ENVIRONMENTAL PROTECTION AGENCY

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[EPA–HQ–OW–2002–0043; FRL–8012–1]

RIN 2040–AD38

National Primary Drinking Water Regulations: Stage 2 Disinfectants and Disinfection Byproducts Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is promulgating today's final rule, the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR), to provide for increased protection against the potential risks for cancer and reproductive and developmental health effects associated with disinfection byproducts (DBPs). The final Stage 2 DBPR contains maximum contaminant level goals for chloroform, monochloroacetic acid and trichloroacetic acid; National Primary Drinking Water Regulations, which consist of maximum contaminant levels (MCLs) and monitoring, reporting, and public notification requirements for total trihalomethanes (TTHM) and haloacetic acids (HAA5); and revisions to the reduced monitoring requirements for bromate. This document also specifies the best available technologies for the final MCLs. EPA is also approving additional analytical methods for the determination of disinfectants and DBPs in drinking water. EPA believes the Stage 2 DBPR will reduce the potential risks of cancer and reproductive and developmental health effects associated with DBPs by reducing peak and average levels of DBPs in drinking water supplies.

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

This rule also makes minor corrections to drinking water regulations, specifically the Public Notification tables. New endnotes were added to these tables in recent rulemakings; however, the corresponding footnote numbering in the tables was not changed. In addition, this rule makes a minor correction to the Stage 1 Disinfectants and Disinfection Byproducts Rule by replacing a sentence that was inadvertently removed.

DATES: This final rule is effective on March 6, 2006. For judicial review purposes, this final rule is promulgated as January 4, 2006. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of March 6, 2006.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2002–0043. All documents in the docket are listed on the *http://www.regulations.gov* Web site.

Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form.

Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Water Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 10 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

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

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

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

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

See the **ADDRESSES** section for information on how to receive a copy of this document and related information.

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Abbreviations Used in This Document

ASDWA Association of State Drinking Water Administrators
ASTM American Society for Testing and Materials
AWWA American Water Works Association
AwwaRF American Water Works Association Research Foundation
BAT Best available technology
BCAA Bromochloroacetic acid
BDCM Bromodichloromethane
CDBG Community Development Block Grant
CWS Community water system
DBAA Dibromoacetic acid
DBCM Dibromochloromethane
DBP Disinfection byproduct
DBPR Disinfectants and Disinfection Byproducts Rule
DCAA Dichloroacetic acid
EA Economic analysis
EC Enhanced coagulation
EDA Ethylenediamine
EPA United States Environmental Protection Agency
ESWTR Enhanced Surface Water Treatment Rule
FACA Federal Advisory Committee Act
GAC Granular activated carbon
GC/ECD Gas chromatography using electron capture detection
GWR Ground Water Rule
GWUDI Ground water under the direct influence of surface water
HAA5 Haloacetic acids (five) (sum of monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid)
HAN Haloacetonitriles (trichloroacetonitrile, dichloroacetonitrile, bromochloroacetonitrile, and dibromoacetonitrile)
IC Ion chromatograph
IC/ICP–MS Ion chromatograph coupled to an inductively coupled plasma mass spectrometer
IDSE Initial distribution system evaluation
ILSI International Life Sciences Institute
IESWTR Interim Enhanced Surface Water Treatment Rule
IPCS International Programme on Chemical Safety
IRIS Integrated Risk Information System (EPA)
LOAEL Lowest observed adverse effect level
LRAA Locational running annual average
LT1ESTWR Long Term 1 Enhanced Surface Water Treatment Rule
LT2ESTWR Long Term 2 Enhanced Surface Water Treatment Rule
MBAA Monobromoacetic acid
MCAA Monochloroacetic acid
MCL Maximum contaminant level
MCLG Maximum contaminant level goal
M–DBP Microbial and disinfection byproducts mg/L Milligram per liter
MRL Minimum reporting level
MRDL Maximum residual disinfectant level
MRDLG Maximum residual disinfectant level goal
NDMA N-nitrosodimethylamine
NDWAC National Drinking Water Advisory Council
NF Nanofiltration
NOAEL No Observed Adverse Effect Level
NODA Notice of data availability
NPDWR National primary drinking water regulation
NRWA National Rural Water Association
NTNCWS Nontransient noncommunity water system
NTP National Toxicology Program
NTTAA National Technology Transfer and Advancement Act
OMB Office of Management and Budget
PAR Population attributable risk
PE Performance evaluation
PWS Public water system
RAA Running annual average
RFA Regulatory Flexibility Act
RfD Reference dose
RSC Relative source contribution
RUS Rural Utility Service
SAB Science Advisory Board
SBAR Small Business Advisory Review
SBREFA Small Business Regulatory Enforcement Fairness Act
SDWA Safe Drinking Water Act, or the ''Act,'' as amended in 1996
SER Small Entity Representative
SGA Small for gestational age
SUVA Specific ultraviolet absorbance
SWAT Surface Water Analytical Tool
SWTR Surface Water Treatment Rule
TC Total coliforms
TCAA Trichloroacetic acid
TCR Total Coliform Rule
THM Trihalomethane
TOC Total organic carbon
TTHM Total trihalomethanes (sum of four THMs: chloroform, bromodichloromethane, dibromochloromethane, and bromoform)
TWG Technical work group
UMRA Unfunded Mandates Reform Act
UV 254 Ultraviolet absorption at 254 nm
VSL Value of Statistical Life
WTP Willingness To Pay

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II. Summary of the Final Rule

A. Why is EPA Promulgating the Stage 2 DBPR?

The Environmental Protection Agency is finalizing the Stage 2 Disinfectants and Disinfection Byproduct Rule (DBPR) to reduce potential cancer risks and address concerns with potential reproductive and developmental risks from DBPs. The Agency is committed to ensuring that all public water systems provide clean and safe drinking water. Disinfectants are an essential element of drinking water treatment because of the barrier they provide against harmful waterborne microbial pathogens. However, disinfectants react with naturally occurring organic and inorganic matter in source water and distribution systems to form disinfection byproducts (DBPs) that may pose health risks. The Stage 2 DBPR is designed to reduce the level of exposure from DBPs without undermining the control of microbial pathogens. The Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) is being finalized and implemented simultaneously with the Stage 2 DBPR to ensure that drinking water is microbiologically safe at the limits set for DBPs.

Congress required EPA to promulgate the Stage 2 DBPR as part of the 1996 Safe Drinking Water Act (SDWA) Amendments (section 1412(b)(2)(C)). The Stage 2 DBPR augments the Stage 1 DBPR that was finalized in 1998 (63 FR 69390, December 16, 1998) (USEPA

1998a). The goal of the Stage 2 DBPR is to target the highest risk systems for changes beyond those required for Stage 1 DBPR. Today's rule reflects consensus recommendations from the Stage 2 Microbial/Disinfection Byproducts (M–DBP) Federal Advisory Committee (the Advisory Committee) as well as public comments.

New information on health effects, occurrence, and treatment has become available since the Stage 1 DBPR that supports the need for the Stage 2 DBPR. EPA has completed a more extensive analysis of health effects, particularly reproductive and developmental endpoints, associated with DBPs since the Stage 1 DBPR. Some recent studies on both human epidemiology and animal toxicology have shown possible associations between chlorinated drinking water and reproductive and developmental endpoints such as spontaneous abortion, stillbirth, neural tube and other birth defects, intrauterine growth retardation, and low birth weight. While results of these studies have been mixed, EPA believes they support a potential hazard concern. New epidemiology and toxicology studies evaluating bladder, colon, and rectal cancers have increased the weight of evidence linking these health effects to DBP exposure. The large number of people (more than 260 million Americans) exposed to DBPs and the potential cancer, reproductive, and developmental risks have played a significant role in EPA's decision to move forward with regulatory changes that target lowering DBP exposures beyond the requirements of the Stage 1 DBPR.

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

The Stage 2 DBPR presents a risk-targeting approach to reduce risks from DBPs. The new requirements provide for more consistent, equitable protection from DBPs across the entire distribution system and the reduction of DBP peaks. New risk-targeting provisions require systems to first identify their risk level; then, only those systems with the greatest risk will need to make operational or treatment changes. The Stage 2 DBPR, in conjunction with the LT2ESWTR, will help public water systems deliver safer water to Americans with the benefits of disinfection to control pathogens and with fewer risks from DBPs.

B. What Does the Stage 2 DBPR Require?

The risk-targeting components of the Stage 2 DBPR focus the greatest amount of change where the greatest amount of risk may exist. Therefore, the provisions of the Stage 2 DBPR focus first on identifying the higher risks through the Initial Distribution System Evaluation (IDSE). The rule then addresses reducing exposure and lowering DBP peaks in distribution systems by using a new method to determine MCL compliance (locational running annual average (LRAA)), defining operational evaluation levels, and regulating consecutive systems. This section briefly describes the requirements of this final rule. More detailed information on the regulatory requirements for this rule can be found in Section IV.

1. Initial Distribution System Evaluation

The first provision, designed to identify higher risk systems, is the Initial Distribution System Evaluation (IDSE). The purpose of the IDSE is to identify Stage 2 DBPR compliance monitoring sites that represent each system's highest levels of DBPs. Because Stage 2 DBPR compliance will be determined at these new monitoring sites, only those systems that identify elevated concentrations of TTHM and HAA5 will need to make treatment or process changes to bring the system into compliance with the Stage 2 DBPR. By identifying compliance monitoring sites with the highest concentrations of TTHM and HAA5 in each system's distribution system, the IDSE will offer increased assurance that MCLs are being met across the distribution system and that customers are receiving more equitable public health protection. Both treatment changes and awareness of TTHM and HAA5 levels resulting from the IDSE will allow systems to better control for distribution system peaks.

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

2. Compliance and Monitoring Requirements

As in Stage 1, the Stage 2 DBPR focuses on monitoring for and reducing concentrations of two classes of DBPs: total trihalomethanes (TTHM) and haloacetic acids (HAA5). These two groups of DBPs act as indicators for the various byproducts that are present in water disinfected with chlorine or chloramine. This means that concentrations of TTHM and HAA5 are monitored for compliance, but their presence in drinking water is representative of many other chlorination DBPs that may also occur in the water; thus, a reduction in TTHM and HAA5 generally indicates an overall reduction of DBPs.

