 2.5 and 4.9 mg/l under baseline conditions to 2.2 and 3.8 mg/l at Stage I, and 2.0 and 3.3 mg/l at Stage II. The median and 95th percentile values for TTHMs are shown to be reduced from 46 and 104 µg/l under baseline conditions to 31 and 58 µg/l at Stage I, and 22 and 30 µg/l at Stage II. The median and 95th percentile values for effluent HAA5 are shown to be reduced from 28 and 86 ug/l under baseline conditions to 20 and 43 µg/l at Stage I, and 14 and 22 µg/l at Stage II.

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Table XV-6: DBP Exposure Profiles for Large Surface Water Systems That Filter But Do Not Soften

CL2/Conv. (baseline)						
	Inf. Br. (ug/l)	*Inf. TOC (mg/l)*	*Eff. TOC (mg/l)*	*Percent TOC Removal**	*TTHM (ug/l)*	*THAA (ug/l)*
Min.	1	0.7	0.5	5%	9.6	2.9
Max.	1,243	15.4	5.5	70%	153.9	130.8
Mean	84	4.6	2.6	33%	50.0	34.6
5th Percentile	4	1.4	1.0	13%	14.6	6.4
25th Percentile	11	2.6	1.6	20%	27.2	14.5
Median	***30***	***3.9***	***2.5***	***30%***	***45.6***	***28.0***
75th Percentile	71	5.2	3.4	42%	67.7	46.6
90th Percentile	141	8.4	4.1	57%	90.0	65.3
95th Percentile	395	10.8	4.9	61%	103.9	85.7

Stage I						
	Inf. Br. (ug/l)	*Inf. TOC (mg/l)*	*Eff. TOC (mg/l)*	*Percent TOC Removal**	*TTHM (ug/l)*	*THAA (ug/l)*
Min.	1	0.7	0.5	9%	9.6	2.9
Max.	1,243	15.4	5.2	88%	63.1	70.5
Mean	84	4.6	2.2	44%	32.9	22.2
5th Percentile	4	1.4	1.0	17%	12.7	6.3
25th Percentile	11	2.6	1.5	32%	22.3	12.4
Median	***30***	***3.9***	***2.2***	***45%***	***30.5***	***19.9***
75th Percentile	71	5.2	2.7	55%	41.6	30.0
90th Percentile	141	8.4	3.3	64%	52.3	40.3
95th Percentile	395	10.8	3.8	71%	58.4	43.1

Stage II						
	Inf. Br. (ug/l)	*Inf. TOC (mg/l)*	*Eff. TOC (mg/l)*	*Percent TOC Removal**	*TTHM (ug/l)*	*THAA (ug/l)*
Min.	1	0.7	0.5	9%	8.0	2.6
Max.	1,243	15.4	4.3	93%	31.6	23.9
Mean	84	4.6	2.0	46%	20.8	14.0
5th Percentile	4	1.4	0.9	17%	9.9	5.6
25th Percentile	11	2.6	1.4	32%	15.4	10.3
Median	***30***	***3.9***	***2.0***	***46%***	***21.7***	***13.8***
75th Percentile	71	5.2	2.5	56%	26.0	18.3
90th Percentile	141	8.4	3.0	68%	28.1	20.9
95th Percentile	395	10.8	3.3	85%	29.5	22.2

* computed from percent removal of TOC across 100 simulated plants; not computed from summary statistics on influent and effluent TOC.

Quantitative changes in exposure from TOC and DBPs were not predicted for ground water systems because of insufficient data. Treatment changes that ground water systems make to comply with the DBP regulations are likely to result in lower reductions of national median TOC and DBP levels than in surface water supplies. This is because of the much smaller percentage of ground water systems that are affected. However, the resultant change from the DBP regulations on the 95th percentile of TOC and DBP levels in ground water systems may be more significant than in surface water systems. This is because membrane filtration, which would be used in the systems with poorest quality, can remove greater than 90% of TOC, resulting in probably similar reductions of TTHMs and HAA5 (USEPA 1992).

4. System Level Cost Estimates

Tables XV–7 and XV–8 present the unit cost estimates that were utilized for each of the different treatment technologies in each system size category. The unit cost estimates were derived from a cost model described in the Cost and Technology document (USEPA 1992) and adjusted per discussion among TWG to reflect site specific factors (USEPA 1994). For systems in size categories serving greater than 10,000 people the estimated system level costs for achieving compliance ranged from $0.01/1000 gallons (chlorine/chloramines) to $1.87/1000 gallons (membrane technology). For systems in size categories serving less than 10,000 people the estimated system level costs for achieving compliance ranged from $.03/1000 gallons (chlorine/chloramines) to $3.49/1000 gallons. Although some technologies are listed as costing more than $3.49/1000 gallons in the smallest size categories (because of large economies of scale), no such technologies would be used because compliance could be achieved with membrane technology.

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Table XV-7: System Level Costs For Different DBP Control Technologies

Unit Treatment Costs for Small Water Systems (cents/Kgal.)					
System Size Category:	**Size #1**	**Size #2**	**Size #3**	**Size #4**	**Size #5**
Population Per System (persons):	***(25-100)***	***(101-500)***	***(501-1K)***	***(1K-3.3K)***	***(3.3K-10K)***
Treatments (sorted by least cost in Size #1)					
Enhanced Coag.	18	15	12	10	9
Enhanced Softening	20	16	13	11	10
CL2/NH2CL	98	26	9	3	3
Enhanced Coag. & CL2/NH2CL	116	41	21	13	12
Membrane	339	349	342	269	294
Enhanced Coag. & Memb.	357	364	354	279	304
Membrane & CL2/NH2CL	437	375	351	272	297
Oz/NH2CL	787	248	151	62	43
Enhanced Coag. & Oz/NH2CL	805	263	164	72	53
GAC10	1,049	387	180	79	54
Enhanced Coag. & GAC10	1,067	401	192	89	63
GAC10 & CL2/NH2CL	1,147	413	188	82	57
Enhanced Coag. & GAC10 & CL2/NH2CL	1,165	427	201	92	66
GAC10 & Oz/NH2CL	1,836	635	331	141	97
Enhanced Coag. & GAC10 & Oz/NH2CL	1,854	650	343	151	106
GAC20	2,512	999	548	268	203
Enhanced Coag. & GAC20	2,530	1,014	561	278	212
GAC20 & CL2/NH2CL	2,610	1,025	557	271	205
Enhanced Coag. & GAC20 & CL2/NH2CL	2,628	1,040	569	281	215
GAC20 & Oz/NH2CL	3,299	1,248	700	330	246
Enhanced Coag. & GAC20 & Oz/NH2CL	3,317	1,263	712	340	255
Oz,DF Filt.	5,986	1,910	886	350	279
Oz/DF Filt./NH2CL	5,986	1,910	886	350	279

Notes:

(1) Based on June 1991 dollars.

(2) Capital costs are amortized on the basis of a range of interest rate assumptions based on system size and ownership.

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Table XV-8: System Level Costs For Different DBP Control Technologies

Unit Treatment Costs for Large Water Systems (cents/Kgal.)

System Size Category:	Size #6	Size #7	Size #8	Size #9	Size #10	Size #11	Size #12
Population Per System (persons):	*(10K-25K)*	*(25K-50K)*	*(50K-75K)*	*(75K-100K)*	*(100K-500K)*	*(500K-1M)*	*(1M+)*
Treatments (sorted by least cost in Size #6)							
CL2/NH2CL	1	1	1	1	1	0	0
Enhanced Coag.	7	6	6	6	5	5	5
Enhanced Softening	7	6	6	6	6	5	5
Enhanced Coag. & CL2/NH2CL	8	7	6	6	6	5	5
Oz/NH2CL	26	20	15	13	10	9	8
Enhanced Coag. & Oz/NH2CL	32	26	21	19	16	14	13
GAC10	36	29	26	22	17	12	10
GAC10 & CL2/NH2CL	38	29	26	22	18	12	10
Enhanced Coag. & GAC10	43	34	31	27	23	17	15
Enhanced Coag. & GAC10 & CL2/NH2CL	44	35	32	28	23	17	15
GAC10 & Oz/NH2CL	62	48	41	35	27	21	18
Enhanced Coag. & GAC10 & Oz/NH2CL	69	54	47	40	33	26	23
GAC20	141	99	91	82	60	43	36
GAC20 & CL2/NH2CL	143	100	92	83	60	44	36
Oz,DE Filt.	146	110	91	82	71	60	55
Oz/Dir. Filt./NH2CL	146	110	91	82	71	60	55
Enhanced Coag. & GAC20	148	105	96	88	65	48	41
Enhanced Coag. & GAC20 & CL2/NH2CL	149	106	97	89	66	49	41
GAC20 & Oz/NH2CL	167	119	106	95	70	52	44
Enhanced Coag. & GAC20 & Oz/NH2CL	174	125	112	101	76	57	49
Membrane	180	152	132	126	115	106	103
Membrane & CL2/NH2CL	181	153	132	127	116	106	103
Enhanced Coag. & Memb.	187	158	137	131	121	111	108

Notes:

(1) Based on June 1991 dollars.

(2) Capital costs are amortized on the basis of a range of interest rate assumptions based on system size and ownership.

5. Effect on Household Costs

Table XV–9 summarizes cost impacts at the household level contained in Figures XV–1 through XV–4 for systems having to install and operate treatment. The impacts presented for Stage II represent the cumulative cost per household of both Stage I and Stage II. The household impacts are based solely upon the community water system analysis since the nontransient noncommunity systems typically do not serve households. These household impacts do include, however, the households in purchased water systems that are served by the affected non-purchased water systems. These household costs reflect only the cost of treatment and do not include the cost of monitoring. Note also that costs of an Enhanced Surface Water Treatment Rule, if such a rule should become necessary, are not included.

TABLE XV–9.—STAGE 1 AND STAGE 2 HOUSEHOLD COST IMPACT SUMMARY

Type of system	Large surface water [1]	Small surface water [1]	Large ground water [1]	Small ground water [1]	Totals
Number of systems	1395	4562	1316	44,310	51,583
Number of households (in millions)	56	6.4	19	12.3	93.7
$/household/yr.	Number of households expected to pay specific increased costs for compliance with stage 1 (in millions)				
0	16.8	1.8	16.0	10.6	45.2
>0–10	30.8	2.4	2.0	1.0	36.2
>10–20	4.5	1.1	0.2	None	5.8
>20–40	2.2	0.1	0.2	0.1	2.6
>40	1.7	1.0	0.6	0.6	3.9
	Number of households expected to pay specific increased costs for compliance with stage 1 and stage 2 (in millions)				
0	13.4	[2]	[2]	[2]	13.4
>0–10	25.2	[2]	[2]	[2]	25.2
>10–20	6.2	[2]	[2]	[2]	6.2
>20–40	6.7	[2]	[2]	[2]	6.7
>40	4.5	[2]	[2]	[2]	4.5

[1] Large systems serve 10,000 or more persons. Small systems serve fewer than 10,000 persons. Surface water systems are Subpart H systems. Ground water systems are systems using only ground water not under the direct influence of surface water.

[2] Today's Stage 2 D/DBP Rule proposal only applies to Subpart H systems serving at least 10,000 persons. As proposed, there are no household compliance costs for other systems.

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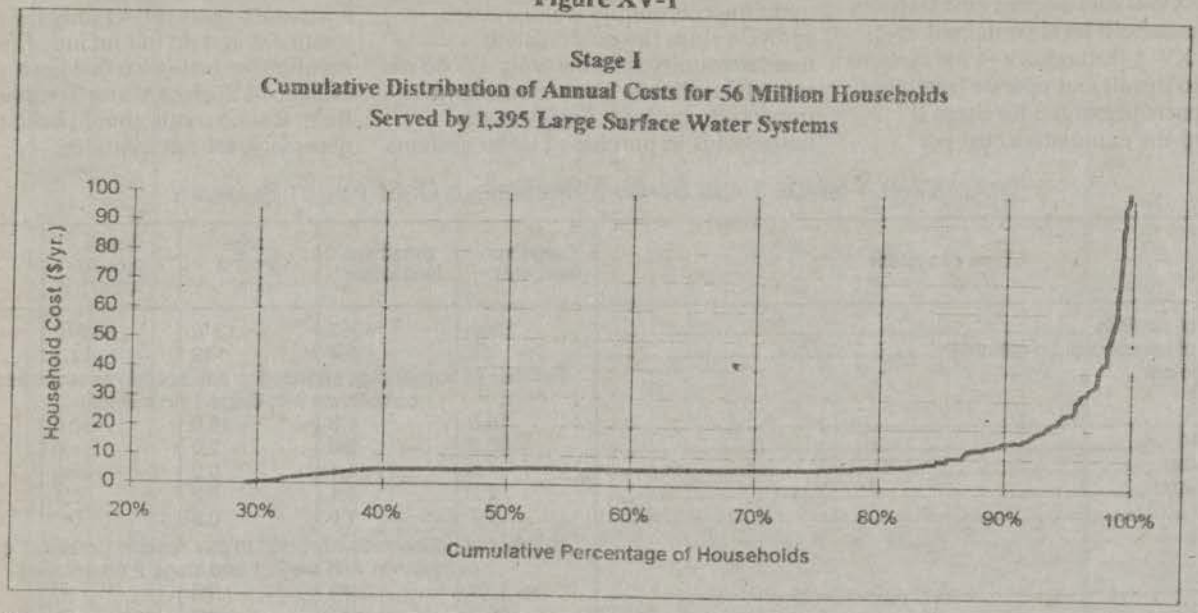
Figure XV-1


Stage I
Cumulative Distribution of Annual Costs for 56 Million Households
Served by 1,395 Large Surface Water Systems
Household Cost ($/yr.)
100
90
80
70
60
50
40
30
20
10
0
20%
30%
40%
50%
60%
70%
80%
90%
100%
Cumulative Percentage of Households

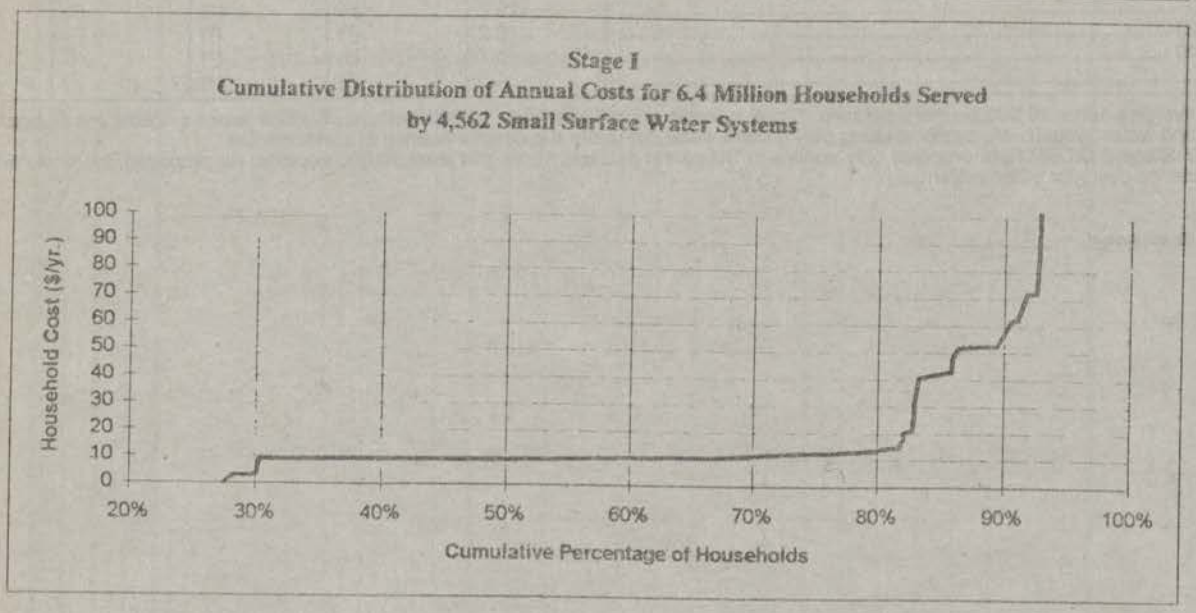
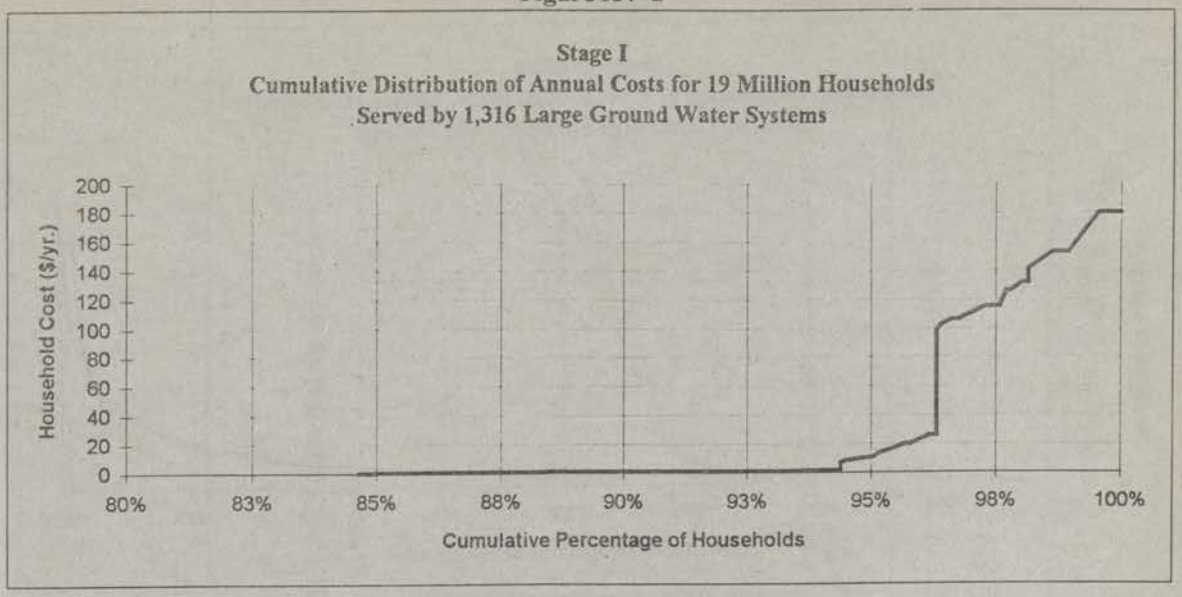

Stage I
Cumulative Distribution of Annual Costs for 6.4 Million Households Served
by 4,562 Small Surface Water Systems
Household Cost ($/yr.)
100
90
80
70
60
50
40
30
20
10
0
20%
30%
40%
50%
60%
70%
80%
90%
100%
Cumulative Percentage of Households

Figure XV-2


Stage I
Cumulative Distribution of Annual Costs for 19 Million Households
Served by 1,316 Large Ground Water Systems
Household Cost ($/yr.)
200
180
160
140
120
100
80
60
40
20
0
80%
83%
85%
88%
90%
93%
95%
98%
100%
Cumulative Percentage of Households

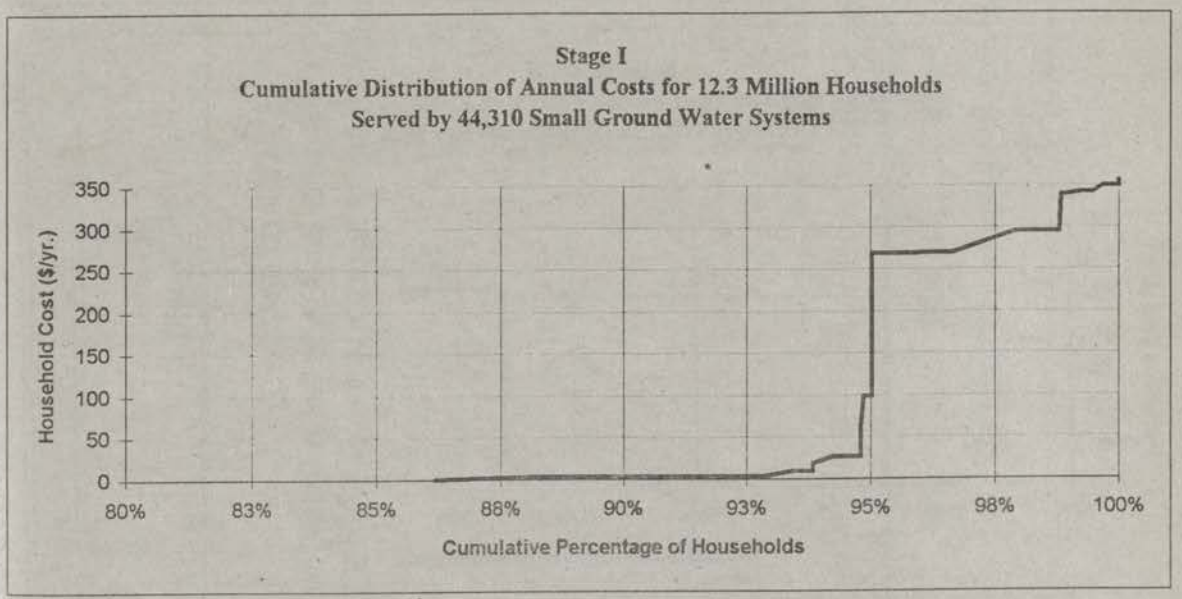
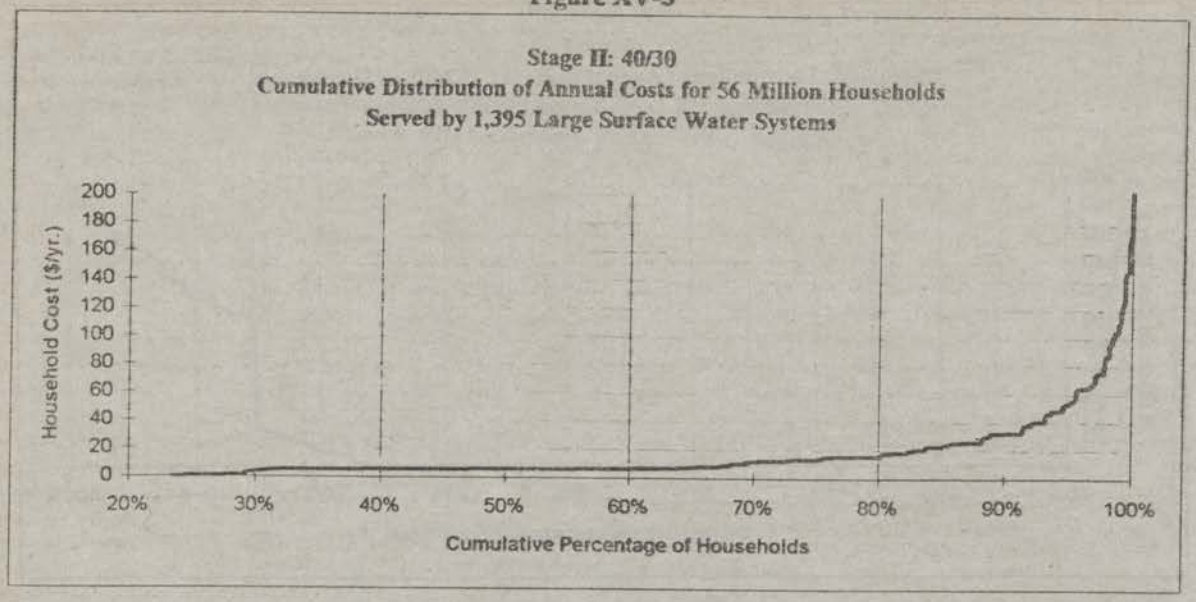

Stage I
Cumulative Distribution of Annual Costs for 12.3 Million Households
Served by 44,310 Small Ground Water Systems
Household Cost ($/yr.)
350
300
250
200
150
100
50
0
80%
83%
85%
88%
90%
93%
95%
98%
100%
Cumulative Percentage of Households

Figure XV-3


Stage II: 40/30
Cumulative Distribution of Annual Costs for 56 Million Households
Served by 1,395 Large Surface Water Systems
Household Cost ($/yr.)
200
180
160
140
120
100
80
60
40
20
0
20%
30%
40%
50%
60%
70%
80%
90%
100%
Cumulative Percentage of Households

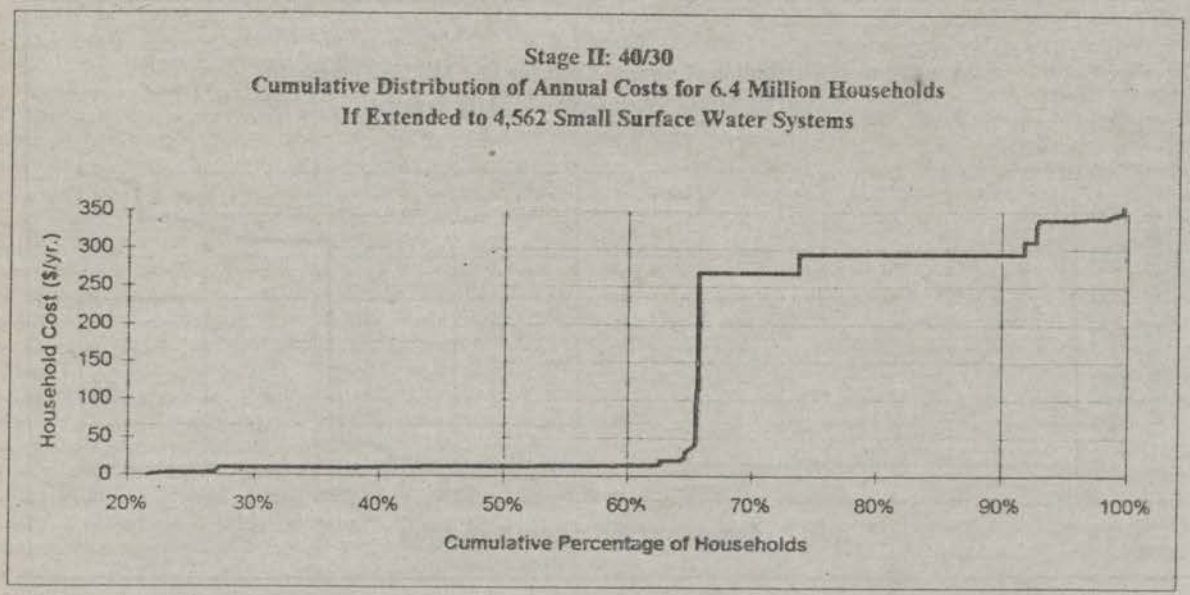
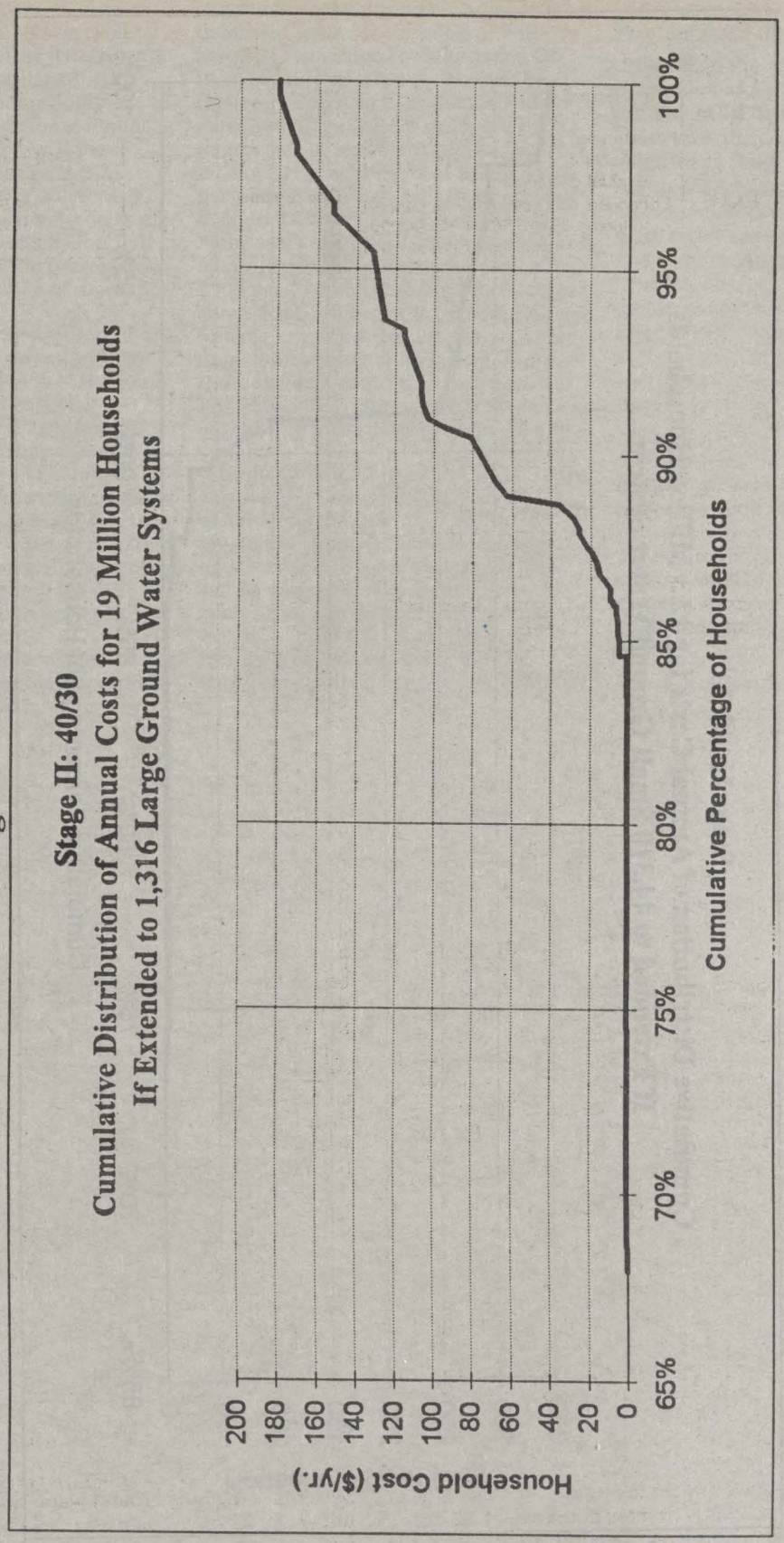
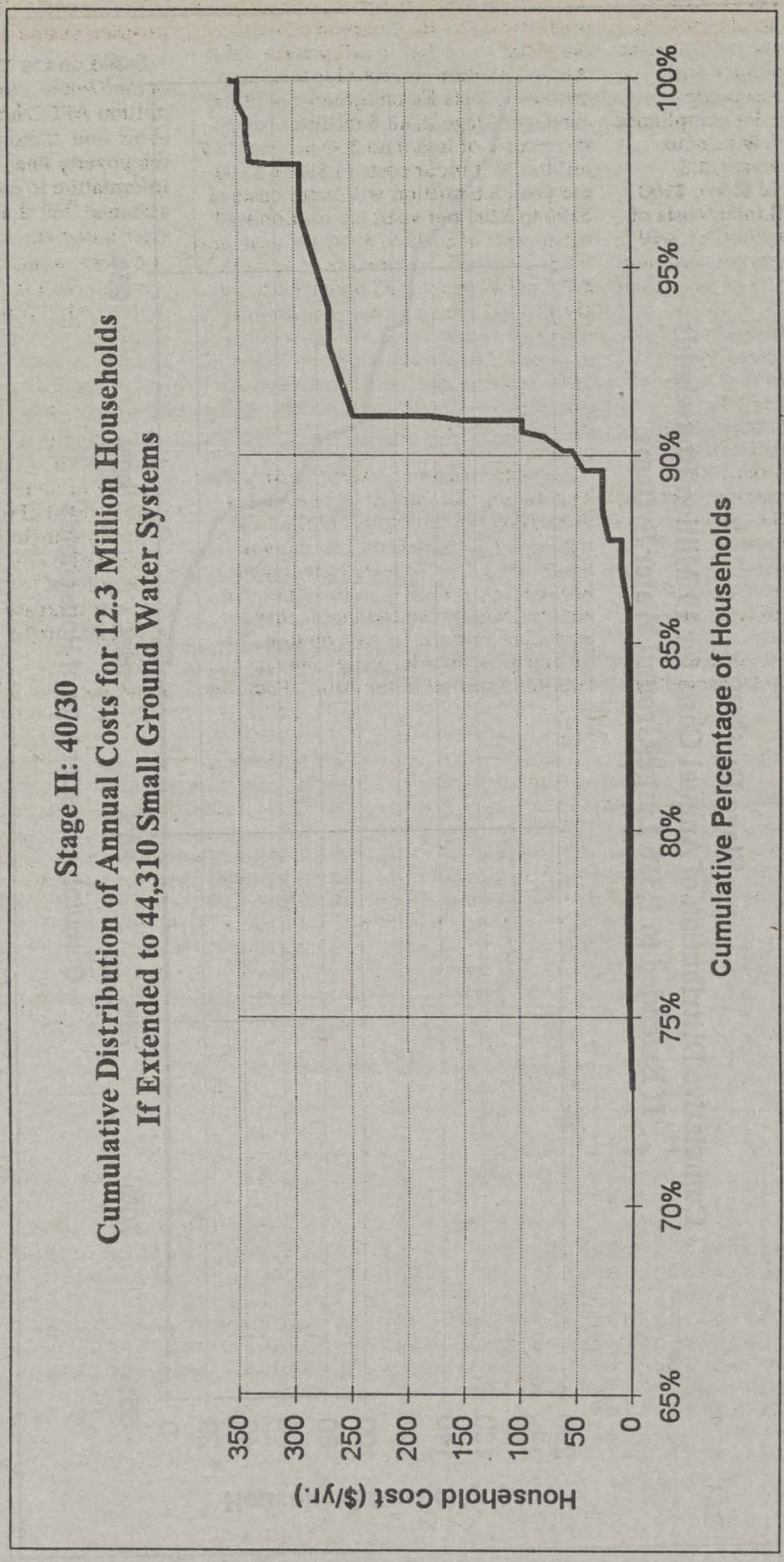

Stage II: 40/30
Cumulative Distribution of Annual Costs for 6.4 Million Households
If Extended to 4,562 Small Surface Water Systems
Household Cost ($/yr.)
350
300
250
200
150
100
50
0
20%
30%
40%
50%
60%
70%
80%
90%
100%
Cumulative Percentage of Households

Figure XV-4

Stage II: 40/30
Cumulative Distribution of Annual Costs for 19 Million Households
If Extended to 1,316 Large Ground Water Systems





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EPA estimates that about 45 million households (48% of the total served by community water systems) will incur no treatment costs for compliance with Stage I. Of 49 million households incurring treatment costs for compliance with Stage I, 45.5 million will incur costs of less than $50 per year, 1.3 million will incur costs of $50 to $100 per year, 1.0 million will incur costs of $100 to $200 per year, 0.8 million will incur costs of $200 to $300 per year, and 0.2 million will incur costs of more than $300 per year.

EPA estimates that 13.4 million of the 56 million households served by large surface water systems (24% of the total) will incur no treatment costs for compliance with Stage II as proposed (applying only to large surface water systems). Of the nearly 43 million households incurring treatment costs for compliance with Stage II as proposed, 39.8 million will incur costs of less than $50 per year, 2.2 million will incur costs of $50 to $100 per year, and 0.8 million will incur costs of $100 to $200 per year.