The second provision of the Stage 2 DBPR is designed to address spatial variations in DBP exposure through a new compliance calculation (referred to as locational running annual average) for TTHM and HAA5 MCLs. The MCL values remain the same as in the Stage 1. The Stage 1 DBPR running annual average (RAA) calculation allowed some locations within a distribution system to have higher DBP annual averages than others as long as the system-wide average was below the MCL. The Stage 2 DBPR bases compliance on a locational running annual average (LRAA) calculation, where the annual average at each sampling location in the distribution system will be used to determine compliance with the MCLs of 0.080 mg/L and 0.060 mg/L for TTHM and HAA5, respectively. The LRAA will reduce exposures to high DBP concentrations by ensuring that each monitoring site is in compliance with the MCLs as an annual average, while providing all customers drinking water that more consistently meets the MCLs. A more detailed discussion of Stage 2 DBPR MCL requirements can be found in Sections IV.C, IV.E, and IV.G of this preamble and in § 141.64(b)(2) and (3) and subpart V of the rule language.

The number of compliance monitoring sites is based on the

population served and the source water type. EPA believes that population-based monitoring provides better risk-targeting and is easier to implement. Section IV.G describes population-based monitoring and how it affects systems complying with this rule.

The Stage 2 DBPR includes new MCLGs for chloroform, monochloroacetic acid, and trichloroacetic acid, but these new MCLGs do not affect the MCLs for TTHM or HAA5.

3. Operational Evaluation Levels

The IDSE and LRAA calculation will lead to lower DBP concentrations overall and reduce short term exposures to high DBP concentrations in certain areas, but this strengthened approach to regulating DBPs will still allow individual DBP samples above the MCL even when systems are in compliance with the Stage 2 DBPR. Today's rule requires systems that exceed operational evaluation levels (referred to as significant excursions in the proposed rule) to evaluate system operational practices and identify opportunities to reduce DBP concentrations in the distribution system. This provision will curtail peaks by providing systems with a proactive approach to remain in compliance. Operational evaluation requirements are discussed in greater detail in Section IV.H.

4. Consecutive Systems

The Stage 2 DBPR also contains provisions for regulating consecutive systems, defined in the Stage 2 DBPR as public water systems that buy or otherwise receive some or all of their finished water from another public water system. Uniform regulation of consecutive systems provided by the Stage 2 DBPR will ensure that consecutive systems deliver drinking water that meets applicable DBP standards, thereby providing better, more equitable public health protection. More information on regulation of consecutive systems can be found in Sections IV.B, IV.E, and IV.G.

C. Correction of § 141.132

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing prior notice and an opportunity for public comment. In addition to promulgating the Stage 2 regulations, this rule also makes a minor correction to the National Primary Drinking Water Regulations, specifically the Stage 1 Disinfection Byproducts Rule. This rule corrects a technical error made in the January 16, 2001, **Federal Register** Notice (66 FR 3769) (see page 3770). This rule restores the following sentence that was inadvertently removed from § 141.132 (b)(1)(iii), ''Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year (for systems which must monitor quarterly) or the result of the sample (for systems which must monitor no more frequently than annually) is no more than 0.060 mg/L and 0.045 mg/L for TTHMs and HAA5, respectively.'' This text had been part of the original regulation when it was codified in the CFR on December 16, 1998. However, as a result of a subsequent amendment to that regulatory text, the text discussed today was removed. EPA recognized the error only after publication of the new amendment, and is now correcting the error. EPA is merely restoring to the CFR language that EPA had promulgated on December 16, 1998. EPA is not creating any new rights or obligations by this technical correction. Thus, additional notice and public comment is not necessary. EPA finds that this constitutes ''good cause'' under 5 U.S.C. 553(b)(B).

III. Background

A combination of factors influenced the development of the Stage 2 DBPR. These include the initial 1992–1994 Microbial and Disinfection Byproduct (M–DBP) stakeholder deliberations and EPA's Stage 1 DBPR proposal (USEPA 1994); the 1996 Safe Drinking Water Act (SDWA) Amendments; the 1996 Information Collection Rule; the 1998 Stage 1 DBPR; new data, research, and analysis on disinfection byproduct (DBP) occurrence, treatment, and health effects since the Stage 1 DBPR; and the Stage 2 DBPR Microbial and Disinfection Byproducts Federal Advisory Committee. The following sections provide summary background information on these subjects. For additional information, see the proposed Stage 2 DBPR and supporting technical material where cited (68 FR 49548, August 18, 2003) (USEPA 2003a).

A. Statutory Requirements and Legal Authority

The SDWA, as amended in 1996, authorizes EPA to promulgate a national primary drinking water regulation (NPDWR) and publish a maximum contaminant level goal (MCLG) for any contaminant the Administrator determines ''may have an adverse effect on the health of persons,'' is ''known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern,'' and for which ''in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems'' (SDWA section 1412(b)(1)(A)). MCLGs are non-enforceable health goals set at a level at which ''no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.'' These health goals are published at the same time as the NPDWR (SDWA sections 1412(b)(4) and 1412(a)(3)).

SDWA also requires each NPDWR for which an MCLG is established to specify an MCL that is as close to the MCLG as is feasible (sections 1412(b)(4) and 1401(1)(C)). The Agency may also consider additional health risks from other contaminants and establish an MCL ''at a level other than the feasible level, if the technology, treatment techniques, and other means used to determine the feasible level would result in an increase in the health risk from drinking water by—(i) increasing the concentration of other contaminants in drinking water; or (ii) interfering with the efficacy of drinking water treatment techniques or processes that are used to comply with other national primary drinking water regulations'' (section 1412(b)(5)(A)). When establishing an MCL or treatment technique under this authority, ''the level or levels or treatment techniques shall minimize the overall risk of adverse health effects by balancing the risk from the contaminant and the risk from other contaminants the concentrations of which may be affected by the use of a treatment technique or process that would be employed to attain the maximum contaminant level or levels'' (section 1412(b)(5)(B)). In today's rule, the Agency is establishing MCLGs and MCLs for certain DBPs, as described in Section IV.

Finally, section 1412(b)(2)(C) of the Act requires EPA to promulgate a Stage 2 DBPR. Consistent with statutory provisions for risk balancing (section 1412(b)(5)(B)), EPA is finalizing the LT2ESWTR concurrently with the Stage 2 DBPR to ensure simultaneous protection from microbial and DBP risks.

B. What is the Regulatory History of the Stage 2 DBPR and How Were Stakeholders Involved?

This section first summarizes the existing regulations aimed at controlling

levels of DBPs in drinking water. The Stage 2 DBPR establishes regulatory requirements beyond these rules that target high risk systems and provide for more equitable protection from DBPs across the entire distribution system. Next, this section summarizes the extensive stakeholder involvement in the development of the Stage 2 DBPR.

1. Total Trihalomethanes Rule

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

2. Stage 1 Disinfectants and Disinfection Byproducts Rule

The Stage 1 DBPR, finalized in 1998 (USEPA 1998a), applies to all community and nontransient noncommunity water systems that add a chemical disinfectant to water. The rule established maximum residual disinfectant level goals (MRDLGs) and enforceable maximum residual disinfectant level (MRDL) standards for three chemical disinfectants—chlorine, chloramine, and chlorine dioxide; maximum contaminant level goals (MCLGs) for three trihalomethanes (THMs), two haloacetic acids (HAAs), bromate, and chlorite; and enforceable maximum contaminant level (MCL) standards for TTHM, five haloacetic acids (HAA5), bromate (calculated as running annual averages (RAAs)), and chlorite (based on daily and monthly sampling). The Stage 1 DBPR uses TTHM and HAA5 as indicators of the various DBPs that are present in disinfected water. Under the Stage 1 DBPR, water systems that use surface water or ground water under the direct influence of surface water and use conventional filtration treatment are required to remove specified percentages of organic materials, measured as total organic carbon (TOC), that may react with disinfectants to form DBPs. Removal is achieved through enhanced coagulation or enhanced softening, unless a system meets one or more alternative compliance criteria.

The Stage 1 DBPR was one of the first rules to be promulgated under the 1996 SDWA Amendments (USEPA 1998a). EPA finalized the Interim Enhanced Surface Water Treatment Rule (63 FR 69477, December 16, 1998) (USEPA 1998b) at the same time as the Stage 1 DBPR to ensure simultaneous compliance and address risk tradeoff issues. Both rules were products of extensive Federal Advisory Committee deliberations and final consensus recommendations in 1997.

3. Stakeholder Involvement

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

The Advisory Committee carefully considered extensive new data on the occurrence and health effects of DBPs, as well as costs and potential impacts on public water systems. In addition, they considered risk tradeoffs associated with treatment changes. Based upon this detailed technical evaluation, the committee concluded that a targeted protective public health approach should be taken to address exposure to DBPs beyond the requirements of the Stage 1 DBPR. While there had been substantial research to date, the Advisory Committee also concluded that significant uncertainty remained regarding the risk associated with DBPs in drinking water. After reaching these conclusions, the Advisory Committee developed an Agreement in Principle (65 FR 83015, December 29, 2000) (USEPA 2000a) that laid out their consensus recommendations on how to further control DBPs in public water systems, which are reflected in today's final rule.

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

The Agreement in Principle also provided recommendations for simultaneous compliance with the LT2ESWTR so that the reduction of DBPs does not compromise microbial protection. The complete text of the Agreement in Principle (USEPA 2000a) can be found online at *www.regulations.gov*.

b. Other outreach processes. EPA worked with stakeholders to develop the Stage 2 DBPR through various outreach activities other than the M-DBP Federal Advisory Committee process. The Agency consulted with State, local, and Tribal governments; the National Drinking Water Advisory Committee (NDWAC); the Science Advisory Board (SAB); and Small Entity Representatives (SERs) and small system operators (as part of an Agency outreach initiative under the Regulatory Flexibility Act). Section VII includes a complete description of the many stakeholder activities which contributed to the development of the Stage 2 DBPR.

Additionally, EPA posted a pre-proposal draft of the Stage 2 DBPR preamble and regulatory language on an EPA Internet site on October 17, 2001. This public review period allowed readers to comment on the Stage 2 DBPR's consistency with the Agreement in Principle of the Stage 2 M-DBP Advisory Committee. EPA received important suggestions on this pre-proposal draft from 14 commenters, which included public water systems, State governments, laboratories, and other stakeholders.

C. Public Health Concerns to be Addressed

EPA is promulgating the Stage 2 rule to reduce the potential risks of cancer and reproductive and developmental health effects from DBPs. In addition, the provisions of the Stage 2 DBPR provide for more equitable public health protection. Sections C and D describe the general basis for this public health concern through reviewing information in the following areas: the health effects associated with DBPs, DBP occurrence, and the control of DBPs.

1. What Are DBPs?

Chlorine has been widely used to kill disease-causing microbes in drinking water. The addition of chlorine in PWSs across the U.S. to kill microbial pathogens in the water supply has been cited as one of the greatest public health advances of the twentieth century (Okun 2003). For example, during the decade 1880–1890, American cities experienced an average mortality rate of 58 per 100,000 from typhoid, which was commonly transmitted through contaminated water. By 1938, this rate had fallen to 0.67 deaths per 100,000, largely due to improved treatment of drinking water (Blake 1956).

During the disinfection process, organic and inorganic material in source waters can combine with chlorine and certain other chemical disinfectants to form DBPs. More than 260 million people in the U.S. are exposed to disinfected water and DBPs (USEPA 2005a). Although chlorine is the most commonly applied disinfectant, other disinfectants, including ozone, chlorine dioxide, chloramine, and ultraviolet radiation, are in use. In combination with these, all surface water systems must also use either chlorine or chloramine to maintain a disinfectant residual in their distribution system. The kind of disinfectant used can produce different types and levels of disinfectant byproducts in the drinking water.

Many factors affect the amount and kinds of DBPs in drinking water. Areas in the distribution system that have had longer contact time with chemical disinfectants tend to have higher levels of DBPs, such as sites farther from the treatment plant, dead ends in the system, and small diameter pipes. The makeup and source of the water also affect DBP formation. Different types of organic and inorganic material will form different types and levels of DBPs. Other factors, such as water temperature, season, pH, and location within the water purification process where disinfectants are added, can affect DBP formation within and between water systems.

THMs and HAAs are widely occurring classes of DBPs formed during disinfection with chlorine and chloramine. The four THMs (TTHM) and five HAAs (HAA5) measured and regulated in the Stage 2 DBPR act as indicators for DBP occurrence. There are other known DBPs in addition to a variety of unidentified DBPs present in disinfected water. THMs and HAAs typically occur at higher levels than other known and unidentified DBPs (McGuire et al. 2002; Weinberg et al. 2002). The presence of TTHM and HAA5 is representative of the occurrence of many other chlorination DBPs; thus, a reduction in the TTHM and HAA5 generally indicates an overall reduction of DBPs.

2. DBP Health Effects

Since the mid 1980's, epidemiological studies have supported a potential association between bladder cancer and chlorinated water and possibly also with colon and rectal cancers. In addition, more recent health studies have reported potential associations between chlorinated drinking water and reproductive and developmental health effects.

Based on a collective evaluation of both the human epidemiology and animal toxicology data on cancer and reproductive and developmental health effects discussed below and in consideration of the large number of people exposed to chlorinated byproducts in drinking water (more than 260 million), EPA concludes that (1) new cancer data since Stage 1 strengthen the evidence of a potential association of chlorinated water with bladder cancer and suggests an association for colon and rectal cancers, (2) current reproductive and developmental health effects data do not support a conclusion at this time as to whether exposure to chlorinated drinking water or disinfection byproducts causes adverse developmental or reproductive health effects, but do support a potential health concern, and (3) the combined health data indicate a need for public health protection beyond that provided by the Stage 1 DBPR.

This section summarizes the key information in the areas of cancer, reproductive, and developmental health studies that EPA used to arrive at these conclusions. Throughout this writeup, EPA uses 'weight of evidence,' 'causality,' and 'hazard' as follows:

- A 'weight of evidence' evaluation is a collective evaluation of all pertinent information. Judgement about the weight of evidence involves considerations of the quality and adequacy of data and consistency of responses. These factors are not scored mechanically by adding pluses and minuses; they are judged in combination.
- Criteria for determining 'causality' include consistency, strength, and specificity of association, a temporal relationship, a biological gradient (dose-response relationship), biological plausibility, coherence with multiple lines of evidence, evidence from human populations, and information on agent's structural analogues (USEPA 2005i). Additional considerations for individual study findings include reliable exposure data, statistical power and significance, and freedom from bias and confounding.
- The term 'hazard' describes not a definitive conclusion, but the possibility that a health effect may be attributed to a certain exposure, in this case chlorinated water. Analyses done for the Stage 2 DBPR follow the 1999 EPA Proposed Guidelines for Carcinogenic Risk Assessment (USEPA 1999a). In March 2005, EPA updated and finalized the Cancer Guidelines and a Supplementary Children's Guidance, which include new considerations on mode of action for cancer risk determination and additional potential risks due to early childhood exposure (USEPA 2005i; USEPA 2005j). Conducting the cancer evaluation using the 2005 Cancer Guidelines would not result in any change from the existing analysis. With the exception of chloroform, no mode of action has been established for other specific regulated DBPs. Although some of the DBPs have given mixed mutagenicity and genotoxicity results, having a positive mutagenicity study does not necessarily mean that a chemical has a mutagenic mode of action. The extra factor of safety for children's health protection does not apply because the new Supplementary Children's Guidance requires application of the children's factor only when a mutagenic mode of action has been identified.

a. Cancer health effects. The following section briefly discusses cancer epidemiology and toxicology information EPA analyzed and some conclusions of these studies and reports. Further discussion of these studies and EPA's conclusions can be found in the proposed Stage 2 DBPR (USEPA 2003a) and the Economic Analysis for the Final Stage 2 Disinfectants and Disinfection Byproducts Rule (Economic Analysis (EA)) (USEPA 2005a).

Human epidemiology studies and animal toxicology studies have

examined associations between chlorinated drinking water or DBPs and cancer. While EPA cannot conclude there is a causal link between exposure to chlorinated surface water and cancer, EPA believes that the available research indicates a potential association between bladder cancer and exposure to chlorinated drinking water or DBPs. EPA also believes the available research suggests a possible association between rectal and colon cancers and exposure to chlorinated drinking water or DBPs. This is based on EPA's evaluation of all available cancer studies. The next two sections focus on studies published since the Stage 1 DBPR. Conclusions are based on the research as a whole.

i. Epidemiology. A number of epidemiological studies have been conducted to investigate the relationship between exposure to chlorinated drinking water and various cancers. These studies contribute to the overall evidence on potential human health hazards from exposure to chlorinated drinking water.

Epidemiology studies provide useful health effects information because they reflect human exposure to a drinking water DBP mixture through multiple routes of intake such as ingestion, inhalation and dermal absorption. The greatest difficulty with conducting cancer epidemiology studies is the length of time between exposure and effect. Higher quality studies have adequately controlled for confounding and have limited the potential for exposure misclassification, for example, using DBP levels in drinking water as the exposure metric as opposed to type of source water. Study design considerations for interpreting cancer epidemiology data include sufficient follow-up time to detect disease occurrence, adequate sample size, valid ascertainment of cause of the cancer, and reduction of potential selection bias in case-control and cohort studies (by having comparable cases and controls and by limiting loss to follow-up). Epidemiology studies provide extremely useful information on human exposure to chlorinated water, which complement single chemical, high dose animal data.

In the Stage 1 DBPR, EPA concluded that the epidemiological evidence suggested a potential increased risk for bladder cancer. Some key studies EPA considered for Stage 1 include Cantor et al. (1998), Doyle et al. (1997), Freedman et al. (1997), King and Marrett (1996), McGeehin et al. (1993), Cantor et al. (1987), and Cantor et al. (1985). Several studies published since the Stage 1 DBPR continue to support an association between increased risk of bladder cancer and exposure to chlorinated surface water (Chevrier et al. 2004; Koivusalo et al. 1998; Yang et al. 1998). One study found no effects on a biomarker of genotoxicity in urinary bladder cells from TTHM exposure (Ranmuthugala et al. 2003). Epidemiological reviews and meta-analyses generally support the possibility of an association between chlorinated water or THMs and bladder cancer (Villanueva et al. 2004; Villanueva et al. 2003; Villanueva et al. 2001; Mills et al. 1998). The World Health Organization (WHO 2000) found data inconclusive or insufficient to determine causality between chlorinated water and any health endpoint, although they concluded that the evidence is better for bladder cancer than for other cancers.

In the Stage 1 DBPR, EPA concluded that early studies suggested a small possible increase in rectal and colon cancers from exposure to chlorinated surface waters. The database of studies on colon and rectal cancers continues to support a possible association, but evidence remains mixed. For colon cancer, one newer study supports the evidence of an association (King et al. 2000a) while others showed inconsistent findings (Hildesheim et al. 1998; Yang et al. 1998). Rectal cancer studies are also mixed. Hildesheim et al. (1998) and Yang et al. (1998) support an association with rectal cancer while King et al. (2000a) did not. A review of colon and rectal cancer concluded evidence was inconclusive but that there was a stronger association for rectal cancer and chlorination DBPs than for colon cancer (Mills et al. 1998). The WHO (2000) review reported that studies showed weak to moderate associations with colon and rectal cancers and chlorinated surface water or THMs but that evidence is inadequate to evaluate these associations.

Recent studies on kidney, brain, and lung cancers and DBP exposure support a possible association (kidney: Yang et al. 1998, Koivusalo et al. 1998; brain: Cantor et al. 1999; lung: Yang et al. 1998). However, so few studies have examined these endpoints that definitive conclusions cannot be made. Studies on leukemia found little or no association with DBPs (Infante-Rivard et al. 2002; Infante-Rivard et al. 2001). A recent study did not find an association between pancreatic cancer and DBPs (Do et al. 2005). A study researching multiple cancer endpoints found an association between THM exposure and all cancers when grouped together (Vinceti et al. 2004). More details on the cancer epidemiology studies since the Stage 1 DBPR are outlined in Table II.D–1.