EPA estimates that 36.3 million households (39% of the total served by community water systems) will incur no treatment costs for compliance with Stage II if extended to all systems. Of the 57.2 million households incurring treatment costs for compliance with an extended Stage II, 48.6 million will incur costs of less than $50 per year, 2.7 million will incur costs of $50 to $100 per year, 2.6 million will incur costs of $100 to $200 per year, 2.5 million will incur costs of $200 to $300 per year, and 0.8 million will incur costs of more than $300 per year. Annual household costs above $200 are projected predominantly for small systems that may be required to install membrane treatment. Some of these systems could find that there are less expensive options available, such as connecting into a larger regional water system.

Impacts on Low Income Families. The Negotiating Committee had several discussions of the impact of the DBP regulatory proposals on low income households and reviewed the impact estimates specifically in this light. An analysis was presented that focused exclusively on the impact on low income households, using data on families enrolled in the Aid to Families with Dependent Children (AFDC) program as an illustration.

Based on the 1992 *Statistical Abstract of the United States*, there were 4.2 million AFDC families (this represents about one- third of all families below the poverty line). In the absence of information to suggest otherwise, it was assumed that these families are distributed across water system types and sizes in the same proportion as the total population. The analysis was performed to illustrate the impact of the Stage II DBP requirements under the assumption that the 40/30 requirement was extended to all water systems. Results are presented in Figure XV–5.

The results in Figure XV–5 show the distribution of impacts in terms of the number of households that would have a given level of impact on their household income in terms of the percent of AFDC income. Based on the current level of AFDC payments, a $22 per year increase in the water bill is equivalent to 0.5 percent of AFDC income.

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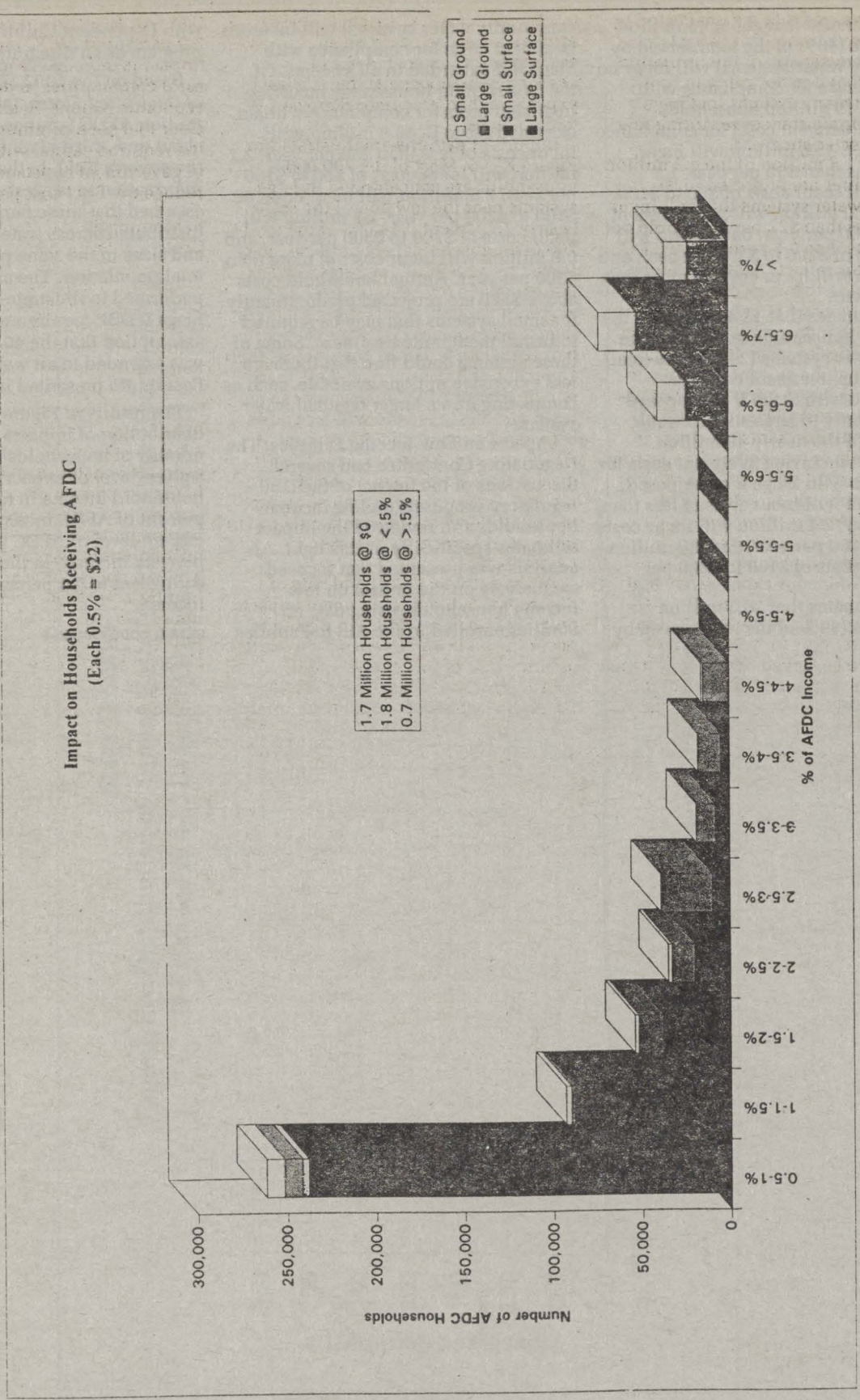
Figure XV-5

Impact on Households Receiving AFDC
(Each 0.5% = $22)



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With the given assumptions about the distribution of AFDC households, it is projected that 1.7 million of the 4.2 million AFDC families would be served

by water systems that are unaffected by the DBP regulations. This reflects a general characteristic of the regulation of DBPs—that it is not going to be a problem in many systems that have fortunate circumstances regarding raw water characteristics.

Another 1.8 million of the 4.2 million AFDC families are projected to be served by water systems that will incur costs of less than $22 per household per year, or less than 0.5 percent of AFDC income. This reflects another feature of the DBP rule—that impacts might not be too severe in many large urban water systems with moderate levels of DBPs and economies of scale. It is noted, however, that the current Stage II cost estimates are based upon generous use of alternative disinfectants. If use of alternative disinfectants becomes unacceptable or inadequate for meeting other concurrent criteria (such as DBP precursor removal), greater use of alternative precursor removal technologies becomes necessary as a means of achieving compliance and utilities could incur expenses several times as great.

About one-sixth of the 4.2 million AFDC households (0.7 million) are projected to be served by water systems that will incur costs of more than $22 per household per year, or more than 0.5 percent of AFDC income. These estimates are also based on an assumption of extensive use of alternative disinfectants that are less expensive than precursor removal technologies.

Important patterns are illustrated in Figure XV–5. Most of the 700,000 households are concentrated in large systems near the low end of the scale. Nearly 75 percent (514,000 of the total 700,000 households) are projected to be served by large water systems. Among these 514,000 households, over 75 percent (390,000) will face costs of less than 2 percent of AFDC income; nearly half (248,000) will face costs of less than 1 percent of AFDC income. Less than one-quarter of AFDC households in large systems (124,000) will face costs between 2 percent and 4.5 percent of AFDC income. None will face costs greater than 4.5 percent of AFDC income. Again, these estimates assume use of alternate disinfectants rather than more costly precursor removal technologies.

At the extreme right-hand side of Figure XV–5, the most extreme impacts on AFDC households are indicated to occur in small water systems. Given the assumptions of this analysis, it is projected that there will be 147,000 AFDC households in small communities that will face costs of between 6.0 and 7.0 percent of AFDC income. This impact is more likely to occur in small rural communities in declining economic regions. Realistically, it is not clear that such communities could raise the required capital without some form of government assistance that might reduce the final cost per household.

6. Monitoring and State Implementation Costs, Labor Burden Estimates

Table XV–10 summarizes the monitoring and state implementation cost and labor burden estimates. In compliance with the Paperwork Reduction Act, EPA estimates the total labor burden of complying with monitoring and reporting requirements to be 1.5 million hours over six years, averaging 250,000 hours per year. This estimate equates to an average of 4 hours per system per year. The labor burden for State program implementation is estimated to total 2.5 million hours over six years, averaging 416,666 hours per year. This estimate implies a per State average of 7,440 hours per year. However, the implementation work load will not be staggered evenly over the six year period or by State.

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Table XV-10: Average Annual Cost and Burden Estimates for Monitoring and Reporting and State Implementation Requirements of DBP Rule

Compliance Activities	Respondents Affected	Annual Cost (K$) * All Respondents	Annual Cost (K$) * Per Respondent	Annual Burden (hrs.) * All Respondents	Annual Burden (hrs.) * Per Respondent
Start-Up Activities					
5165 Surface Water Systems <10K	5,165 plants	227 (3.5 yrs.)	0.04	6,898 (3.5 yrs.)	1.3
1395 Surface Water Systems >10K	1,725 plants	134 (3.5 yrs.)	0.08	4,165 (3.5 yrs.)	2.4
68171 Ground Water Systems <10K	54,034 systems **	2,071 (3.5 yrs.)	0.04	63,587 (3.5 yrs.)	1.2
1320 Ground Water Systems >10K	1,250 systems **	94 (3.5 yrs.)	0.08	2,904 (3.5 yrs.)	2.3
Subtotal:		2,526 (3.5 yrs.)		77,555 (3.5 yrs.)	
Stage I Monitoring					
5165 Surface Water Systems <10K	5,165 treat. sites	15,628 (2.5 yrs.)	3.0	115,544 (2.5 yrs.)	22
1395 Surface Water Systems >10K	1,725 treat. sites	13,275 (3.5 yrs.)	7.7	91,921 (3.5 yrs.)	53
68171 Ground Water Systems <10K	84,757 treat. sites **	54,941 (1 yr.)	0.6	319,226 (1 yr.)	4
1320 Ground Water Systems >10K	10,590 treat. sites **	20,704 (2.5 yrs.)	2.0	146,667 (2.5 yrs.)	14
Subtotal:		54,923 (3.5 yrs.) ***		370,415 (3.5 yrs.) ***	
PWS Total:		57,449 (3.5 yrs.)		447,970 (3.5 yrs.)	

States and Territories	States Affected	Annual Cost (K$) All States	Annual Cost (K$) Per State	Annual Burden (hrs.) All States	Annual Burden (hrs.) Per State
State Implementation	56	22,921 (3.5 yrs.)	409	700,129 (3.5 yrs.)	12,502
Total:		80,370 (3.5 yrs.)		1,148,098 (3.5 yrs.)	

* Average annual costs and burden are computed over the implementation period. One-time start-up costs and burden are divided by 3.5 to obtain annual average.

** Systems currently disinfect or will disinfect under the Ground Water Disinfection Rule.

*** Total cost or burden of Stage I monitoring divided by 3.5 (ears).

The total cost of compliance with the monitoring requirements is estimated to be $283 million over six years, averaging $47 million per year. The total cost of state implementation is estimated to be $82 million over six years, averaging $14 million per year. The cost of monitoring and of state implementation will not be evenly spread over the six year period.

C. Concepts of Cost Analysis

The Negotiating Committee reviewed the cost of capital assumptions normally employed by EPA in analyzing drinking water regulations. EPA typically assumes a 7 percent interest rate and a 20-year term. These assumptions result in a Capital Recovery Factor of 0.09439. The Capital Recovery Factor is multiplied times the capital cost to arrive at the amount of the annual payment required including principal and interest. During the negotiation, it was pointed out that the standard EPA assumption is too low for investor owned utilities considering other carrying costs of capital investment (e.g., taxes, depreciation), although it be reasonable for municipal utilities considering current interest rates. It was also noted that the standard EPA assumption is too low an estimate for the cost of capital in small investor owned systems and other small private systems (e.g., homeowner's associations, trailer parks, etc.) considering differences in credit risk and access to capital.

An analysis was presented by a member of the Negotiating Committee indicating that a Capital Recovery Factor of 0.17172 is appropriate for large investor owned utilities and that a Capital Recovery Factor of 0.20105 is appropriate for small privately owned water systems. Based on current interest rates for municipal bonds, the TWG determined that Capital Recovery Factors of 0.09439 and 0.10185 are appropriate for large and small municipally owned water systems, respectively. EPA and NAWC data on the mix of ownership types by system size were then used to develop weighted composite Capital Recovery Factors for use in the analysis. The results are summarized as follows:

Category	Ownership of systems	Capital recovery factors	Composite factors
<1,000	priv 87	0.20105	0.18815
	publ 13	0.10185	
1,000–10,000	priv 25	0.20105	0.12665
	publ 75	0.10185	
10,000–100,000	priv 14	0.17172	0.10522
	publ 86	0.09439	
100,000+	priv 17.5	0.17172	0.10792
	publ 82.5	0.09439	

Capital costs are based on the EPA Cost and Technology Document which represents fourth quarter 1991 costs. These costs were not adjusted for inflation, but very little inflation has occurred since then.

D. Benefits

Despite the enormous uncertainties for estimating reductions in risk resulting from different regulatory strategies, the Negotiating Committee recognized that the existing risks could be large, and therefore should be reduced. The Negotiating Committee reached a consensus that the Stage 1 requirements were of sufficient benefit to be proposed for all system sizes, but could not agree on Stage 2 reductions. Until extensive epidemiological and toxicological studies have been completed, it is not possible to draw definitive quantitative conclusions regarding the precise extent of cancer and non-cancer adverse health effects resulting from disinfection byproducts.

Nevertheless, based on exposure estimates described above. an analysis was developed to provide some quantitative indication of the range of possibilities implied by the Stage I and Stage II proposals in terms of the cost-per-case-of-cancer-avoided. Toxicological and epidemiological analyses can be applied to the exposures predicted by the DBPRAM to suggest a range of annual cancer incidence that might be avoided if systems were to comply with the proposed D/DBP regulations.

During the regulatory negotiations, some negotiators argued that the national baseline incidence of cancer attributed to DBPs in drinking water may be less than 1 case per year; others argued that over 10,000 cases per year are linked to DBPs. The lower bound baseline risk estimate was based on the maximum likelihood estimates of toxicological risk (best case estimates as opposed to upper 95% confidence bound estimates) associated with THM levels (i.e., chloroform, bromoform, bromodichloromethane, and dibromochloromethane) predicted by the DBPRAM (USEPA, 1994). Not included in the lower bound estimate were any risks resulting from exposure to HAAs or other DBPs. Although dichloroacetic acid has been classified as a probable human carcinogen (see Section V of this preamble), risks have not been included for this chemical because the Agency has not yet quantified its carcinogenic potential. Also, since cancer bioassays are only currently underway for the brominated HAAs, potential risks from their exposure could not be quantified. No national risk estimates were possible for bromate because of the lack of national occurrence data or model to predict bromate formation.

An upper bound base-line estimate of over 10,000 cancer cases per year was considered based upon the central tendency estimate of the pooled relative risks from a meta-analysis study which statistically combined the results of ten previously published epidemiology studies (Morris et al. 1992). The basis for estimating risks from the meta-analysis was questioned by some members of the Negotiating Committee, including EPA, because (a) the studies used in the meta-analysis were of different design and thus not subject to a meta-analysis and (b) potential confounding factors or bias may not have been adequately controlled (Farland and Gibb, 1993; Craun 1993; Murphy 1993). Also, the epidemiologic studies used in the meta-analysis considered exposure to populations before the advent of the 1979 MCLs for TTHMs; that regulation significantly reduced exposure to chlorinated DBPs (McGuire et al 1989). Other members of the Negotiating Committee, however, commented that many of the "biases" noted in studies used in the meta-analysis would tend to underestimate cancer risks and that, taken as a whole, these studies are highly suggestive of a link between DBPs and certain cancers.

They also noted that current THM rules do not apply to most public water systems (those serving fewer than 10,000 people) which serve about 20% of the U.S. population. Also, these rules do not necessarily control many other DBPs which may be of health risk significance.

While research is needed to establish better risk estimates associated with disinfected water, the above estimates appear to reasonably bound the potential for cancer risk (it should be noted, however, using the upper bound of the meta-analysis estimate would have resulted in a higher baseline cancer risk estimate). In order to estimate the benefits of reducing DBP exposure, EPA made certain assumptions. All assumptions are based on results of DBPRAM estimates of conditions in large surface water systems that filter but do not soften. These systems represent about 80 percent of the population served by surface water systems and over 50 percent of the population served by all public water systems. However, this analysis does not address the benefits to consumers using smaller systems. One approach used was to assume that the percent reduction in TTHM and HAA5 median effluent concentrations reflects an equivalent percent reduction in cancer risk. A second approach was to assume that the percent reduction in median TOC effluent concentration reflects an equivalent percent reduction in cancer risk. These alternatives were evaluated under the assumption that there would be no compromising the SWTR risk goal of no more than one case of giardiasis per 10,000 people per year. In other words, this microbial treatment objective was used to constrain the DBPRAM model while predicting a) the baseline levels of TTHMs, HAA5, and TOC under the existing SWTR, and b) the new concentrations of TTHMs, HAA5, and TOC resulting from systems attempting to meet the Stage 1 and Stage 2 requirements (USEPA, 1994). This modeling constraint, which is in effect an ESWTR consistent with the objectives of the SWTR, avoids increases in microbial risk and simplifies the benefits analysis. The preamble to the proposed ESWTR, elsewhere in today's **Federal Register**, discusses how the DPBRAM has also been used to predict increases in microbial risk that might result if systems complied with more stringent DBP standards without an ESWTR.

In Stage 1, the DBPRAM predicted that the baseline median TTHM and HAA5 effluent concentrations would be reduced by 33 and 29 percent, respectively, while the TOC effluent concentration would be reduced by 12 percent. Assuming that the change in the median effluent TTHM and HAA5 levels reflects the same changes in exposure from cancer risk (relative to the respective toxicological and epidemiological baseline risk levels previously alluded to), the Stage I proposal would result in avoidance of between 0.29 to 0.33 cases per year and 2,900 to 3,300 cases per year. The lower bound of cancer cases avoided per year is likely to be understated because, in the absence of risk estimates available for other DBPs, it is assumed that all cancer cases caused by exposure to DBPs can be represented by the maximum likelihood toxicological risk estimate from exposure to THMs alone.

Under the assumptions described above and assuming that the change in median effluent TOC reflects the same changes in exposure from cancer risk, the Stage I proposal would result in avoidance of between 0.12 and 1,200 cases of cancer per year. In Stage 2, the change in median TTHM and HAA5 effluent concentrations was a reduction of 48 and 50 percent, respectively, from the baseline prior to Stage 1, while the change in TOC effluent concentration was a reduction of 18 percent. Assuming the change in median effluent TTHM and HAA5 levels reflects the same change in exposure from cancer risk, the Stage II proposal would result in a cumulative (Stage 1 plus 2) avoidance of between 0.50 to 0.52 cases per year and 5,000 to 5,200 cases per year. Assuming the change in median effluent TOC reflects the change in exposure from cancer risk, the Stage II proposal would result in cumulative avoidance of between 0.2 and 2,000 cases of cancer per year.

If the total annual cost of treatment is $1.04 billion to meet Stage I targets, then the cost per case of cancer avoided ranges between $8.67 billion and $867,000 per case, based on changes in median effluent TOC. If based on Stage I changes in median effluent TTHMs and THAAs, the cost per case of cancer avoided ranges between $3.59 billion and $359,000. Assuming that DBPs other than THMs pose some cancer risk, the upper bound cost estimates per cancer case avoided are likely to be overstated. Similarly, until more conclusive epidemiology data become available, the lower bound cost estimate per case will remain highly controversial. If one were to assume there is a 10 percent chance that the baseline cancer risks suggested by Morris et al. (1992) were true, then the estimated costs per case of cancer avoided would range from $8.67 million per case (based on changes in median TOC) to $3.59 million per case (based on changes in median TTHMs). The lack of better evidence for causality in the epidemiological studies would indicate there is a possibility that the associations cited in the Morris study are due to omitted variables or deficiencies in the data, in which case the cost effectiveness may be even worse than these estimates.

In principle, the cost-effectiveness of the rule should be evaluated in terms of the expected (mean) outcome and the likelihood of this and other outcomes. Quantitative data on the likelihood of different outcomes are unavailable, however, and as a result EPA has been able to quantify the expected cost effectiveness only in terms of the ranges reported here. EPA believes that likely cost-effectiveness outcomes will fall in this range. Whether the expected cost effectiveness of the proposal is closer to the high-end or low-end estimates depends primarily on whether future epidemiological or toxicological studies can provide stronger evidence of a causal effect of exposure to disinfected (e.g., chlorinated) water on cancer risks.

Cost-effectiveness will be affected by the size and the water quality of a particular system, and the technology used for achieving compliance. Economies of scale for technologies used to achieve compliance will make household compliance costs higher in smaller systems than in larger systems (see Table XV–8). However, because many large systems will already have reduced exposure from DBPs under the existing TTHM standard (which only pertains to systems serving greater than 10,000 people), reductions in exposure from DBPs in many small systems is also likely to be greater than in larger system. Although the data are limited, this presumption appears to be supported by Figures VI–11 and VI–13 in section VI of this preamble. Figures VI–11 and VI–13 suggest that a substantial number of systems serving less than 10,000 people have much higher TTHM (and DBP) concentrations than systems serving 10,000 people or greater. EPA solicits data and comment on the extent to which reductions in exposure can be expected to differ between systems serving 10,000 people or more and systems serving less than 10,000 people.

For systems using enhanced coagulation, the technology most likely to be used to achieve compliance among surface water supplies (see Table XV–4), there are relatively small differences in economies of scale (see Tables XV–6 and XV–7) and small differences in cost effectiveness between small and large

systems. Table XV–4 indicates that approximately 17% of the surface water supplies serving fewer than 10,000 people will use technologies (ozone or membrane technology) that would result in significantly higher household costs than those expected in most larger-sized systems. Similarly, Table XV–5 indicates that approximately 4% of the ground water supplies serving fewer than 10,000 people will use a technology (membrane technology) that would result in significantly higher household costs than in most larger-sized systems. Depending on the reductions in exposure, which would be very significant in systems using membrane technology, the cost-effectiveness in some small systems is likely to be substantially less than in larger-sized systems. EPA solicits comments on what data and approaches could be used for estimating differences in cost-effectiveness for large versus small systems complying with Stage 1 requirements.

Maintaining the assumptions as described above, if the total annual cost of treatment is $2.56 billion to meet Stage II targets (extended to all systems), then the cost per case of cancer avoided ranges between $5.3 billion and $512,000 if based on changes in median TTHM and HAA5 effluent concentrations. If based on Stage II changes in median effluent TOC, the cost per case of cancer avoided ranges between $12.8 billion and $1.28 million per case.

Under the above assumptions, the Stage 1 requirements are significantly more cost effective than the Stage 2 requirements for reducing risk, whatever that risk may be. Despite the enormous uncertainties for estimating reductions in risk resulting from different regulatory strategies, the Negotiating Committee believed that the Stage 1 requirements were of sufficient benefit to be proposed for all system sizes. Some negotiators argued that Stage 2 controls should only be proposed now for larger systems and revisited when more information became available; others argued that such controls should be put in place sooner. The ultimate decision was to propose Stage 2 rules but to provide an opportunity for consideration of more data at a second regulatory negotiation (or similar proceeding) before Stage 2 is finalized.

XVI. Other Requirements

A. Consultation with State, Local, and Tribal Governments

Two Executive Orders (E.O. 12875, Enhancing Intergovernmental Partnerships, and E.O 12866, Regulatory Planning and Review) explicitly require Federal agencies to consult with State, local, and tribal entities in the development of rules and policies that will affect them, and to document what they did, the issues that were raised, and how the issues were addressed.

As described in section II of today's rule, SDWA section 1412 requires EPA to promulgate NPDWRs for at least 25 contaminants every three years. The contaminants listed in today's rule are being proposed in response to that Congressional mandate.

To comply with this rule, PWSs will need to meet specified levels for total trihalomethanes, haloacetic acids, certain other byproducts, and certain disinfectants. To meet these standards, certain systems will need to employ enhanced coagulation, enhanced precipitative softening, and/or other treatment technologies. The total annual cost of the rule, including monitoring, is expected to be about $1.1 billion per year. Systems serving more than 10,000 persons are expected to come into compliance in 1998 and 2000 and bear $700 million of the cost. Systems serving fewer than 10,000 persons are expected to come into compliance in the years 2000 to 2002 and bear about $400 million of the total cost.

The Agency first sought public input to the rule in a strawman rule published in October 1989. Comments received in response to the strawman rule are summarized in section IV of today's rule. In June 1991 EPA issued a status report designed to update the public on the Agency's thinking on rule criteria. Comments were also received on the status report; they, too, are summarized in section IV.

In 1992, EPA considered entering into a negotiated rulemaking on this rule primarily because no clear path for addressing all the major issues associated with the rule was apparent. EPA hired a facilitator to explore this option with external stakeholders and, in November 1992, decided to proceed with the negotiation. The 18 negotiators, including EPA, met from November 1992 until June 1993 at which time agreement was reached on the content of the proposed rule. Today's proposed regulatory and preamble language has been agreed to by the 17 negotiators who remained at the table through June 1993. A summary of those negotiations is contained in section IV.

The negotiators included persons representing State and local governments. At the table were:

(1) Association of State Drinking Water Administrators, a group representing state government officials responsible for implementing the regulations,

(2) Association of State and Territorial Health Officials, a group representing statewide public health interests and the need to balance spending on a variety of health priorities,

(3) National Association of Regulated Utilities Commissioners, a group representing funding concerns at the state level,

(4) National Association of County Health Officials, a group representing local government general public health interests,

(5) National League of Cities, a group representing local elected and appointed officials responsible for balancing spending needs across all government services,

(6) National Association of State Utility Consumer Advocates, a group representing consumer interests at the state level, and

(7) National Consumer Law Center, a group representing consumer interests at the local level.

In addition, several associations representing public municipal and investor-owned water systems also served on the committee.

As part of the negotiation process, each of these representatives was responsible for obtaining endorsement from their respective organization on the positions they took at the negotiations and on the final signed agreement. During the negotiations, the group heard from many other parties who attended the public negotiations and were invited to express their views. As is true with any negotiation, all sides presented initial positions which were ultimately modified to obtain consensus from all sides. However, all parties mentioned above signed the final agreement on behalf of their associations. This agreement reflected basic consensus that the cost of the rule was offset by its public health benefits and its promotion of responsible drinking water treatment practices.

The only original negotiator who did not sign the agreement left the negotiations in March 1993. That negotiator represented the National Rural Water Association (NRWA), a group representing primarily small public and private water systems. NRWA believed that since systems serving populations under 10,000 persons are not subject to the current trihalomethane standard, it would be more reasonable to require that small systems comply with the current trihalomethane standards rather than the standards proposed today. NRWA objected to the costs of the rule on small systems given its belief that the risks to

humans from D/DBP are poorly understood. NRWA in its letter of resignation stated that "[t]here is insufficient good, reliable scientific data showing clear risks to human health from the levels of D/DBP found on average in drinking water." It should be noted that although NRWA objected to the cost of the rule, they had supported an option with approximately the same estimated cost earlier in the negotiation process. The NRWA position that small systems should meet the current trihalomethane standard was rejected by the remaining negotiators, several of whom also represent small water systems.

The contents of today's proposed rule has been available to the public for several months as part of the regulatory negotiation signature process. EPA has briefed numerous groups, including government organizations, on its contents. The Agency has received several letters from public water systems objecting to the cost of the proposed rule and questioning its potential health benefit. These letters are contained in the public docket supporting today's rule. The Agency recognizes that many persons are concerned whether the proposed rule is warranted. The technical issues are complex. The process needed to develop a common level of understanding among the negotiators as to what was known and unknown and what are reasonable estimates of potential costs and benefits was time-consuming. It is unreasonable to expect persons not at the negotiating table to have that same level of understanding and to all share the same view. However, the discussions throughout the negotiated rulemaking process were informed by a broad spectrum of opinions. The Agency believes this consensus proposal is not only the preferred approach but one which will generate informed debate and comment.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 602 *et eq.*, requires EPA to explicitly consider the effect of proposed regulation on small entities. By policy, EPA has decided to consider regulatory alternatives if there is any economic impact on any number of small entities. The Small Business Administration defines a "small water utility" as one which serves fewer than 3,300 people. If there is a significant effect on a substantial number of small systems, the Agency must seek means to minimize the effects.

In accordance with the Regulatory Flexibility Act EPA has conducted a Regulatory Flexibility Analysis indicating what the predicted impacts on small systemns could be and how such impacts could be minimized. A detailed description of this effort is available in the Regulatory Impact Analysis (USEPA, 1994). Following is a summary of the key elements of the Regulatory Flexibility Analysis.

Throughout the negotiated rulemaking process, small systems were defined as those serving fewer than 10,000 persons. This definition was used because there is an existing SDWA standard of 0.10 mg/l for total trihalomethanes that applies only to systems serving at least 10,000 persons. Systems serving fewer than 10,000 persons are presently unregulated with respect to disinfection byproducts. There are, as a result, two different baseline conditions from which water systems will approach additional disinfection byproduct control. The major impact will be the requirement to install and operate water treatment equipment to meet specific standards of quality in the delivered water. These requirements pertain primarily to systems that actually treat water. Systems that purchase treated water from another source may see an increase in their wholesale costs, but a data base sufficient to track all the wholesale treated water transactions in the country does not exist. Impacts are therefore evaluated in terms of the systems that treat water. The data with which to characterize the capacities and flows of these facilities does exist and provides an adequate basis for assessing total capital and operating costs.

EPA estimates that there are a total of 76,051 community and nontransient noncommunity water systems that treat water. Of these, an estimated 73,336 (96%) serve fewer than 10,000 persons. Despite their overwhelming dominance in terms of industry structure, these systems provide water to only 22 percent of the total population served by public water supplies.

Of the total 68,171 small groundwater systems, it is estimated that 8,324 (12%) will have to modify treatment to comply with the Stage 1 proposal. The TWG forecast that 5,403 (8%) systems will comply with the very inexpensive technology of chloramines while 2,921 (4%) systems will require more expensive membrane treatment systems. Use of these technologies by small systems will result in total capital costs of $1.1 billion.

Of the total 5,165 small surface water systems, it is estimated that 3,611 (70%) will have to modify treatment to comply with the Stage 1 proposal. The TWG forecast that 3,318 (64%) systems will comply with cost effective combinations of enhanced coagulation, chloramines, and ozone. Another 293 (6%) systems will require more expensive membrane treatment systems. This will result in total capital costs of $0.6 billion.

EPA believes that the proposed rule could have a significant impact on a substantial number of small systems. Therefore, the Agency has attempted to provide less burdensome alternatives to achieve the rule's goals for small systems wherever possible. These considerations, discussed in greater detail in Section IX of this preamble and in the Regulatory Impact Analysis (USEPA, 1994), include:

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

(b) Reduced monitoring. There are reduced monitoring provisions for systems that meet specified prerequisites. EPA believes that many small systems will qualify for this reduced monitoring.

(c) Extended compliance dates. Systems that use only ground water not under the direct influence of surface water serving at least 10,000 people and Subpart H systems serving fewer than 10,000 people have 42 months from promulgation of this rule to comply. Systems that use only ground water not under the direct influence of surface water serving fewer than 10,000 people have 60 months from promulgation of this rule to comply. These staggered compliance dates will allow smaller systems to learn from the experience of larger systems on how to most cost effectively comply with the Stage 1 D/DBP rule. Larger systems will generate a significant amount of treatment and cost effectiveness data under the Information Collection Rule and in their efforts to achieve compliance with the Stage 1 requirements. EPA intends to summarize this information and make it available through guidance documents that will assist smaller systems in achieving compliance with both the Stage 1 D/DBP rule and long-term ESWTR.

The staggered compliance dates for smaller systems will also enable them to consider any new Stage 2 requirements, scheduled to be proposed in 1998, while achieving compliance with the Stage 1 requirements. The delayed compliance schedule should facilitate the selection of the most cost effective means for achieving compliance with both the Stage 1 and Stage 2 requirements.

(d) The Negotiating Committee considered other options for systems serving less than 10,000 people. These ranged from requiring smaller systems to meet the same compliance schedule as for larger systems to only extending the existing TTHM standard to systems serving less than 10,000 people. The Negotiating Committee rejected the former option for the above reasons and to enable the development of an ESWTR (i.e., the long-term ESWTR rather than the interim ESWTR) that would be more reasonable for smaller systems to comply with (see proposed ESWTR in today's **Federal Register**, and the proposed Information Collection Rule, 59 *FR* 6332; February 10, 1994). The Negotiating Committee rejected the latter option, over the objections of the National Rural Water Association, because it believed that all systems should be subject to the same level of protection. Also, setting only a TTHM standard in the absence of other criteria could lead to increased exposure from other DBPs that might pose greater health risks.

C. 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.* An Information Collection Request document has been prepared by EPA (ICR No. 270.33) and a copy may be obtained from Sandy Farmer, Information Policy Branch (MC:2136), EPA, 401 M Street SW., Washington, DC 20460, or by calling (202) 260–2740.

The reporting and recordkeeping burden for this proposed collection of information will be phased-in starting in 1997. The specific burden anticipated for each category of respondent, by year, is shown below:

1997

Public Water Systems—monitoring and reporting
Hours per respondent: 0
Total hours: 0
Public Water Systems—recordkeeping
Hours per respondent: 0
Total hours: 0
State Program Costs—reporting
Hours per respondent: 2,650
Total hours: 148,424
State Program Costs—recordkeeping
Hours per respondent: 1,500
Total hours: 84,000

1998

Public Water Systems—monitoring and reporting
Hours per respondent: 5.3
Total hours: 328,605
Public Water Systems—recordkeeping
Hours per respondent: .05
Total hours: 3,319
State Program Costs—reporting
Hours per respondent: 11,643
Total hours: 652,032
State Program Costs—recordkeeping
Hours per respondent: 600
Total hours: 33,640

1999

Public Water Systems—monitoring and reporting
Hours per respondent: 3.9
Total hours: 239,424
Public Water Systems—recordkeeping
Hours per respondent: .04
Total hours: 2,418
State Program Costs—reporting
Hours per respondent: 9,119
Total hours: 510,672
State Program Costs—recordkeeping
Hours per respondent: 0
Total hours: 0

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch (MC:2136), EPA, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, OPM, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in the proposal.

D. National Drinking Water Advisory Council and Science Advisory Board

In accordance with section 1412 (d) and (e) of the Act, the Agency has submitted this proposed rule to the Science Advisory Board, National Drinking Water Advisory Council (NDWAC), and the Secretary of Health and Human Services for their review. The Agency will take their comments into account in developing the final rule. NDWAC supported the use of regulatory negotiation to develop this rule.

XVII. Request for Public Comment

The proposed rule represents criteria that were agreed to be proposed by the Negotiating Committee. Part A of this Section lists the parts of the rule for which members of the Negotiating Committee, including EPA, requested comment. Part B of this Section lists the parts of the rule that pertain to small systems for which EPA requests public comments but which were not requested by Members of the Negotiating Committee. Members of the Negotiating Committee agreed not to file negative comments on the settled portions of the proposed rule or the preamble to the extent that they have the same substance and effect as the recommended rule and preamble. Each member of the Negotiating Committee may comment in support of the settled portions of the proposed rule. Each member of the Negotiating Committee may comment fully on or respond to comments solicited in the preamble or on issues that were not the subject of negotiations. The public at large is invited to comment on all aspects of the rule or preamble including the appropriateness of numerical criteria, monitoring requirements, and applicability. EPA will consider all public comments received in developing the final rule.

A. Request for Comment

Section V

The appropriateness of adopting the term "MRDLG" in lieu of MCLGs for disinfectants in the final rule.

—Any additional data on known concentrations of chlorine in drinking water, food, and air.
—The following issues concerning chlorine: placing chlorine in Category III for developing an MRDLG, selection of the specified study and NOAEL as the basis for the MRDLG, the 80% RSC, the appropriateness of the UF of 100, and the cancer classification for chlorine.
—Any additional data on known concentrations of chloramines in drinking water, food, and air.
—The following issues concerning chloramines: the proposed MRDLG for chloramines and the RSC of 80%, the significance of the findings of immunotoxicity for setting the RfD instead of the NTP study, the significance of the finding of mononuclear cell leukemia in female F344 rats, the significance of the finding of tubular cell neoplasms in high-dose exposed mice, and whether the adjusted MRDLG, which takes into account the measurement of monochloramine as total chlorine, is appropriate.
—The significance of the epidemiological studies with chlorine and chloramines as indicators of risk. EPA recognizes that there are different interpretations of these epidemiological studies and specifically solicits comment on the rationale for EPA's interpretations. EPA further requests comments on the studies suggesting a reproductive risk related to disinfectant byproduct exposure.

—Any additional data on known concentrations of chlorine dioxide, chlorate, and chlorite in drinking water, food, and air.
—For chlorine dioxide, the SAB's suggestion that a child's body weight of 10 kg and water consumption of 1 L/d may be more appropriate for setting the MRDLG than the adult parameters, given the acute nature of the toxic effect. EPA also requests comment on the appropriateness of the 300-fold uncertainty factor, the studies selected as the basis for the RfD, and the 80% relative source contribution.
—For chlorite, the SAB's suggestion that EPA consider basing the MCLG on the child body weight of 10 kg and water consumption of 1 L/day instead of the adult default values. EPA requests comments on the SAB's suggestion, along with the study selected as the basis for the MCLG, the uncertainty factor and the RSC of 80%.
—The decision not to propose an MCLG for chlorate at this time.
—Any additional data on known concentrations of chloroform in drinking water, food, and air.

The basis for the proposed MCLG for chloroform.

—Any additional data on known concentrations of BDCM in drinking water, food, and air.
—The basis of the proposed MCLG for BDCM and the use of tumor data of large intestine and kidney, but not liver, in quantitative estimation of carcinogenic risk of BDCM from oral exposure.
—Any additional data on known concentrations of DBCM in drinking water, food, and air.
—The basis for the proposed MCLG for DBCM, the RSC of 80%, and the cancer classification for DBCM.
—Any additional data on known concentrations of bromoform in drinking water, food, and air.
—The different viewpoints between IARC and EPA regarding bromoform's carcinogenic potential.
—The basis for the proposed MCLG for bromoform.
—Any additional data on known concentrations of DCA in drinking water, food, and air.
—The basis for the proposed MCLG for DCA in drinking water and the cancer classification of Group B2.
—Any additional data on known concentrations of TCA in drinking water, food, and air.
—The basis for the MCLG and the cancer classification for TCA.
—Any additional data on known concentrations of CH in drinking water, food, and air.
—For CH, the Category II approach for setting an MCLG, the extra safety factor of 1 instead of 10 for a Category II contaminant, and whether the endpoint of liver weight increase and hepatomegaly is a LOAEL or NOAEL given the lack of histopathology.
—Any additional data on known concentrations of bromate in drinking water, food, and air.
—The MCLG of zero for bromate based on carcinogenic weight of evidence and the mechanism of action for carcinogenicity related to DNA adduct.

Section VIII

—The timetable for promulgation of the final rule and the compliance dates therein.
—How monitoring and compliance requirements should be split among wholesalers and retailers of water. Does § 141.29 (consecutive systems) provide the State adequate flexibility and authority to address individual situations? Are any specific federal regulatory requirements necessary to handle such situations? If so, what are they?
—How the following situations should be handled in compliance determinations.
—When the monthly source water TOC is less than 2.0 mg/l and enhanced coagulation is not required.
—When seasonal variations cause the system to determine that TOC is not amenable to any level of enhanced coagulation and the system would be eligible for a waiver of enhanced coagulation requirements.

EPA believes that assigning a value of 1.00 for these months is a reasonable approach.

Section IX

—Whether exemptions to this rule should be granted if a system could demonstrate to the State, that due to unique water quality characteristics, it could not avoid through the use of BAT the possibility of increasing its total health risk by complying with the Stage 1 regulations. When might such situations occur? What specific conditions, if any, should be met for a system to be granted an exemption under such a provision. What provisions should EPA require of States to grant these exemptions? Should such exemptions be granted for a limited period but be renewable by the State if no new health risk information became available?
—Whether the TOC percent removal levels in Table IX–1 are representative of what 90 percent of systems required to use enhanced coagulation could be expected to achieve with elevated, but not unreasonable, coagulant addition.
—Whether filtration should be required as part of the bench-/pilot-scale procedure for determination of Step 2 enhanced coagulation. If so, what type of filter should be specified for bench-scale studies?
—Whether a slope of 0.3 mg/L of TOC removed per 10 mg/L of alum added should be considered representative of the point of diminishing returns for coagulant addition under Step 2. EPA also solicits comment on how the slope should be determined (e.g., point-to point, curve-fitting). If the slope varies above and below 0.3/10, where should the Step 2 alternate TOC removal requirement be set—at the first point below 0.3/10? At some other point?
—Whether any additional regulatory requirements, guidance, or explanation is required to define "multiple wells". EPA requests comment on whether there should be an upper limit of sampling frequency for systems that either cannot determine that they are drawing water from a single aquifer or are drawing water from multiple aquifers. For example, should a system that must draw water from many aquifers to satisfy demand be allowed to limit monitoring as if they were drawing from no more than four aquifers (routine sampling would thus be limited to four samples per quarter from systems serving at least 10,000 people or to four samples per year for systems serving fewer than 10,000 people)? Does EPA need to develop any additional guidance for any other aspect of this requirement?
—How often bench-or pilot-scale studies should be performed to determine compliance under step 2. Should such frequency of testing be included in the rule or left to guidance? Is quarterly monitoring appropriate for all systems? What is the best method to present the testing data to the primacy agency that reflects changing influent water quality conditions and also keeps transactional costs to a minimum? How should compliance be determined if the system is not initially meeting the percent TOC reduction required because of difficult to treat water and a desire to demonstrate alternative performance criteria?
—Whether data are available on the use of ferrous salts in the softening process which can help define a step 2 for enhanced softening. For softening plants, is enhanced

softening properly defined by the percent removals in Table IX–1 or by 10 mg/L removal of magnesium? Is there a step 2 definition? Can ferrous salts be used at softening pH levels to further enhance TOC removals?

—Whether preoxidation is necessary in water treatment to control water quality problems such as iron, manganese, sulfides, zebra mussels, Asiatic clams, taste and odor. Will allowing preoxidation before precursor removal by enhanced coagulation generate excessive DBP levels?

—Whether biologically active filtration following ozonation is sufficient to remove most byproducts believed to result from ozonation? What parameters should be measured in and/or out of the biologically active filter to demonstrate that ozone byproducts are being removed? For example, would it be sufficient to demonstrate greater than 90 percent removal of formaldehyde to establish that a filter is biologically active?

—Whether disinfection credit should be allowed for chlorine dioxide used prior to enhanced coagulation if virtually no halogenated organic DBPs are formed. Should some other limit, in addition to or in lieu of that proposed, be set (e.g., 5 µ/L TTHMs) on DBPs formed by high purity chlorine dioxide to ensure sufficient control for the production of excessive halogenated organic DBPs if disinfection credit were to be allowed with chlorine dioxide prior to enhanced coagulation?

—The appropriateness of allowing systems to add a disinfectant before enhanced coagulation when water temperatures are less than or equal to 5 °C if excessive DBPs are not produced or identification of alternative means for addressing this issue.

—Whether GAC10 and GAC20 reasonable definitions of GAC performance? Do they span the expected level of GAC applications in drinking water treatment for the control of TTHMs and THAAs? Is the Jefferson Parish, Louisiana TOC removal representative of the "general case" of TOC removal?

—Whether any Subpart H systems with a TOC >4.0 mg/l should be allowed to reduce monitoring? Under what conditions (e.g., system has installed nanofiltration)?

—Whether reduced monitoring for ground water systems serving fewer than 10,000 people could be expanded beyond what is in the proposal. The additional options presented below would rely on having each entry point of the system go through three years of routine monitoring to qualify for reduced monitoring. After this period, if the entry points meet additional criteria, then the entry points would be subject to minimal additional monitoring.

Option One: Any ground water system serving fewer than 10,000 people that has a raw water TOC of less than 1.0 mg/l, and has both TTHM and HAA5 values less than 25 percent of the MCLs (20 µg/l and 15 µg/l, respectively) after three years of routine and reduced monitoring, can reduce the monitoring for TTHMs and HAA5s to one sample every nine years, taken at the maximum distribution system residence time during the warmest month.

Option Two: Any ground water system serving fewer than 10,000 people that has a raw water TOC of less than 0.5 mg/l, and has both TTHM and HAA5 values less than 25 percent of the MCLs (20 µg/l and 15 µg/l, respectively) after three years of routine and reduced monitoring, is exempt from the distribution system monitoring requirements for TTHMs and HAA5s for as long as TOC monitoring is conducted once every three years and the raw water TOC remains less than 0.5 mg/l.

These options are not mutually exclusive, that is, both could be used simultaneously or some hybrid could be developed. The Agency seeks comment on whether either or both of these options are reasonable in adequately protecting the public health and should therefore be considered as criteria for reduced monitoring. Are there other options for reduced monitoring that should be considered? What are they?

—Comment on the cost impact of pH adjustment on systems with both high alkalinity and high bromide levels.

—Comment on the relative costs of adjusting pH to reduce bromate formation versus the costs of other technologies to meet the MCLs in this proposed rule.

—Whether the monitoring is frequent enough to adequately determine variations in sample results caused by time and/or location in the distribution system? If not, what is a more appropriate monitoring schedule? Should requirements differ for systems based on population served, raw water source, or other factors? If so, should the proposed requirements be changed? How should they be changed? If requirements should not be based on these factors, what should the requirements be? Does averaging of sample results taken in various locations over the course of a year to determine compliance adequately protect individuals that are in locations that may regularly have higher than average levels? If it does not, how should the proposed requirements be changed?

—Data to show that a lower quantitation level (at least down to 5 µg/L) can be obtained by those laboratories that will perform compliance monitoring for bromate in natural drinking water matrices. If the improved methodology uses equipment and/or reagents that are not currently required for EPA method 300.0, data to indicate the commercial availability and costs of these items would also need to be presented.

—A treatment technique that could ensure that bromate can be kept below 5 µg/L, even if quantitation at 5 µg/l is not achieveable under routine laboratory conditions.

—Other treatment techniques which allow ozone to meet disinfection and oxidation requirements while minimizing bromate formation.

—The feasibility of developing a treatment technique requirement for bromate, lowering the MCL based upon improved analytical techniques, and the time frame under which such alternative standards could be developed.

—The following approaches for promulgating a final rule for chlorite:

(1) An MCL at the MCLG.

(2) An MCL lower than the proposed MCL of 1.0 mg/l, but above the MCLG, depending upon all data that became available in the near term.

(3) Depending on new data that become available, EPA could promulgate an MCL at the proposed MCL of 1.0 mg/l if the Agency determined that the systems currently using chlorine dioxide could not meet disinfection requirements in any other feasible manner, taking cost into consideration.

—The approaches for regulating chlorite. Specifically, EPA requests comment on the following:

—Is the basis for EPA's MCLG and concern for acute health effects appropriate? See Section V. for a complete discussion.

—Are there any particular water quality characteristics for systems currently using chlorine dioxide which make it ineffective to use any other disinfection technology? What are the lowest chlorite levels these systems can achieve? What technologies would need to be adopted and at what costs if such systems with these particular water quality characteristics would no longer use

chlorine dioxide to meet the other regulatory criteria proposed herein?
—Should EPA set the chlorite MCL at a level so that chlorine dioxide remains a viable disinfection alternative for some systems even if this level is above the MCLG? If so, what would be the rationale for doing so?
—Is 1.0 mg/l the lowest level that systems needing chlorine dioxide can reliably achieve?
—How should EPA change the compliance monitoring requirements for chlorite to reflect concern about acute effects? Should such changes include increasing the frequency or changing the location of monitoring to be similar to those for chlorine dioxide? How would the MCL be affected by changes in the monitoring requirements?
—How should EPA change the public notification requirements for chlorite to reflect concern about acute effects?
—What level of residual chloramine would be feasible to achieve by most systems without increasing microbial risk.
—Information on improvements which may have been made to disinfectant methods to measure low concentrations of disinfectant residuals, but that are not reflected in the 18th edition of Standard Methods. EPA is also seeking information on new methodology that may be applicable for compliance monitoring.
—The technical adequacy of the analytical methods proposed for compliance with the proposed MRDLs.
—For bromate, whether use of a sample concentration technology prior to ion chromatographic analysis should be considered as a new methodolgy or a modification to Method 300.0 under today's rule. EPA also solicits comments on the applicability of sample concentration technology to today's proposed MCL for bromate.
—Data that demonstrate the need for a preservative in samples collected at the entrance point to the distribution system for measurement of bromate.
—The proposed turbidity threshold of 1 NTU to remove turbidity, which is known to interfere with accurate TOC measurement when the sample turbidity is greater than 1 NTU, and on the sample filtration procedure described in Section IX and in the proposed methods.
—What precision can be routinely expected on differential TOC measurements of jar test samples. EPA is also interested in new methods or modifications to the methods proposed today that would improve the reproducibility of TOC measurement.

Section X

—Other optional or mandatory performance criteria that EPA or the States should consider for certification of laboratories, or approval of analysts.

Section XI

—Whether exemptions to this rule should be granted if a system could demonstrate to the State, that due to unique water quality characteristics, it could not avoid through the use of BAT the possibility of increasing its total health risk by complying with the Stage 1 regulations. When might such situations occur? What specific conditions, if any, should be met for a system to be granted an exemption under such a provision. What provisions should EPA require of States to grant these exemptions? Should such exemptions be granted for a limited period but be renewable by the State if no new health risk information became available?

Section XII

—The proposed State reporting requirements. EPA particularly requests comment from the States on whether the proposed reporting requirements are reasonable.
—Whether the State should be required to keep the monitoring plan on file at the State after submission to make it available for public review?

Section XIV

—The proposed public notification rule language. Of particular interest is the acute violation language in § 141.32(e)(85) for violations of the chlorine dioxide MCL. Also of interest is the language in § 141.32(e)(86) for violations of the TTHM and HAA5 MCLs and the enhanced coagulation treatment technique requirement.

Section XV

—Data and comment on the extent to which reductions in exposure to TTHMs and DBPs can be expected to differ between systems serving 10,000 people or more and systems serving less than 10,000 people.

Section XVI

—The burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden.

B. Request for Additional Public Comments by EPA

The Negotiating Committee considered several regulatory options for systems serving less than 10,000 people. These ranged from requiring smaller systems to meet the same compliance schedule as for larger systems to only extending the existing TTHM standard to systems serving less than 10,000 people. The Negotiating Committee rejected the former option for reasons discussed in Section XVI of this preamble. The Negotiating Committee rejected the latter option, over the objections of the National Rural Water Association (which was initially represented on the Negotiating Committee but then withdrew from the negotiations), because it believed that all systems should be subject to the same level of protection. Also, setting only a TTHM standard in the absence of other criteria could lead to increased exposure from other DBPs that might pose greater health risks.

EPA recognizes that several factors still make it significantly more difficult for smaller systems than larger systems to achieve compliance with the Stage 1 requirements. Because the larger systems already have substantial experience with lowering TTHM levels, they will be more familiar than smaller systems with available technologies and operating conditions for lowering DBP levels. Because of economies of scale, the costs for systems to achieve the same incremental reduction in DBPs is substantially greater in smaller systems than in larger systems. For about 4% of systems serving less than 3,300 people (and less than 1% of the U.S. population receiving public drinking water), costs for compliance are estimated to be about $300 per household per year. For these reasons, EPA remains concerned about the ability of small communities to afford compliance and is interested in comments on this issue as well. Specifically, EPA is interested in further comment on alternative regulatory approaches for various small and medium system sizes.

The parties reached consensus on the approach for staggered compliance schedules for systems serving fewer than 10,000 people (i.e., June 2000 for systems using surface water and ground water under the direct influence of surface water that serve fewer than 10,000 people and January 2002 for ground water systems serving fewer than 10,000 people). EPA is interested in comments on these important issues. Again, EPA recognizes the problems faced by small- and medium-sized systems and is interested in further comment on alternative compliance approaches and possible solutions for various small and medium system sizes (e.g., <1,000; 1,000–3,300; >3,300–10,000).

Because of the Agency's commitment to develop rules based on the best reasonably available scientific data, EPA intends to conduct research on the best way to reduce exposure from both DBPs and pathogens in small systems cost effectively. Based on information collected under the ICR, EPA intends to also refine models to more accurately predict occurrence of DBPs as a function of different treatment technologies, including those used by small systems. EPA intends to use available data in refining its estimates and solicits additional data on the occurrence of DBPs in drinking water systems, the concentration of pathogens in source water, and the effectiveness of treatment on microbial contaminants, especially for smaller systems. Also, as part of the major research effort leading to negotiation of the Stage 2 D/DBP rule, EPA intends to investigate technologies to determine whether small systems will be able to comply with D/DBP regulations at lower costs in future years.

XVIII. References and Public Docket

References in this section are organized by type. Subsection A lists Federal Register references. Subsection B lists analytical method references. Subsection C lists health criteria document references. Subsection D lists other references.

A. Federal Register References

1. U.S. Environmental Protection Agency. National Interim Primary Drinking Water Regulations; Control of Trihalomethanes in Drinking Water. Vol. 44, No. 231. November 29, 1979. pp. 68624–68707.

2. U.S. Environmental Protection Agency. National Revised Primary Drinking Water Regulations, Volatile Synthetic Organic Chemicals in Drinking Water; Advanced Notice of Proposed Rulemaking. Vol. 47, No. 43, Thursday, Mar. 4, 1982—Part IV. pp. 9350–9358.

3. U.S. Environmental Protection Agency. National Interim Primary Drinking Water Regulations; Trihalomethanes. Vol. 48, No. 40. Monday, Feb. 28, 1983. pp. 8406–8414.

4. U.S. Environmental Protection Agency. National Primary Drinking Water Regulations; Synthetic Organic Chemicals, Inorganic Chemicals and Microorganisms: Proposed Rule. Vol. 50, No. 219. Wednesday, Nov. 13, 1985—Part IV. pp. 46936–47025.

5. U.S. Environmental Protection Agency. National Primary Drinking Water Regulations—Synthetic Organic Chemicals; Monitoring for Unregulated Contaminants; Final Rule. Vol. 52, No. 130. July 8, 1987—Part II. pp. 25690–25717.

6. Federal Register. U.S. Environmental Protection Agency. Drinking Water Regulations; Public Notification; Final Rule. Vol. 52, No. 208. Wednesday, Oct. 28, 1987—Part II. pp. 41534–41550.

7. U.S. Environmental Protection Agency. National Primary Drinking Water Regulations. Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper. Vol. 53, No. 160. Thursday, Aug. 18, 1988. pp. 31516–31578.

8. U.S. Environmental Protection Agency. National Primary and Secondary Drinking Water Regulations; Proposed Rule. Vol. 54, No. 97. Monday, May 22, 1989. pp. 22062–22160.

9. U.S. Environmental Protection Agency. Drinking Water; National Primary Drinking Water Regulations; Filtration, Disinfection; Turbidity, *Giardia lamblia*, Viruses, *Legionella*, and Heterotrophic Bacteria; Final Rule. Part II. Vol. 54, No. 124. Thursday, June 29, 1989. pp. 27486–27541.

10. U.S. Environmental Protection Agency. National Primary Drinking Water Regulations; Synthetic Organic Chemicals and Inorganic Chemicals; Proposed Rule. Vol. 55, No. 143. Wednesday, July 25, 1990—Part II. pp. 30370–30448.

11. U.S. Environmental Protection Agency. Notice of Availability of Proposed Guidance for Determining Unreasonable Risk to Health. Vol. 55, No. 191. Tuesday, Oct. 2, 1990. p. 40205.

12. U.S. Environmental Protection Agency National Primary Drinking Water Regulations: Lead and Copper. Notice of Availability with Request for Comments. Vol. 55, No. 203. Friday, Oct. 19, 1990. pp.42409–42413.

13. U.S. Environmental Protection Agency. National Revised Primary Drinking Water Regulations—Synthetic Organic Chemicals and Inorganic Chemicals; Monitoring for Unregulated Contaminants; National Primary Drinking Water Regulations Implementation; National Secondary Drinking Water Regulations. Vol. 56, No. 20. Wednesday, Jan. 30, 1991. pp. 3526–3597.

14. U.S. Environmental Protection Agency. National Primary and Secondary Drinking Water Regulations; Synthetic Organic Chemicals and Inorganic Chemicals; Final Rule. Vol. 57, No. 138. Friday, July 17, 1992—Part III. pp. 31776–31849.

15. U.S. Environmental Protection Agency. Intent to Form an Advisory Committee to negotiate the Drinking Water Disinfection By-Products Rule and Announcement of Public Meeting. Vol. 57, No. 179. September 15, 1992. pp. 42533–42536.

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List of Subjects

40 CFR Part 141

Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Adminstrative practice and procedure, Reporting and recordkeeping requirements, Water supply.

Dated: June 7, 1994.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, chapter I of title 40 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 and 300j–9.

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

Note: The definition for "subpart H systems" has been proposed (59 FR 6332, February 10, 1994) and is included in this proposal for the convenience of the reader.

§ 141.2 Definitions.

* * * * *

Biologically active filtration (BAF) means conventional filtration treatment or direct filtration preceded by continuous application of ozone (in possible combination with hydrogen peroxide), but no other continuous chemical disinfectant, utilizing filtration media and rate (i.e., empty bed contact time) sufficient to remove substantial levels of biodegradeable ozone byproducts.

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

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

* * * * *

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

GAC20 means granular activated carbon filter beds with an empty-bed contact time of 20 minutes based on average daily flow and a carbon reactivation frequency of every 60 days.

* * * * *

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

* * * * *

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

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

* * * * *

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

* * * * *

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

* * * * *

3. Subpart B is amended by revising § 141.12 to read as follows:

§ 141.12 Maximum contaminant levels for total trihalomethanes.

The maximum contaminant level of 0.10 mg/l for total trihalomethanes (the sum of the concentrations of bromodichloromethane, dibromochloromethane, tribromomethane (bromoform), and trichloromethane (chloroform)) applies to Subpart H community water systems which serve a population of 10,000 people or more until [insert date 18 months after date of publication of the final rule in the **Federal Register**]. This level applies to community water systems that use only ground water not under the direct influence of surface water and serve a population of 10,000 people or more until [insert date 42 months after date of publication of the final rule in the **Federal Register**]. Compliance with the maximum contaminant level for total trihalomethanes is calculated pursuant to § 141.30. After [insert date 42 months after date of publication of the final rule in the **Federal Register**], this section expires.

4. Section 141.30 is amended by adding paragraph (g) to read as follows:

§ 141.30 Total trihalomethanes sampling, analytical and other requirements.

* * * * *

(g) The requirements in paragraphs (a) through (f) of this section apply to Subpart H community water systems which serve a population of 10,000 or more until [insert date 18 months after date of publication of the final rule in the **Federal Register**]. The requirements in paragraphs (a) through (f) of this section apply to community water systems which use only ground water not under the direct influence of surface water that add a disinfectant (oxidant) in any part of the treatment process and serve a population of 10,000 or more until [insert date 42 months after date of publication of the final rule in the **Federal Register**]. After [insert date 42 months after date of publication of the final rule in the **Federal Register**], this section and Appendix A (Summary of Public Comments and EPA responses on Proposed Amendments to the National Interim Primary drinking Water Regulations for Control of Trihalomethanes in Drinking Water), Appendix B (Summary of Major Comments), and Appendix C (Analysis of Trihalomethanes) of this part expire.

5. Section 141.32 is amended by revising paragraph (a) introductory text; removing the word "MCLs" and adding, in its place, the words "MCLs and MRDL(s)" in paragraph (a)(1)(iii); removing the words "maximum contaminant level" and adding, in its place, the words "maximum contaminant level and maximum residual disinfectant level" in paragraph (c); and adding paragraphs (a)(1)(iii)(E) and (e)(83) through (88) to read as follows:

Subpart D—Reporting, Public Notification and Recordkeeping

§ 141.32 Public notification.

* * * * *

(a) *Maximum Contaminant Levels (MCLs), Maximum Residual Disinfectant Levels (MRDLs), treatment technique, and variance and exemption schedule violations.* The owner or operator of a public water system which fails to comply with an applicable MCL, MRDL, or treatment technique established by this part or which fails to comply with the requirements of any schedule prescribed pursuant to a variance or exemption, shall notify persons served by the system as follows:

(1) * * *

(iii) * * *

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

* * * * *

(e) * * *

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

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

(85) *Chlorine dioxide.* The United States Environmental Protection Agency (EPA) sets drinking water standards and requires disinfection of drinking water. The Safe Drinking Water Act also requires disinfection of all public water systems. Chlorine dioxide is used in water treatment to kill bacteria and other disease-causing microorganisms and can be used to control tastes and odors. However, at high doses, chlorine dioxide in drinking water has been shown to damage blood in laboratory animals. Also, high levels of chlorine dioxide given to pregnant laboratory animals in drinking water have been shown to cause delays in development of the nervous system of their offspring. These effects may occur as a result of a short term exposure to excessive chlorine dioxide levels. To protect against such potentially harmful exposures, EPA requires chlorine dioxide monitoring at the treatment plant, where disinfection occurs, and at representative points in the distribution system serving water users. EPA has set a drinking water standard for chlorine dioxide to protect against the risk of these adverse effects.

Note: In addition to paragraph (e)(85) of this section, systems must include either paragraph (e)(85)(i) or paragraph (e)(85)(ii) of this section. Systems with a violation at the treatment plant, but not in the distribution system, are required to use the language in paragraph (e)(85)(i) of this section and treat the violation as a nonacute violation. Systems with a violation at the treatment plant and in the distribution system are required to use the language in paragraph (e)(85)(ii) of this section and treat the violation as an acute violation.

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

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

(86) *Disinfection byproducts and treatment technique for DBPs.* The United States Environmental Protection Agency (EPA) sets drinking water standards and requires the disinfection of drinking water. The Safe Drinking Water Act also requires disinfection for all public water systems. However, when used in the treatment of drinking water, disinfectants combine with

organic and inorganic matter present in water to form chemicals called disinfection byproducts (DBPS). EPA has determined that a number of DBPs are a health concern at certain levels of exposure. Certain DBPs, including some trihalomethanes (THMs) and some haloacetic acids (HAAs), have been shown to cause cancer in rats. Other DBPs have been shown to damage the liver and the nervous system, and cause reproductive or developmental effects in laboratory animals. There is also some evidence that exposure to certain DBPs may produce adverse effects in people. EPA has set standards to limit exposure to THMs, HAAs, and other DBPs.

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

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

Subpart F—Maximum Contaminant Level Goals

6. Subpart F is amended by adding new §§ 141.53 and 141.54 to read as follows:

§ 141.53 Maximum contaminant level goals for disinfection byproducts.

(a) MCLGs are zero for the following contaminants:

(1) Chloroform;
(2) Bromodichloromethane;
(3) Bromoform;
(4) Bromate; and
(5) Dichloroacetic acid.

(b) MCLGs for the following contaminants are as indicated:

Contaminant	MCLG (mg/l)
Chloral hydrate	0.04
Chlorite	0.08
Dibromochloromethane	0.06
Trichloroacetic acid	0.3

§ 141.54 Maximum residual disinfectant level goals for disinfectants.

The MRDLGs for disinfectants are as follows:

Disinfectant residual	MRDLG (mg/l)
Chloramines	4 (as Cl_2)
Chlorine	4 (as Cl_2)
Chlorine dioxide	0.3 (as ClO_2)

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

7. Subpart G is amended by adding §§ 141.64 and 141.65 to read as follows:

§ 141.64 Maximum contaminant levels for disinfection byproducts.

(a) The following Maximum Contaminant Levels (MCLs) for disinfection byproducts apply to community water systems and nontransient, noncommunity water systems; compliance dates are indicated in paragraph (d)(1) of this section:

Contaminant	MCL (mg/l)
Bromate	0.010
Chlorite	1.0
Haloacetic acids (five) (HAA5)	0.060
Total trihalomethanes (TTHM)	0.080

(b)(1) For Subpart H systems that serve more than 10,000 people, the HAA5 and TTHM MCLs (the Stage 1 MCLs) in paragraph (a) of this section will be superseded by the MCLs (the Stage 2 MCLs) in paragraph (b) of this section 18 months after publication of the final MCLs in paragraph (b) of this section in the **Federal Register** with compliance as indicated in paragraph (d)(2) of this section. The MCLs in paragraph (a) of this section continue to apply for all other systems.

Contaminant	MCL (mg/l)
Haloacetic acids (five)	0.030
Total trihalomethanes	0.040

(2) Prior to the publication of the final MCLs in paragraph (b) of this section in the **Federal Register**, the Administrator shall conduct a second regulatory negotiation or similar proceeding intended to develop a consensus rulemaking through negotiation to review these levels. The Administrator shall provide notice to the public of the availability of the monitoring data collected in accordance with §§ 141.140 through 141.142 and the results of health effects research relating to disinfectants and disinfection byproducts completed during the period 1994–1996. Thereafter, the Agency shall initiate the second regulatory negotiation or similar proceeding to ensure that the affected interests that participated in the 1993 negotiated rulemaking participate fully with the Agency in the evaluation of the proposed Stage 2 MCLs in light of the monitoring data, health effects research, and other information developed since the proposal of the Stage 2 MCLs. If the second negotiated rulemaking or similar proceeding produces a consensus among the affected interests, the Agency will proceed in accordance with that consensus. The Agency agrees to take action on the proposed Stage 2 MCLs by December 31, 1998, and to publish notice of that action in the **Federal Register**. If data prior to this second rulemaking warrants earlier action on acute health effects, a meeting shall be convened to review the results of these data and to develop recommendations.

(c)(1) The Administrator, pursuant to Section 1412 of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for disinfection byproducts identified in paragraph (a) of this section:

Disinfection byproduct	Best available technology (stage 1)
TTHMs	Enhanced coagulation or enhanced softening or GAC10, with chlorine as the primary and residual disinfectant.
HAA5	Enhanced coagulation or enhanced softening or GAC10, with chlorine as the primary and residual disinfectant.
Bromate.	Control of ozone treatment process to reduce production of bromate.
Chlorite	Control of treatment processes to reduce disinfectant demand and control of disinfection treatment processes to reduce disinfectant levels.

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

Disinfection byproduct	Best available technology (stage 2)
TTHMs	Enhanced coagulation or enhanced softening, and GAC10; or GAC20; with chlorine as the primary and residual disinfectant.
HAA5 .	Enhanced coagulation or enhanced softening, and GAC10; or GAC20; with chlorine as the primary and residual disinfectant.

(d) Compliance dates for community water systems and nontransient noncommunity water systems. (1) Compliance with the MCLs in paragraph (a) of this section. Subpart H systems serving 10,000 or more persons must comply with the MCLs contained in paragraph (a) of this section beginning [insert date 18 months after date of publication of the final rule in the **Federal Register**]. Subpart H systems serving fewer than 10,000 persons or systems using only ground water not under the direct influence of surface water serving 10,000 or more persons must comply with the MCLs in paragraph (a) of this section beginning [insert date 42 months after date of publication of the final rule in the **Federal Register**]. Systems using only ground water not under the direct influence of surface water serving fewer than 10,000 persons must comply with paragraph (a) of this section beginning [insert date 60 months after date of publication of the final rule in the **Federal Register**].

(2) Compliance with the MCLs in paragraph (b) of this section. Subpart H systems serving 10,000 or more persons must comply with the listed MCLs or alternative requirements as developed under the negotiated rulemaking or similar process contained in paragraph (b) of this section beginning 18 months after date of publication of the final MCLs in paragraph (b) of this section in the **Federal Register**.

(3) A system that is installing GAC or membrane technology to comply with this section may apply to the State for an extension of up to 42 months past the dates in paragraphs (d) (1) or (2) of this section, but not to exceed 60 months from the date of publication of the final rule in the **Federal Register**. In granting the extension, States must set a schedule for compliance and may specify any interim measures that the system must take. Failure to meet the schedule or interim treatment requirements constitutes a violation of National Primary Drinking Water Regulations.

§ 141.65 Maximum residual disinfectant levels.

(a) The maximum residual disinfectant levels (MRDLs) are as follows:

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

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

(c) Compliance dates. (1) CWSs and NTNCWSs. Subpart H systems serving 10,000 or more persons must comply with this section beginning [insert date 18 months after date of publication of the final rule in the **Federal Register**]. Subpart H systems serving fewer than 10,000 persons or systems using only ground water not under the direct influence of surface water serving 10,000 or more persons must comply with this subpart beginning [insert date 42 months after date of publication of the final rule in the **Federal Register**]. Systems using only ground water not under the direct influence of surface water and serving fewer than 10,000 persons must comply with this subpart beginning [insert date 60 months after date of publication of the final rule in the **Federal Register**].

(2) *Transient NCWSs.* Subpart H systems serving 10,000 or more persons and using chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning [insert date 18 months after date of publication of the final rule in the **Federal Register**]. Subpart H systems serving fewer than 10,000 persons and using chlorine dioxide as a disinfectant or oxidant or systems using only ground water not under the direct influence of surface water serving 10,000 or more persons and using chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning [insert date 42 months after date of publication of the final rule in the **Federal Register**]. Systems using only ground water not under the direct influence of surface water and serving fewer than 10,000 persons and using chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning [insert date 60 months after date of publication of the final rule in the **Federal Register**].

8. A new Subpart L is proposed to be added to read as follows:.

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

Sec.

141.130 General requirements.
141.131–141.132 [Reserved]
141.133 Analytical and monitoring requirements.
141.134 Reporting and recordkeeping requirements.
141.135 Treatment technique for control of Disinfection Byproduct Precursors (DBP).

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

§ 141.130 General requirements.

(a) The requirements of this subpart L constitute national primary drinking water regulations. Subpart L of this part establishes criteria under which community water systems (CWSs) and nontransient, noncommunity water systems (NTNCWSs) which add a chemical disinfectant to the water in any part of the drinking water treatment process must modify their practices to meet MCLs and MRDLs in §§ 141.64 and 141.65 and must meet the treatment technique requirements for disinfection byproduct precursors in § 141.135. In addition, subpart L of this part establishes criteria under which transient NCWSs that use chlorine dioxide as a disinfectant or oxidant must modify their practices to meet the MRDL for chlorine dioxide in § 141.65. MCLs for TTHMs and HAA5 and treatment technique requirements for disinfection byproduct precursors are established to limit the levels of known and unknown disinfection byproducts which may have adverse health effects. These disinfection byproducts may include chloroform; bromodichloromethane; dibromochloromethane; bromoform; dichloroacetic acid; trichloroacetic acid; and chloral hydrate (trichloroacetaldehyde).