TABLE II.D–1.—SUMMARY OF CANCER EPIDEMIOLOGY STUDIES REVIEWED FOR STAGE 2 DBPR

Author(s)	Study type	Exposure(s) studied	Outcome(s) measured	Findings
Do et al. 2005	Case-control study in Canada, 1994–1997.	Estimated chlorinated DBPs, chloroform, BDCM concentrations.	Pancreatic cancer.	No association was found between pancreatic cancer and exposure to chlorinated DBPs, chloroform, or BDCM.
Chevrier et al. 2004..	Case-control study in France, 1985–1987.	Compared THM levels, duration of exposure, and 3 types of water treatment (ozonation, chlorination, ozonation/chlorination).	Bladder cancer.	A statistically significant decreased risk of bladder cancer was found as duration of exposure to ozonated water increased. This was evident with and without adjustment for other exposure measures. A small association was detected for increased bladder cancer risk and duration of exposure to chlorinated surface water and with the estimated THM content of the water, achieving statistical significance only when adjusted for duration of ozonated water exposures. Effect modification by gender was noted in the adjusted analyses.

TABLE II.D–1.—SUMMARY OF CANCER EPIDEMIOLOGY STUDIES REVIEWED FOR STAGE 2 DBPR—Continued

	Study type	Exposure(s) studied	Outcome(s) measured	Findings
Vinceti et al. 2004.	Retrospective cohort study in Italy, 1987–1999.	Standardized mortality ratios from all causes vs. cancer for consumers drinking water with high THMs.	15 cancers including colon, rectum, and bladder.	Mortality ratio from all cancers showed a statistically significant small increase for males consuming drinking water with high THMs. For females, an increased mortality ratio for all cancers was seen but was not statistically significant. Stomach cancer in men was the only individual cancer in which a statistically significant excess in mortality was detected for consumption of drinking water with high THMs.
Ranmuthugala et al. 2003.	Cohort study in 3 Australian communities, 1997.	Estimated dose of TTHM, chloroform, and bromoform from routinely-collected THM measurements and fluid intake diary.	Frequency of micronuclei in urinary bladder epithelial cells.	Relative risk estimates for DNA damage to bladder cells for THM dose metrics were near 1.0. The study provides no evidence that THMs are associated with DNA damage to bladder epithelial cells, and dose-response patterns were not detected.
Infante-Rivard et al. 2002.	Population-based case-control study in Quebec, 1980–1993.	Estimated prenatal and postnatal exposure to THMs and polymorphisms in two genes.	Acute lymphoblastic leukemia.	Data are suggestive, but imprecise, linking DNA variants with risk of acute lymphoblastic leukemia associated with drinking water DBPs. The number of genotyped subjects for GSTT1 and CYP2E1 genes was too small to be conclusive.
Infante-Rivard et al. 2001.	Population-based case-control study in Quebec, 1980–1993.	Compared water chlorination (never, sometimes, always) and exposure to TTHMs, metals, and nitrates.	Acute lymphoblastic leukemia.	No increased risk for lymphoblastic leukemia was observed for prenatal exposure at average levels of TTHMs, metals or nitrates. However, a non-statistically significant, small increased risk was seen for postnatal cumulative exposure to TTHMs and chloroform (both at above the 95th exposure percentile of the distribution for cases and controls), for zinc, cadmium, and arsenic, but not other metals or nitrates.
King et al. 2000a.	Population-based case-control study in southern Ontario, 1992–1994.	Compared source of drinking water and chlorination status. Estimated TTHM levels, duration of exposure, and tap water consumption.	Colon and rectal cancer.	Colon cancer risk was statistically associated with cumulative long term exposure to THMs, chlorinated surface water, and tap water consumption metrics among males only. Exposure-response relationships were evident for exposure measures combining duration and THM levels. Associations between the exposure measures and rectal cancer were not observed for either gender.
Cantor et al. 1999.	Population-based case-control study in Iowa, 1984–1987.	Compared level and duration of THM exposure (cumulative and average), source of water, chlorination, and water consumption.	Brain cancer	Among males, a statistically significant increased risk of brain cancer was detected for duration of chlorinated versus non-chlorinated source water, especially among high-level consumers of tap water. An increased risk of brain cancer for high water intake level was found in men. No associations were found for women for any of the exposure metrics examined.
Cantor et al. 1998.	Population-based case-control study in Iowa, 1986–1989.	Compared level and duration of THM exposure (cumulative and average), source of water, chlorination, and water consumption.	Bladder cancer	A statistically significant positive association between risk of bladder cancer and exposure to chlorinated groundwater or surface water reported for men and for smokers, but no association found for male/female non-smokers, or for women overall. Limited evidence was found for an association between tapwater consumption and bladder cancer risk. Suggestive evidence existed for exposure-response effects of chlorinated water and lifetime THM measures on bladder cancer risk.
Hildesheim et al. 1998.	Population-based case-control study in Iowa, 1986–1989.	Compared level and duration of THM exposure (cumulative and average), source of water, chlorination, and water consumption.	Colon and rectal cancer.	Increased risks of rectal cancer was associated with duration of exposure to chlorinated surface water and any chlorinated water, with evidence of an exposure-response relationship. Risk of rectal cancer is statistically significant increased with >60 years lifetime exposure to THMs in drinking water, and risk increased for individuals with low dietary fiber intake. Risks were similar for men and women and no effects were observed for tapwater measures. No associations were detected for water exposure measures and risk of colon cancer.
Koivusalo et al. 1998.	Population-based case-control study in Finland, 1991–1992.	Estimated residential duration of exposure and level of drinking water mutagenicity.	Bladder and kidney cancer.	Drinking water mutagenicity was associated with a small, statistically significant, exposure-related excess risk for kidney and bladder cancers among men; weaker associations were detected for mutagenic water and bladder or kidney cancer among women. The effect of mutagenicity on bladder cancer was modified by smoking status, with an increased risk among non-smokers.

TABLE II.D–1.—SUMMARY OF CANCER EPIDEMIOLOGY STUDIES REVIEWED FOR STAGE 2 DBPR—Continued

	Study type	Exposure(s) studied	Outcome(s) measured	Findings
Yang et al. 1998.	Cross-sectional study in Taiwan, 1982–1991.	Examined residence in chlorinated (mainly surface water sources) relative to non-chlorinated (mainly private well) water.	Cancer of rectum, lung, bladder, kidney, colon, and 11 others.	Residence in chlorinating municipalities (vs. non-chlorinating) was statistically significantly associated with the following types of cancer in both males and females: rectal, lung, bladder, and kidney cancer. Liver cancer and all cancers were also statistically significantly elevated in chlorinated towns for males only. Mortality rates for cancers of the esophagus, stomach, colon, pancreas, prostate, brain, breast, cervix uteri and uterus, and ovary were comparable for chlorinated and non-chlorinated residence.
Doyle et al. 1997.	Prospective cohort study in Iowa, 1987–1993.	Examined chloroform levels and source of drinking water.	Colon, rectum, bladder, and 8 other cancers in women.	Statistically significant increased risk of colon cancer, breast cancer and all cancers combined was observed for women exposed to chloroform in drinking water, with evidence of exposure-response effects. No associations were detected between chloroform and bladder, rectum, kidney, upper digestive organs, lung, ovary, endometrium, or breast cancers, or for melanomas or non-Hodgkin's lymphoma. Surface water exposure (compared to ground water users) was also a significant predictor of colon and breast cancer risk.
Freedman et al. 1997.	Population-based case-control study in Maryland, 1975–1992.	Estimated duration of exposure to chlorinated water. Compared exposure to chlorinated municipal water (yes/no).	Bladder cancer	There was a weak association between bladder cancer risk and duration of exposure to municipal water for male cigarette smokers, as well as an exposure-response relationship. No association was seen for those with no history of smoking, suggesting that smoking may modify a possible effect of chlorinated surface water on the risk of bladder cancer.
King and Marrett 1996.	Case-control study in Ontario, Canada, 1992–1994.	Compared source of drinking water and chlorination status. Estimated TTHM levels, duration of exposure, and tap water consumption.	Bladder cancer	Statistically significant associations were detected for bladder cancer and chlorinated surface water, duration or concentration of THM levels and tap water consumption metrics. Population attributable risks were estimated at 14 to 16 percent. An exposure-response relationship was observed for estimated duration of high THM exposures and risk of bladder cancer.
McGeehin et al. 1993.	Population-based case-control study in Colorado, 1990–1991.	Compared source of drinking water, water treatment, and tap water versus bottled water. Estimated duration of exposure to TTHMs and levels of TTHMs, nitrates, and residual chlorine.	Bladder cancer	Statistically significant associations were detected for bladder cancer and duration of exposure to chlorinated surface water. The risk was similar for males and females and among nonsmokers and smokers. The attributable risk was estimated at 14.9 percent. High tap water intake was associated with risk of bladder cancer in a exposure-response fashion. No associations were detected between bladder cancer and levels of TTHMs, nitrates, and residual chlorine.
Cantor et al. 1987 (and Cantor et al. 1985).	Population-based case-control study in 10 areas of the U.S., 1977–1978.	Compared source of drinking water. Estimated total beverage and tap water consumption and duration of exposure.	Bladder cancer	Bladder cancer was statistically associated with duration of exposure to chlorinated surface water for women and nonsmokers of both sexes. The largest risks were seen when both exposure duration and level of tap water ingestion were combined. No association was seen for total beverage consumption.
Reviews/Meta-analyses				
Villanueva et al. 2004.	Review and meta-analysis of 6 case-control studies.	Individual-based exposure estimates to THMs and water consumption over a 40-year period.	Bladder cancer	The meta-analysis suggests that risk of bladder cancer in men increases with long-term exposure to TTHMs. An exposure-response pattern was observed among men exposed to TTHMs, with statistically significant risk seen at exposures higher than 50 ug/L. No association between TTHMs and bladder cancer was seen for women.
Villanueva et al. 2003 (and Goebell et al. 2004).	Review and meta-analysis of 6 case-control studies and 2 cohort studies.	Compared source of water and estimated duration of exposure to chlorinated drinking water.	Bladder cancer	The meta-analysis findings showed a moderate excess risk of bladder cancer attributable to long-term consumption of chlorinated drinking water for both genders, particularly in men. Statistically significance seen with men and combined both sexes. The risk was higher when exposure exceeded 40 years.