(b) Compliance dates. (1) CWSs and NTNCWSs. Unless otherwise noted, compliance with the requirements of this subpart shall begin as follows: Subpart H systems serving 10,000 or more persons must comply with this subpart beginning [insert date 18 months after date of publication of the final rule in the **Federal Register**]. Subpart H systems serving fewer than 10,000 persons or systems using only

ground water not under the direct influence of surface water serving 10,000 or more persons must comply with this subpart beginning [insert date 42 months after date of publication of the final rule in the **Federal Register**]. Systems using only ground water not under the direct influence of surface water serving fewer than 10,000 persons must comply with this subpart beginning [insert date 60 months after date of publication of the final rule in the **Federal Register**].

(2) Transient NCWSs. Subpart H systems serving 10,000 or more persons and using chlorine dioxide as a disinfectant or oxidant must comply with any requirements for chlorine dioxide in this subpart beginning [insert date 18 months after date of publication of the final rule in the **Federal Register**]. Subpart H systems serving fewer than 10,000 persons and using chlorine dioxide as a disinfectant or oxidant or systems using only ground water not under the direct influence of surface water serving 10,000 or more persons and using chlorine dioxide as a disinfectant or oxidant must comply with any requirements for chlorine dioxide in this subpart beginning [insert date 42 months after date of publication of the final rule in the **Federal Register**]. Systems using only ground water not under the direct influence of surface water and serving fewer than 10,000 persons and using chlorine dioxide as a disinfectant or oxidant must comply with any requirements for chlorine dioxide in this subpart beginning [insert date 60 months after date of publication of the final rule in the **Federal Register**].

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

(d) Control of Disinfection Byproducts. (1) All CWS and NTNCWS must comply with MCLs in § 141.64.

(2) All CWS and NTNCWS must comply with monitoring requirements in § 141.133.

(e) Control of Disinfectant Residuals. (1) All CWS and NTNCWS must comply with MRDLs in § 141.65. All transient NCWSs that use chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL in § 141.65.

(2) All CWS and NTNCWS must comply with monitoring requirements in § 141.133. All transient NCWSs that use chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide monitoring requirements in § 141.133.

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

§§ 141.131–141.132 [Reserved]

§ 141.133 Analytical and monitoring requirements.

(a) Analytical Requirements. Only the analytical method(s) specified in this paragraph (a), or otherwise approved by EPA, may be used to demonstrate compliance with the requirements of this subpart. These methods are effective for compliance monitoring [insert date 30 days after date of publication of the final rule in the **Federal Register**].

(1) Disinfection Byproducts. (i) Disinfection byproducts must be measured by the methods listed below:

Approved Methods for Disinfection Byproduct Compliance Monitoring

Byproduct measured[1]	Methodology[2]				
	EPA method[3]	TTHMs[4]	HAA5[5]	Chlorite	Bromate
P&T/GC/EICD & PID	502.2[6]	X			
P&T/GC/MS	524.2	X			
LLE/GC/ECD	551	X			
LLE/GC/ECD	[7]6233 B	.....	X		
SPE/GC/ECD	552.1	.....	X		
IC	300.0	.....	.....	X	X

[1] X indicates method is approved for measuring specified disinfection byproduct.
[2] P&T=purge and trap; GC=gas chromatography; EICD=electrolytic conductivity detector; PID=photoionization detector; MS=mass spectrometer; LLE=liquid/liquid extraction; ECD=electron capture detector; SPE=solid phase extractor; IC=ion chromatography
[3] As set forth in Methods for the Determination of Organic Compounds in Drinking Water, USEPA, 1988 (revised July 1991) (available through National Technical Information Service (NTIS), EPA/600/4–88/039, PB91–231480) for Method 502.2; Methods for the Determination of Organic Compounds in Drinking Water-Supplement II, USEPA, 1992, (available through NTIS, EPA/600/R–92/129, PB92–207703), for Methods 524.2 and 552.1; Methods for the Determination of Organic Compounds in Drinking Water-Supplement I, USEPA, July 1990 (available through National Technical Information Service (NTIS), EPA/600/4–90/020, PB91–146027) for Method 551; and Methods for the Determination of Inorganic Substances in Environmental Samples, EPA/600/R/93/100—August 1993 for Method 300.0.
[4] Total trihalomethanes.
[5] Total haloacetic acids.
[6] If TTHMs are the only analytes being measured in the sample, then a PID is not required.
[7] Method 6233 B, as set forth in Standard Methods for the Examination of Water and Wastewater, 1992 (18th Ed.), American Public Health Association et al.

(ii) Analysis under this section for disinfection byproducts shall be conducted by laboratories that have received certification by EPA or the State after meeting the following conditions. To receive certification to conduct analyses for the contaminants in § 141.64(a) (1) through (4), the laboratory must: annually analyze performance evaluation (PE) samples provided by EPA Environmental Monitoring Systems Laboratory or equivalent State samples, and achieve quantitative results on a minimum of 80% of the analytes included in each PE sample. The acceptance limit is defined as the 95% confidence interval calculated around the mean of the PE study data between a maximum and minimum acceptance limit of +/−50% and +/−15% of the study mean.

(2)(i) Disinfectant Residuals. Residual disinfectant concentrations for free chlorine, combined chlorine (chloramines), and chlorine dioxide must be measured by the methods listed below:

APPROVED METHODS FOR DISINFECTANT RESIDUAL COMPLIANCE MONITORING

Methodology	Residual measured[1]				
	Standard method[2]	Free chlorine	Combined chlorine	Total chlorine	Chlorine dioxide
Amperometric Titration	4500–Cl D	X	X	X	.....
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 H	X	.....	.....	.....
Iodometric Electrode	4500–Cl I	.....	.....	X	.....
Amperometric Titration	4500–ClO_2 C	.....	.....	.....	X
DPD Method	4500–ClO_2 D	.....	.....	.....	X
Amperometric Titration (proposed)	4500–ClO_2 E	.....	.....	.....	X

[1] X indicates method is approved for measuring specified disinfectant residual.
[2] As set forth in Standard Methods for the Examination of Water and Wastewater, 1992 (18th Ed.), American Public Health Association et al.

(ii) Residual disinfectant concentrations for chlorine and chloramines may also be measured by using DPD colorimetric test kits if approved by the State. Measurement for residual disinfectant concentration must be conducted by a party approved by EPA or the State.

(3) *Additional Analytical Methods.* Systems required to analyze parameters not included in paragraphs (a)(1) and (2) of this section shall use the following methods. Measurement for these parameters must be conducted by a party approved by EPA or the State.

(i) Alkalinity. All methods allowed in § 141.89(a) for measuring alkalinity.

(ii) Bromide. EPA method 300.0.

(iii) Total Organic Carbon-Method 5310 C (Persulfate-ultraviolet Oxidation Method) or Method 5310 D (Wet-oxidation Method) as set forth in *Standard Methods for the Examination of Water and Wastewater*, 1992 (18th Ed.), American Public Health Association et al. Samples shall not be filtered prior to this analysis. For compliance monitoring, TOC and not dissolved organic carbon (DOC) data are required.

(b) Routine monitoring requirements for disinfection byproducts, disinfectant residuals, and total organic carbon. All samples must be taken during normal operating conditions. Failure to monitor in accordance with the monitoring plan required under the provisions of § 141.133(d) is a monitoring violation. Where compliance is based on a running annual average of monthly or quarterly samples or averages and the system's failure to monitor makes it impossible to determine compliance with MCLs or MRDLs, this failure to monitor will be treated as a violation for the entire period covered by the annual average.

(1) Disinfection byproducts. (i) TTHMs and HAA5. (A) Subpart H systems serving 10,000 or more persons shall take four water samples each quarter for each treatment plant in the system. At least 25 percent of all samples collected each quarter, including those samples taken in excess of the required frequency, shall be taken at locations within the distribution system that represent the maximum residence time of the water in the system. The remaining samples shall be taken at locations within the distribution system that represent the entire system, taking into account the number of persons served, different sources of water, and different treatment methods employed.

(B) Systems using only ground water sources not under the direct influence of surface water that use a chemical disinfectant and serve 10,000 or more persons shall take one water sample each quarter for each treatment plant in the system. Samples shall be taken at locations within the distribution system that represent the maximum residence time of the water in the system. At least 25 percent of all samples collected each quarter, if samples are taken in excess of the required frequency, shall be taken at locations within the distribution system that represent the maximum residence time of the water in the system. The remaining samples must be taken at locations representative of at least average residence time in the distribution system. Multiple wells within a system drawing water from a single aquifer shall, with State approval in accordance with criteria developed under § 142.16(f)(6), be considered one treatment plant for determining the minimum number of samples required.

(C) Subpart H systems serving from 500 to 9,999 persons shall take one water sample each quarter for each treatment plant in the system. Samples shall be taken at a point in the distribution system that represents the maximum residence time in the distribution system. At least 25 percent of all samples collected each quarter, if samples are taken in excess of the required frequency, shall be taken at locations within the distribution system that represent the maximum residence time of the water in the system. The remaining samples must be taken at locations representative of at least average residence time in the distribution system.

(D) Subpart H systems serving fewer than 500 persons shall take one sample per year for each treatment plant in the system. Samples shall be taken at a point in the distribution system reflecting the maximum residence time in the distribution system and during the month of warmest water temperature. If the sample (or average of the annual samples, if more than one sample is taken) exceeds the MCL, the system must increase monitoring to one sample per treatment plant per quarter, taken at a point in the distribution system reflecting the maximum residence time in the distribution system, until the system meets criteria in paragraph (c) of this section for reduced monitoring.

(E) Systems using only ground water sources not under the direct influence of surface water that use a chemical disinfectant and serve less than 10,000 persons shall sample once per year for each treatment plant in the system. Samples shall be taken at a point in the distribution system reflecting the maximum residence time in the distribution system and during the month of warmest water temperature. If the sample (or the average of the annual samples, when more than one sample is taken) exceeds the MCL, the system must increase monitoring to one sample per treatment plant per quarter, taken at a point in the distribution system reflecting the maximum residence time in the distribution system, until the system meets criteria in paragraph (c) of this section for reduced sampling.

Multiple wells drawing water from a single aquifer shall, with State approval in accordance with criteria developed under § 142.16(f)(6), be considered one treatment plant for determining the minimum number of samples required.

(ii) Chlorite. Community and nontransient noncommunity water systems using chlorine dioxide, for disinfection or oxidation, shall take three samples each month in the distribution system. One sample must be taken at each of the following locations: near the first customer, in a location representative of average residence time, and near the end of the distribution system (reflecting maximum residence time in the distribution system). Any additional sampling must be conducted in the same manner (i.e., three-sample sets, at the specified locations).

(iii) Bromate. Community and nontransient noncommunity systems using ozone, for disinfection or oxidation, shall take one sample per month for each treatment plant in the system using ozone. Samples must be taken monthly at the entrance to the distribution system while the ozonation system is operating under normal conditions.

(iv) Compliance. (A) TTHMs and HAA5. For systems monitoring quarterly, compliance with MCLs in § 141.64 shall be based on a running annual arithmetic average, computed quarterly, of quarterly arithmetic averages of all samples collected by the system as prescribed by this section under paragraphs (b)(1)(i)(A), (B), and (C) of this section. If the arithmetic average of quarterly averages covering any consecutive four-quarter period exceeds the MCL, the supplier of water shall report to the State pursuant to § 141.134 and notify the public pursuant to § 141.32. Systems on a reduced monitoring schedule whose annual average exceeds the MCL will revert to routine monitoring immediately. For systems monitoring less frequently than quarterly, compliance shall be based on an average of samples taken that year under the provisions of § 141.133(b)(1)(i)(D) through (E) or § 141.133(c)(1)(iii)(C). If the average of these samples exceeds the MCL, the system must increase monitoring to once per quarter per treatment plant. All samples taken and analyzed under the provisions of this section must be included in determining compliance, even if that number is greater than the minimum required. If, during the first year following the effective date, any individual quarter's average will cause the running annual average of that system to exceed the MCL, the system is out of compliance at the end of that quarter.

(B) Bromate. Compliance shall be based on a running annual arithmetic average, computed quarterly, of monthly samples (or, for months in which the system takes more than one sample, the average of all samples taken during the month) collected by the system as prescribed by paragraph (b)(1)(iii) of this section. If the average of samples covering any consecutive four-quarter period exceeds the MCL, the system shall report to the State pursuant to § 141.134 and notify the public pursuant to § 141.32. If a PWS fails to complete 12 consecutive months' monitoring, compliance with the MCL for the last four-quarter compliance period shall be based on an average of the available data.

(C) Chlorite. Compliance shall be based on a monthly arithmetic average of samples as prescribed by paragraph (b)(1)(ii) of this section. If the arithmetic average of samples covering any month exceeds the MCL, the system shall report to the State pursuant to § 141.134 and notify the public pursuant to § 141.32.

(2) Disinfectant residuals. (i) Chlorine and chloramines. (A) Subpart H systems must measure the residual disinfectant level at the same points in the distribution system and at the same time as total coliforms are sampled, as specified in § 141.21. Systems may use the results of residual disinfectant concentration sampling conducted under § 141.74(b)(6)(i) for unfiltered systems or § 141.74(c)(3)(i) for systems which filter, in lieu of taking separate samples.

(B) Community and nontransient noncommunity systems using only ground water not under the direct influence of surface water must measure the residual disinfectant level at the same points in the distribution system and at the same time as total coliforms are sampled, as specified in § 141.21.

(ii) Chlorine Dioxide. (A) Routine Monitoring. Community, nontransient noncommunity, and transient noncommunity water systems must monitor for chlorine dioxide only if chlorine dioxide is used by the system for disinfection or oxidation. If monitoring is required, systems shall take daily samples at the entrance to the distribution system. For any daily sample that exceeds the MRDL, the system is required to take samples in the distribution system the following day at the locations required by paragraph (b)(2)(ii)(B) of this section, in addition to the sample required at the entrance to the distribution system.

(B) Additional Distribution System Monitoring. On each day following a routine sample monitoring result that exceeds the MRDL, the system is required to take three chlorine dioxide distribution system samples.

(*1*) If chlorine dioxide or chloramines are used to maintain a disinfectant residual in the distribution system, or if chlorine is used to maintain a disinfectant residual in the distribution system and there are no disinfection addition points after the entrance to the distribution system (i.e., no booster chlorination), three samples shall be taken as close to the first customer as possible at intervals of at least six hours.

(*2*) If chlorine is used to maintain a disinfectant residual in the distribution system and there are one or more disinfection addition points after the entrance to the distribution system (i.e., booster chlorination), one sample shall be taken at each of the following locations: as close to the first customer as possible, in a location representative of average residence time, and as close to the end of the distribution system as possible (reflecting maximum residence time in the distribution system).

(C) CT credit prior to enhanced coagulation or enhanced softening. Subpart H systems required to operate enhanced coagulation or enhanced softening under the provisions of § 141.135 may receive credit for compliance with CT requirements specified by the State if the following monitoring is completed and the criteria in § 141.135(a)(2)(i)(B)(*3*) are met.

(*1*) For each chlorine dioxide generator, the system must demonstrate that the generator is achieving at least 95 percent chlorine dioxide yield and producing no more than five percent chlorine by measuring a minimum of once per week. Measurements shall be conducted by using Standard Method 4500–ClO_{22} E. Chlorine dioxide yield and chlorine presence shall be measured as described in Aieta *et al*, Journal AWWA, 76:1, pp.66 and 67, respectively. Guidance on generator effluent sampling, safety, dilutions, replication, and the measurement of these and related species may be found in [cite Hoehn's upcoming AWWARF report] and in Aieta *et al*, Journal AWWA, 76:1, pp.64 through 70, as noted.

(*2*) On any day that a generator fails to achieve at least 95 percent chlorine dioxide yield and no more than five percent chlorine, and on subsequent days until these conditions are achieved, the system may not receive credit for compliance with CT requirements in subpart H of this part.

(3) On any day that a generator fails to achieve at least 95 percent chlorine dioxide yield but achieves at least 90 percent conversion efficiency and/or produces more than five percent chlorine but less than 10 percent, the system may take immediate corrective action to achieve a minimum of 95 percent chlorine yield and a maximum of five percent chlorine. If subsequent measurements conducted on the same day demonstrate at least 95 percent chlorine dioxide yield and no more than five percent chlorine, the system may receive credit for compliance with CT requirements in subpart H of this part on that day. If the generator continues to fail to demonstrate at least 95 percent chlorine dioxide yield and no more than five percent chlorine, the system may not receive credit for compliance with CT requirements in subpart H of this part on that day.

(4) After achieving the conditions in paragraph (b)(2)(ii)(C)(1) of this section, the system may operate no more than one week without measurement. If however, in the interim, the system changes generator operating conditions (e.g., changes chlorine dioxide dose, changes conditions to match changing plant flow rate) or generator conditions (e.g., a new batch of sodium chlorite or a different ratio of chlorite to chlorine or acid is used), the system shall remeasure for chlorine dioxide yield and chlorine presence and meet the conditions in paragraphs (b)(2)(ii)(C)(1) or (3) of this section to receive CT credit.

(iii) Compliance. (A) Chlorine and chloramines. (1) Compliance shall be based on a running annual arithmetic average, computed quarterly, of quarterly averages of all samples collected by the system as prescribed in this section. If the average of quarterly averages covering any consecutive four-quarter period exceeds the MRDL, the system shall report to the State pursuant to § 141.134 and notify the public pursuant to § 141.32.

(2) In cases where systems switch between the use of chlorine and chloramines for residual disinfection during the year, compliance shall be determined by including together all monitoring results of both chlorine and chloramines in calculating compliance pursuant to paragraph (b)(2)(iii)(C)(1) of this section. Reports submitted pursuant to § 141.134 will clearly indicate which residual disinfectant was analyzed for each sample.

(B) Chlorine dioxide. (1) Acute violations. Compliance shall be based on consecutive daily samples collected by the system as prescribed in this section. If any daily sample taken at the entrance to the distribution system exceeds the MRDL, and on the following day one (or more) of the three samples taken in the distribution system exceed the MRDL, the system will be in violation of the MRDL and shall take immediate corrective action to lower the level of chlorine dioxide below the MRDL and will notify the public pursuant to the procedures for acute health risks in § 141.32(a)(1)(iii)(E). Failure to take samples in the distribution system the day following an exceedance of the chlorine dioxide MRDL at the entrance to the distribution system shall also be considered an MRDL violation and the system shall notify the public of the violation in accordance with the provisions for acute violations under § 141.32(a)(1)(iii)(E).

(2) Nonacute violations. Compliance shall be based on consecutive daily samples collected by the system as prescribed in this section. If any two consecutive daily samples taken at the entrance to the distribution system exceed the MRDL and all distribution system samples taken are below the MRDL, the system will be in violation of an MRDL and shall take corrective action to lower the level of chlorine dioxide below the MRDL at the point of sampling and will notify the public pursuant to the procedures for nonacute health risks in § 141.32. Failure to monitor at the entrance to the distribution system the day following an exceedance of the chlorine dioxide MRDL at the entrance to the distribution system shall also be considered an MRDL violation and the system shall notify the public of the violation in accordance with the provisions for nonacute violations under § 141.32.

(3) Disinfection Byproduct Precursors (DBPP). (i) Subpart H systems. Community and nontransient noncommunity systems which use conventional filtration treatment (as defined in § 141.2) must monitor each treatment plant water source for TOC prior to any continuous disinfection treatment; except that systems using ozone followed by biologically active filtration (as defined in § 141.2) may measure TOC in the treated water following biological filtration but before the addition of a residual disinfectant and systems using chlorine dioxide that meet the standards for including CT credit for its use prior to enhanced coagulation or enhanced softening contained in § 141.135(a)(2)(i)(B)(3) or § 141.135(a)(2)(ii)(B)(3) may measure TOC in the treated water at any point prior to the continuous addition of any other disinfectant. All systems required to monitor under paragraph (b)(3) of this section must also monitor for TOC in the source water prior to any treatment at the same time as monitoring for TOC in the treated water. These samples (source water and treated water, prior to disinfection) are referred to as paired samples. At the same time as the source water sample is taken, all systems must monitor for alkalinity in the source water prior to any treatment.

(ii) Frequency. All systems required to monitor under paragraph (b)(3)(i) of this section must take one paired sample per month per plant at a time representative of normal operating conditions and influent water quality. At the same time, the system must take a source water alkalinity sample in order to make the appropriate calculations required to comply with § 141.135.

(iii) Compliance. Compliance shall be determined as specified by § 141.135(b). Systems may begin monitoring to determine whether Step 1 TOC removals can be met 12 months prior to the compliance date for the system. This monitoring is not required and failure to monitor during this period is not a violation. However, any system that: Does not monitor during this period, and then determines in the first 12 months after the compliance date that it is not able to meet the Step 1 requirements in § 141.135(a)(2) and must therefore apply for alternate performance criteria, is not eligible for retroactive approval of alternate performance criteria as allowed pursuant to § 141.135(a)(3). Systems may apply for alternate performance criteria any time after the compliance date.

(c) Reduced monitoring requirements for disinfection byproducts, disinfectant residuals, and total organic carbon. Systems may reduce monitoring, except as otherwise provided, in accordance with the following.

(1) Disinfection byproducts. (i) Chlorite. Systems required to analyze for chlorite may not reduce monitoring.

(ii) Bromate. Systems required to analyze for bromate may reduce monitoring from monthly to once per quarter, if the system demonstrates that the average raw water bromide concentration is less than 0.05 mg/l based upon representative monthly measurements for one year.

(iii) TTHMs and HAA5. (A) Any Subpart H system which has a source water TOC level, before any treatment, of greater than 4.0 mg/l may not reduce its monitoring.

(B) Systems may reduce monitoring if they have a running annual average for TTHMs and HAA5 that is no more than 0.040 mg/l and 0.030 mg/l, respectively, with the following exceptions. Systems using ground water not under the direct

influence of surface water that serve fewer than 10,000 persons and are required to take only one sample per year may reduce monitoring if either: the average of two consecutive representative annual samples is no more than 0.040 mg/l and 0.030 mg/l for TTHMs and HAA5, respectively, or any representative annual sample is less than 0.020 mg/l and 0.015 mg/l for TTHMs and HAA5, respectively. Systems using surface water or ground water under the direct influence of surface water in whole or in part that serve fewer than 500 persons may not reduce their monitoring to less than one sample per year. Systems must meet the requirements for reduction of monitoring for both TTHMs and HAA5 to qualify for reduced monitoring. The system may reduce monitoring only after the system has completed at least one year of monitoring in accordance with paragraph (b)(1)(i) of this section.

(C) Reduced monitoring frequency. (*1*) Subpart H systems serving 10,000 persons or more that are eligible for reduced monitoring in paragraph (c)(1)(iii)(B) of this section may reduce the monitoring frequency for TTHMs and HAA5 to one sample per quarter per treatment plant. Samples shall be taken at a point in the distribution system reflecting the maximum residence time in the distribution system.

(*2*) Systems using only ground water not under the direct influence of surface water and serving 10,000 persons or more that are eligible for reduced monitoring in paragraph (c)(1)(iii)(B) of this section may reduce the monitoring frequency for TTHMs and HAA5 to one sample per year per treatment plant. Samples shall be taken at a point in the distribution system reflecting the maximum residence time in the distribution system and during the month of warmest water temperature.

(*3*) Subpart H systems serving between 500 to 9,999 persons that are eligible for reduced monitoring may reduce the monitoring frequency for TTHMs and HAA5 to one sample per year per treatment plant. Samples shall be taken at a point in the distribution system reflecting the maximum residence time in the distribution system and during the month of warmest water temperature.

(*4*) Systems using only ground water sources not under the direct influence of surface water and serving fewer than 10,000 persons, may reduce the monitoring frequency for TTHMs and HAA5 to one sample per three year monitoring cycle, with this three-year cycle beginning on the January 1 following the quarter in which the system qualifies for reduced monitoring. Samples shall be taken at a point in the distribution system reflecting the maximum residence time in the distribution system and during the month of warmest water temperature.

(D) Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year (for systems which must monitor quarterly) or the result of the sample (for systems which must monitor no more frequently than annually) is no more than 0.060 mg/l and 0.045 mg/l for TTHMs and HAA5, respectively. Systems that do not meet these levels must resume monitoring at the frequency identified in § 141.133(b)(1) in the quarter immediately following the quarter in which the system exceeded 75 percent of either MCL.

(E) The State may return a system to routine monitoring at the State's discretion.

(2) Disinfectant residuals. Monitoring for disinfectant residuals may not be reduced.

(3) TOC. Subpart H systems with a treated water TOC of less than 2.0 mg/l for two consecutive years, or less than 1.0 mg/l for one year, may reduce monitoring for both TOC and alkalinity to one paired sample per plant per quarter.

(d) Monitoring plans. (1) Each system required to monitor under this subpart must develop and implement a monitoring plan. The system shall maintain the plan and make it available for inspection by the State and the general public no later than 30 days following the applicable effective dates in § 141.130(b). All Subpart H systems serving more than 3300 people shall submit a copy of the monitoring plan to the State no later than the date of the first report required under § 141.134. The State may also require the plan to be submitted by any other system. The plan must include at least the following elements.

(i) Locations for collecting samples for any parameters included in this subpart.

(ii) How the system will calculate compliance with MCLs and MRDLs.

(2) After review, the State may require changes in any plan elements.

§ 141.134 Reporting and recordkeeping requirements.

(a) Systems required to sample quarterly or more frequently must report to the State within 10 days after the end of each quarter in which samples were collected. Systems required to sample less frequently than quarterly must report to the State within 10 days after the end of each monitoring period in which samples were collected.

(b) Systems required to monitor for the following compounds must report the following information.

(1) TTHMs and HAA5.

(i) Systems monitoring for TTHMs and HAA5 under the requirements of §§ 141.133(b) or (c) on a quarterly or more frequent basis must report at least the following information. The State may choose to perform paragraphs (b)(1)(i)(C) through (E) of this section in lieu of having the system report that information.

(A) the number of samples taken during the last quarter,

(B) the location, date, and result of each sample taken during the last quarter,

(C) the arithmetic average of all samples taken in the last quarter,

(D) the arithmetic average of the arithmetic averages reported under paragraph (b)(1)(i)(C) of this section for the last four quarters, and

(E) whether the MCL was exceeded.

(ii) Systems monitoring for TTHMs and HAA5 under the requirements of § 141.133(b) or (c) less frequently than quarterly (but at least annually) must report at least the following information. The State may choose to perform paragraphs (b)(1)(ii)(C) through (D) of this section in lieu of having the system report that information.

(A) the number of samples taken during the last year,

(B) the location, date, and result of each sample taken during the last quarter,

(C) the arithmetic average of all samples taken over the last year, and

(D) whether the MCL was exceeded.

(iii) Systems monitoring for TTHMs and HAA5 under the requirements of § 141.133(c) less frequently than annually must report at least the following information:

(A) the location, date, and result of the last sample taken, and

(B) whether the MCL was exceeded.

(2) Systems monitoring for chlorite under the requirements of § 141.133(b) must report at least the following information. The State may choose to perform paragraphs (b)(2)(iii) through (iv) of this section in lieu of having the system report that information.

(i) the number of samples taken each month for the last 3 months,

(ii) the location, date, and result of each sample taken during the last quarter,

(iii) for each month in the reporting period, the arithmetic average of all samples taken in the month, and

(iv) whether the MCL was exceeded, and which month it was exceeded.

(3) Systems monitoring for bromate under the requirements of § 141.133(b)

or (c) must report at least the following information. The State may choose to perform paragraphs (b)(3)(iii) through (iv) of this section in lieu of having the system report that information.

(i) the number of samples taken during the last quarter,

(ii) the location, date, and result of each sample taken during the last quarter,

(iii) the arithmetic average of the monthly arithmetic averages of all samples taken in the last year, and

(iv) whether the MCL was exceeded.

(4) Systems monitoring for chlorine or chloramines under the requirements of § 141.133(b) must report at least the following information:

(i) the number of samples taken during each month of the last quarter,

(ii) the monthly arithmetic average of all samples taken in each month for the last 12 months, and

(iii) the arithmetic average of all monthly averages for the last 12 months, and

(iv) whether the MRDL was exceeded.

(5) Systems monitoring for chlorine dioxide under the requirements of § 141.133(b) must report at least the following information:

(i) the dates, results, and locations of samples taken during the last quarter,

(ii) whether the MRDL was exceeded, and

(iii) whether the MRDL was exceeded in any two consecutive daily samples and whether the resulting violation was acute or nonacute.

(6) Disinfection Byproduct Precursors and enhanced coagulation or enhanced softening.

(i) Reports from systems monitoring monthly or quarterly for TOC under the requirements of § 141.133(b)(3) and required to meet the enhanced coagulation or enhanced softening requirements in § 141.135 (a)(2) or (a)(3) must include at least the following information. The State may choose to perform paragraphs (b)(6)(i) (C) through (E) of this section in lieu of having the system report that information.

(A) the number of paired (raw water and treated water, prior to continuous disinfection) samples taken during the last quarter,

(B) the location, date, and result of each paired sample taken during the last quarter and the associated source water alkalinity,

(C) for each month in the reporting period that paired samples were taken, the arithmetic average of the percent reduction of TOC for each paired sample and the required TOC percent removal,

(D) calculations for determining compliance with the TOC percent removal requirements, as provided in § 141.135(b)(1), and

(E) whether the system is in compliance with the enhanced coagulation or enhanced softening percent removal requirements in § 141.135(a) for the last four quarters.

(ii) Systems monitoring monthly or quarterly for TOC under the requirements of § 141.133(b) and meeting one or more of the criteria in § 141.135(a)(1) for avoiding the requirement for enhanced coagulation and enhanced softening must report at least the following information. The State may choose to perform paragraphs (b)(6)(ii) (D) through (I) of this section in lieu of having the system report that information.

(A) the criterion that the system is using to avoid enhanced coagulation or enhanced softening,

(B) the number of paired samples taken during the last quarter,

(C) the location, date and result of each sample (identified as either source water or treated water) taken during the last quarter,

(D) the monthly arithmetic average (or quarterly sample result) of all treated water samples taken in the quarter and the running annual arithmetic average based on monthly averages (or quarterly samples) (for systems meeting the criterion in § 141.135(a)(1)(i) for avoiding enhanced coagulation or enhanced softening),

(E) the monthly arithmetic average of all treated water samples taken for each month of the quarter, the quarterly average of the monthly averages, and the running annual average of the quarterly averages (for systems meeting the criterion in § 141.135(a)(1)(ii) for avoiding enhanced coagulation or enhanced softening),

(F) the running annual average of alkalinity of the source water (for systems meeting the criterion in § 141.135(a)(1)(ii) for avoiding enhanced coagulation or enhanced softening),

(G) the running annual average for both TTHMs and THAAs (for systems meeting the criterion in § 141.135(a)(1) (ii) or (iii) for avoiding enhanced coagulation or enhanced softening),

(H) the running annual average of the amount of magnesium hardness removal (in mg/l) (for systems meeting the criterion in § 141.135(a)(1)(iv) for avoiding enhanced coagulation or enhanced softening),

(I) whether the system is in compliance with the particular criterion in § 141.135(a)(1) (i) through (iv) that the system is using to avoid enhanced coagulation or enhanced softening.

§ 141.135 Treatment technique for control of Disinfection Byproduct Precursors (DBP).

(a)(1) Subpart H systems using conventional filtration treatment (as defined in § 141.2) must operate with enhanced coagulation or enhanced softening to achieve the TOC percent removal levels specified in this section unless the system meets at least one of the criteria listed in paragraphs (a)(1)(i) through (iv) of this section:

(i) The system's treated TOC level, measured according to § 141.133(b)(3), is less than 2.0 mg/l, calculated quarterly as a running annual average.

(ii) The system's source water TOC level, measured as required by § 141.133(b)(3), is less than 4.0 mg/l, calculated quarterly as a running annual average; the source water alkalinity, measured according to § 141.133(a)(4), is greater than 60 mg/l, calculated quarterly as a running annual average; and, prior to the effective date for compliance in § 141.130, either the TTHM and HAA5 running annual averages are no greater than 0.040 mg/l and 0.030 mg/l, respectively, or the system has made a clear and irrevocable financial commitment not later than the effective date for compliance in § 141.30(b) to use of technologies that will limit the levels of TTHMs and HAA5 to no more than 0.040 mg/l and 0.030 mg/l, respectively. Systems must submit evidence of a clear and irrevocable financial commitment, in addition to a schedule containing milestones and periodic progress reports for installation and operation of appropriate technologies, to the State for approval not later than the effective date for compliance in § 141.30(b) of this part. These technologies must be installed and operating not later than the effective date for Stage 2 of the Disinfectant/Disinfection Byproduct Rule. Violation of the approved schedule will constitute a violation of the National Primary Drinking Water Regulation.

(iii) The TTHM and HAA5 running annual averages are no greater than 0.040 mg/l and 0.030 mg/l, respectively, and the system uses only chlorine for disinfection.

(iv) Systems practicing softening and removing at least 10 mg/l of magnesium hardness (as $CaCO_3$), calculated quarterly as a running annual average, except those that use ion exchange, are not subject to performance criteria for the removal of TOC.

(2) Enhanced coagulation performance requirements.

(i) Systems not practicing softening. (A) Systems (except those noted in paragraph (a)(2)(i)(D) of this section)

must achieve the percent reduction of TOC specified in paragraph (a)(2)(i)(E) of this section between the raw water source and the treated water prior to continuous disinfection, unless the State approves a system's request for alternative performance standards under paragraph (a)(3) of this section. Continuous disinfection is defined as the continuous addition of a chemical disinfectant for the purposes of achieving a level of inactivation credit to meet the minimum inactivation/removal treatment requirements of subpart H of this part.

(B) Continuous disinfection does not include: the addition of a chemical disinfectant for filter maintenance (when applied intermittently), or the use of a disinfectant (other than provided for in paragraph (a)(2)(i)(C) of this section) as an oxidant for the purposes of controlling water quality problems such as iron, manganese, sulfides, zebra mussels, Asiatic clams, taste, and odor. In determining compliance with the CT requirements specified by the State, the system shall not include any credit for disinfectants used either for filter maintenance or for controlling water quality problems except as allowed below in paragraphs (a)(2)(i)(B)(*1*) through (*4*) of this section.

(*1*) Systems may include CT credit during periods when the water temperature is below 5 °C and the TTHM and HAA5 quarterly averages are no greater than 0.040 mg/l and 0.030 mg/l, respectively.

(*2*) Systems receiving disinfected water from a separate entity as their source water shall be allowed to include credit for this disinfectant in determining compliance with the CT requirements. If the TTHM and HAA5 quarterly averages are no greater than 0.040 mg/l and 0.030 mg/l, respectively, systems may use the measured "C" (residual disinfectant concentration) and the actual contact time (as T_{10}). If either the TTHM or HAA5 quarterly average is greater than 0.040 mg/l or 0.030 mg/l, respectively, systems must use a "C" (residual disinfectant concentration) of 0.2 mg/l or the measured value, whichever is lower; and the actual contact time (as T_{10}). This credit shall be allowed from the disinfection feedpoint, through a closed conduit only, and ending at the delivery point to the treatment plant.

(*3*) Systems using chlorine dioxide as an oxidant or disinfectant may include CT credit for its use prior to enhanced coagulation or enhanced softening if the following standards are met: the chlorine dioxide generator must generate chlorine dioxide on-site and minimize the production of chlorine as shown by complying with monitoring and performance standards in § 141.133(b)(2)(ii)(C).

(*4*) Systems using ozone and biologically active filtration may include CT credit for its use prior to enhanced coagulation or enhanced softening.

(C) Systems not required to operate with enhanced coagulation may continue to include, in compliance calculations, continuous addition of a chemical disinfectant for the purposes of achieving a level of inactivation credit to meet the minimum inactivation/removal treatment requirements of subpart H of this part, even when such addition is also made for the purpose of controlling water quality problems.

(D) Systems using ozone and biologically active filtration must achieve the TOC percent reduction specified in paragraph (a)(2)(i)(E) of this section before the addition of a residual disinfectant. Systems using chlorine dioxide that meet the requirements for including CT credit specified in paragraph (a)(2)(i)(B)(*3*) of this section must achieve the TOC percent reduction specified in paragraph (a)(2)(i)(E) of this section before the addition of a residual disinfectant.

(E) Required TOC reductions, indicated in the table below, are based upon specified source water parameters measured in accordance with § 141.133(b)(3).

REQUIRED REMOVAL OF TOC BY ENHANCED COAGULATION FOR SUBPART H SYSTEMS USING CONVENTIONAL TREATMENT [2]

Source water total organic carbon (mg/l)	Source water alkalinity (mg/l)		
	0–60 (percent)	>60–120 (percent)	>120 [1] (percent)
>2.0–4.0	40.0	30.0	20.0
>4.0–8.0	45.0	35.0	25.0
>8.0	50.0	40.0	30.0

[1] Systems practicing softening must meet the TOC removal requirements in this column.

[2] Systems meeting at least one of the conditions in § 141.135(a)(1) (i) through (iv) are not required to operate with enhanced coagulation.

(ii) Systems practicing softening. (A) Systems (except those noted in paragraph (a)(2)(ii)(D) of this section) must achieve the percent reduction of TOC specified in paragraph (a)(2)(ii)(E) of this section between the raw water source and treated water prior to continuous disinfection. Continuous disinfection is defined as the continuous addition of a chemical disinfectant for the purposes of achieving a level of inactivation credit to meet the minimum inactivation/removal treatment requirements of subpart H of this section.

(B) Continuous disinfection does not include: the addition of a chemical disinfectant for filter maintenance (when applied intermittently), or the use of a disinfectant (other than provided for in paragraph (a)(2)(ii)(C) of this section) as an oxidant for the purposes of controlling water quality problems such as iron, manganese, sulfides, zebra mussels, Asiatic clams, taste, and odor. In determining compliance with the CT requirements in subpart H of this part, the system shall not include any credit for disinfectants used either for filter maintenance or for controlling water quality problems except as allowed by paragraphs (a)(2)(ii)(B) (*1*) through (*4*) of this section.

(*1*) Systems may include CT credit during periods when the water temperature is below 5°C and the TTHM and HAA5 quarterly averages are no greater than 0.040 mg/l and 0.030 mg/l, respectively.

(*2*) Systems receiving disinfected water from a separate entity as their source water shall be allowed to include credit for this disinfectant in determining compliance with the CT requirements. If the TTHM and HAA5 quarterly averages are no greater than 0.040 mg/l and 0.030 mg/l, respectively, systems may use the measured "C" (residual disinfectant concentration) and the actual contact time (as T_{10}). If either the TTHM or HAA5 quarterly average is greater than 0.040 mg/l or 0.030 mg/l, respectively, systems must use a "C" (residual disinfectant concentration) of 0.2 mg/l or the measured value, whichever is lower; and the actual contact time (as T_{10}). This credit shall be allowed from the disinfection feed point, through a closed conduit only, and ending at the delivery point to the treatment plant.

(*3*) Systems using chlorine dioxide as an oxidant or disinfectant may include CT credit for its use prior to enhanced coagulation or enhanced softening if the following standards are met: the chlorine dioxide generator must generate chlorine dioxide on-site and minimize the production of chlorine as shown by complying with monitoring and performance standards in § 141.133(b)(2)(ii)(C).

(*4*) Systems using ozone and biologically active filtration may include CT credit for its use prior to enhanced coagulation or enhanced softening.

(C) Systems not required to operate with enhanced softening may continue to include, in compliance calculations, continuous addition of a chemical disinfectant for the purposes of achieving a level of inactivation credit to meet the minimum inactivation/removal treatment requirements of subpart H of this part, even when such addition is also made for the purpose of controlling water quality problems.

(D) Systems using ozone and biologically active filtration must achieve the TOC percent reduction specified in paragraph (a)(2)(ii)(E) of this section before the addition of a residual disinfectant. Systems using chlorine dioxide that meet the requirements for including CT credit specified in paragraph (a)(2)(ii)(B)(3) of this section must achieve the TOC percent reduction specified in paragraph (a)(2)(ii)(E) of this section before the addition of a residual disinfectant.

(E) Required TOC reductions are indicated in the table in paragraph (a)(2)(i)(E) of this section. Systems practicing softening are required to meet the percent reductions in the far-right column (Source water alkalinity >120 mg/l) for the specified source water TOC.

(3) Non-softening Subpart H conventional treatment systems that cannot achieve the TOC removals required by paragraph (a)(2) of this section due to water quality parameters or operating conditions must apply to the State, within three months of failure to achieve the TOC removals required by paragraph (a)(2) of this section, for alternative performance criteria. If the State approves the alternate performance criteria, the State may make those criteria retroactive for the purposes of determining compliance. If the State does not approve the alternate performance criteria, the system must meet the TOC removals contained in paragraph (a)(2)(i)(E) of this section.

(i) Such application must include, as a minimum, results of bench- or pilot-scale testing for alternate enhanced coagulation level. "Alternate enhanced coagulation level" is defined as coagulation at a coagulant dose and pH as determined by the method outlined in paragraph (a)(3)(ii) of this section such that an incremental addition of 10 mg/l of alum (or equivalent amount of ferric salt) results in a TOC removal of 0.3 mg/l. The percent removal of TOC at this point on the "coagulant dose versus TOC removal" curve is then defined as the minimum TOC removal required for the system. Once approved by the State, this minimum requirement supersedes the minimum TOC removal required by the table in paragraph (a)(2)(i)(E) of this section. This requirement will be effective until such time as the State approves a new value based on the results of a new bench- and pilot-scale test triggered by changes in source water quality. Failure to achieve State-set alternative minimum TOC removal levels is a violation of paragraph (a)(3) of this section.

(ii)(A) Bench- or pilot-scale testing of enhanced coagulation shall be conducted by using representative water samples and adding 10 mg/l increments of alum (or equivalent amounts of ferric salt) until the pH is reduced to a level less than or equal to the enhanced coagulation maximum pH shown in the table below.

ENHANCED COAGULATION MAXIMUM PH

Alkalinity (mg/l as $CaCO_3$)	Maximum pH
0–60	5.5
>60–120	6.3
>120–240	7.0
>240	7.5

(B) For waters with alkalinities of less than 60 mg/l for which addition of small amounts of alum or equivalant addition of iron coagulant drives the pH below 5.5 before significant TOC removal occurs, the system must add necessary chemicals to maintain the pH between 5.3 and 5.7 in samples until the TOC removal of 0.3 mg/l per 10 mg/l alum added or equivalant addition of iron coagulant is reached.

(iii) The system may operate at any coagulant dose or pH necessary (consistent with other NPDWRs) to achieve the minimum TOC percent removal determined under paragraph (a)(3)(i) of this section.

(iv) If the TOC removal is consistently less than 0.3 mg/l of TOC per 10 mg/l of incremental alum dose at all dosages of alum or equivalant addition of iron coagulant, the water is deemed to contain TOC not amenable to enhanced coagulation. The system may then apply to the State for a waiver of enhanced coagulation requirements.

(b) *Compliance calculations.* (1) Subpart H systems other than those identified in paragraph (b)(2) of this section shall comply with the TOC compliance requirements contained in paragraph (a) of this section. Systems shall calculate compliance quarterly by the following method:

(i) Determine actual monthly TOC percent removal, equal to: (1-(treated water TOC/source water TOC)) × 100.

(ii) Determine the required monthly TOC percent removal (from either the table in paragraph (a)(2)(i)(E) of this section or from paragraph (a)(3) of this section).

(iii) Divide paragraph (b)(1)(i) of this section by paragraph (b)(2)(ii) of this section.

(iv) Add together the results of paragraph (b)(1)(iii) of this section for the last 12 months and divide by 12.

(v) If paragraph (b)(1)(iv) of this section <1.00, the system is not in compliance with the TOC percent removal requirements.

(2) Subpart H systems using conventional treatment but not operating enhanced coagulation must comply with the DBP precursor treatment technique identified in paragraphs (a)(1) (i) through (iv) of this section.

(c) *Treatment technique requirements for Disinfection Byproduct Precursors.* The Administrator identifies the following as treatment techniques to control the level of disinfection byproduct precursors in drinking water treatment and distribution systems: For Subpart H systems using conventional treatment, enhanced coagulation or enhanced softening.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

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

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

2. Section 142.14 is amended by adding paragraphs (d)(12) and (d)(13) to read as follows:

§ 142.14 Records kept by states.

* * * * *

(d) * * *

(12) Records of the currently applicable or most recent State determinations, including all supporting information and an explanation of the technical basis for each decision, made under the following provisions of 40 CFR part 141, subpart L for the control of disinfectants and disinfection byproducts. These records must also include interim measures toward installation.

(i) States must keep records of systems that are installing GAC or membrane technology in accordance with § 141.64(d)(3). These records must include the date by which the system is required to have completed installation.

(ii) States must keep records of systems that are required, by the State, to meet alternative minimum TOC removal requirements in accordance

with § 141.135(a)(3). Records must include the alternative limits and rationale for establishing such limits.

(iii) States must keep records of Subpart H systems using conventional treatment meeting any of the enhanced coagulation or enhanced softening exemption criteria in § 141.135(a)(1).

(iv) States must keep a register of qualified operators that have met the State requirements developed under § 142.16(f)(2).

(13) Records of systems with multiple wells considered to be one treatment plant in accordance with § 141.133(b)(1).

* * * * *

3. Section 142.15 is amended by adding paragraphs (c)(5) through (c)(8) to read as follows:

§ 142.15 Reports by states.

* * * * *

(c) * * *

(5) Reports of systems that must meet alternative minimum TOC removal levels and the alternate performance criteria specified in § 141.135(a)(3).

(6) Any extensions granted for compliance with MCLs in § 141.64 as allowed by § 141.64(c)(3) and the date by which compliance must be achieved.

(7) A list of systems required to monitor for various disinfectants and disinfection byproducts.

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

* * * * *

4. Section 142.16 is amended by adding paragraph (f) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

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

(1) Section 141.64(d)(3) (interim treatment requirements). Determine the interim treatment requirements for those systems electing to install GAC or membrane filtration and granted additional time to comply with § 141.64(a).

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

(3) Approve alternative TOC removal levels, as allowed under the provisions of § 141.135(a).

(4) Section 141.133(a)(2) (State approval of parties to conduct analyses). Approve parties to conduct pH, alkalinity, temperature, and residual disinfectant concentration measurements. The State's process for approving parties performing water quality measurements for systems subject to requirements of subpart H of this part may be used for approving parties measuring water quality parameters for systems subject to requirements of subpart L of this part, if the State determines the process is appropriate and applicable.

(5) Section 144.133(a)(2) (DPD colorimetric test kits). Approve DPD colorimetric test kits for free and total chlorine measurements. Approval granted under § 141.74(a)(5) for the use of such test kits for free chlorine testing would be considered acceptable approval for the use of DPD test kits in measuring free chlorine residuals as required in subpart L of this part.

(6) Section 141.133(b)(3)(ii)(C) (multiple wells as a single source). Define the criteria to determine if multiple wells are being drawn from a single aquifer and therefore be considered a single source for compliance with monitoring requirements.

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July 29, 1994

Part III

Environmental Protection Agency

40 CFR Parts 141 and 142
National Primary Drinking Water Regulations: Enhanced Surface Water Treatment Requirements; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[WH-FRL-4998-1]

National Primary Drinking Water Regulations: Enhanced Surface Water Treatment Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the Surface Water Treatment Rule to provide additional protection against disease-causing organisms (pathogens) in drinking water. This action would primarily focus on treatment requirements for the waterborne pathogens *Giardia, Cryptosporidium,* and viruses. With the exception of one requirement (sanitary surveys), this action would apply to all public water systems that use surface water or ground water under the influence of surface water, and serve 10,000 people or more. Among the features of the rule would be a stricter watershed control requirement for systems using surface water that wish to avoid filtration; a change in the definition of ground water under the influence of surface water to include the presence of *Cryptosporidium;* a periodic sanitary survey requirement for all systems using surface water or ground water under the influence of surface water, including those that serve fewer than 10,000 people; a health goal (maximum contaminant level goal) of zero for *Cryptosporidium;* and several alternative requirements for augmenting treatment control of *Giardia, Cryptosporidium,* and viruses.

DATES: Comments should be postmarked or delivered by hand on or before May 30, 1996. Comments received after this date may not be considered. Public hearings will be held at the addresses indicated below under **ADDRESSES** on August 30, 1996 (and 31, if necessary) in Denver, CO and on September 13, 1994 (and 14, if necessary) in Washington, DC.

ADDRESSES: Send written comments to ESWTR Docket Clerk, Water Docket (MC-4101); U.S. Environmental Protection Agency; 401 M Street, SW; Washington, DC 20460. Please submit any references cited in your comments. EPA would appreciate an original and three copies of your comments and enclosures (including references). Commenters who want EPA to acknowledge receipt of their comments should include a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted because EPA cannot ensure that they will be submitted to the Water Docket. The Agency requests commenters to follow the instructions regarding format provided in Section IX of the Preamble, immediately before the list of references.

The Agency will hold public hearings on the proposal at two different locations indicated below:

1. Denver Federal Center, 6th and Kipling Streets, Building 25, Lecture Halls A and B (3d Street), Denver, CO 80225 on August 30 (and 31, if necessary), 1994.
2. EPA Education Center Auditorium, 401 M Street SW., Washington, D.C. 20460, on September 13 (and 14, if necessary), 1994.

The hearings will begin at 1:00 p.m., with registration at 12:30 p.m., on the first day. The hearings will begin at 9:30 a.m., with registration at 9:00 a.m., on the second day. The Hearings will end at 4:00 p.m., unless concluded earlier. Anyone planning to attend the public hearings (especially those who plan to make statements) may register in advance by writing the ESWTR Public Hearing Officer, Office of Ground Water and Drinking Water (4603), USEPA, 401 M Street, S.W., Washington, D.C. 20460; or by calling Tina Mazzocchetti, (703) 931-4600. Oral and written comments may be submitted at the public hearing. Persons who wish to make oral presentations are encouraged to have written copies (preferably three) of their complete comments for inclusion in the official record.

The proposed rule with supporting documents and all comments received are available for review at the Water Docket at the address above. For access to Docket materials, call (202) 260-3027 between 9 am and 3:30 pm for an appointment.

FOR FURTHER INFORMATION CONTACT: The Safe Drinking Water Hotline, Telephone (800) 426-4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. Eastern Time. For technical inquiries, contact Stig Regli or Paul S. Berger, Ph.D., Office of Ground Water and Drinking Water (MC 4603), U.S. Environmental Protection Agency, 401 M Street SW., Washington DC 20460; telephone (202) 260-7379 (Regli) or (202) 260-3039 (Berger); or Bruce A. Macler, Ph.D., Water Management Division, Region 9, U.S. Environmental Protection Agency, 75 Hawthorne Street (W-6-1), San Francisco, CA 94105-3901; telephone (415) 744-1884.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Statutory Authority
II. Regulatory Background
III. Discussion of Proposed Rule
A. Basis for Amending Existing SWTR: Limitations of SWTR
B. General Approach for Revising SWTR
C. Proposed Maximum Contaminant Level Goal and Treatment Technique for *Cryptosporidium*
D. Proposed Revisions to SWTR under All Treatment Alternatives
1. Inclusion of *Cryptosporidium* in definition of "groundwater under the direct influence of surface water"
2. Inclusion of *Cryptosporidium* in watershed control requirements
3. Sanitary surveys for all surface water systems
4. Possible supplemental requirements
E. Alternative Treatment Requirements
1. Options for defining pathogen densities in source waters
2. Treatment alternatives for controlling pathogens
IV. State Implementation
A. Special State Primacy Requirements
B. State Recordkeeping Requirements
C. State Reporting Requirements
V. Public Notification Language
VI. Economic Analysis
A. Cost of Proposed Rule
B. Benefits of Proposed Rule
VII. Other Statutory Requirements
A. Executive Order 12866
B. Regulatory Flexibility Act
C. Paperwork Reduction Act
D. Science Advisory Board, National Drinking Water Advisory Council, and Secretary of Health and Human Services
E. Consultation with State, Local, and Tribal Governments
VIII. Request for Public Comment
IX. Instructions to Commenters
X. References

I. Statutory Authority

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

At the same time EPA publishes an MCLG, which is a non-enforceable health goal, it also must publish a National Primary Drinking Water Regulation (NPDWR) that specifies either a maximum contaminant level (MCL) or treatment technique (Section 1401(1), 1412(a)(3), and 1412(b)(7)(A)). A treatment technique may be set in lieu

of an MCL if it is not "economically or technologically feasible" to determine the level of a contaminant.

Section 1412(b)(3) of the Act requires EPA to publish regulations for at least 25 contaminants at three year intervals. Section 1412(b)(9) requires EPA to review each NPDWR every three years and revise it if appropriate.

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

Section 1445(a)(1) of the Act requires a public water system to "establish and maintain such records, make such reports, conduct such monitoring, and provide such information as the Administrator may reasonably require by regulation . . .".

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

II. Regulatory Background

Two NPDWRs control disease-causing microorganisms (pathogens) in public water supplies—the Total Coliform Rule (TCR)(54 FR 27544; June 29, 1989) and the Surface Water Treatment Rule (SWTR)(54 FR 27486; June 29, 1989). A third regulation, the Groundwater Disinfection Rule (GWDR), which is currently under development, will add further protection for systems using ground water.

The SWTR met the requirements of Section 1412(b)(7)(C) and, for surface waters, Section 1412(b)(8) of the SDWA, as amended in 1986. The SWTR requires all systems using surface water, or ground water under the direct influence of surface water, to disinfect. In addition, all such systems are required to filter their water unless they demonstrate that they have an effective watershed protection program and meet other EPA-specified requirements (§ 141.71). The watershed control program must minimize the potential for source water contamination by *Giardia* cysts and viruses, and typically includes characterization of watershed hydrology, land ownership by the system, and activities on the watershed that might have an adverse effect on source water quality. The rule also requires an annual on-site inspection of all systems that wish to avoid filtration. This inspection must demonstrate that the required watershed control program and disinfection treatment processes are adequately designed and maintained. The SWTR also established MCLGs of zero for *Giardia lamblia*, viruses and *Legionella*.

The SWTR requires all systems to achieve at least 99.9% (3-log) removal/inactivation of *Giardia lamblia* cysts, and 99.99% (4-log) removal/inactivation of enteric viruses. The intention of these provisions was to provide appropriate multiple barriers of treatment to control pathogen occurrence in finished drinking water. This rule was promulgated as a treatment technique rather than an MCL, because EPA believed that routine monitoring for the pathogens was not economically or technologically feasible. Another pathogen, *Cryptosporidium*, was considered for regulation under the SWTR, but was not addressed, because EPA lacked sufficient health, occurrence, and water treatment control data regarding this organism at that time.

The TCR established MCLGs of zero for total coliforms, which includes fecal coliforms and *E. coli*. MCLs, monitoring requirements, and analytical requirements were promulgated for these organisms. The TCR requires all public water systems that collect fewer than five samples per month to have an on-site sanitary survey every five years (ten years for some systems). The purpose of this requirement is to help ensure the long-term quality and safety of drinking water in small systems that cannot be accomplished by infrequent coliform monitoring.

The TCR and SWTR were promulgated to minimize both epidemic and endemic waterborne microbial illness. The public health goal, as described in the preamble to the SWTR, was to provide treatment to ensure an acceptable risk of less than one waterborne microbial illness per year per 10,000 people.

In addition to the SWTR, TCR, and GWDR, EPA is also developing a rule that would limit concentration levels of disinfectants and the chemical disinfection byproducts (DBPs) resulting from their use. The use of chemical disinfectants in water treatment results in a substantial decrease in waterborne microbial illness and is an integral part of a multiple-barrier removal/inactivation approach. However, disinfectants and DBPs may present potential health risks themselves. DBPs form when disinfectants used for microbial control in drinking water react with various organic chemicals in the source water. Some of these are known to be toxic to humans or are considered to be probable human carcinogens. As such, a number of disinfectants and DBPs were included on the 1991 Drinking Water Priority List (56 FR 1470, January 14, 1991) as candidates for future regulations. To address these health issues, EPA is proposing elsewhere in today's **Federal Register** the disinfectants/disinfection byproducts (D/DBP) rule, which includes NPDWRs for several disinfectants and disinfectant byproducts.

To develop the D/DBP Rule, EPA instituted a formal regulation negotiation process in 1992 with potentially affected parties (57 FR 53866; Nov. 13, 1992). The committee established to negotiate the regulation included representatives from water utilities, State and local health and regulatory agencies, environmental groups, consumer groups, and EPA (hereafter the Negotiating Committee or the Committee). One of the major goals addressed by the Committee was to develop an approach that would reduce the level of exposure from disinfectants and DBPs without undermining the control of pathogens. The intention was to ensure that drinking water is microbiologically safe at the limits set for disinfectants and DBPs and that these chemicals do not pose an unacceptable risk at these limits. The approach in developing this rule considered the constraints of simultaneously treating water for these different concerns. As part of this effort, the Negotiating Committee decided that the SWTR may need to be revised to address health risk from high densities of pathogens in poor quality source waters and from the protozoan, *Cryptosporidium*. If such requirements were deemed necessary, and could be promulgated concurrently with new D/DBP regulations (the regulations proposed elsewhere in today's **Federal Register** and termed "Stage 1 D/DBPR"), a system could comply with both regulations and meet the intended public health goals.

The Negotiating Committee also decided that to develop a reasonable set

of rules, including today's proposed rule, and to understand more fully the limitations of the current SWTR, additional field data were critical. Thus, the Committee agreed to the development of an information collection rule (ICR) that would require, in part, systems serving a population of 10,000 or greater to determine the density of specific pathogens in their source water and to characterize their treatment processes. Under the ICR, systems serving populations greater than 100,000 would also be required to monitor for pathogens in their finished water (depending upon the pathogen density in the source water), and the concentration of DBPs and parameters related to their formation at various steps in the treatment process. To this end, EPA proposed the ICR on February 10, 1994 (59 FR 6332) that would require this additional information. The Committee agreed to the requirements in the proposed ICR as necessary and reasonable.

According to the regulatory strategy developed by the Committee, systems serving a population of 10,000 or greater would use the monitoring and treatment data collected under the ICR to decide what additional treatment measures, if any, would be necessary to protect the public from pathogens while controlling for DBPs. This decision would be based on criteria specified either in amendments to the SWTR or by guidance. Today's proposed rule includes a variety of regulatory options, from requiring systems to provide minimum levels of treatment based upon the density of pathogens in the source water to maintaining the existing requirements of the SWTR.

According to the Committee's strategy, amendments to the SWTR would be developed under two rules. The first of these rules, which is today's proposed rule, would be an interim enhanced SWTR (ESWTR) that would only pertain to systems serving 10,000 people or greater. Data collected under the ICR would be used to determine the appropriate regulatory option(s) under this rule, and then to implement it at the time systems are required to comply with the Stage 1 D/DBP regulations. Following the full compilation and analysis of all data collected under the ICR rule and from other research findings, EPA would propose a long-term ESWTR with which systems serving fewer than 10,000 people would comply while also complying with the Stage 1 D/DBP rule. The long-term ESWTR might also include additional refinements for systems serving 10,000 people or greater. Today's proposal also satisfies the provision in section 1412(b)(9) of the SDWA for review of NPDWRs every three years; the SWTR was promulgated on June 29, 1989, and became effective in stages, beginning December 31, 1990.

III. Discussion of Proposed Rule

A. Basis for Amending Existing SWTR: Limitations of SWTR

As discussed above, the SWTR requires all systems using surface water, or ground water under the direct influence of surface water, to disinfect. It also requires all such systems to filter their water unless they can demonstrate that they have an effective watershed control program, meet source water quality criteria, achieve minimum disinfection requirements, and have no evidence of reported waterborne disease among the served population. The SWTR also specifies that systems using surface water must treat water to remove/inactivate at least 99.9% of the *Giardia lamblia* cysts and at least 99.99% of the enteric viruses, regardless of their densities in the source waters. The SWTR does not require a system to monitor its source water or drinking water for these pathogens. At the time of promulgation, EPA recognized a variety of uncertainties and unknowns regarding potential health risks, but these were not possible to address at that time. Subsequently, additional information has become available that indicated possible deficiencies in the SWTR. Some of these deficiencies are described below.

SWTR Did Not Address Cryptosporidium

During the development of the SWTR, the United States experienced its first recognized waterborne disease outbreak of cryptosporidiosis, caused by the protozoan, *Cryptosporidium* (D'Antonio et al., 1985). Other outbreaks caused by this pathogen have since been reported both in the United States and other countries (Smith et al., 1988; Hayes et al., 1989; Levine and Craun, 1990; Moore et al., 1993; Craun, 1993). Because of the lack of data before 1989 on *Cryptosporidium* oocyst occurrence and removal by treatment, EPA decided to regulate this pathogen in a future rulemaking, rather than to delay publication of the SWTR until this data was available. Thus, the SWTR does not now specifically address *Cryptosporidium* treatment removal/inactivation requirements, watershed control requirements for *Cryptosporidium* for systems that wish to avoid filtration, or a definition of ground water under the influence of surface water that includes *Cryptosporidium*. Moreover, the assumptions about *Giardia* reduction under the SWTR may not be applicable to *Cryptosporidium*, which, based on laboratory studies, is much more resistant to common disinfection practices than is *Giardia* (Korich et al., 1990; Korich et al., 1992). Since publication of the SWTR in 1989, some information on *Cryptosporidium* occurrence and control measures has been published. EPA will have new data available shortly from systems that monitor for this organism under the ICR and from research currently being carried out by the Agency and the water industry. As a result, EPA believes that it will soon be in a better position to develop a suitable regulation for *Cryptosporidium*.

Specified Pathogen Reductions May Be Inadequate

The 3-log removal/inactivation of *Giardia* and 4-log removal/inactivation of enteric viruses required by the SWTR were developed to provide adequate protection from pathogens in average quality source water, and thus may be inadequate when a system is supplied by poorer quality source water with high levels of these or other pathogens. In developing the SWTR, EPA assumed, on the basis of data available at that time, that this level of treatment was adequate for the vast majority of systems.

Additionally, risk assessments for the pathogens of concern had high degrees of uncertainty, such that the risks associated with a given level of pathogen contamination were unclear. Moreover, methods for quantifying these organisms were not generally available. Therefore, the Agency believed that a simple, yet conservative treatment requirement was most appropriate. However, it was apparent during the development of the SWTR that the level of treatment being specified might not always be adequate. Therefore, the Agency published associated guidance recommending greater treatment for systems supplied by poorer quality source waters (EPA, 1991a).

Subsequent data on *Giardia* and virus densities in source water and drinking water, however, bring into question the assumption that the treatment specified in the SWTR was adequate for most systems. These new data suggest that the concentrations of *Giardia* cysts and viruses in the source waters of many systems may be too great for the specified level of treatment to adequately control waterborne pathogens. For example, LeChevallier et al. (1991a,b) examined *Giardia* and *Cryptosporidium* levels in the source

waters and filtered drinking waters of 66 surface water systems in 14 States and one Canadian province. They detected at least one of these two organisms in 97% of the raw water samples. *Giardia* densities ranged from 0.04 to 66 cysts/L (geometric mean of 2.77 cysts/L), while *Cryptosporidium* densities ranged from 0.07 to 484 oocysts/L (geometric mean of 2.70 oocysts/L).

These investigators also detected at least one of the two organisms in the drinking water of 39% of the systems. For those drinking waters that were positive, *Giardia* densities ranged from 0.29–64 cysts/100L (geometric mean 4.45 cysts/100L), while *Cryptosporidium* densities ranged from 0.13 to 48 oocysts/100L (geometric mean 1.52 oocysts/100L). According to the investigators, 78% of the systems that were positive for *Giardia* or *Cryptosporidium* met the turbidity standards specified by the SWTR. Based on a risk assessment model developed for *Giardia*, 24% of the 66 systems might not meet the health goal in the SWTR of no more than the one *Giardia* infection annually per 10,000 people per year (LeChavallier et al., 1991b). (This incidence of infection is a conservative estimate of illness, since not all infected people become ill.) This study suggests that the SWTR may need to be revised if an annual 10^{-4} risk level, or some other desired risk level, is to be achieved by all systems in the United States.

EPA used the data in LeChevallier et al. (1991a,b) to calculate the percentage of systems that use source waters containing various densities of *Giardia* cysts. The Agency calculated that about 85% of the source waters in the study contained 10 cysts/100L or more, while about 45% contained 100 cysts/100L or more. Many of these systems currently provide four, five, or even six or more logs of removal/inactivation and therefore are able to achieve EPA's 10^{-4} annual risk goal. However, if such systems were to reduce existing levels of disinfection to more easily meet new D/DBP regulations, and only marginally meet the three-log removal/inactivation requirement for *Giardia* specified in the current SWTR, they could experience significant increases in microbial risk (Regli et al., 1993; Grubbs et al., 1992; EPA, 1994)).

An epidemiology study by Payment et al. (1991) also suggests that the pathogen density reductions specified by the SWTR may not be sufficient for adequate protection. The goal of this study was to determine the extent to which drinking water caused gastrointestinal disease in a community served by poor quality source water that was subjected to full conventional treatment. In this study, the investigators carried out a trial where 299 households in a community drank water from a reverse-osmosis water filter, while 307 households used the usual tapwater. According to the data, 35% of the reported gastrointestinal illness was associated with the drinking water. The etiologic agent(s) were not identified, but a plausible explanation is that pathogens were in the finished water. A recent analysis by Haas et al. (1993) also suggests that high levels of microbial risk far above the health goal of the existing SWTR may be occurring in systems with highly contaminated source waters that may only minimally comply with the SWTR.

Several other recent studies have shown that *Giardia* and *Cryptosporidium* cysts/oocysts can be found in filtered drinking waters in systems served by highly contaminated source waters (Clancy, 1993; EPA, 1993). If treatment is inadequate in reducing pathogens to an acceptable level, EPA must consider revising and strengthening treatment requirements. A mitigating factor is that, based upon a microscopic examination of the cysts/oocysts detected by LeChevallier et al. (1991b), most of the cysts/oocysts in the drinking water may not be viable. This observation, however, has not yet been confirmed.

Virus CT Values May Be Greater Than Assumed by SWTR

The SWTR assumes that disinfection more readily controls viruses than may actually be the case. The Guidance Manual to the SWTR (EPA, 1991a) identifies the disinfection CT values (disinfectant concentration times the contact time) for viruses. These data are based on laboratory studies in which a dispersed suspension (i.e., non-cell associated, non-aggregated) of hepatitis A virus was used. These CT values relative to the much higher CT values needed for *Giardia* inactivation for systems to comply with the SWTR have led to the assumption by some that systems which satisfactorily control for *Giardia* cysts will adequately control for pathogenic viruses. (The CT values to comply with the level of disinfection inactivation requirements for viruses in the Guidance Manual to the SWTR are one to two orders of magnitude below the CT values necessary to achieve the inactivation requirements for *Giardia*.)

However this assumption may not always be valid. In environmental waters, viruses are usually aggregated or associated with cell debris, some of which may not be removed entirely by filtration processes. Such cell-associated aggregates are considerably more resistant to disinfection than free viruses (Williams, 1985; Sobsey, 1991). Moreover, some pathogenic enteric viruses may be substantially more resistant to disinfection than hepatitis A (Keswick et al., 1985). In addition, laboratory studies to determine CT values for viruses, even with applied uncertainty factors, may underestimate the actual CT values necessary to achieve the desired level of inactivation, since viruses in the environment may be hardier and less susceptible to disinfection.

The detection of viruses in fully treated waters (i.e., after coagulation, sedimentation, filtration, and disinfection) (Gerba and Rose, 1990; Payment, 1985; Hurst, 1991) also suggests that viruses in environmental sources have greater CT values than those published in the Guidance Manual. Hurst (1991), for example, summarized the published data on viruses in drinking water, and found that the percentage of samples positive for viruses ranged from 0 to 100%. In one study, Payment et al. (1985) detected enteroviruses in 7% of finished water samples (1,000 L samples from 7 systems), with an average density of 0.0006 most probable number of cytopathogenic units. In another study, Payment (1981) detected 1–10 enteroviruses/100L in most drinking water samples in a system using poor quality source water.

The above data also suggests that EPA needs to reassess the 4-log level of treatment required for viruses under the SWTR. Under this requirement, a system may only provide a 2-log inactivation of viruses by disinfection and still meet the 4-log overall treatment requirement (under current EPA guidance, systems using conventional treatment are assumed to achieve a 2-log removal of viruses by clarification processes alone). For some systems, virus densities in surface waters may be sufficiently high to warrant at least a 4-log or greater level of inactivation by disinfection alone (and a 6-log or greater removal of viruses with clarification and disinfection) to achieve desired risk levels (Regli et al., 1991). The Agency would like to determine what minimum level of disinfection inactivation is necessary for surface water supplies to ensure adequate virus control, regardless of *Giardia* densities. EPA intends to use data from the ICR to: (1) Help clarify the adequacy of using *Giardia* as a target organism to control for viruses in systems with different source water qualities, (2) determine what assumptions can be made regarding quantification of virus

removal for different treatment processes and disinfection conditions, and (3) determine what, if any, changes to the SWTR are needed to control pathogenic viruses.

DBP Rule May Undermine Pathogen Control

Some systems currently exceed the required *Giardia* and virus reductions specified by the SWTR. The DBP Rule may potentially undermine pathogen control in these systems by prompting them to reduce DBP concentrations at the expense of pathogen control (e.g., by shifting point of disinfection to later in the treatment chain, reducing disinfection dose, or switching to a weaker disinfectant such as chloramines). These systems would still have to comply with the removal/inactivation criteria in the current SWTR, but would do so with a lower margin of safety. This situation might result in a substantial increase in waterborne illness for systems using a poor quality source water. For example, according to a model developed by EPA (Regli et al., 1993), a reduction of the MCL for total trihalomethanes (TTHMs) (one of the toxic byproducts) from 100µg/L to 75µg/L could increase the incidence of waterborne giardiasis in some systems by as many as 10,000 per million people per year, if the existing SWTR is not amended to require higher levels of treatment for poor quality source waters.