TABLE II.D–1.—SUMMARY OF CANCER EPIDEMIOLOGY STUDIES REVIEWED FOR STAGE 2 DBPR—Continued

	Study type	Exposure(s) studied	Outcome(s) measured	Findings
Villanueva et al. 2001.	Qualitative review of 31 cancer studies.	Compared exposure to TTHM levels, mutagenic drinking water, water consumption, source water, types of disinfection (chlorination and chloramination), and residence times.	Cancer of bladder, colon, rectum, and 5 other cancers..	Review found that although results for cancer studies varied and were not always statistically significant, evidence for bladder cancer is strongest, and all 10 of the bladder cancer studies showed increased cancer risks with ingestion of chlorinated water. The authors felt associations with chlorinated water and cancer of the colon, rectum, pancreas, esophagus, brain, and other cancers were inconsistent.
WHO 2000	Qualitative reviews of various studies in Finland, U.S., and Canada.	Various exposures to THMs.	Various cancers	Studies reviewed reported weak to moderate increased relative risks of bladder, colon, rectal, pancreatic, breast, brain or lung cancer associated with long-term exposure to chlorinated drinking water. The authors felt evidence is inconclusive for an association between colon cancer and long-term exposure to THMs; that evidence is insufficient to evaluate a causal relationship between THMs and rectal, bladder, and other cancers. They found no association between THMs and increased risk of cardiovascular disease.
Mills et al. 1998.	Qualitative review of 22 studies.	Examined TTHM levels and water consumption. Compared source of water and 2 types of water treatment (chlorination and chloramination).	Cancer of colon, rectum, and bladder.	Review suggests possible increases in risks of bladder cancer with exposure to chlorinated drinking water. The authors felt evidence for increased risk of colon and rectal cancers is inconclusive, though evidence is stronger for rectal cancer.

Overall, bladder cancer data provide the strongest basis for quantifying cancer risks from DBPs. EPA has chosen this endpoint to estimate the primary benefits of the Stage 2 DBPR (see Section VI).

ii. Toxicology. Cancer toxicology studies provide additional support that chlorinated water is associated with cancer. In general, EPA uses long term toxicology studies that show a dose response to derive MCLGs and cancer potency factors. Short term studies are used for hazard identification and to design long term studies. Much of the available cancer toxicology information was available for the Stage 1 DBPR, but there have also been a number of new cancer toxicology and mode of action studies completed since the Stage 1 DBPR was finalized in December 1998.

In support of this rule, EPA has developed health criteria documents which summarize the available toxicology data for brominated THMs (USEPA 2005b), brominated HAAs (USEPA 2005c), MX (USEPA 2000b), MCAA (USEPA 2005d), and TCAA (USEPA 2005e). The 2003 IRIS assessment of DCAA (USEPA 2003b) and an addendum (USEPA 2005k) also provides analysis released after Stage 1. It summarizes information on exposure from drinking water and develops a slope factor for DCAA. IRIS also has toxicological reviews for chloroform (USEPA 2001a), chlorine dioxide and chlorite (USEPA 2000c), and bromate (USEPA 2001b), and is currently reassessing TCAA.

Slope factors and risk concentrations for BDCM, bromoform, DBCM and DCAA have been developed and are listed in Table II.D–2. For BDCM, bromoform, and DBCM, table values are derived from the brominated THM criteria document (USEPA 2005b), which uses IRIS numbers that have been updated using the 1999 EPA Proposed Guidelines for Carcinogenic Risk Assessment (USEPA 1999a). For DCAA, the values are derived directly from IRIS.

TABLE II.D–2.—QUANTIFICATION OF CANCER RISK

Disinfection byproduct	LED_{10}[a]		ED_{10}[a]	
	Slope factor $(mg/kg/day)^{-1}$	10^{-6} Risk concentration (mg/L)	Slope factor $(mg/kg/day)^{-1}$	10^{-6} Risk concentration (mg/L)
Bromodichloromethane	0.034	0.001	0.022	0.002
Bromoform	0.0045	0.008	0.0034	0.01
Dibromochloromethane	0.04	0.0009	0.017	0.002
Dichloroacetic Acid	0.048	0.0007	0.015[b]	0.0023[b]

[a] LED_{10} is the lower 95% confidence bound on the (effective dose) ED_{10} value. ED_{10} is the estimated dose producing effects in 10% of animals.

[b] The ED_{10} risk factors for DCAA have been changed from those given in the comparable table in the proposed Stage 2 DBPR to correct for transcriptional errors.

More research on DBPs is underway at EPA and other research institutions. Summaries of on-going studies may be found on EPA's DRINK Web site (*http://www.epa.gov/safewater/drink/intro.html*). Two-year bioassays by the National Toxicology Program (NTP) released in abstract form have recently been completed on BDCM and chlorate. The draft abstract on BDCM reported no evidence of carcinogenicity when BDCM was administered via drinking

water (NTP 2005a). Another recent study, a modified two-year bioassay on BDCM in the drinking water, reported little evidence of carcinogenicity (George et al. 2002). In a previous NTP study, tumors were observed, including an increased incidence of kidney, liver, and colon tumors, when BDCM was administered at higher doses by gavage in corn oil (NTP 1987). EPA will examine new information on BDCM as it becomes available. In the chlorate draft abstract, NTP found some evidence that it may be a carcinogen (NTP 2004). Chlorate is a byproduct of hypochlorite and chlorine dioxide systems. A long-term, two-year bioassay NTP study on DBA is also complete but has not yet undergone peer review (NTP 2005b).

b. Reproductive and developmental health effects. Both human epidemiology studies and animal toxicology studies have examined associations between chlorinated drinking water or DBPs and reproductive and developmental health effects. Based on an evaluation of the available science, EPA believes the data suggest that exposure to DBPs is a potential reproductive and developmental health hazard.

The following section briefly discusses the reproductive and developmental epidemiology and toxicology information available to EPA. Further discussion of these studies and EPA's conclusions can be found in the proposed Stage 2 DBPR (USEPA 2003a) and the Economic Analysis (USEPA 2005a).

i. Epidemiology. As discussed previously, epidemiology studies have the strength of relating human exposure to DBP mixtures through multiple intake routes. Although the critical exposure window for reproductive and developmental effects is much smaller than that for cancer (generally weeks versus years), exposure assessment is also a main limitation of reproductive and developmental epidemiology studies. Exposure assessment uncertainties arise from limited data on DBP concentrations and maternal water usage and source over the course of the pregnancy. However, classification errors typically push the true risk estimate towards the null value (Vineis 2004). According to Bove et al. (2002), ''Difficulties in assessing exposure may result in exposure misclassification biases that would most likely produce substantial underestimates of risk as well as distorted or attenuated exposure-response trends.'' Studies of rare outcomes (e.g., individual birth defects) often have limited statistical power because of the small number of cases being examined. This limits the ability to detect statistically significant associations for small to moderate relative risk estimates. Small sample sizes also result in imprecision around risk estimates reflected by wide confidence intervals. In addition to the limitations of individual studies, evaluating reproductive and developmental epidemiology studies collectively is difficult because of the methodological differences between studies and the wide variety of endpoints examined. These factors may contribute to inconsistencies in the scientific body of literature as noted below.

More recent studies tend to be of higher quality because of improved exposure assessments and other methodological advancements. For example, studies that use THM levels to estimate exposure tend to be higher quality than studies that define exposure by source or treatment. These factors were taken into account by EPA when comparing and making conclusions on the reproductive and developmental epidemiology literature. What follows is a summary of available epidemiology literature on reproductive and developmental endpoints such as spontaneous abortion, stillbirth, neural tube and other birth defects, low birth weight, and intrauterine growth retardation. Information is grouped, where appropriate, into three categories on fetal growth, viability, and malformations, and reviews are described separately afterward. Table II.D–3 provides a more detailed description of each study or review.

Fetal growth. Many studies looked for an association between fetal growth (mainly small for gestational age, low birth weight, and pre-term delivery) and chlorinated water or DBPs. The results from the collection of studies as a whole are inconsistent. A number of studies support the possibility that exposure to chlorinated water or DBPs are associated with adverse fetal growth effects (Infante-Rivard 2004; Wright et al. 2004; Wright et al. 2003; Källén and Robert 2000; Gallagher et al. 1998; Kanitz et al. 1996; Bove et al. 1995; Kramer et al. 1992). Other studies showed mixed results (Porter et al. 2005; Savitz et al. 2005; Yang 2004) or did not provide evidence of an association (Toledano et al. 2005; Jaakkola et al. 2001; Dodds et al. 1999; Savitz et al. 1995) between DBP exposure and fetal growth. EPA notes that recent, higher quality studies provide some evidence of an increased risk of small for gestational age and low birth weight.

Fetal viability. While the database of epidemiology studies for fetal loss endpoints (spontaneous abortion or stillbirth) remains inconsistent as a whole, there is suggestive evidence of an association between fetal loss and chlorinated water or DBP exposure. Various studies support the possibility that exposure to chlorinated water or DBPs is associated with decreased fetal viability (Toledano et al. 2005; Dodds et al. 2004; King et al. 2000b; Dodds et al. 1999; Waller et al. 1998; Aschengrau et al. 1993; Aschengrau et al. 1989). Other studies did not support an association (Bove et al. 1995) or reported inconclusive results (Savitz et al. 2005; Swan et al. 1998; Savitz et al. 1995) between fetal viability and exposure to THMs or tapwater. A recent study by King et al. (2005) found little evidence of an association between stillbirths and haloacetic acids after controlling for trihalomethane exposures, though non-statistically significant increases in stillbirths were seen across various exposure levels.

Fetal malformations. A number of epidemiology studies have examined the relationship between fetal malformations (such as neural tube, oral cleft, cardiac, or urinary defects, and chromosomal abnormalities) and chlorinated water or DBPs. It is difficult to assess fetal malformations in aggregate due to inconsistent findings and disparate endpoints being examined in the available studies. Some studies support the possibility that exposure to chlorinated water or DBPs is associated with various fetal malformations (Cedergren et al. 2002; Hwang et al. 2002; Dodds and King 2001; Klotz and Pyrch 1999; Bove et al. 1995; Aschengrau et al. 1993). Other studies found little evidence (Shaw et al. 2003; Källén and Robert 2000; Dodds et al. 1999; Shaw et al. 1991) or inconclusive results (Magnus et al. 1999) between chlorinated water or DBP exposure and fetal malformations. Birth defects most consistently identified as being associated with DBPs include neural tube defects and urinary tract malformations.

Other endpoints have also been examined in recent epidemiology studies. One study suggests an association between DBPs and decreased menstrual cycle length (Windham et al. 2003), which, if corroborated, could be linked to the biological basis of other reproductive endpoints observed. No association between THM exposure and semen quality was found (Fenster et al. 2003). More work is needed in both areas to support these results.

Reviews. An early review supported an association between measures of fetal viability and tap water (Swan et al.

1992). Three other reviews found data inadequate to support an association between reproductive and developmental health effects and THM exposure (Reif et al. 1996; Craun 1998; WHO 2000). Mills et al. (1998) examined data on and found support for an association between fetal viability and malformations and THMs. Another review presented to the Stage 2 MDBP FACA found some evidence for an association with fetal viability and some fetal malformations and exposure to DBPs but reported that the evidence was inconsistent for these endpoints as well as for fetal growth (Reif et al. 2000). Reif et al. (2000) concluded that the weight of evidence from epidemiology studies suggests that ''DBPs are likely to be reproductive toxicants in humans under appropriate exposure conditions,'' but from a risk assessment perspective, data are primarily at the hazard identification stage. Nieuwenhuijsen et al. (2000) found some evidence for an association between fetal growth and THM exposure and concluded evidence for associations with other fetal endpoints is weak but gaining weight. A qualitative review by Villanueva et al. (2001) found evidence generally supports a possible association between reproductive effects and drinking chlorinated water. Graves et al. (2001) supports a possible association for fetal growth but not fetal viability or malformations. More recently, Bove et al. (2002) examined and supported an association between small for gestational age, neural tube defects and spontaneous abortion endpoints and DBPs. Following a meta-analysis on five malformation studies, Hwang and Jaakkola (2003) concluded that there was evidence which supported associations between DBPs and risk of birth defects, especially neural tube defects and urinary tract defects.

TABLE II.D–3.—SUMMARY OF REPRODUCTIVE/DEVELOPMENTAL EPIDEMIOLOGY STUDIES

Author(s)	Study type	Exposure(s) studied	Outcome(s) measured	Findings
Porter et al. 2005.	Cross-sectional study in Maryland, 1998–2002.	Estimated THM and HAA exposure during pregnancy.	Intrauterine growth retardation.	No consistent association or dose-response relationship was found between exposure to either TTHM or HAA5 and intrauterine growth retardation. Results suggest an increased risk of intrauterine growth retardation associated with TTHM and HAA5 exposure in the third trimester, although only HAA5 results were statistically significant.
Savitz et al. 2005.	Population-based prospective cohort study in three communities around the U.S., 2000–2004.	Estimated TTHM, HAA9, and TOC exposures during pregnancy. Indices examined included concentration, ingested amount, exposure from showering and bathing, and an integration of all exposures combined.	Early and late pregnancy loss, preterm birth, small for gestational age, and term birth weight.	No association with pregnancy loss was seen when looking at high exposure of TTHM compared to low exposure of TTHM. When examining individual THMs, a statistically significant association was found between bromodichloromethane (BDCM) and pregnancy loss. A similar, non-statistically significant association was seen between dibromochloromethane (DBCM) and pregnancy loss. Some increased risk was seen for losses at greater than 12 weeks' gestation for TTHM, BDCM, and TOX (total organic halide), but most results generally did not provide support for an association. Preterm birth showed a small inverse relationship with DBP exposure (i.e. higher exposures showed less preterm births), but this association was weak. TTHM exposure of 80 ug/L was associated with twice the risk for small for gestational age during the third trimester and was statistically significant.
Toledano et al. 2005.	Large cross-sectional study in England, 1992–1998.	Linked mother's residence at time of delivery to modeled estimates of TTHM levels in water zones.	Stillbirth, low birth weight.	A significant association between TTHM and risk of stillbirth, low birth weight, and very low birth weight was observed in one of the three regions. When all three regions were combined, small, but non-significant, excess risks were found between all three outcomes and TTHM and chloroform. No associations were observed between reproductive risks and BDCM or total brominated THMs.
Dodds et al. 2004 (and King et al. 2005).	Population-based case-control study in Nova Scotia and Eastern Ontario, 1999–2001.	Estimated THM and HAA exposure at residence during pregnancy. Linked water consumption and showering/bathing to THM exposure.	Stillbirth	A statistically significant association was observed between stillbirths and exposure to total THM, BDCM, and chloroform. Associations were also detected for metrics, which incorporated water consumption, showering and bathing habits. Elevated relative risks were observed for intermediate exposures for total HAA and DCAA measures; TCAA and brominated HAA exposures showed no association. No statistically significant associations or dose-response relationships between any HAAs and stillbirth were detected after controlling for THM exposure.

TABLE II.D–3.—SUMMARY OF REPRODUCTIVE/DEVELOPMENTAL EPIDEMIOLOGY STUDIES—Continued

Author(s)	Study type	Exposure(s) studied	Outcome(s) measured	Findings
Infante-Rivard 2004.	Case-control study of newborns in Montreal, 1998–2000.	Estimated THM levels and water consumption during pregnancy. Exposure from showering and presence of two genetic polymorphisms.	Intrauterine growth retardation.	No associations were found between exposure to THMs and intrauterine growth retardation. However, a significant effect was observed between THM exposure and intrauterine growth retardation for newborns with the CYP2E1 gene variant. Findings suggest that exposure to THMs at the highest levels can affect fetal growth but only in genetically susceptible newborns.
Wright et al. 2004.	Large cross-sectional study: Massachusetts, 1995–1998.	Estimated maternal third-trimester exposures to TTHMs, chloroform, BDCM, total HAAs, DCA, TCA, MX and mutagenicity in drinking water.	Birth weight, small for gestational age, preterm delivery, gestational age.	Statistically significant reductions in mean birth weight were observed for BDCM, chloroform, and mutagenic activity. An exposure-response relationship was found between THM exposure and reductions in mean birth weight and risk of small for gestational age. There was no association between preterm delivery and elevated levels of HAAs, MX, or mutagenicity. A reduced risk of preterm delivery was observed with high THM exposures. Gestational age was associated with exposure to THMs and mutagenicity.
Yang et al. 2004 (and Yang et al. 2000).	Large cross-sectional studies in Taiwan, 1994–1996.	Compared maternal consumption of chlorinated drinking water (yes/no).	Low birth weight, preterm delivery.	Residence in area supplied with chlorinated drinking water showed a statistically significant association with preterm delivery. No association was seen between chlorinated drinking water and low birth weight.
Fenster et al. 2003.	Small prospective study in California, 1990–1991.	Examined TTHM levels within the 90 days preceding semen collection.	Sperm motility, sperm morphology.	No association between TTHM level and sperm mobility or morphology. BDCM was inversely associated with linearity of sperm motion. There was some suggestion that water consumption and other ingestion metrics may be associated with different indicators of semen quality.
Shaw et al. 2003.	2 case-control maternal interview studies: CA, 1987–1991.	Estimated THM levels for mothers' residences from before conception through early pregnancy.	Neural tube defects, oral clefts, selected heart defects.	No associations or exposure-response relation were observed between malformations and TTHMs in either study.
Windham et al. 2003.	Prospective study: CA, 1990–1991.	Estimated exposure to THMs through showering and ingestion over average of 5.6 menstrual cycles per woman.	Menstrual cycle, follicular phase length (in days).	Findings suggest that THM exposure may affect ovarian function. All brominated THM compounds were associated with significantly shorter menstrual cycles with the strongest finding for chlorodibromomethane. There was little association between TTHM exposure and luteal phase length, menses length, or cycle variability.
Wright et al. 2003.	Cross-sectional study: Massachusetts, 1990.	Estimated TTHM exposure in women during pregnancy (average for pregnancy and during each trimester).	Birth weight, small for gestational age, preterm delivery, gestational age.	Statistically significant associations between 2nd trimester and pregnancy average TTHM exposure and small for gestational age and fetal birth weight were detected. Small, statistically significant increases in gestational duration/age were observed at increased TTHM levels, but there was little evidence of an association between TTHM and preterm delivery or low birth weight.
Cedergren et al. 2002.	Retrospective case-control study: Sweden, 1982–1997.	Examined maternal periconceptional DBP levels and used GIS to assign water supplies.	Cardiac defects	Exposure to chlorine dioxide in drinking water showed statistical significance for cardiac defects. THM concentrations of 10 ug/L and higher were significantly associated with cardiac defects. No excess risk for cardiac defect and nitrate were seen.
Hwang et al. 2002.	Large cross-sectional study in Norway, 1993–1998.	Compared exposure to chlorination (yes/no) and water color levels for mother's residence during pregnancy.	Birth defects (neural tube defects, cardiac, respiratory system, oral cleft, urinary tract).	Risk of any birth defect, cardiac, respiratory system, and urinary tract defects were significantly associated with water chlorination. Exposure to chlorinated drinking water was statistically significantly associated with risk of ventricular septal defects, and an exposure-response pattern was seen. No other specific defects were associated with the exposures that were examined.