This situation is further evidence that EPA may need to revise the SWTR to ensure that measures taken by systems to comply with the forthcoming DBP Rule do not increase the health risk from pathogens.

B. General Approach for Revising SWTR

Under the negotiated rulemaking, the Negotiating Committee agreed to propose three rules: (1) ICR, proposed on February 10, 1994 (59 FR 6332), (2) D/DBP regulations (proposed in today's **Federal Register**), and (3) ESWTR. EPA is planning to remedy the shortcomings of the SWTR indicated above through two sequential stages—an interim ESWTR and a long-term ESWTR. Today's rule proposes the interim ESWTR. The Agency and the Negotiating Committee decided that this phased approach was appropriate because of the uncertainties associated with lack of data. EPA needs much more data on the concentrations of *Giardia*, *Cryptosporidium*, and enteric viruses for various qualities of source waters, with variations over time and season, to determine the need for additional treatment. Some members of the Negotiating Committee believed that health effects information, especially dose response data for pathogens of concern, is also important to ensure that EPA selects the most appropriate control option. In addition, EPA needs more field data on the effectiveness of different types of water treatment for controlling these pathogens. Data from the ICR and various research studies would provide much of this information, sufficient in EPA's view to refine the present proposed interim rule. Additional work would culminate in a long-term ESWTR that would be protective for all surface water system sizes (including those that serve fewer than 10,000 people) and would also include possible refinements to any interim requirements for larger systems. EPA believes that the interim and long-term ESWTR rules are essential for providing adequate human health protection; however, some members of the Negotiating Committee believed that the most appropriate regulatory criteria to provide this protection are not yet apparent.

Schedule of Regulations

Table I–1 indicates the schedule agreed to by the Negotiating Committee for proposing, promulgating, and implementing these rules. Implementation dates for the ICR are indicated under the columns of the Stage 2 D/DBP rule and ESWTR to reflect the relationship between these rules. Although the schedule for proposing these rules has slipped slightly, EPA believes the scheduled promulgation dates for the ESWTR and D/DBP Rule can still be met.

The Negotiating Committee believes that the December 1996 scheduled date for promulgating the Stage 1 D/DBP Rule reflects the shortest time possible by which the interim ESWTR, if necessary, could also be promulgated. EPA is proposing that the Stage 1 D/DBP regulations and the interim ESWTR become effective on the same date of June 30, 1998, for those surface water systems, or ground water systems under the direct influence of surface water, serving 10,000 people or more. This strategy is necessary so that systems do not degrade pathogen control in attempting to comply with the Stage 1 D/DBP regulations.

TABLE I–1.—PROPOSED D/DBP, ESWTR, ICR RULE DEVELOPMENT SCHEDULE

Time line	State 1 DBP rule	Stage 2 DBP rule	ESWTR
12/93	.....	Propose information collection requirements for systems>100k.	Propose information collection requirements for systems >10k.
3/94	Propose required enhanced coagulation for systems with conventional treatment. MCLs–TTHMs (80µg/l), HAA5 (60ug/l), bromate, chlorite. Disinfectant limits	Propose Stage 2. MCLs for TTHMs (40 µg/l), HAA5 (30 µg/l), BAT is precursor removal with chlorination.	Propose interim ESWTR for systems>10k.
6/94	.....	Promulgate ICR	Promulgate ICR.
8/94	Close of public comment period	.....	Public comment period for proposed ESWTR closes.
10/94	.....	Systems>100k begin ICR monitoring	Systems>100k begin ICR monitoring.
1/95	.....	.....	Systems 10–100k begin source water monitoring.
10/95	.....	SW systems>100k, GW systems>50k begin bench/pilot studies unless source water quality criteria met.	
11/95	.....	.....	NOA for monitoring data, direction of interim ESWTR.
1/96	.....	.....	Systems>10k complete ICR monitoring. End NOA public comment period.

TABLE I–1.—PROPOSED D/DBP, ESWTR, ICR RULE DEVELOPMENT SCHEDULE—Continued

Time line	State 1 DBP rule	Stage 2 DBP rule	ESWTR
3/96	.....	Systems complete ICR monitoring	Systems>100k complete ICR monitoring.
12/96	Promulgate Stage 1	.....	Promulgate interim ESWTR for systems>10k.
6/97	.....	Notice of availability for Stage 2 reproposal	Propose long-term ESWTR for systems<10k, possible changes for systems>10k.
10/97	.....	Complete and submit results of bench/pilot studies.	
12/97	.....	Initiate reproposal—begin with 3/94 proposal.	
6/98	Effective. Effective for SW systems serving greater>10k, extended compliance date for GAC or membrane technology	Close of public comment period	Interim ESWTR effective for systems>10k. 1994–6 monitoring data used to determine treatment level.
12/98	.....	Propose for CWSs, NTNCWSs	Publish long-term ESWTR.
6/00	Stage 1 limits effective for surface water systems<10k, GW systems>10k	Promulgate Stage 2 for all CWSs, NTNCWSs.	Long-term ESWTR effective for all system sizes.
1/02	Stage 1 limits effective for GW systems<10k unless Stage 2 criteria supersede	Stage 2 effective, compliance for GAC/membranes by 2004.	

EPA is proposing to delay the effective date of the Stage 1 D/DBP regulations for systems serving less than 10,000 people until June 30, 2000, to allow such systems time to comply with the long-term ESWTR. EPA believes that this date reflects the shortest time possible that would allow the long-term ESWTR to be proposed, promulgated, and become effective, thereby providing the necessary protection from any downside microbial risk that might otherwise result when systems of this size achieve compliance with the Stage 1 D/DBP rule.

Since EPA is proposing the interim ESWTR before systems begin collecting the monitoring data specified by the ICR, the Agency's final direction for the interim ESWTR is not yet clear. For this reason, the Agency is proposing a number of regulatory alternatives, including one that would not revise the existing SWTR. After EPA receives and processes pertinent monitoring data generated under the ICR, the Agency will prepare a **Federal Register** notice (referred to as a Notice of Availability) that will present the processed data to the public, the Agency's interpretation of that data, and the specific regulatory strategy the Agency is considering. Public comments on this **Federal Register** package will influence the direction the Agency ultimately takes in developing the interim ESWTR.

EPA is extending the comment period to the proposed interim ESWTR to May 30, 1996, which is beyond the original date indicated in Table I–1 (August 1994). The Agency believes this adjustment is necessary to take into account the slippage in the anticipated ICR promulgation date, which will necessarily also result in a slippage in the NOA publication date to early Spring 1996. The Agency believes that it would be more reasonable and efficient for EPA not to close the comment period for the ESWTR before the comment period ends for the NOA.

Unlike the interim ESWTR, the long-term ESWTR will cover all surface water systems, including those serving fewer than 10,000 people. The anticipated primary thrust of these final regulations will be to cover these smaller systems, rather than to make major changes in the treatment requirements for larger systems, although some refinements are possible. EPA expects the criteria for defining the specified treatment needed for smaller systems will be simpler than that for the larger systems and may, for example, only require monitoring of easily measured indicators rather than pathogens, especially if an adequate correlation is observed between indicator and pathogen densities under the ICR and other related research. Pathogen monitoring in small systems may be possible, if inexpensive, simple analytical tests for viruses and/or protozoa can be developed, evaluated, and approved. EPA may also cover small systems by using the ICR data to develop national occurrence patterns that would allow the Agency to establish more appropriate treatment criteria for small systems. The Agency anticipates that by characterizing source water quality using any one or a combination of these approaches, a small system could evaluate the adequacy of its existing level of treatment for pathogen control and determine the need for treatment modifications.

Data Collection and Monitoring

If EPA decides to revise the SWTR to require higher levels of treatment for poorer quality source waters, information on microbial densities in these sources gathered under the ICR can be used by utilities, States and EPA to determine required levels of treatment for individual systems. If such information is not available for a system (e.g., if a system that had not performed ICR monitoring serves a community which grows in population from less than to greater than 10,000 people), EPA would require such a system to collect sufficient information on microbial densities of its source water and treatment practices to allow the State to make this determination. The ESWTR may also require systems serving 10,000 people or greater to monitor their source waters periodically to determine whether changes have occurred in the quality of that water since the ICR monitoring. Any deterioration in source water quality may necessitate additional pathogen control measures.

For monitoring subsequent to the ICR for *Giardia* and *Cryptosporidium*, EPA intends to require the use of the immunofluorescence method specified by the ICR. If performance data support their use, newer assays currently under development may be considered. One of

these assays is based on the observation that particles in a rotating electric field also rotate if the frequency is right. Investigators using this principle have developed a novel assay, referred to as the electrorotation assay, that can apparently easily distinguish between the target organism (e.g., *Cryptosporidium*) and other organisms and particle debris if the field frequency is adjusted properly. At this frequency, the target organism rotates and other particles do not, an observation easily visualized under the microscope. Preliminary data reported by the developer for sterile natural water samples spiked with *Cryptosporidium* are similar to those obtained with an immunofluorescence method. If these data are confirmed, the assay would be far less expensive, simpler, and more rapid than the standard method.

In addition to this assay, other potential assays for *Giardia* and *Cryptosporidium* include polymerase chain reaction (PCR) and flow cytometry. The PCR is a powerful and rapid tool for detecting genetic material that is initially present in very low concentrations. It involves the amplification of genetic material in a laboratory instrument until sufficient quantities are available for analysis. Recent publications have described the use of PCR in detecting *Giardia* and its potential for differentiating between live and dead cysts (Mahbubani, et al. 1991). Flow cytometry is a process that measures physical or chemical characteristics of cells passing single file through the measuring apparatus in a fluid stream (Shapiro, 1992). This process is rapid and may be useful for distinguishing between and quantifying *Giardia* and *Cryptosporidium*.

C. Proposed Maximum Contaminant Level Goal and Treatment

Technique for *Cryptosporidium*

As stated above, the protozoan *Cryptosporidium parvum* has recently been implicated in a number of large waterborne disease outbreaks in the United States. The disease cryptosporidiosis is caused by ingestion of the environmentally-resistant oocysts of *Cryptosporidium*, which are readily carried by the waterborne route. Both human and other animals may excrete these oocysts. Transmission of this disease often occurs through ingestion of the infective oocysts from contaminated water or food, but may also result from direct or indirect contact with infected persons or animals. Symptoms of cryptosporidiosis include diarrhea, abdominal discomfort, nausea, vomiting, dehydration, weight loss, and other gastrointestinal symptoms (Current et al., 1983). These may persist for several days to several months. Young children and immunocompromised persons are most susceptible to infection (Wittenberg et al., 1989; De Mol et al., 1984), but people of all ages may become infected. While cryptosporidiosis is generally a self-limiting disease with a complete recovery in otherwise healthy persons, it can be very serious in immunosuppressed persons, such as persons with AIDS, those receiving treatment for certain types of cancer, and organ-transplant recipients (De Mol et al., 1984; CDC, 1982). Several studies in Great Britain have documented a waterborne route for cryptosporidiosis in AIDS patients and in persons receiving immunosuppressive transplant therapy (Casemore, 1990). There appears to be an immune response to *Cryptosporidium*, but it is not known if this results in protection (Fayer and Ungar, 1986). Data suggest that a person, once infected, can transmit this infection by direct contact to other susceptible persons (Casemore and Jackson, 1984).

Between 1984–1993, there were a number of reported outbreaks of significant waterborne cryptosporidiosis in the U.S. and Great Britain, totaling many tens of thousands of cases (D'Antonio et al., 1985; Smith et al., 1988; Hayes et al., 1989; Herwaldt et al., 1991; Levine and Craun, 1990; Moore et al., 1993). The trend in numbers of outbreaks has been on the increase, probably due to greater recognition and subsequent reporting of *Cryptosporidium* in outbreaks during recent years. Prevalence data for human cryptosporidiosis in all age groups ranged from 1 to 2 percent in Europe, 0.6 to 4.3 percent for North America, and 3 to 20 percent for Asia, Australia, Africa, and South America (EPA, 1993). The role of water in the transmission of cryptosporidiosis has been proven. However, the known percentages of cases from water compared to other routes may substantially under-represent the water route. The route of transmission for many cases of cryptosporidiosis was not determined, but may have been waterborne.

During the spring of 1993, there was a severe waterborne disease outbreak of cryptosporidiosis in Milwaukee, Wisconsin, with an estimated 400,000 cases of diarrhea and apparently several deaths associated with the disease in severely immunocompromised persons. Another recent outbreak of waterborne cryptosporidiosis occurred in Jackson County, Oregon, during the winter and spring of 1992, where as many as 15,000 people (10% of the population) displayed cryptosporidiosis-like symptoms (AWWA, 1992).

It is estimated that over 162 million people are served by public water systems using surface water, most of which are filtered and disinfected. Of these, as of June 1989, an estimated 21 million people were receiving unfiltered surface water that is only disinfected. EPA anticipates that, as a result of the SWTR, more than 80 percent of the unfiltered systems will install filtration. Nevertheless, in spite of filtration and disinfection, *Cryptosporidium* oocysts have been found in filtered drinking water (LeChevallier et al., 1991b; EPA, 1993) and most waterborne outbreaks of cryptosporidiosis have been associated with filtered surface water systems. Therefore, it appears that surface water systems that filter and disinfect may still be vulnerable to *Cryptosporidium*, depending on source water quality and treatment effectiveness. In addition, some surface water systems that were able to avoid filtration under the SWTR may need to filter to provide adequate protection against *Cryptosporidium*.

EPA is proposing an MCLG for *Cryptosporidium* because *Cryptosporidium* oocysts have been demonstrated to be a significant health threat for all persons consuming untreated or inadequately treated surface waters and ground waters under the influence of surface waters. The proposed MCLG is based upon animal studies and the human epidemiology of waterborne outbreaks of cryptosporidiosis.

While it is clear that *Cryptosporidium* can infect humans, dose-response data for infection and illness rates are lacking. Therefore, risk assessments for this organism based on human data are not currently possible. However, the results of several animal studies have been published on the infectious dose of *Cryptosporidium* oocysts. Korich et al. (1990) examined neonatal mice inoculated with 600, 6,000, or 60,000 oocysts. In this study, the mean infectious dose (ID50) was determined by initial experiments to be 60 oocysts. Mice receiving 60 or more oocysts were typically infected while those receiving less than 60 oocysts often did not demonstrate any infection. The work of Miller et al. (1990), while limited because of the small number of animals tested, was conducted on Macaque monkeys. Ten oocysts via oral intubation were capable of causing infection and the signs and symptoms resembled the effects seen in children and immunocompromised humans with cryptosporidiosis. Feeding studies in mice described by Ernest et al. (1986)

indicated that inoculation with 100, 500, or 1,000 oocysts caused infection in 22, 66, and 78 percent, respectively, of the mice in each dose group. Studies to date strongly suggest that there are strain differences or virulence factors that may greatly influence the ability of *Cryptosporidium* to infect humans and animals via the oral route. The comparative infectivity of specific strains for humans and various animal models has not been accurately established.

The use of animal models for determining infectious dose may overestimate the number of oocysts required for human infection. Also, technical questions remain that affect EPA's consideration of the reliability and meaning of the available data. For example, the length of time and procedures used in storage of oocysts in the laboratory before infectivity studies begin may influence infectivity determinations. There are currently no proven *in-vitro* methods to determine whether oocysts used in testing are all viable.

Because some strains of *Cryptosporidium parvum* appear to be highly infectious, and because there is no current generally accepted practical means for distinguishing whether detected oocysts are viable or for determining the infectious dose of any particular strain, EPA believes this organism should be assumed to be without an infectivity threshold for purposes of this rule. That is, consumption of one *Cryptosporidium* oocyst would be considered sufficient to initiate human infection as a possible consequence. Also, direct person-to-person spread of infection may readily occur, thus magnifying the significance of the original waterborne infection. Therefore, the presence of this organism at any level in consumed drinking water cannot be considered safe for human consumption. For these reasons and to be consistent with EPA drinking water standards for *Giardia*, enteric viruses, *Legionella*, *E. coli* and coliform bacteria, EPA proposes that the MCLG for *Cryptosporidium* oocysts in water be zero. Public comments are requested on this rationale for setting an MCLG of zero and a treatment technique for *Cryptosporidium*.

D. Proposed Revisions to SWTR Under all Treatment Alternatives

This section proposes three revisions of the SWTR that would apply regardless of which of the four treatment alternatives in Section E that EPA selects. This section also requests public comment on several additional measures (Section 4, below).

1. Inclusion of Cryptosporidium in Definition of "Groundwater Under the Direct Influence of Surface Water"

The SWTR at 40 CFR 141.2 defines "groundwater under the direct influence of surface water" as "any water beneath the surface of the ground with (1) significant occurrence of insects or other macroorganisms, algae, or large-diameter pathogens such as *Giardia lamblia*, or (2) significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlate to climatological or surface water conditions * * *". Systems using such ground waters as a source for drinking water are subject to the provisions of the SWTR. Determination of whether a ground water is under the direct influence of surface water requires careful evaluation of site-specific information on water quality, well construction characteristics, and hydrogeology.

EPA defined groundwater under the direct influence of surface water in the SWTR to ensure that public water supply systems using this type of source water would provide appropriate treatment to minimize health risks from pathogens. Since viruses and bacteria are known to contaminate true ground waters, EPA focused attention on those contaminants that do not normally occur in true ground waters and whose presence suggests direct surface water contamination.

Among those contaminants are certain pathogenic protozoa, such as *Cryptosporidium parvum* and *Giardia lamblia*. These protozoa are common in surface waters. At the time of promulgation of the SWTR, routine methods for detection of *Cryptosporidium* were not generally available and, therefore, *Cryptosporidium* was not specifically addressed under the definition of "groundwater under the direct influence of surface water". EPA is currently revising its existing guidance (EPA, 1991a; EPA, 1992) to address this issue.

EPA proposes to amend the SWTR by including *Cryptosporidium* in the definition of a "ground water under the direct influence of surface water". Under the rule, a system using ground water considered vulnerable to *Cryptosporidium* contamination would be subject to the provisions of the SWTR. The Agency proposes that this determination be made by the State for individual sources using State-established criteria for requirements and documentation. The Agency believes that this would allow States sufficient flexibility to accommodate local and regional hydrogeological conditions and maintain consistency with State well construction requirements, watershed management policies, and wellhead protection plans.

Because *Cryptosporidium* can occur episodically, the inability to detect this organism in a ground water at any given time would not necessarily suggest that ground water is not under the direct influence of surface water. The presence of *Cryptosporidium*, however, would indicate fecal contamination and direct influence of surface water.

The SWTR does not necessarily require a system that uses ground water to filter if it detects *Cryptosporidium*, *Giardia*, or other contaminants associated with surface water in the ground water, or if the groundwater is categorized as being under the direct influence of surface water. The presence of these organisms may be the result of faulty well construction that can be remedied by inexpensive measures. Also, the rule allows States to grant removal/inactivation credit for the "natural disinfection" achieved during flow from the surface water source to a well; such natural disinfection could mitigate the treatment level that might otherwise be required. For the State to grant removal/inactivation credit for a system, that system would have to demonstrate the extent to which *Giardia* and *Cryptosporidium* are removed by site-specific natural removal processes before the water enters the well.

However, strategies for granting such credits are currently limited because accurate pathogen removal/inactivation rates during transport through the ground cannot yet be easily predicted.

EPA solicits comment on the inclusion of *Cryptosporidium* in the determination of ground water under the influence of surface water, on the larger consideration of revisions to guidance on this issue, and on the most appropriate procedures for determining removal/inactivation credits and treatment requirements for systems using ground waters under the direct influence of surface water.

2. Inclusion of *Cryptosporidium* in Watershed Control Requirements

The SWTR at § 141.71 specifies the conditions under which a public water system using a surface water source can avoid filtration. Among the conditions is a requirement that the system maintain a watershed control program that minimizes the potential for source water contamination by *Giardia lamblia* and viruses (§ 141.71(b)(2)). This program must include a characterization of the watershed hydrology characteristics, land ownership, and

activities which may have an adverse effect on source water quality.

EPA is proposing to extend the watershed control requirements to include the control of *Cryptosporidium* in the source water in a manner analogous to the existing requirements in § 141.71(b)(2) for *Giardia* cysts and viruses. The rationale is that *Cryptosporidium* is a pathogen that cannot be easily controlled with conventional disinfection practices, and therefore its presence in source water serving unfiltered surface water systems must be limited. Specifically, *Cryptosporidium* would be included in the watershed protection control provisions wherever *Giardia* is mentioned.

3. Sanitary Surveys for all Surface Water Systems

The SWTR at § 141.71(b)(3) requires that systems wishing to avoid filtration must be subject to an annual on-site inspection performed by the State or a party approved by the State. The results of this system inspection must indicate to the State's satisfaction that the disinfection treatment process and the watershed control program are adequately designed and maintained.

EPA proposes to amend the SWTR to require all systems that use surface water, or ground water under the direct influence of surface water, to have a periodic sanitary survey, regardless of whether they filter or not. States would be required to review the results of each sanitary survey to determine whether the existing monitoring and treatment practices for that system are adequate, and if not, what corrective measures are needed to provide adequate drinking water quality. If EPA publishes a regulation that requires systems to treat their water on the basis of pathogen densities in the source water (see Section E below), the Agency would require systems, as part of the sanitary survey, to assess quantitatively whether the source water quality has changed sufficiently since the previous sanitary survey to warrant changes in treatment practice.

Under this rule, the system would be responsible for insuring that the sanitary survey is accomplished. Only the State or an agent approved by the State would be able to conduct this sanitary survey, except in the unusual case where a State has not yet implemented this requirement, i.e., the State has neither performed a sanitary survey nor generated a list of approved agents. For these unusual cases, the Agency solicits comment on what EPA prerequisites, if any, should be specified in the rule or guidance for individuals performing sanitary surveys (e.g., BS degree in environmental engineering, professional engineer certificate, sanitarians, etc.).

Sanitary surveys are defined in § 141.2 as "an on-site review of the water source, facilities, equipment, operation and maintenance of a public water system for the purpose of evaluating the adequacy of such sources, facilities, equipment, operation and maintenance for producing and distributing safe drinking water." Guidance for conducting a sanitary survey for unfiltered systems appears in the SWTR Guidance Manual (EPA, 1991), even though such a survey is not specifically required by the SWTR. EPA solicits comment on how this Guidance Manual should be revised to address concerns for filtered systems, and for *Cryptosporidium*.

The requirement for a sanitary survey under this rule would be similar to that in the TCR, which requires periodic sanitary surveys for some systems. Specifically, the TCR at § 141.21(d) requires periodic sanitary surveys for systems that collect fewer than five routine samples per month. These surveys are performed by the State or a party approved by the State. The results of the sanitary surveys are to be used by the State to determine whether the monitoring frequency is appropriate, and if not, what the new frequency should be and whether the system needs to undertake any specific measures to improve water quality. These surveys are to be performed every five years or ten years, depending on circumstances. These surveys are somewhat more extensive than the on-site inspection required under the existing SWTR and include an evaluation of the distribution system.

In addition to the sanitary survey in the TCR and the proposed requirement for surface water systems, EPA intends to propose a sanitary survey requirement in the forthcoming Groundwater Disinfection Rule for all public water supply systems using groundwater that wish to avoid disinfection.

The Agency believes that periodic sanitary surveys, along with appropriate corrective measures, are indispensable for assuring the long-term quality and safety of drinking water. Many States already perform sanitary surveys on most or all systems. By taking steps to correct deficiencies exposed by a sanitary survey, the system provides an additional barrier to microbial contamination of drinking water.

Compliance with this requirement would not eliminate the requirement for unfiltered systems to conduct annual on-site inspections, although applicable information from these on-site inspections could be used to satisfy some elements of the sanitary survey. During the years when the sanitary survey is conducted, the sanitary survey would fulfill the on-site inspection requirement.

With promulgation of these rules, EPA hopes to focus more attention on watersheds and watershed protection activities to enhance and maintain the quality of both surface waters and ground waters as sources for drinking water. The Agency recognizes that in many areas of the United States, watersheds that serve as drinking water sources are increasingly vulnerable to degradation. Moreover, the current status of technology and scarce funding may limit the levels of water treatment reasonably possible. Therefore, the Agency wishes to minimize the contamination of source waters to maintain or improve the health benefits from drinking water treatment. While the rule proposed here derives from provisions of the SDWA, protection of watersheds is also consistent with provisions of the Clean Water Act.

One issue that the Negotiating Committee considered throughout the negotiation process was the relationship and role of watershed protection to these regulations. The committee sought to promote watershed protection and to provide incentives to establish new watershed protection programs and to improve existing ones. This goal was prompted by the benefits that watershed protection provides not only for disinfectant byproduct control, but for the control of a wide range of potential drinking water contaminants.

Watershed protection minimizes pathogen contamination in water sources, and hence the amount of physical treatment and/or disinfectant needed to achieve a specified level of microbial risk in a finished water supply. It also may reduce the level of turbidity, pesticides, volatile organic compounds, and other synthetic organic drinking water contaminants found in some water sources. Watershed protection results in benefits for water supply systems by minimizing reservoir sedimentation and eutrophication and by reducing water treatment operation and maintenance costs. Watershed protection also provides other environmental benefits through improvements in fisheries and ecosystem protection.

The types of watershed programs that the committee wished to encourage are those that consider agricultural controls, silvicultural controls, urban non-point controls, point discharge controls, and land use protection that are tailored to

the environmental and human characteristics of the individual watershed. These characteristics include the hydrology and geology of the watershed; the nature of human sources of contaminants; and the legal, financial and political constraints of entities that affect the watershed.

Sanitary survey frequency. EPA is considering requiring sanitary surveys either every three years or every five years, and requests public comment on this issue. There is a major concern that changes over time in watershed characteristics, such as those resulting from development or other changes in land use, may degrade surface source water quality significantly. Treatment facilities and distribution systems likewise may deteriorate over time. It is important to address such adverse changes as soon as possible. Consequently, more frequent sanitary surveys should result in safer and more reliable drinking water. This is the advantage of a three-year survey over a five-year survey.

Yet a survey every five years is less expensive and is more consistent with the provisions of the TCR. EPA considers a five-year frequency to be minimal for assessing watershed and system conditions associated with surface waters. To provide adequate lead time to the State for implementing any sanitary survey requirement, EPA would not require systems to complete the initial sanitary survey until five years after the effective date of this rule. This lead time would not apply to systems that collect fewer than five samples per month under the TCR, since they should already have had their initial survey.

EPA does not believe this sanitary survey requirement would be onerous to systems, since systems collecting fewer than five samples/month (i.e., serving fewer than 4101 people) are already required to conduct sanitary surveys under the TCR, and larger systems should have greater financial resources than these smaller ones.

4. Possible Supplemental Requirements

a. Uncovered Finished Water Reservoirs. EPA guidelines recommend that all finished water reservoirs and storage tanks be covered (EPA, 1991a,b). The American Water Works Association (AWWA) also has issued a policy statement strongly supporting the covering of reservoirs that store potable water (AWWA, 1993). In addition, a workshop in 1981 convened by EPA, in conjunction with the American Society for Microbiology, to advise EPA on a variety of drinking water issues recommended that EPA require systems to cover all new finished water reservoirs (EPA, 1983). By covering reservoirs and storage tanks, systems would reduce the potential for contamination of the finished water by pathogens and hazardous chemicals. It would also limit the potential for taste and odor problems and increased operation and maintenance costs resulting from environmental factors such as sunlight (Bailey and Lippy, 1978).

Potential sources of contamination to uncovered reservoirs and tanks include airborne chemicals, surface water runoff, animal carcasses, animal or bird droppings, growth of algae and other aquatic organisms due to sunlight that results in biomass, and violations of reservoir security (Bailey and Lippy, 1978).

Because of these adverse consequences, EPA is considering whether to issue regulations that require systems to cover finished water reservoirs and storage tanks. The Agency solicits public comment on whether such a national regulation is appropriate, whether such a requirement should be at State discretion only, what costs would be incurred by systems under such a regulation, and under what conditions a waiver from this rule would be appropriate.

Cross-Connection Control Program. Plumbing cross-connections are actual or potential connections between a potable and non-potable water supply (EPA, 1989b). According to Craun (1991), 24% of the waterborne disease outbreaks that occurred during 1981–1990 were caused by water contamination in the distribution system, primarily as the result of cross-connections and main repairs. During this period, 11 reported outbreaks with 1350 associated cases were blamed on cross-connection problems in community water systems (Craun, 1994). While the vast majority of outbreaks associated with cross connections are caused by pathogens, a few are caused by chemicals.

EPA does not have a regulation mandating a cross-connection control program, but does address the issue in the TCR. Section 141.63(d)(3), for example, identifies proper maintenance of the distribution system as one of the best technologies, treatment techniques, and other means for achieving compliance with the MCL for total coliforms. In a subsequent clarification, EPA explained that this statement in the rule includes a cross-connection control program. In addition, in a rule that stayed the no variances provision of the TCR, i.e., allows States to grant variances, EPA recommended that one of the criteria that States could use to identify systems that could operate under a variance without posing an unreasonable risk to health was that the system has a cross-connection control program acceptable to the State and performs an audit of its effectiveness (56 FR 1556, January 15, 1991). The AWWA also has a policy statement on cross connections urging systems to set up a program for their control (AWWA, 1993).

EPA is seeking public comment on whether EPA should require States and/or systems to have a cross-connection control program; what specific criteria, if any, should be included therein; and how often such a program should be evaluated. Should EPA require that only those connections identified as a cross connection by the public water system or the State be subject to a cross connection program? EPA also seeks comment on what conditions would a waiver from this rule be appropriate. In addition, the Agency requests commenters to identify other regulatory measures EPA should consider to prevent the contamination of drinking water already in the distribution system (e.g., minimum pressure requirements in the distribution system).

State notification of high turbidity levels. The SWTR requires filtered systems to report turbidity measurements to the State within ten days after the end of each month the system serves water to the public (§ 141.75(b)(1)). If at any time the turbidity exceeds 5 NTU, however, the system must notify the State as soon as possible, but no later than the end of the next business day (§ 141.75(b)(3)(ii)). In addition, the system must notify the public as soon as possible, but in no case later than 14 days after the violation (non-acute violation, § 141.32(a) and § 141.32(b)(10)).

EPA is considering broadening the requirement for systems to notify the State as soon as possible. The Agency might, for example, require systems to notify the State as soon as possible if at any point during the month it becomes apparent that a system will exceed the monthly turbidity performance standard in § 141.73 (0.5 NTU for conventional filtration or direct filtration, 1 NTU for slow sand filtration or diatomaceous earth) for an extended period of time (e.g., more than 12 consecutive hours), regardless of whether the system will violate the monthly standard. In addition, the Agency might require systems to notify the State as soon as possible if at any point during the month it becomes apparent that a system will violate the monthly

turbidity performance standard in § 141.73, rather than await the end of the month, as specified in the existing SWTR.

There are sound public health reasons for requiring swift State notification for persistent turbidity levels above the performance standards in § 141.73. Pathogens may accompany the turbidity particles that exit the filters, especially with poor quality source waters. High turbidity levels in the filtered water, even for a limited time, may represent a significant risk to the public. Increasing the disinfection residual in such cases is essential, but some pathogens (e.g., *Giardia* and *Cryptosporidium*) are relatively resistant to disinfection. Early notification would allow the states to require the system to issue an immediate public notice of the turbidity violation if the nature of the violation is considered to be an immediate health concern.

EPA solicits comment on whether the Agency should require systems to notify the State as soon as possible for persistent turbidity levels above the performance standards or for any other situation that is not now a violation of the turbidity standards.

E. Alternative Treatment Requirements

This section proposes five alternative treatment requirements for removing *Giardia*, *Cryptosporidium*, and/or viruses. The final rule might include one or some combination of these alternatives. These regulatory alternatives would require systems to remove a specified level of pathogen based upon its density in the raw water, as measured either under the ICR or another comparable approach. The greater the pathogen density in raw water, the greater would be the pathogen reduction required by treatment. This section also examines several statistical options for defining pathogen densities in source waters.

The Regulatory Impact Analysis for this proposal includes preliminary estimates of the incremental costs for several of these options and discusses what incremental risk reductions would be needed to offset these costs from a cost benefit perspective. As the ICR data become available, EPA intends to develop the risk reduction and cost estimates of these different options for defining pathogen densities in source waters, for different treatment alternatives, and to publish this analysis in a Notice of Availability. After reviewing public comments and additional information and data, EPA intends to select one or more options that provides the greatest improvement in public health taking into account any adverse health effects associated with treatment strategies required and the costs of these improvements.

1. Options for Defining Pathogen Densities in Source Waters

EPA is considering several options for defining the raw water pathogen density that systems would use to determine their needed level of treatment. As part of this, EPA is considering both the technical and public health implications of these options.

The public health risk from waterborne microorganisms depends on their density in source water and their infectious dose levels. Since the calculated infectious dose levels for *Giardia* and other pathogens do not address high-risk populations, e.g., the very young and old and immunocompromised individuals, they may not be conservative with respect to protecting public health. Therefore, EPA could provide a margin of safety for such populations by requiring a system to define the pathogen density used for determining the required treatment level in terms of a conservative statistical method, i.e., one that would provide a higher pathogen density than an arithmetic mean. Such analysis would also need to consider various assumptions regarding the likelihood of a detected organism being viable and infectious. Currently it is not yet possible to determine whether a protozoan cyst in water is viable or, if viable, infectious. EPA and other groups, however, are conducting research in this area.

The approach EPA selects for calculating pathogen density should consider the wide temporal and spatial variations in densities that occur in raw water and should be appropriate for the calculation of the attendant health risks. Among the approaches being considered by the Agency are the arithmetic mean, geometric mean, 90th percentile, and maximum measured value. These are discussed below.

EPA expects that systems subject to this rule will use their data collected under the ICR as a basis for determining source water pathogen densities and selection of appropriate treatment levels. The Negotiating Committee recommended this approach so that systems would have sufficient time to determine the need for, design, and install any necessary treatment to comply with both the ESWTR and D/DBPR requirements in a consistent, integrated manner. This approach would require States, as part of their primacy applications for the ESWTR, to include provisions for acquiring ICR data from EPA's ICR data base when it becomes available, directly from the system or a database.

EPA recognizes that some systems that currently serve fewer than 10,000 people, and thus not subject to ICR monitoring, may eventually, as a result of their growth, become subject to the interim ESWTR. Once such a system serves 10,000 people or more, the rule would require it to collect data sufficient to determine the source water pathogen densities in a manner analogous to that specified in the ICR. The system would then use these data to determine the level of treatment needed. EPA solicits comment on this approach.

a. Use of arithmetic mean of data. The arithmetic mean is the sum of the pathogen densities from all collected samples divided by the number of samples. An arithmetic mean would be calculated for each pathogen. The arithmetic mean is most appropriate when the densities are relatively uniform, both spatially and temporally, and symmetrical about the mean.