TABLE II.D–3.—SUMMARY OF REPRODUCTIVE/DEVELOPMENTAL EPIDEMIOLOGY STUDIES—Continued

Author(s)	Study type	Exposure(s) studied	Outcome(s) measured	Findings
Dodds and King 2001.	Population-based retrospective cohort in Nova Scotia, 1988–1995.	Estimated THM, chloroform, and bromodichloromethane (BDCM) exposure.	Neural tube defects, cardiovascular defects, cleft defects, chromosomal abnormalities.	Exposure to BDCM was associated with increased risk of neural tube defects, cardiovascular anomalies. Chloroform was not associated with neural tube defects, but was associated with chromosomal abnormalities. No association between THM and cleft defects were detected.
Jaakkola et al. 2001.	Large cross-sectional study in Norway, 1993–1995.	Compared chlorination (yes/no) and water color (high/low) for mother during pregnancy.	Low birth weight, small for gestational age, preterm delivery.	No evidence found for association between prenatal exposure to chlorinated drinking water and low birth weight or small for gestational age. A reduced risk of preterm delivery was noted for exposure to chlorinated water with high color content.
Källén and Robert 2000.	Large cross-sectional cohort study in Sweden, 1985–1994.	Linked prenatal exposure to drinking water disinfected with various methods (no chlorine, chlorine dioxide only, sodium hypochlorite only).	Gestational duration, birth weight, intrauterine growth, mortality, congenital malformations, and other birth outcomes.	A statistically significant difference was found for short gestational duration and low birth weight among infants whose mother resided in areas using sodium hypochlorite, but not for chlorine dioxide. Sodium hypochlorite was also associated with other indices of fetal development but not with congenital defects. No other effects were observed for intrauterine growth, childhood cancer, infant mortality, low Apgar score, neonatal jaundice, or neonatal hypothyroidism in relation to either disinfection method.
Dodds et al. 1999 (and King et al. 2000b).	Population-based retrospective cohort study in Nova Scotia, 1988–1995.	Estimated TTHM level for women during pregnancy.	Low birth weight, preterm birth, small for gestational age, stillbirth, chromosomal abnormalities, neural tube defects, cleft defects, major cardiac defects.	A statistically significant increased risk for stillbirths and high total THMs and specific THMs during pregnancy was detected, with higher risks observed among asphyxia-related stillbirths. Bromodichloromethane had the strongest association and exhibited an exposure-response pattern. There was limited evidence of an association between THM level and other reproductive outcomes. No congenital anomalies were associated with THM exposure, except for a non-statistically significant association with chromosomal abnormalities.
Klotz and Pyrch 1999 (and Klotz and Pyrch 1998).	Population-based case-control study in New Jersey, 1993–1994.	Estimated exposure of pregnant mothers to TTHMs and HAAs, and compared source of water.	Neural tube defects	A significant association was seen between exposure to THMs and neural tube defects. No associations were observed for neural tube defects and haloacetic acids or haloacetonitriles.
Magnus et al. 1999.	Large cross-sectional study in Norway, 1993–1995.	Compared chlorination (yes/no) and water color (high/low) at mothers' residences at time of birth.	Birth defects (neural tube defects, major cardiac, respiratory, urinary, oral cleft).	Statistically significant associations were seen between urinary tract defects and chlorination and high water color (high content of organic compounds). No associations were detected for other outcomes or all birth defects combined. A non-statistically significant, overall excess risk of birth defects was seen within municipalities with chlorination and high water color compared to municipalities with no chlorination and low color.
Gallagher et al. 1998.	Retrospective cohort study of newborns in Colorado, 1990–1993.	Estimated THM levels in drinking water during third trimester of pregnancy.	Low birth weight, term low birthweight, and preterm delivery.	Weak, non-statistically significant association with low birth weight and TTHM exposure during the third trimester. Large statistically significant increase for term low birthweight at highest THM exposure levels. No association between preterm delivery and THM exposure.
Swan et al. 1998.	Prospective study in California, 1990–1991.	Compared consumption of cold tap water to bottled water during early pregnancy.	Spontaneous abortion ...	Pregnant women who drank cold tap water compared to those who consumed no cold tap water showed a significant finding for spontaneous abortion at one of three sites.

TABLE II.D–3.—SUMMARY OF REPRODUCTIVE/DEVELOPMENTAL EPIDEMIOLOGY STUDIES—Continued

Author(s)	Study type	Exposure(s) studied	Outcome(s) measured	Findings
Waller et al. 1998 (and Waller et al. 2001).	Prospective cohort in California, 1989–1991.	Estimated TTHM levels during first trimester of pregnancy via ingestion and showering.	Spontaneous abortion ...	Statistically significant increased risk between high intake of TTHMs and spontaneous abortion compared to low intake. BDCM statistically associated with increased spontaneous abortion; other THMs not. Reanalysis of exposure yielded less exposure misclassification and relative risks similar in magnitude to earlier study. An exposure-response relationship was seen between spontaneous abortion and ingestion exposure to TTHMs.
Kanitz et al. 1996.	Cross-sectional study in Italy, 1988–1989.	Compared 3 types of water treatment (chlorine dioxide, sodium hypochlorite, and chlorine dioxide/sodium hypochlorite).	Low birth weight, body length, cranial circumference, preterm delivery, and other effects.	Smaller body length and small cranial circumference showed statistical significant association with maternal exposure to chlorinated drinking water. Neonatal jaundice linked statistically to prenatal exposure to drinking water treated with chlorine dioxide. Length of pregnancy, type of delivery, and birthweight showed no association.
Bove et al. 1995 (and Bove et al. 1992a & 1992b).	Large cohort cross-sectional study in New Jersey, 1985–1988.	Examined maternal exposure to TTHM and various other contaminants.	Low birth weight, fetal deaths, small for gestational age, birth defects (neural tube defects, oral cleft, central nervous system, major cardiac).	Weak, statistically significant increased risk found for higher TTHM levels with small for gestational age, neural tube defects, central nervous system defects, oral cleft defects, and major cardiac defects. Some association with higher TTHM exposure and low birth weight. No effect seen for preterm birth, very low birth weight, or fetal deaths.
Savitz et al. 1995.	Population-based case-control study: North Carolina, 1988–1991.	Examined TTHM concentration at residences and water consumption (during first and third trimesters).	Spontaneous abortion, preterm delivery, low birth weight.	There was a statistically significant increased miscarriage risk with high THM concentration, but THM intake (based on concentration times consumption level) was not related to pregnancy outcome. No associations were seen for preterm delivery or low birth weight. Water source was not related to pregnancy outcome either, with the exception of a non-significant, increased risk of spontaneous abortion for bottled water users. There was a non-statistically significant pattern of reduced risk with increased consumption of water for all three outcomes.
Aschengrau et al. 1993.	Case-control study in Massachusetts, 1977–1980.	Source of water and 2 types of water treatment (chlorination, chloramination).	Neonatal death, stillbirth, congenital anomalies.	There was a non-significant, increased association between frequency of stillbirths and maternal exposure to chlorinated versus chloraminated surface water. An increased risk of urinary track and respiratory track defects and chlorinated water was detected. Neonatal death and other major malformations showed no association. No increased risk seen for any adverse pregnancy outcomes for surface water versus ground and mixed water use.
Kramer et al. 1992.	Population-based case-control study in Iowa, 1989–1990.	Examined chloroform, DCBM, DBCM, and bromoform levels and compared type of water source (surface, shallow well, deep well).	Low birth weight, prematurity, intrauterine growth retardation.	Statistically significant increased risk for intrauterine growth retardation effects from chloroform exposure were observed. Non-significant increased risks were observed for low birth weight and chloroform and for intrauterine growth retardation and DCBM. No intrauterine growth retardation or low birth weight effects were seen for the other THMs, and no effects on prematurity were observed for any of the THMs.
Shaw et al. 1991 (and Shaw et al. 1990).	Small case-control study: Santa Clara County, CA, 1981–1983.	Estimated chlorinated tap water consumption, mean maternal TTHM level, showering/bathing exposure at residence during first trimester.	Congenital cardiac anomalies.	Following reanalysis, no association between cardiac anomalies and TTHM level were observed.
Aschengrau et al. 1989.	Case-control study in Massachusetts, 1976–1978.	Source of water and exposure to metals and other contaminants.	Spontaneous abortion ...	A statistically significantly association was detected between surface water source and frequency of spontaneous abortion.

TABLE II.D–3.—SUMMARY OF REPRODUCTIVE/DEVELOPMENTAL EPIDEMIOLOGY STUDIES—Continued

Author(s)	Study type	Exposure(s) studied	Outcome(s) measured	Findings
Reviews/ Meta-analyses				
Hwang and Jakkola 2003.	Review and meta-analysis of 5 studies.	Compared DBP levels, source of water, chlorine residual, color (high/low), and 2 types of disinfection: chlorination and chloramination.	Birth defects (respiratory system, urinary system, neural tube defects, cardiac, oral cleft).	The meta-analysis supports an association between exposure to chlorination by-products and the risk of any birth defect, particularly the risk of neural tube defects and urinary system defects.
Bove et al. 2002.	Qualitative review of 14 studies.	Examined THM levels. Compared drinking water source and type of water treatment.	Birth defects, small for gestational age, low birth weight, preterm delivery, spontaneous abortion, fetal death.	Review found the studies of THMs and adverse birth outcomes provide moderate evidence for associations with small for gestational age, neural tube defects, and spontaneous abortions. Authors felt risks may have been underestimated and exposure-response relationships distorted due to exposure misclassification.
Graves et al. 2001.	Review of toxicological and epidemiological studies using a weight of evidence approach.	Examined water consumption, duration of exposure, THM levels, HAA levels, and other contaminants. Compared source of water, water treatment, water color (high/low), etc.	Low birth weight, preterm delivery, small for gestational age, intrauterine growth retardation, specific birth defects, neonatal death, decreased fertility, fetal resorption, and other effects.	Weight of evidence suggested positive association with DBP exposure for growth retardation such as small for gestational age or intrauterine growth retardation and urinary tract defects. Review found no support for DBP exposure and low birth weight, preterm delivery, some specific birth defects, and neonatal death, and inconsistent findings for all birth defects, all central nervous system defects, neural tube defects, spontaneous abortion, and stillbirth.
Villanueva et al. 2001.	Qualitative review of 14 reproductive and developmental health effect studies.	Compared exposure to TTHM levels, mutagenic drinking water, water consumption, source water, types of disinfection (chlorination and chloramination), and residence times.	Spontaneous abortion, low birth weight, small for gestational age, neural tube defects, other reproductive and developmental outcomes.	Review found positive associations between increased spontaneous abortion, low birth weight, small for gestational age, and neural tube defects and drinking chlorinated water in most studies, although not always with statistical significance.
Nieuwenhuijsen et al. 2000.	Qualitative review of numerous toxicological and epidemiological studies.	Examined levels of various DBPs, water consumption, and duration of exposure. Compared water color, water treatment, source of water, etc.	Low birth weight, preterm delivery, spontaneous abortions, stillbirth, birth defects, etc.	The review supports some evidence of association between THMs and low birth weight, but inconclusive. Review found no evidence of association between THMs and preterm delivery, and that associations for other outcomes (spontaneous abortions, stillbirth, and birth defects) were weak but gaining weight.
Reif et al. 2000.	Qualitative reviews of numerous epidemiological studies.	Compared source of water supply and methods of disinfection. Estimated TTHM levels.	Birth weight, low birth weight, intrauterine growth retardation, small for gestational age, preterm deliver, somatic parameters, neonatal jaundice, spontaneous abortion, stillbirth, developmental anomalies.	Weight of evidence suggested DBPs are reproductive toxicants in humans under appropriate exposure conditions. The review reports findings between TTHMs and effects on fetal growth, fetal viability, and congenital anomalies as inconsistent. Reviewers felt data are at the stage of hazard identification and did not suggest a dose-response pattern of increasing risk with increasing TTHM concentration.
WHO 2000	Qualitative reviews of various studies in Finland, U.S., and Canada.	Various exposures to THMs.	Various reproductive and developmental effects.	Review found some support for an association between increased risks of neural tube defects and miscarriage and THM exposure. Other associations have been observed, but the authors believed insufficient data exist to assess any of these associations.
Craun, ed. 1998.	Qualitative review of 10 studies, focus on California cohort study.	Examined THM levels and water consumption, and compared source of water and water treatment (chlorine, chloramines, chlorine dioxide).	Stillbirth, neonatal death, spontaneous abortion, low birth weight, preterm delivery, intrauterine growth retardation, neonatal jaundice, birth defects.	Associations between DBPs and various reproductive effects were seen in some epidemiological studies, but the authors felt these results do not provide convincing evidence for a causal relationship between DBPs and reproductive effects.