Use of the arithmetic mean is most useful when the distribution of measured values approximates a normal distribution. Relative to the geometric mean, the arithmetic mean allows an easier calculation of confidence intervals and may be more conservative. When considering the multiple exposures associated with drinking water ingestion at the low microbial risk levels associated with treated water, risks can be considered as additive and linearly related. Under these circumstances, the arithmetic mean is superior to the geometric mean in the estimation of central tendency (Regli et al., 1991).

b. Use of geometric mean of data. The geometric mean is defined by the equation:

$$G_m = \log^{-1}(1/n \times [\log X_1 + \log X_2 + \ldots \log X_n]),$$

Where n = number of samples and X_i is the measured density for each sample. For example, the geometric mean of the values 1, 10, and 100 would be 10. The geometric mean is more appropriate than the arithmetic mean for representing the central tendency for data that have a skewed distribution. However, the geometric mean is less conservative, i.e., it would generally estimate a lower mean density and therefore lower risk for pathogens than the arithmetic mean (for example, the arithmetic mean of 1, 10, and 100 is 37, versus the geometric mean of 10). Nevertheless, depending upon the assumptions made in the risk

assessment calculation (e.g., percentage of cysts/oocysts viable), use of the geometric mean may be adequately conservative for estimating exposures and consequently appropriate levels of treatment (Regli et al., 1991).

c. Use of the 90th percentile value. Another alternative for defining pathogen density is to base this value on the 90th percentile of all data for a particular pathogen. This is the value below which fall 90% of the data points and above which fall 10% of the data points. This approach is more conservative in terms of risk than the arithmetic mean and geometric mean, because for sources where pathogen density varies significantly throughout the year, use of this value will be more representative of the elevated risk associated with peak contamination periods.

Use of the 90th percentile measured value, however, has the obvious drawback that it requires a sufficient number of samples to provide a good 90th percentile estimate without interpolation. In many cases, particularly for small water systems, cost considerations will prevent extensive sampling. For example, the proposed ICR would require only six raw water samples over the period of a year for systems from 10,000 to 100,000 people served. The 90th percentile value could be interpolated from the two highest values.

d. Use of the maximum measured value. This approach would dictate the use of the highest density measured under the ICR for raw water. Since few systems have the resources for routine, frequent, and long-term sampling for pathogens such as *Giardia*, *Cryptosporidium* and viruses, it is clear that episodic periods of microbial contamination may escape detection. EPA is particularly concerned with the risks from unusually high level contamination events that might exceed the removal/inactivation capacity of a treatment system. While the maximum measured value may not be representative of the normal pathogen density in a source water, it would be more indicative of potential short-term risks.

Additionally, since the published dose-response values for *Giardia* and other pathogens were developed in healthy adult populations and therefore are not conservative with respect to protecting public health, EPA might select use of the maximum value, which is the most conservative statistical option, to offset this problem. Alternatively, it may be more appropriate to use a less conservative method for estimating microbial densities but to use more conservative criteria for deriving the actual level of treatment requirements as they relate to pathogen densities. For example, if EPA assumes that all *Giardia* cysts detected are viable and infectious to humans in specifying the level of treatment needed, this approach may be sufficiently conservative to warrant the density calculation by one of the other above described methods.

A major problem with basing the density calculation on the maximum value is that if a utility collects more than the minimum number of samples required in the interest of better defining potential exposures, it has a greater likelihood of collecting a sample with a higher pathogen density than would occur with the minimum required number of samples. In this case, the system may face a more stringent (and thus more expensive) standard.

Use of the maximum measured density may be more appropriate than other statistical methods for systems that have not collected sufficient data to allow calculation of an adequately representative mean value or 90th percentile value. With such limited data, the maximum value might be suitable for determining level of treatment.

EPA is soliciting comment on which approach is most appropriate for defining pathogen density. The Agency is also requesting comment on whether the approach used should be based on the number of pathogen samples collected, i.e., the maximum measured value would be required for systems taking only six samples under the ICR (systems serving between 10,000 and 100,000 people) and 90th percentile value for systems that collect at least 10 samples.

2. Treatment alternatives for controlling pathogens. To determine what regulatory controls are most appropriate for controlling pathogens in drinking water, EPA must decide what constitutes acceptably safe drinking water. The SDWA frames this discussion in determining MCLGs and MCLs. MCLG levels, which are not legally enforceable, are based solely on health concerns. As required by the SDWA, they are set "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety". The corresponding enforceable regulation consists of either an MCL set as close to the MCLG as feasible, taking cost and availability of treatment into account; or, when it is not technologically or economically feasible to monitor for the contaminants, a treatment technique(s) to achieve an acceptable risk.

The SWTR promulgated an MCLG for *Giardia* of zero, i.e., no *Giardia* cysts should be allowed in drinking water. A system using surface water cannot usually attain this goal in any practical sense. Therefore, the SWTR preamble suggested a more practical health goal for *Giardia*: drinking water should not cause more than one *Giardia lamblia* infection annually per 10,000 exposed persons (10^{-4} risk). In contrast to this goal, EPA policy for specific chemical carcinogens is for theoretical lifetime upper bound risks to be no greater than within a range of 10^{-4} to 10^{-6}. For non-carcinogenic chemical contaminants, EPA policy is to base the MCLG on the reference dose (RfD) for the given chemical. The RfD is calculated to be below any known level of exposure resulting in adverse health effects, so that drinking water at the resulting MCLG over a lifetime should be without known risk.

In developing the D/DBP rule (proposed elsewhere in today's **Federal Register**), EPA is attempting to ensure that drinking water remains microbiologically safe at the limits set for disinfectants and byproducts, and that the disinfectants and byproducts themselves do not pose an unacceptable risk at these limits.

Based on data on microbial illness and death in the U.S. compiled by Bennett et al. (1987), the estimated annual risk of waterborne illness during 1985 was about 4×10^{-3} and the estimated lifetime risk of death was about 3×10^{-4}. As stated above, the goal of the SWTR was for systems to achieve a risk of less than 10^{-4} infections per year for *Giardia*. Because *Giardia* is relatively difficult to inactivate compared to virus and bacterial pathogens, the SWTR assumed that water treatment adequate to achieve a 10^{-4} risk for *Giardia* would provide an even higher level of protection against pathogenic viruses and bacteria in untreated surface waters. Applying the Bennett et al. (1987) data regarding the ratio of mortality to waterborne illness (0.1 percent = 10^{-3}), if a system achieves an incidence of 10^{-4} waterborne infections per year or less, the associated lifetime risk of death would be less than 7×10^{-6}. This is a 40-fold decrease in risk relative to those estimated by Bennett et al. (1987), who used 1985 data.

The above calculations refer to the average individual and an average pathogenic organism. Available dose-response data show that the risk of infection for a given pathogen density in

the consumed water ranges over several orders of magnitude for different organisms (Regli et al., 1991). Setting a generic microbiological drinking water standard based on one dose-response curve will either overestimate or underestimate risks from other organisms. The risk of death from infection likewise varies widely with the organism (Bennett et al., 1987). Therefore, the severity of the illness associated with a given organism must be considered.

Additional considerations in assessing acceptable waterborne microbial risks involve the human subpopulations sensitive to infection, illness and death. Infection does not always result in illness; many infections are asymptomatic (Rendtorff, 1954; Lopez et al., 1980). The progression and severity of illness following microbial infection are more a function of individual physiology than the magnitude of dose, as is true for many toxic chemicals. Acute gastrointestinal illness, the most common microbial illness, is generally considered non-life threatening in normally healthy adults. However, this is not necessarily true for those subpopulations that are more sensitive to microbial infection or illness. Some studies (Glass et al., 1991; Lew et al., 1991) indicate that infants and those over 70 years old have mortalities of 3–5 percent from diarrhea requiring hospitalization. As discussed above, *Cryptosporidium* infections, mild in healthy persons, are sometimes fatal to the immuno-compromised. Other identified sensitive human subpopulations include pregnant women and those with cardiovascular disease. EPA estimates that about 15% of the U.S. population is in these higher risk groups.

Prudent health policy would be to protect these groups from their higher risks of waterborne microbial infection. Use of a one percent mortality-to-illness rate (instead of a 0.1 percent) to represent more deadly organisms and a 10-fold uncertainty factor (as used in EPA's RfD calculations) to account for these sensitive subpopulations may be appropriate for estimating potential risks resulting from systems achieving regulatory goals. A risk calculation based on this approach, assuming that the system achieves the risk goal of 10^{-4} annual infections for the average population, might result in a 7×10^{-5} (i.e., $10^{-4} \times 10^{-2} \times 70$ years) lifetime risk of death for certain subpopulations. The 7×10^{-5} lifetime risk of death (which is a more severe endpoint than cancer) is barely within the 10^{-4}–10^{-6} guideline for excess lifetime cancer risk that EPA uses for regulating chemical carcinogens in drinking water.

These calculations, while based on estimates and approximations and having large uncertainties, suggest that the risk level of 10^{-4} annual infections may be acceptable, albeit barely so. If EPA were to accept a more stringent annual risk level of 10^{-5} or 10^{-6} infections to achieve a greater consistency between lifetime mortality risks from waterborne pathogens and most regulated drinking water chemicals, substantial increases in treatment might be required. EPA solicits comment on the appropriateness and magnitude of specific acceptable risk levels for microbial infection and illness.

To counter waterborne illness, EPA is proposing five treatment alternatives for controlling *Giardia*, *Cryptosporidium*, and/or viruses. Within each alternative, several options are addressed. The Agency may promulgate one or more of these alternatives. Alternative A addresses enhanced treatment for *Giardia* only. Alternatives B and C address treatment for *Cryptosporidium* only. Alternative D addresses enhanced treatment for viruses only. Alternative E maintains existing level of treatment requirements for *Giardia* and viruses. EPA requests comment on what alternative(s) is most suitable.

a. Alternative A. Enhanced treatment for Giardia. This alternative bases the extent of treatment required on the *Giardia* density in the source water. The SWTR currently requires a 99.9 percent (3–log) removal/inactivation of *Giardia* for all surface waters, regardless of *Giardia* cyst concentration in the source water. As discussed above and in the SWTR, EPA believes that for source waters of high quality (low pathogen densities), this level of treatment should result in less than one case of giardiasis (and most other waterborne disease) per 10,000 people per year. This risk level for *Giardia* is associated with an infectious *Giardia* cyst density in the source water of less than one cyst/100 liters and assumes that 3 logs of removal/inactivation is consistently achieved on such source water. For more information about *Giardia* risk calculations and associated uncertainties and assumptions, refer to Rose et al. (1991), Regli et al. (1991), and Macler and Regli (1993).

Under Alternative A, systems using source waters with higher *Giardia* densities would be required to meet higher levels of treatment to satisfy the desired acceptable risk level, e.g., the annual 10^{-4} risk or perhaps a more stringent goal. Specifically, under one option of alternative A, EPA is proposing that systems meet the level of treatment for *Giardia* associated with the following *Giardia* concentrations in the source water to achieve a 10^{-4} annual risk level:

No. of giardia/100L	Required treatment level (percent)
<1	99.9 (3-log).
1–9	99.99 (4-log).
10–99	99.999 (5-log).
>99	99.9999 (6-log).

The determination by utilities and States of removal and inactivation efficiencies for specific treatment strategies would be based on EPA guidance and information, as is currently done under the existing SWTR. EPA would revise the existing SWTR Guidance Manual based on data collected under the ICR and research to complement any criteria promulgated under the ESWTR. The Agency expects that data collected under the ICR will be used by States and utilities to define the source water concentration and consequently the appropriate level of treatment for individual systems. If a utility has not collected data on pathogen densities in source water under the ICR, it would be required to do so to define the appropriate level of treatment.

Depending on the method used for calculating pathogen density, assumptions used for estimating risk (e.g., whether to assume that all or only a portion of the detected cysts in the source water are viable and infectious to humans), the desired acceptable risk level, concern about DBP risk, and the technical and economic feasibility of achieving different levels of treatment, it may be appropriate to specify treatment requirements that address higher source water pathogen concentrations than described above. EPA is not aware to what extent physical removal greater than 2.5 logs can reasonably be achieved by systems using conventional water treatment approaches commonly practiced in the United States. The Agency believes that systems that optimize their treatment may be able to achieve substantially higher levels of removal. Membrane filtration techniques, although promising for much higher levels of removal, may not yet be technologically or economically feasible for large numbers of systems. The balance of the removal/inactivation requirement may have to rely on the use of chemical disinfectants. However, while EPA has confidence in the use of disinfectants to achieve current SWTR requirements, it has not been demonstrated that CT values

extrapolated from tables in the SWTR or other sources are valid for higher levels of disinfection (e.g., to achieve a 4- or 5-log reduction of *Giardia*). EPA requests comment on approaches to achieve higher levels of treatment by physical means and on the use of existing CT values in the EPA guidance (EPA, 1991) to predict, by extrapolation, higher levels of inactivation that could be achieved by disinfection.

EPA is considering an alternative version of the above described treatment requirements that would instead require greater *Giardia* reductions for source waters beginning with *Giardia* concentrations of 10 or more cysts/100 liters, as indicated below:

No. giardia/100L	Required treatment level (percent)
10–99	99.99 (4-log).
100–999	99.999 (5-log).
>1000	99.9999 (6-log).

EPA solicits comment on the two treatment options described above and on associated variations.

b. Alternative B. Specific treatment for Cryptosporidium. EPA is proposing a treatment technique rather than an MCL for *Cryptosporidium*, because EPA believes that it is not currently economically or technologically feasible for a system to monitor for this organism in the finished water to determine whether it meets an acceptable risk level. The Agency bases its belief on three factors: (1) The variability of *Cryptosporidium* spatially and temporally may be considerable, and consequently systems would have to collect frequent samples and inordinately large sample volumes to properly characterize the density of this organism, (2) current methods for *Cryptosporidium* analysis are difficult and expensive, (3) it is not yet possible to predict the risk resulting from a specific level of exposure to *Cryptosporidium*, and (4) even if *Cryptosporidium* could be detected at the lowest concentrations of concern in the finished water, the exposure and associated risk would have already occurred, thereby reducing the significance of monitoring non-compliance.

Under this rule, all community and non-community public water systems using any surface water source, or groundwater under the direct influence of surface water, would be required to treat these sources as described below. EPA anticipates that human dose-response data for *Cryptosporidium* will be available within the next year and will include these data in a Notice of Availability, probably in March 1996. Because they are not yet available, basing the treatment level on a specific acceptable risk level, as proposed by EPA for *Giardia*, cannot be used for *Cryptosporidium* in the present notice. Data collected to date suggest that the dose-response for *Cryptosporidium* may be similar to that for *Giardia*. If this is true, then the required reduction level for *Cryptosporidium* may be the same as for *Giardia* to achieve an equivalent risk level for similar source water densities.

In the absence of dose-response data, EPA is proposing a wide variety of options. One sub-alternative would be to base the level of treatment on the *Cryptosporidium* densities found in the source water, as presented in the Table below.

No. cryptosporidium/100L	Required treatment level (percent)
<1	99.9 (3-log).
1–9	99.99 (4-log).
10–99	99.999 (5-log).
>99	99.9999 (6-log).

EPA is concerned, however, that it may not be technologically or economically feasible to achieve the treatment levels above, given that *Cryptosporidium* is much more resistant to disinfection than is *Giardia*. Conventional treatment of coagulation, sedimentation and filtration may not reliably achieve more than 2.5-log or 3-log *Cryptosporidium* oocyst reduction under typical operating conditions. While membrane filtration technologies (ultrafiltration, nanofiltration), possibly following conventional treatment processes, appear to promise considerably greater reductions in *Cryptosporidium* densities, their widespread use for this purpose raises other concerns such as waste disposal of the concentrate, water wastage, potential failure of the membrane, and significant costs. Unless systems can feasibly achieve higher removal levels for *Cryptosporidium* by physical means, they would have to achieve this additional reduction by the use of disinfectants. However, uncertainties exist with respect to disinfection of *Cryptosporidium*. Current data suggests that chlorine and chlorine-based disinfectants are relatively ineffective in inactivating *Cryptosporidium*, and the Agency is not certain if alternative disinfectants, such as ozone, are more effective than chlorine to allow systems to comply with the removal/inactivation levels above.

With this in mind, EPA is also considering two other treatment sub-alternatives for *Cryptosporidium*, as follows:

No. cryptosporidium/100L	Required treatment level (percent)
<1	99 (2-log).
1–9	99.9 (3-log).
10–99	99.99 (4-log).
>99	99.999 (5-log).

No. cryptosporidium/100L	Required treatment level (percent)
<10	99 (2-log).
10–99	99.9 (3-log).
>99	99.99 (4-log).

EPA requests comment on all treatment alternatives discussed above for *Cryptosporidium*.

c. Alternative C. 99% (2-log) removal of Cryptosporidium. Under this alternative, EPA would require systems to achieve at least 99% (2-log) removal of *Cryptosporidium* by filtration (with pretreatment) alone. This alternative is based on the premise that the 3-log removal/inactivation requirement specified for *Giardia* is not economically or technologically feasible for *Cryptosporidium*, since laboratory data suggests that *Cryptosporidium* is considerably more resistant to disinfection than is *Giardia*. In addition, it may not be practical to remove more than two logs of *Cryptosporidium* consistently by clarification and filtration processes. EPA believes, however, that a two-log removal of *Cryptosporidium* is feasible using current conventional treatment methods of coagulation, sedimentation and filtration, as specified under the SWTR.

Under this treatment option, EPA would continue to assess new field and laboratory data to control *Cryptosporidium* by physical removal and disinfection. If these data indicate that proportionally higher levels of *Cryptosporidium* removal/inactivation can be achieved at a reasonable cost, then EPA would revise the ESWTR accordingly as part of the long-term ESWTR regulatory development. The Agency would also revise the SWTR Guidance Manual to suggest approaches for improving system design and operations for controlling *Cryptosporidium*. When sufficient human dose-response information for *Cryptosporidium* becomes available to allow calculation of drinking water health risks from this organism, EPA will consider a risk-based approach to establishing adequate treatment levels.

EPA solicits comment on whether a higher minimum removal requirement than two logs should be specified for

Cryptosporidium under this alternative. The Agency also requests comment on whether the removal requirement should be increased if treatment were to include disinfection.

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

The SWTR considered *Giardia* to be a surrogate for viruses, and assumed that if viruses were present in the source water, treatment requirements adequate to reduce *Giardia* by three logs would also reduce viruses to safe levels. This assumption may not be appropriate if a system were to achieve a 3-log removal of *Giardia* by physical means and provide little disinfection inactivation. Viruses may be present in substantial numbers even in the absence of detectable *Giardia* cysts.

Treatment designed to minimize *Giardia* may not be optimal for viruses. Viruses are substantially smaller than *Giardia* cysts or *Cryptosporidium* oocysts and may pass through certain filter media that will remove the larger protozoa. Therefore, use of data on *Giardia*, *Cryptosporidium*, or even coliform bacteria (intermediate in size between viruses and protozoa) in assessing treatment efficacy may not be adequate for virus control. Studies by Payment et al. (1991) showed that conventionally treated water meeting current Canadian microbial drinking water advisory levels still led to substantial illness in the studied population. These authors suggested that much of this illness could have resulted from viral infection.

For the above reasons, particularly for strengthening the treatment barrier by disinfection, EPA is proposing to require that systems provide sufficient disinfection such that by disinfection alone it would achieve at least a 0.5-log inactivation of *Giardia* or, alternatively, a 4-log inactivation of viruses. This requirement would be independent of the level of physical removal, e.g., if filtration was able to remove three logs of *Giardia*, the system would still have to provide at least an additional 0.5-log inactivation of *Giardia* or 4-log inactivation of viruses by disinfection. Therefore, this would mean that the system would provide 6 logs of virus removal/inactivation, assuming it is removing 2-logs of viruses by filtration alone. EPA would provide guidance to indicate the appropriate CT values to use with these two alternatives.

The SWTR assumed that a 0.5-log inactivation of *Giardia* would result in a 4-log inactivation of viruses. This assumption was based on a study where the effect of free chlorine on the hepatitis A virus was examined (Sobsey, 1991). Subsequent investigations, however, have suggested that some viruses, such as the Norwalk agent, are substantially more resistant to disinfection by chlorine than is the hepatitis A agent. Additionally, use of disinfectants other than free chlorine to achieve the 0.5-log inactivation of *Giardia* may not yield a 4-log inactivation of viruses. Therefore, a requirement to provide sufficient disinfection to inactivate 4 logs of viruses may be more conservative than the alternative requirement of providing sufficient disinfection to inactivate 0.5 logs of *Giardia*.

Either of these two approaches could result in several additional logs of pathogen removal/inactivation for systems that practice conventional treatment. For example, where the system can remove by physical means at least 2-logs of viruses, the disinfection requirement would yield a total 6-log removal/inactivation of viruses (i.e, 2 logs by physical means and 4 logs by disinfection).

e. Alternative E. No change to existing SWTR treatment requirements for Giardia and viruses. Under this alternative, the existing SWTR requirements for treatment for *Giardia* and viruses would not change. For *Cryptosporidium* control, EPA could either regulate this organism directly (e.g., Alternative C above) or make a finding that *Cryptosporidium* is adequately controlled by filtration and disinfection requirements in the existing SWTR. The Agency may choose this alternative to allow the Agency time to fully develop analyses of the ICR data and accumulate additional data on pathogen occurrence, treatment performance, and health effects, given the view that the current SWTR has not been in effect long enough to evaluate the projected improvements in drinking water quality and resulting public health benefits. EPA would consider additional regulatory alternatives while developing the long-term ESWTR, based on this new data. The Agency requests comment on this alternative, as well.

IV. State Implementation

This section describes the regulations and other procedures and policies States would have to adopt, or have in place, to implement the rule proposed today. States must continue to meet all other conditions of primacy in 40 CFR Part 142.

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

40 CFR Part 142 sets out the specific program implementation requirements for States to obtain primacy for the public water supply supervision (PWSS) program, as authorized under section 1413 of the Act. In addition to adopting the basic primacy requirements, States may be required to adopt special primacy provisions pertaining to a specific regulation. These regulation-specific provisions may be necessary where implementation of the NPDWR involves activities beyond those in the generic rule. States are required by 40 CFR 142.12 to include these regulation-specific provisions in an application for approval of their program revisions. These State primacy requirements would apply to the rule proposed today, along with the special primacy requirements discussed below.

To implement today's proposed rule, States would be required to adopt revisions to § 141.2, Definitions; § 141.52, Maximum contaminant level goals for microbiological contaminants; § 141.70, General requirements; § 141.71, Criteria for avoiding filtration; and § 141.74, Analytical and monitoring requirements.

A. Special State Primacy Requirements

In addition to adopting drinking water regulations at least as stringent as the Federal regulations listed above, EPA would require that States adopt certain additional provisions related to this

regulation to have their program revision application approved by EPA. Because this rule would provide considerable State latitude on implementation, today's rule would require a State to include, as part of its State program submission, its implementation policies and procedures. This information would advise the regulated community of State requirements and help EPA in its oversight of State programs. In concert with promulgating the interim ESWTR, EPA would revise the SWTR Guidance Manual (EPA, 1991). This guidance would assist States in developing appropriate criteria in the regulations they adopted.

To ensure that the State program includes all the elements necessary for a complete enforcement program, today's notice proposes that to obtain EPA approval for implementing this rule, the State's application would be required to include the following:

(1) Adoption of the promulgated ESWTR.

(2) Description of the protocol the State will use to judge the adequacy of watershed protection programs for minimizing the potential for contamination by *Giardia* cysts, *Cryptosporidium* oocysts, and viruses in the source water. The SWTR required States to specify the methodology they would use to judge the adequacy of a watershed control program to control the presence of waterborne *Giardia*. This rule would add *Cryptosporidium*. The addition of *Cryptosporidium* is significant because it may prohibit or substantially limit certain watershed uses such as cattle farming and feedlots. The location of cattle feedlots on a watershed would require additional control measures.

(3) Description of the criteria and methods the State will use for the conduct and review of sanitary surveys. If the State elects to allow non-State personnel to conduct the surveys, the State must specify the criteria for approval and oversight of these personnel and of the surveys.

(4) Description of the procedures for determining the level of treatment required of systems to meet removal and/or inactivation requirements under the rule. If Alternative A described in Section IIIE above is promulgated, demonstration by the State that it has in place enforceable design and operating criteria for achieving the levels of *Giardia* removal and/or inactivation required. If either Alternative B or C described in Section IIIE above is promulgated, demonstration by the State that it has in place enforceable design and operating criteria for achieving the levels of *Cryptosporidium* removal and/or inactivation required. Compliance with the design and operating criteria would be judged on a system-by-system basis.

B. State Recordkeeping Requirements

Changes to the existing recordkeeping requirements to implement the provisions proposed in this notice would require, under general recordkeeping requirements, States to maintain records on the level of treatment necessary to achieve the required levels of removal and/or inactivation of *Giardia*, *Cryptosporidium* and/or viruses. States would also be required to maintain a record of any decisions made as a result of sanitary surveys. These records must be kept for 40 years (as currently required by § 142.14 for other State decision records) or until a subsequent determination is made, whichever is shorter. If the final rule requires systems to base level of treatment on source water pathogen densities, then the State must maintain record of these densities.

C. State Reporting Requirements

Currently States must report to EPA information under 40 CFR 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of State public water supply programs. Today's rule would require States to provide additional information to EPA within the context of the existing special report requirements for the SWTR (§ 142.15(c)(1)) on microbial densities in the source water and the resulting required levels of treatment for each public water system supplied by a surface water source or by ground water under the direct influence of surface water.

V. Public Notice Language

The SDWA (section 1414(c)) requires that notices of violation of the MCL or treatment requirement for a specific contaminant include EPA-specified language on the adverse health effects of that contaminant. Requirements for public notification are found in 40 CFR 141.32. In this notice, EPA is proposing that the existing language for violating the treatment technique requirements in Subpart H of the SWTR, found in 40 CFR 141.32(e)(10), not be changed. This decision is based on EPA's belief that language is sufficiently broad to include the adverse health effects from *Cryptosporidium* exposure.

VI. Economic Analysis

A. Cost of Proposed Rule

This proposed rule would result in treatment costs, monitoring costs, and State implementation costs. These costs are difficult to estimate because of uncertainty in the number of systems that would have to improve treatment and the extent of that improved treatment. This information would depend primarily on the results of future monitoring under the ICR. Under the ICR, systems using surface water and serving 10,000 people or more would determine raw water pathogen densities and, in some cases, the efficiency of treatment for reducing pathogen concentrations. Given the above uncertainties, the cost estimates can now only be addressed in the most general way, across a wide range of possibilities.

With regard to treatment costs, if ICR results indicate that the existing SWTR ensures adequate levels of treatment for most systems, then minimal additional treatment costs would be necessary. Regardless of whether the SWTR is amended to require higher levels of treatment, at least some systems would be expected to upgrade existing levels of treatment based on EPA guidance and ICR monitoring results. Similarly, some systems might reduce existing levels of disinfection upon a finding that their source water is of better quality than expected. Also, some costs will be incurred by systems correcting for deficiencies identified through the sanitary survey requirement.

If ICR monitoring indicates that many source waters contain considerably higher pathogen concentrations than anticipated under the SWTR, then substantial national treatment costs would result in mitigating the associated health risk. These costs could involve increasing disinfection contact time or dosage, switching to stronger disinfectants, or improving filtration efficiencies through upgrades or installation of new technologies.

In estimating possible costs resulting from an ESWTR EPA assumed that (1) national *Giardia* density in source waters are represented by the survey results of LeChevallier et al. (1991a), (2) all systems are at least meeting the treatment requirements of the existing SWTR, (3) some systems, as indicated by the survey results of LeChevallier et al (1991), are providing higher levels of treatment than required by the SWTR, (4) systems would be required to provide sufficient treatment of their source water to achieve no greater than a 10^{-4} annual risk level for *Giardia*, based on the dose-response data and

risk assessment methodology developed by Rose et al. (1991) and Grubbs et al. (1992), (5) additional *Giardia* reduction beyond the requirements of the SWTR to achieve the 10^{-4} risk level would be achieved solely by using chlorine as the disinfectant and providing additional disinfectant contact time (i.e., increasing the CT value by increasing the contact basin size), (6) when all ancillary construction costs including site-specific factors are taken into account, the average total capital cost per system is twice the capital cost of increasing the size of the contact basin alone. Based on the assumptions of Rose et al. (1991) and Grubbs et al. (1992), EPA calculates that systems would need a *Giardia* removal/inactivation level of 3, 4, 5, or 6 logs for *Giardia* concentrations in the source water of <1 cysts/100 L, 1–9 cysts/100 L, 10–99 cysts/100 L, and 100 cysts/100 L or greater, respectively.

National cost estimates for systems to comply with an interim ESWTR as described above are provided in Table VI–1. As discussed in Section III.B of this preamble, depending upon the criteria that are promulgated under the interim ESWTR, EPA also intends to propose requirements for systems serving less than 10,000 people, under a long-term ESWTR, to prevent any undue downside microbial risks that might otherwise result while systems of this size achieve compliance with the Stage 1 D/DBP rule. Therefore, Table VI–1 also includes cost estimates for systems serving less than 10,000 people, even though these costs are not attributed to the interim ESWTR.

Table VI–1 presents the additional contact basin costs needed for twelve system size categories (population served); for each size category, the number and type of systems affected (filtered without softening or filtered with softening), the associated total capital costs, and the associated total annualized costs. In this calculation, operation and maintenance costs are assumed to be negligible since systems are already disinfecting and most of the additional inactivation could be achieved by additional disinfectant contact time. Details of this analysis and other assumptions are described in the Regulatory Impact Analysis for the ESWTR (EPA, 1994). Under this approach, EPA estimates that the capital and annualized costs nationwide for systems serving at least 10,000 people would be $3661 million and $391 million, respectively. Using the same assumptions for systems serving fewer than 10,000 people would result in an additional $820 million capital costs and $114 million annualized costs nationwide, or a total for all system sizes of $4481 million in capital costs and $504 million in annualized costs.

The 10^{-4} annual risk level target was used as an example; costs for achieving different acceptable risk levels, of course, will differ considerably. Although other treatment measures could be used to reduce *Giardia* levels, EPA believed that the national cost based on providing additional disinfectant contact time is probably representative, on average, of other modifications that systems might implement. The Agency chose this methodology for estimating costs because it was the most simple. Moreover, insufficient data prevents the Agency from predicting with any reliability the mix of different technologies systems would use to comply. EPA recognizes that in lieu of expanding contact basin size, some systems may achieve the required *Giardia* reductions through increased disinfectant dosages, improved sedimentation and filtration efficiencies, or use of a stronger disinfectant such as ozone. Smaller systems, especially those serving fewer than 1,000 people, might use cartridge filters, or membrane technology rather than additional contact time to achieve compliance with the long-term ESWTR and other drinking water regulations at lower cost. In addition, the costs for utilities to meet the D/DBP regulations (proposed elsewhere in today's **Federal Register**) are not necessarily additive with the costs for utilities to meet either the interim or long-term ESWTR. For example, systems installing membrane technology to comply with the D/DBP rule would also be expected through use of this technology to comply with the ESWTR. Use of technologies other than increasing contact basin time might be more feasible and less expensive for some systems, depending on site-specific factors (e.g., limited availability of land) and overall treatment objectives (e.g., meeting other regulatory requirements such as the D/DBR rule).

EPA solicits comment on how many systems might use these alternative approaches for meeting ESWTR requirements and whether the use of such technologies would lead to substantially different cost estimates. EPA does not believe there are sufficient data to predict the costs for reducing *Cryptosporidium* to a desired risk level as has been done for *Giardia*. EPA solicits comment on what approaches might be taken for estimating national treatment costs for systems to provide different levels of *Cryptosporidium* removal depending on *Cryptosporidium* densities in the source water. Also, EPA requests comment on whether it is reasonable to assume that any treatment changes that are made to remove *Cryptosporidium* would also remove *Giardia*, thereby not duplicating costs for compliance.

Table VI–2 indicates a range of estimated increases in household costs by system size category for systems needing to achieve an additional 0.5 log to 3 log reduction of *Giardia* to comply with the ESWTR option described above. By this analysis 35 percent of the systems would not be required to make any changes in treatment and would incur no costs. For the interim ESWTR, estimated increases in household costs for systems required to make changes in treatment would range from $11 to $49 per household per year in the smallest size category (serving a median population of 15,000 people) to $3.1 to $24 per household per year in the largest size category (serving a median population of 1,550,000 people).

If the analyzed criteria for the interim ESWTR were extended to smaller systems under the long-term ESWTR, and systems used additional disinfectant contact time to meet such criteria, increases in annualized household costs would range from $360 to $1100 per household per year in the smallest size category (serving a median population of 57 people) to $27 to $85 per household per year in systems with a median population of 5,500. As stated above, EPA believes that smaller systems should be able to use a more economic treatment alternative than additional disinfectant contact time.

EPA solicits comment on whether the system level costs to achieve the different log reductions indicated in Table VI–2 by disinfection, or other means, are reasonable and accurate.

Table VI–3 indicates the estimated labor effort by the number of full time employees (FTEs), hours, and dollar costs for States to implement the interim ESWTR. If systems, rather than the State, were to fund some or all sanitary surveys, then State costs would be reduced accordingly. Further details of this analysis are available in the Regulatory Impact Analysis (EPA, 1994)

TABLE VI–1—ESTIMATED NATIONAL CONTACT BASIN COSTS FOR ENHANCED SWTR

System size category	Population per system	Cost estimates based on additional disinfectant contact basin size[1]								
		Number of affected systems			Total capital cost (M$)			Total annualized cost (M$)		
		Filtering systems			Filtering systems			Filtering systems		
		W/out soft	W/soft	Total	W/out soft	W/soft	Total	W/out soft	W/soft	Total
1	25–100	493	8	501	22	0.5	23	4	0.09	4
2	101–500	454	13	467	42	1.4	43	8	0.3	8
3	501–1K	415	47	462	86	12	98	16	2	18
4	1K–3.3K	586	61	647	200	24	224	25	3	28
5	3.3K–10K	627	104	731	360	72	432	45	9	54
6	10K–25K	291	67	358	330	94	424	34	10	44
7	25K–50K	167	42	209	340	110	450	36	12	47
8	50K–75K	77	24	101	230	92	322	24	10	34
9	75K–100K	63	7	70	250	37	287	26	4	30
10	100K–500K	88	24	112	620	230	850	67	25	92
11	500K–1M	22	5	27	600	170	770	64	18	83
12	1M+	9	1	10	460	97	557	50	11	60
Totals:										
Interim Rule (Systems > 10K).		716	170	887	2830	831	3661	302	88	391
Long-Term Rule (All Systems).		3,290	404	3,694	3,540	941	4,481	401	103	504

Notes:

[1] Cost estimates were developed on the basis of the following assumptions: 1) 35 percent of surface water systems currently meet ESWTR inactivation requirements (based on LeChevallier et al., 1991); 2) the amount of additional inactivation required by systems that do not currently meet ESWTR requirements is based on the distribution of source water *Giardia* concentrations in the LeChevallier data; and 3) the additional basin volume is based upon CT requirements of the SWTR guidance document with: pH = 8 (non-softening) or 9 (softening), $t_{10} : t_{theoretical} = 0.7$, temperature = 5 °C, and $C1_2$ residual = 1 mg/l.

TABLE VI–2—ESTIMATED INCREASES IN ANNUAL HOUSHOLD COSTS FOR SYSTEMS EXPANDING CONTACT BASIN SIZE TO MEET AN ENHANCED SWTR[2]

Cat. #	Median pop.	Total household costs, $/hh/yr[3]					
		Filter[4]			Filter and Soften[4]		
		Min	Avg[1]	Max	Min	Avg[1]	Max
1	57	360	420	960	430	500	1,100
2	225	170	200	450	200	240	540
3	750	88	120	310	110	150	350
4	1,910	36	52	110	43	59	130
5	5,500	27	28	67	30	34	85
6	15,000	11	15	40	13	19	49
7	35,000	7.9	12	30	10	15	39
8	60,000	6.6	10	26	8.8	13	34
9	88,100	6.1	8.8	24	7.5	12	32
10	175,000	5.1	8.5	24	6.6	11	33
11	730,000	3.5	6.7	20	4.7	9.1	27
12	1,550,000	3.1	6.0	18	4.2	8.2	24

Notes:

[1] Costs assume that 35 percent of systems currently meet ESWTR requirements (LeChevallier et al., 1991) and therefore do not require contact basin modifications.

[2] Assumes *Giardia* and level of treatment distributions per LeChevallier et al, 1991 are nationally representative of arithmetic averages, and that systems under ESWTR are required to provide additional disinfection inactivation to meet a less than 1/10,000 annual infection rate at the first customer calculated according to the *Giardia* infectivity dose response curve of Rose et al. (1991).

[3] Household costs represent costs for affected systems. Minimum costs are based on costs for systems requiring additional 0.5 log inactivation while maximum costs are based on requiring an additional 3-log inactivation. Average costs are based on distribution of costs for achieving different inactivations based on data by LeChevallier et al. (1991).

[4] Contact basin size dependent upon chlorine residual, pH and temperature. Contact basin costs will increase if chlorine residual or temperature decrease or if pH increases. For non-softening systems ("Filter" and "Unfilt") pH=8, temperature=5 °C, and chlorine residual=1 mg/L. For softening systems ("Soften"), pH=9, temperature=5 °C, and chlorine residual=1 mg/L.

TABLE VI–3.—INTERIM ENHANCED SURFACE WATER TREATMENT RULE STATE PROGRAM COSTS MODEL

Variable	Default assumptions		National burden		Cost
			In FTEs	In hours	
Regulation Adoption and Program Development.	0.5 FTE per State	1	28.0	47,040	$1,540,000
Review Plans and Specs	10 days/large system	112	[1] N/A	[1] N/A	[1] N/A
Log Removal Determination	3 days per surface water system	19	19.0	31,958	1,046,250
Subtotal (x)			47	78,998	2,586,250
Staff Training (Rule Specific)	10 days per technical FTE=f(x)	0	2.1	3,591	117,557
Sanitary Surveys[3]	5 days/lg. sys./survey; 2 days/sm. sys./survey.	79	78.7	132,147	4,326,250
Total			128	214,736	7,030,057
Average Annual Cost over 3.5 years[2]			37	61,353	2,008,588

[1] Costs for reviewing plans and specifications for the ESWTR are counted as a joint activity undertaken with the same step of implementing the Stage 1 DBP Rule and are included in the DBP Rule RIA.
[2] Total cost and burden are divided by 3.5 years, the time between promulgation of this rule and the final ESWTR.
[3] Recordkeeping burden is assumed to equal approximately 2% of the burden shown (i.e. approximately 1.6 FTEs, 2,640 hours, $86,000).

B. Benefits of Proposed Rule

The level of reduction of waterborne illness resulting from implementation of this rule will largely depend on the particular option(s) promulgated. Even if EPA could predict the most suitable option(s), the Agency cannot yet predict the number of illnesses avoided until more data become available. EPA anticipates that much of such data, particularly on national pathogen occurrence and existing treatment levels, will become available under the forthcoming ICR.

With the limited available data, EPA has used a disinfection byproducts risk assessment model (DBPRAM) to estimate potential risks from *Giardia* that might result from systems complying with different DBP standards both with the existing SWTR and an ESWTR (Grubbs et al 1992; Regli et al 1993; Cromwell et al 1992). In this analysis, EPA assumed that the ESWTR would require systems to remove/inactivate *Giardia* by 3, 4, 5, or 6 logs if the *Giardia* concentrations in the source water were <1 cysts/100 L, 1–9 cysts/100 L, 10–99 cysts/100 L, and 100 cysts/100 L or more, respectively. This assumption is consistent with current EPA guidance (EPA, 1991a).

Because of the limited data, EPA used the DBPRAM only for the category of surface water systems that serve at least 10,000 people and practice coagulation, sedimentation, and filtration, but do not soften the water. Collectively this group of systems provides water to about 103 million people.

EPA assumed as part of the modeling effort that (1) *Giardia* densities in source waters in the U.S. are represented by the survey data of LeChevallier et al. (1991a), (2) systems are using, or will use, the least expensive technologies to comply with the SWTR and existing TTHM standard, and (3) systems comply only minimally with both the SWTR (i.e., provide a 3-log removal/inactivation of *Giardia* cysts and maintain a disinfectant residual throughout the distribution system) and the existing TTHM standard. Using these assumptions, the model predicts that, without revising the SWTR, several hundred thousand people would become infected by *Giardia* each year. These predicted risks may be significantly overstated because many systems currently appear to provide more treatment than is minimally required under the SWTR (LeChevallier et al., 1991b). Also, concentrations of *Giardia* cysts in source waters in the U.S. may be significantly less than those indicated by the survey results of LeChevallier et al. (1991a), which did not cover all geographical locations.

The DBPRAM also predicted that, in the absence of any revision to the SWTR, as the hypothetical MCL for DBPs decreases (i.e., either for TTHMs or the sum of five haloacetic acids), the incidence of *Giardia* infection significantly increases. One reason for this result is that lower MCLs would lead systems to use more efficient precursor removal technologies, resulting in a lower disinfectant demand in the water. Therefore, since less disinfectant is necessary, a lower CT value may result at the first customer. Without the removal of DBP precursors (or associated disinfectant demand), systems would need to maintain a higher CT value at the first customer to maintain a disinfectant residual throughout the distribution system.

A second reason why the predicted incidence of *Giardia* infection increases as the MCL for DBPs is lowered is that the model assumes that many systems would switch to chloramine as a residual disinfectant, or to ozone followed by chloramine, to limit the formation of chlorinated DBPs. Chloramine is a weaker disinfectant than chlorine and consequently would result in less *Giardia* inactivation. Similarly, the model also assumes that if a system were to switch to ozone for primary disinfection, followed by chloramine, the system would provide only enough disinfection to inactivate 0.5 logs of *Giardia* to minimally meet the SWTR (assuming that 2.5 log of *Giardia* removal is achieved by physical means). This latter assumption may underestimate the actual level of *Giardia* inactivation that a system would likely provide, since for a relatively small increase in cost compared to that for ozone installation, the system could achieve (by increasing the ozone dose or contact time) a significantly greater level of inactivation than the 3-log reduction specified by the SWTR for *Giardia*.

The DBPRAM also predicts that under more stringent DBP standards, if such systems were to only minimally meet the SWTR, the incidence of waterborne disease outbreaks would significantly increase in systems with the worst quality source waters (but apparently not in those with good quality source waters) (Grubbs et al., 1992; Regli et al., 1993). In its modeling effort, EPA defined waterborne disease outbreaks (epidemic disease) as one in which at least 1% of the population became infected (conservatively used as an indicator for illness) within a 30-day period; this definition was used because EPA believes that at incidence lower than 1% health authorities are generally not aware that an outbreak is in progress, unless the disease is typically very debilitating or life-threatening. According to Harrington et al. (1985),

the total cost of disease avoidance behavior, such as boiling or purchase of bottled water by the entire community, during an outbreak far exceeds the total cost of treating the illness.

The DBPRAM predicts that ESWTR compliance, as described above, would result in no more than a few hundred infections caused by waterborne *Giardia* per year per 100 million people. This is several hundred thousand cases fewer than predicted in the absence of an ESWTR. In the absence of more data and for the purpose of simplicity, the model assumes that systems would use the arithmetic mean (based on LeChevallier et al., 1991a) to calculate pathogen densities, and use the coldest water temperature and maximum flow rate (design rate) to determine disinfection conditions at which plants would operate. Use of the arithmetic mean may underestimate the predicted risk since values above the mean may result in a greater number of infections than values below the mean.

In contrast, using the design flow rate throughout the year for model predictions overestimates the predicted risk, because the flow rate should be significantly less during colder weather, which would result in longer contact times and greater CT values, and therefore greater inactivation of *Giardia* than if the system operated under design flow conditions during this period. In addition, use of the coldest water temperature throughout the year for model predictions also overestimates the predicted risk, because disinfectants are more effective at warmer water temperatures for a given CT. In the absence of more data, EPA cannot determine whether the model assumptions, collectively, may significantly bias the model predictions. EPA solicits comment on this issue and requests suggestions on how EPA can improve the assumptions in the model, based upon data collected under the ICR (59 FR 6332; proposed February 10, 1994).

The model also predicts that if systems complied with an ESWTR, no waterborne disease outbreaks (as defined above) attributed to *Giardia* would occur. Since *Giardia* is more resistant to disinfection than most other pathogens (*Cryptosporidium* being a notable exception), EPA assumes that the incidence of waterborne disease caused by other pathogens would also be substantially reduced.

The disease, giardiasis, causes a gastrointestinal disorder that may be mild or severe and incapacitating, and that generally lasts from one to four weeks. Although mortality is very low (0.0001%), some patients, including otherwise healthy individuals, require hospitalization (about 4600 annually) (Bennett et al., 1987; Addiss and Lengerich, 1994). An individual with giardiasis typically has one or more of the following symptoms: diarrhea, cramps, abdominal distress, flatulence, fatigue, vomiting, chills, fever, and marked weight loss. In one study of 105 stool-positive cases of travelers returning to the U.S., 39 percent had mild symptoms, 41 percent had moderate symptoms, 6.7 percent had incapacitating or severe symptoms, and 13.3 percent had no symptoms (Wolfe, 1990). All age groups are affected. The average time between infection and the onset of disease is about two weeks, although this may vary considerably. Chronic cases that persist for months or longer are not uncommon.

In the original SWTR Regulatory Impact Analysis (EPA, 1989a), the estimated economic cost associated with waterborne giardiasis was based on a study of costs incurred during an outbreak of waterborne giardiasis in 1983 that occurred in Scranton, Pennsylvania (Harrington, et al., 1985). In this study, the investigators estimated that the medical cost and the cost of time lost from work associated with the outbreak was in the range of $1245 to $1878 per case (1984 dollars). The lower cost values the time loss for homemakers, retired persons, and unemployed persons as zero, while the higher cost values the time loss for these people at the average wage rate.

The above estimate was based on the results of a survey of 370 people who had "confirmed" cases of giardiasis, i.e., a positive stool sample. EPA assumed in the analysis that the costs associated with confirmed cases are representative of the costs associated with those who had symptoms of giardiasis, but where no stool sample was examined, since medical costs (minus the cost for a stool specimen examination) and cost for time lost from work should be similar when symptoms are similar.

The $1245-$1878 estimate above does not take into account fatalities associated with waterborne disease. According to Bennett et al. (1987), about 0.1 percent of cases of waterborne disease are fatal. Although these investigators estimate that the mortality rate for giardiasis is much lower than 0.1 percent, EPA believes that control of *Giardia* will also control other waterborne disease agents that have a higher mortality rate than *Giardia*. Therefore, by omitting the risk of mortality associated with waterborne disease, EPA's analysis may represent a significant underestimate of the benefits. In addition, EPA's analysis did not consider benefits associated with avoiding the economic and psychological costs to the affected community (including businesses and government) associated with a waterborne disease outbreak, nor did it consider the benefits of additional public confidence in an enhanced water supply. These benefits were not considered in the analysis because of the difficulty of quantifying them.

Adjusting the $1878/case value for inflation (through 1993), and including a factor for willingness-to-pay, EPA estimates the benefit would be $3,000 per *Giardia* infection avoided. Using this estimate, the 400,000 to 500,000 *Giardia* infections per year that could be avoided in large surface water systems would have an economic value of $1.2 to $1.5 billion per year. This suggests that the benefit nationwide of avoiding *Giardia* infections in large systems is as much as three or four times greater than the estimated $391 million national cost per year to provide additional disinfectant contact time.

At a household level, the Interim ESWTR would impose costs ranging from $11– $49/household/year in systems serving 15,000 people to $3–$24/household/year in systems serving 1,550,000. Household costs are a useful guide for examining cost-benefit tradeoffs, because they are easier to understand in assessing the public's willingness to pay for a more stringent rule. EPA does not believe that the household costs predicted by this analysis represents an unreasonable premium for the systems affected by the Interim ESWTR, considering the nature of microbial risk.

There are at least three approaches for examining the tradeoff between costs and benefits. One approach is to determine the cost of the ESWTR alone. In a second approach, EPA could use the combined cost of the SWTR and ESWTR, since customers of many water systems are already paying, or will soon be paying, an extra premium for microbial protection as a result of the original SWTR. If this second approach is used (the most expensive estimate of ESWTR cost), and if the cost of the original SWTR is adjusted for inflation and factored into the above analysis, the overall ratio of benefits to costs would still be about a break-even proposition. Household costs would be significantly higher for previously unfiltered systems and modestly higher for previously filtered systems. In the third approach, EPA could assume that a large share of the cost of an ESWTR should be borne by the DBP rule, since the treatment changes needed to meet more stringent DBP regulations may increase the

pathogen risk that the ESWTR must address.

The accounting difficulty of sorting between microbial and DBP costs will become even more complicated later in developing the Long-Term ESWTR, which will cover small systems. Household costs for providing additional disinfectant contact time in small systems are significantly greater than those for the larger systems. However, it is not clear that small systems will choose to meet the Long-Term ESWTR by increasing the contact time. Such options as small scale membrane treatment systems may provide a more economical means of meeting both microbial and DBP treatment requirements simultaneously. In that case, the microbial and DBP-related control costs would be truly indistinguishable from each other.

A similar analysis to the one described above for *Giardia* is not yet feasible for *Cryptosporidium* because of much greater data deficiencies. The analysis of national benefits for the different ESWTR options must remain highly speculative, even for *Giardia*, until more data become available. EPA intends to develop a more complete cost and benefit analysis for the different ESWTR options based on data generated under the ICR and complementary research. This analysis would examine the costs of the various treatment options indicated in Section IIIE above, using various statistical approaches to calculate pathogen densities (e.g., mean value versus 90th percentile value), acceptable risk levels, pathogen infectivities, and various assumptions about the analytical methods (e.g., cyst/oocyst viability, percent recovery) and include a broader discussion of the benefits. EPA intends to present such analysis in a Notice of Availability in the **Federal Register** by November 1995. This Notice will indicate the basis for EPA's preferred ESWTR option(s) and solicit comment on the appropriateness for promulgating this option(s) as part of the interim ESWTR. EPA solicits comment on approaches that can be used for this analysis.

VII. Other Statutory Requirements

A. Executive Order 12866

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 entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

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

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

B. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 602 *et seq.*, requires EPA to explicitly consider the effect of proposed regulation on small entities. By policy, EPA has decided to consider regulatory alternatives if there is any economic impact on any number of small entities. The Small Business Administration defines a "small water utility" as one which serves fewer than 3,300 people.

The proposed rule is consistent with the objectives of the Regulatory Flexibility Act because it will not have any economic impact on any small entities. Except for the sanitary survey requirement, which EPA believes will be conducted by States, the rule would only apply to systems serving at least 10,000 people. Therefore, the Agency believes that this notice would have no adverse effect on any number of small entities.

C. 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.* An Information Collection Request document has been prepared by EPA (ICR No. 270.32) and a copy may be obtained from Sandy Farmer, Information Policy Branch (MC:2136), EPA, 401 M Street, SW, Washington, DC 20460, or by calling (202) 260–2740.

The reporting and recordkeeping burden for this proposed collection of information will be phased in starting in 1997. The specific burden anticipated for each category of respondent, by year, is shown below:

1997

Public Water Systems—monitoring and reporting
Hours per respondent: 0
Total hours: 0
Public Water Systems—recordkeeping
Hours per respondent: 0
Total hours: 0
State Program Costs—reporting
Hours per respondent: 1,599
Total hours: 89,518
State Program Costs—recordkeeping
Hours per respondent: 16
Total hours: 904

1998

Public Water Systems—monitoring and reporting
Hours per respondent: 0
Total hours: 0
Public Water Systems—recordkeeping
Hours per respondent: 0
Total hours: 0
State Program Costs—reporting
Hours per respondent: 1,149
Total hours: 64,337
State Program Costs—recordkeeping
Hours per respondent: 12
Total hours: 650

1999

Public Water Systems—monitoring and reporting
Hours per respondent: 0
Total hours: 0
Public Water Systems—recordkeeping
Hours per respondent: 0
Total hours: 0
State Program Costs—reporting
Hours per respondent: 699
Total hours: 39,157
State Program Costs—recordkeeping
Hours per respondent: 7
Total hours: 396

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch (MC:2136), EPA, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, OPM, Washington, DC 20503, marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

D. Science Advisory Board, National Drinking Water Advisory Council, and Secretary of Health and Human Services

In accordance with section 1412 (d) and (e) of the SDWA, EPA consulted

with the Science Advisory Board, National Drinking Water Advisory Council, and Secretary of Health and Human Services and requested their comments in developing this rule.

E. Consultation With State, Local, and Tribal Governments

Two Executive Orders (E.O. 12875, Enhancing Intergovernmental Partnerships, and E.O. 12866, Regulatory Planning and Review) explicitly require Federal agencies to consult with State, local, and tribal entities in the development of rules and policies that will affect them, and to document what they did, the issues that were raised, and how the issues were addressed.

As described in Section I of today's rule, SDWA Section 1412 requires EPA to promulgate NPDWRs, to review each NPDWR every three years, and to revise it as appropriate. In 1989, EPA issued the SWTR, in accordance with SDWA Section 1412(b)(7)(C). That rule went into effect in 1991. That rule has since been reviewed and is being reproposed today.

This proposal, which pertains only to systems serving more than 10,000 persons, contains several options for final promulgation. Depending on the option selected, PWSs with poorer quality source waters may need to remove microbiological contaminants above levels currently required under the SWTR. PWSs may also be required to treat for *Cryptosporidium*. There are currently insufficient data to develop an annual cost estimate of compliance with this rule.

In 1992, EPA considered entering into a negotiated rulemaking on a related Disinfectant/Disinfection By-Products rule primarily because no clear path for addressing all the major issues associated with the D/DBP rule was apparent. EPA hired a facilitator to explore this option with external stakeholders and, in November 1992, decided to proceed with the negotiation. The 18 negotiators, including EPA, met from November 1992 until June 1993 at which time agreement was reached on the content of the D/DBP proposed rule. That rule is proposed elsewhere in today's Federal Register. During the negotiations, the negotiators identified the possible need for a companion rule on surface water treatment. The purpose of the companion rule was to guard against the possibility of increasing microbial risk while controlling for disinfectant/disinfection byproduct risk. The contents of today's proposed regulatory and preamble language for enhanced surface water treatment have been agreed to by the 17 negotiators who remained at the table through June 1993. A summary of those negotiations is contained in Section II.

The negotiators included persons representing State and local governments. At the table were:

(1) Association of State Drinking Water Administrators, a group representing state government officials responsible for implementing the regulations,

(2) Association of State and Territorial Health Officials, a group representing statewide public health interests and the need to balance spending on a variety of health priorities,

(3) National Association of Regulated Utilities Commissioners, a group representing funding concerns at the state level,

(4) National Association of County Health Officials, a group representing local government general public health interests,

(5) National League of Cities, a group representing local elected and appointed officials responsible for balancing spending needs across all government services,

(6) National Association of State Utility Consumer Advocates, a group representing consumer interests at the state level, and

(7) National Consumer Law Center, a group representing consumer interests at the local level.

In addition, several associations representing public municipal and investor-owned water systems also served on the committee.

As part of the negotiation process, each of these representatives was responsible for obtaining endorsement from their respective organization on the positions they took at the negotiations and on the final signed agreement. During the negotiations, the group heard from many other parties who attended the public negotiations and were invited to express their views. As is true with any negotiation, all sides presented initial positions which were ultimately modified to obtain consensus from all sides. However, all parties mentioned above signed the final agreement on behalf of their associations. This agreement reflected basic consensus that the possible cost of the rule would be offset by its public health benefits and its promotion of responsible drinking water treatment practices.

The only original negotiator who did not sign the agreement left the negotiations in March 1993. That negotiator represented the National Rural Water Association (NRWA), a group representing primarily small public and private water systems. At the time that group left the negotiations, they were objecting to the cost of the D/DBP rule, which applies to all system sizes. Except for a sanitary survey requirement that EPA believes will be conducted by States, the interim ESWTR would only apply to systems serving greater than 10,000 persons and thus does not affect NRWA members. Earlier in the negotiations, NRWA accepted the position that any control of disinfectants and disinfection by-products should not come at the expense of decreased protection from microbial contamination. The NRWA position that small systems should meet a less stringent trihalomethane standard than larger systems was rejected by the remaining negotiators, several of whom also represent small water systems.

The contents of today's proposed rule has been available to the public for several months as part of the regulatory negotiation signature process. EPA has briefed numerous groups, including government organizations, on its contents. The Agency has received several letters from public water systems objecting to the cost of the proposed rule and questioning its potential health benefit. These letters are contained in the public docket supporting today's rule. The Agency recognizes that many persons are concerned whether the proposed rule is warranted. The technical issues are complex. The process needed to develop a common level of understanding among the negotiators as to what was known and unknown and what are reasonable estimates of potential costs and benefits was time-consuming. It is unreasonable to expect persons not at the negotiating table to have that same level of understanding and to all share the same view. However, the discussions throughout the negotiated rulemaking process were informed by a broad spectrum of opinions. The Agency believes this consensus proposal is not only the preferred approach but one which will generate informed debate and comment.

VIII. Request for Public Comment

EPA solicited public comments on specific issues earlier in the preamble and welcomes comments on any other issue the public may wish to address. For ease in referring to requests for comments we are listing them below. In addition, at the end of this section, the Agency is requesting comment on other issues not addressed earlier in the preamble.

- (III.C) Rationale for setting MCLG of zero and a treatment technique for *Cryptosporidium*

• (III.D.1) Ground water under the direct influence of surface water
—Including *Cryptosporidium* in rule language in definition of ground water under the direct influence of surface water
—Revising guidance defining ground water under the influence of surface water
—Most appropriate procedure for determining credits for removal/inactivation and treatment requirements for systems using ground waters under the direct influence of surface water
• (III.D.3) Sanitary surveys
—Prerequisites for individuals performing sanitary survey (academic degree, etc.)
—Revisions needed in SWTR Guidance Manual for conducting sanitary survey for filtered systems and for evaluating vulnerability to *Cryptosporidium*
—Frequency of sanitary surveys (three vs. five years)
• (III.D.4) Possible supplemental requirements
—Whether to publish national rule to require systems to cover finished water reservoirs and storage tanks, or whether this should be left to State discretion. What would the cost be for such a rule, and what waiver provisions would be appropriate.
—Whether EPA should require States and/or systems to have a cross-connection control program; what specific criteria, if any, should be included therein; how often such a program should be evaluated; under what conditions a waiver could be granted; and whether only those connections identified as a cross-connection by the public water system or the State should be subject to a cross-connection program.
—Identification of measures other than cross-connection control program to prevent the contamination of drinking water already in the distribution system (e.g., minimum pressure requirements in the distribution system).
—Whether to require systems to notify the State for persistent turbidity levels above the performance standard (but not in violation of this standard)
• (III.E) Alternative Treatment Requirements
1. Options for defining pathogen densities
—Appropriateness of requiring systems whose population served grows to over 10,000 to perform ICR monitoring.
—Appropriateness of the four approaches for calculating pathogen densities, and whether approach selected should be based on number of pathogen samples collected
2. Treatment alternative for controlling pathogens
—Appropriateness and magnitude of specific acceptable risk levels for microbes
—Which treatment approach(es) is most appropriate
—Identification of approaches for achieving levels of pathogen removal greater than 2.5 logs by physical means
—Utility of extrapolating CT values in SWTR Guidance Manual to predict the effect on pathogens of higher levels of disinfection
—Appropriateness of two treatment alternatives, with possible variations, for removal of *Giardia*
—Appropriateness of indicated treatment alternatives for *Cryptosporidium*
—Feasibility of removing more than two logs of *Cryptosporidium* (with and without disinfection being considered). -
Appropriateness of not
—Changing treatment specifications in SWTR
• (VI) Economic Analysis
—What approaches are reasonable for estimating the national treatment costs of requiring systems to remove a level of *Cryptosporidium* that would depend on *Cryptosporidium* densities in the source water
—Are the system level costs in Table VI–2 for increasing the disinfectant contact time reasonable and accurate
—The number of systems that might use control measures other than increasing contact basin time requirements and whether the use of such technologies would lead to substantially different cost estimates
—Assumption in estimating economic impact that treatment changes to control *Cryptosporidium* will also control *Giardia*
—Soundness of assumptions made in disinfection byproducts risk assessment model (DBPRAM) used to estimate potential risks from *Giardia* that might result from systems complying with different DBP standards both with the existing SWTR and an ESWTR, and how these assumptions could be improved

Other Issues

• How should EPA decide, in developing a forthcoming Notice of Availability, what treatment approach(es) is most suitable for additional public comment?
• What criteria, if any, should the ESWTR include to ensure that systems optimize treatment plant performance?
• Should any turbidity performance criteria in the SWTR be modified? For example, should the ESWTR require systems to base compliance with the turbidity standards on monitoring the turbidity at the effluent of each filter separately, in lieu of (or in addition to) the confluence of all filters? Should any performance standard value be changed?
• To what extent should the ESWTR address the issue of recycling filter backwash, given its potential for increasing the densities of *Giardia* and *Cryptosporidium* on the filter?
• Should the ESWTR define minimum certification criteria for surface water treatment plant operators? Currently, the SWTR (§ 141.70) requires such systems to be operated by "qualified personnel who meet the requirements specified by the State."
• Should the ESWTR include a performance standard(s) for particle removal?
• Under what conditions could systems be allowed different log removal credits than is currently recommended in the SWTR Guidance Manual?

IX. Instructions to Commenters

To ensure that EPA can read, understand and therefore properly respond to comments, the Agency would prefer that commenters type or print comments in ink, and cite, where possible, the paragraph(s) in this proposed regulation (e.g. 141.76(b)) to which each comment refers. Commenters should use a separate paragraph for each method or issue discussed.

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List of Subjects

40 CFR Part 141

Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Administrative practice and procedure, Reporting and recordkeeping requirements, Water supply

Dated: June 7, 1994.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble, Title 40 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.

2. Section 141.2 is amended by revising the definition of "Ground water under the direct influence of surface water" to read as follows:

§ 141.2 Definitions.

* * * * *

Ground water under the direct influence of surface water means any water beneath the surface of the ground with:

(1) Significant occurrence of insects or other macroorganisms, algae, or large-diameter pathogens such as *Giardia lamblia* or *Cryptosporidium*, or

(2) Significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlate to climatological or surface water conditions. Direct influence must be determined for individual sources in accordance with criteria established by the State. The State determination of direct influence may be based on site-specific measurements of water quality and/or documentation of well construction characteristics and geology with field evaluation.

* * * * *

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

§ 141.52 Maximum contaminant level goals for microbiological contaminants.

* * * * *

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

4. Section 141.71 is amended by revising the first three sentences of paragraph (b)(2) introductory text to read as follows:

§ 141.71 Criteria for avoiding filtration.

* * * * *

(b) * * *

(2) The public water system must maintain a watershed control program which minimizes the potential for contamination by *Giardia lamblia* cysts, *Cryptosporidium* oocysts, and viruses in the source water. The State must determine whether the watershed control program is adequate to meet this goal. The adequacy of a program to limit potential contamination by *Giardia lamblia* cysts, *Cryptosporidium* oocysts, and viruses must be based on: * * *

5. Section 141.73 is amended by revising paragraph (d) to read as follows:

§ 141.73 Filtration.

* * * * *

(d) *Other filtration technologies.* A public water system may use a filtration technology not listed in paragraphs (a) through (c) of this section if it demonstrates to the State, using pilot plant studies or other means, that the alternative filtration technology, in combination with disinfection treatment that meets the requirements of § 141.72(b), consistently achieves 99.9 percent removal and/or inactivation of *Giardia lamblia* cysts and 99.99 percent removal and/or inactivation of viruses and 99 percent removal of *Cryptosporidium* oocysts between the source water and the first customer. For a system that makes this demonstration the requirements of paragraph (b) of this section apply.

6. Section 141.74 is amended by adding a new paragraph (d) to read as follows:

§ 141.74 Analytical and monitoring requirements.

* * * * *

(d) Sanitary surveys for all systems. (1) A public water system that uses a surface water source or a ground water source under the influence of surface water shall be subject to an initial sanitary survey by [insert date 5 years after publication of the final rule] and a subsequent sanitary survey every five years [ALTERNATIVE: every three years] thereafter.

(2) The sanitary survey shall be performed by either the State, or an agent approved by the State. An agent approved by the State shall be paid by the system. In exceptional circumstances, the State may approve the public water system to conduct its own sanitary survey. In this case, the public water system shall certify that the system conducted the sanitary survey is in accordance with § 141.2 and that the sanitary survey report is true and accurate.

(3) If the State or an agent approved by the State is not available to conduct the sanitary survey within the time frame specified in this section, the system must conduct the sanitary survey. If an agent approved by the State or the system itself conducts the sanitary survey, the system must submit the sanitary survey report to the State within 90 days of completing the survey and before the end of the five year period.

Alternative A

7. Section 141.70 is amended by revising paragraph (a)(1) to read as follows:

§ 141.70 General requirements.

(a) * * *

(1)(i) At least 99.9 percent (3-log) removal and/or inactivation of *Giardia lamblia* cysts for systems serving fewer than 10,000 people. A system serving 10,000 people or more must achieve a *Giardia* removal/inactivation level by [insert date 18 months after publication of the final rule in the **Federal Register** that depends on the concentration of *Giardia* in the source water(s), as follows:

(A) If the source water(s) contains less than 1 cyst/100 liters, the system must achieve at least 99.9 percent (3-log) reduction;

(B) If the source water(s) contains 1 to 9 cysts/100 liters, the system must

achieve at least 99.99 percent (4-log) reduction [OPTION: 99.9 percent (3-log) reduction];

(C) If the source water(s) contains 10 to 99 cysts/100 liters, the system must achieve at least 99.999 percent (5-log) reduction [OPTION: 99.99 percent (4-log) reduction];

(D) If the source water(s) contains more than 99 cysts/ 100 liters, the system must achieve at least 99.9999 percent (6-log) reduction [OPTION: 99.999 percent (5-log) reduction].

(ii) Systems must achieve the required *Giardia* removal/inactivation level, as specified above, between the source water and the first customer. To calculate the *Giardia* density in source water from monitoring data obtained during the sampling period specified by § 141.140 of this part, use the:

Option 1: Arithmetic mean of measured values.

Option 2: Geometric mean of measured values.

Option 3: 90th percentile value of measured values.

Option 4: Highest measured value.

* * * * *

Alternative B

8. Section 141.70 is amended by adding new paragraph (a)(3) to read as follows:

§ 141.70 General requirements.

(a) * * *

(3) Beginning 18 months after promulgation of this rule, a system serving 10,000 people or more must achieve a *Cryptosporidium* removal/ inactivation level between the source water and first customer that depends on the concentration of *Cryptosporidium* in the source water(s), as follows:

(i) If the source water(s) contains less than 1 oocyst/100 liters, the system must achieve at least 99.9 percent (3-log) reduction [OPTION: 99 percent (2-log) reduction];

(ii) If the source water(s) contains 1 to 9 oocysts/100 liters, the system must achieve at least 99.99 percent (4-log) reduction [OPTION 1: 99.9 percent (3-log) reduction; OPTION 2: 99 percent (2-log) reduction];

(iii) If the source water(s) contains 10 to 99 oocysts/100 liters, the system must achieve at least 99.999 percent (5-log) reduction [OPTION 1: 99.99 percent (4-log) reduction; OPTION 2: 99.9 percent (3-log) reduction];

(iv) If the source water(s) contains more than 99 oocysts/ 100 liters, the system must achieve at least 99.9999 percent (6-log) reduction [OPTION 1: 99.999 percent (5-log) reduction; OPTION 2: 99.99 percent (4-log) reduction];

Systems must achieve the required *Cryptosporidium* removal/inactivation level, as specified above, between the source water and the first customer. To calculate the *Cryptosporidium* density in source water from monitoring data obtained during the sampling period specified by section 141.140 of this part, use the:

Option 1: Arithmetic mean of measured values.

Option 2: Geometric mean of measured values.

Option 3: 90th percentile value of measured values.

Option 4: Highest measured value.

* * * * *

Alternative C

9. Section 141.73 is amended by adding a new paragraph (e) to read as follows:

§ 141.73 Filtration.

* * * * *

(e) Public water systems that filter their source water must achieve at least 99 percent (2-log) removal of *Cryptosporidium* between the source water and the first customer.

Alternative D

10. Section 141.72 is amended by adding a new paragraph (c) to read as follows:

§ 141.72 Disinfection.

* * * * *

(c) Public water systems that serve 10,000 people or more and use either surface water or ground water under the direct influence of surface water must achieve, by disinfection alone, at least a 0.5-log inactivation of *Giardia* [ALTERNATIVE 1: 4-log inactivation of viruses].

Alternative E

11. No change in existing SWTR regarding level of removal/inactivation requirements.

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.

2. Section 142.16 is amended by adding paragraph (g) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(g) An application for approval of a State program revision that adopts the requirement specified below must contain the following:

(1) The State must designate the method it will use to judge the adequacy of watershed protection programs in minimizing the potential for contamination by *Giardia lamblia* cysts, Cryptosporidium oocysts, and viruses in the source water.

(2) The State must describe its criteria for the conduct of sanitary surveys and the method it will use to judge the adequacy of each sanitary survey. If the State elects to allow non-State personnel to conduct the surveys, the State must specify the criteria to be used to approve the non-State personnel. If the State intends to allow public water systems to conduct sanitary surveys, the State must specify procedures it will use for oversight and review of the surveys.

Alternative A

3. The following special primacy requirements are associated with Alternative A from item 7, above.

(3) Section 141.70(a)(1). The State must demonstrate that it has in place enforceable design and operating criteria for achieving the levels of *Giardia lamblia* removal/inactivation required. Alternatively, the State may institute a procedure for establishing design and operating conditions on a system-by-system basis (e.g., a permit system).

Alternative B

4. The following special primacy requirements are associated with Alternative B from item 8, above.

(3) Section 141.70(a)(3). The State must demonstrate that it has in place enforceable design and operating criteria for achieving the levels of *Cryptosporidium* removal/inactivation required. Alternatively, the State may institute a procedure for establishing design and operating conditions on a system-by-system basis (e.g., a permit system).

Alternative C

5. The following special primacy requirements are associated with Alternative C from item 9, above.

(3) Section 141.73(e). The State must demonstrate that it has in place enforceable design and operating criteria for achieving 2-log removal of *Cryptosporidium* between the source water and the first customer. Alternatively, the State may institute a procedure for establishing design and operating conditions on a system-by-system basis. (e.g., a permit system)

Alternative D

6. The following special primacy requirements are associated with Alternative D from item 10, above.

(4) Section 141.72(c). The State must demonstrate that it has in place enforceable design and operating criteria for achieving the level of *Giardia* (virus) inactivation required. Alternatively, the State may institute a procedure for establishing design and operating conditions on a system-by-system basis (e.g., a permit system).

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