TABLE II.D–3.—SUMMARY OF REPRODUCTIVE/DEVELOPMENTAL EPIDEMIOLOGY STUDIES—Continued

Author(s)	Study type	Exposure(s) studied	Outcome(s) measured	Findings
Mills et al. 1998.	Qualitative review of 22 studies.	Examined TTHM levels and water consumption. Compared source of water and 2 types of water treatment (chlorination and chloramination).	Various reproductive and developmental effects.	Review found studies suggest possible increases in adverse reproductive and developmental effects, such as increased spontaneous abortion rates, small for gestational age, and fetal anomalies, but that insufficient evidence exists to establish a causal relationship.
Reif et al. 1996.	Review of 3 case-control studies and 1 cross-sectional study.	Examined THM levels at residences, dose consumption, chloroform. Compared source of waters and 2 types of water treatment (chlorination and chloramination).	Birth defects (central nervous system, neural tube defects, cardiac, oral cleft, respiratory, urinary tract), spontaneous abortion, low birth weight, growth retardation, preterm delivery, intrauterine growth retardation, stillbirth, neonatal death.	Studies reviewed suggest that exposure to DBPs may increase intrauterine growth retardation, neural tube defects, major heart defects, and oral cleft defects. Review found epidemiologic evidence supporting associations between exposure to DBPs and adverse pregnancy outcomes to be sparse and to provide an inadequate basis to identify DBPs as a reproductive or developmental hazard.
Swan et al. 1992.	Qualitative review of 5 studies in Santa Clara County, CA (Deane et al. 1992, Wrensch et al. 1992, Hertz-Picciotto et al. 1992, Windham et al. 1992, Fenster et al. 1992).	Compared maternal consumption of residence tap water to bottled water.	Spontaneous abortion ...	Four of the studies reviewed suggest that women drinking bottled water during the first trimester of pregnancy may have reduced risk of spontaneous abortion relative to drinking tap water. No association seen in the fifth study. Review concluded that if findings are causal and not due to chance or bias, data suggest a 10–50% increase in spontaneous abortion risk for pregnant women drinking tap water over bottled water.

ii. Toxicology. To date, the majority of reproductive and developmental toxicology studies have been short term and higher dose. Many of these studies are summarized in a review by Tyl (2000). A summary of this review and of additional studies is provided in the proposed Stage 2 DBPR (USEPA 2003a). Individual DBP supporting documents evaluate and assess additional studies as well (USEPA 2000b; USEPA 2000c; USEPA 2001a; USEPA 2001b; USEPA 2003b; USEPA 2005b; USEPA 2005c; USEPA 2005d; USEPA 2005e; USEPA 2005k). A number of recent studies have been published that include in vivo and in vitro assays to address mechanism of action. Overall, reproductive and developmental toxicology studies indicate a possible reproductive/developmental health hazard although they are preliminary in nature for the majority of DBPs, and the dose-response characteristics of most DBPs have not been quantified. Some of the reproductive effects of DCAA were quantified as part of the RfD development process, and impacts of DCAA on testicular structure are one of the critical effects in the study that is the basis of the RfD (USEPA 2003b).

A few long term, lower dose studies have been completed. Christian et al. (2002a and 2002b) looked for an association between BDCM and DBAA and reproductive and developmental endpoints. The authors identified a NOAEL and LOAEL of 50 ppm and 150 ppm, respectively, based on delayed sexual maturation for BDCM and a NOAEL and LOAEL of 50 ppm and 250 ppm based on abnormal spermatogenesis for DBAA. The authors concluded that similar effects in humans would only be seen at levels many orders of magnitude higher than that of current drinking water levels. As discussed in more detail in the proposal, EPA believes that because of key methodological differences indicated as being important in other studies (Bielmeier et al. 2001; Bielmeier et al. 2004; Kaydos et al. 2004; Klinefelter et al. 2001; Klinefelter et al. 2004), definitive conclusions regarding BDCM and DBAA cannot be drawn. Other multi-generation research underway includes a study on BCAA, but this research is not yet published.

Biological plausibility for the effects observed in reproductive and developmental epidemiological studies has been demonstrated through various toxicological studies on some individual DBPs (e.g., Bielmeier et al. 2001; Bielmeier et al. 2004; Narotsky et al. 1992; Chen et al. 2003; Chen et al. 2004). Some of these studies were conducted at high doses, but similarity of effects observed between toxicology studies and epidemiology studies strengthens the weight of evidence for a possible association between adverse reproductive and developmental health effects and exposure to chlorinated surface water.

c. Conclusions. EPA's weight of evidence evaluation of the best available science on carcinogenicity and reproductive and developmental effects, in conjunction with the widespread exposure to DBPs, supports the incremental regulatory changes in today's rule that target lowering DBPs and providing equitable public health protection.

EPA believes that the cancer epidemiology and toxicology literature provide important information that contributes to the weight of evidence for potential health risks from exposure to chlorinated drinking water. At this time, the cancer epidemiology studies support a potential association between exposure to chlorinated drinking water and cancer, but evidence is insufficient to establish a causal relationship. The epidemiological evidence for an association between DBP exposure and colon and rectal cancers is not as consistent as it is for bladder cancer, although similarity of effects reported in animal toxicity and human epidemiology studies strengthens the evidence for an association with colon and rectal cancers. EPA believes that the overall cancer epidemiology and toxicology data support the decision to

pursue additional DBP control measures as reflected in the Stage 2 DBPR.

Based on the weight of evidence evaluation of the reproductive and developmental epidemiology data, EPA concludes that a causal link between adverse reproductive or developmental health effects and exposure to chlorinated drinking water or DBPs has not been established, but that there is a potential association. Despite inconsistent findings across studies, some recent studies continue to suggest associations between DBP exposure and various adverse reproductive and developmental effects. In addition, data from a number of toxicology studies, although the majority of them were conducted using high doses, demonstrate biological plausibility for some of the effects observed in epidemiology studies. EPA concludes that no dose-response relationship or causal link has been established between exposure to chlorinated drinking water or disinfection byproducts and adverse developmental or reproductive health effects. EPA's evaluation of the best available studies, particularly epidemiology studies is that they do not support a conclusion at this time as to whether exposure to chlorinated drinking water or disinfection byproducts causes adverse developmental and reproductive health effects, but do provide an indication of a potential health concern that warrants incremental regulatory action beyond the Stage 1 DBPR.

D. DBP Occurrence and DBP Control

New information on the occurrence of DBPs in distribution systems raises issues about the protection provided by the Stage 1 DBPR. This section presents new occurrence and treatment information used to identify key issues and to support the development of the Stage 2 DBPR. For a more detailed discussion see the proposed Stage 2 DBPR (USEPA 2003a). For additional information on occurrence of regulated and nonregulated DBPs, see the Occurrence Assessment for the Final Stage 2 Disinfectants and Disinfection Byproducts Rule (USEPA 2005f).

1. Occurrence

EPA, along with the M-DBP Advisory Committee, collected, developed, and evaluated new information that became available after the Stage 1 DBPR was published. The Information Collection Rule (ICR) (USEPA 1996) provided new field data on DBP exposure for large water systems and new study data on the effectiveness of several DBP control technologies. The unprecedented amount of information collected under the ICR was supplemented by a survey conducted by the National Rural Water Association, data provided by various States, the Water Utility Database (which contains data collected by the American Water Works Association), and ICR Supplemental Surveys for small and medium water systems.

After analyzing the DBP occurrence data, EPA and the Advisory Committee reached three significant conclusions that in part led the Advisory Committee to recommend further control of DBPs in public water systems. First, the data from the Information Collection Rule showed that the RAA compliance calculation under the Stage 1 DBPR allows elevated TTHM or HAA5 levels to regularly occur at some locations in the distribution system while the overall average of TTHM or HAA5 levels at all DBP monitoring locations is below the MCLs of the Stage 1 DBPR. Customers served at those sampling locations with DBP levels that are regularly above 0.080 mg/L TTHM and 0.060 mg/L HAA5 experience higher exposure compared to customers served at locations where these levels are consistently met.

Second, the new data demonstrated that DBP levels in single samples can be substantially above 0.080 mg/L TTHM and 0.060 mg/L HAA5. Some customers receive drinking water with concentrations of TTHM and HAA5 up to 75% above 0.080 mg/L and 0.060 mg/L, respectively, even when their water system is in compliance with the Stage 1 DBPR. Some studies support an association between acute exposure to DBPs and potential adverse reproductive and developmental health effects (see Section III.C for more detail).

Third, the data from the Information Collection Rule revealed that the highest TTHM and HAA5 levels can occur at any monitoring site in the distribution system. In fact, the highest concentrations did not occur at the maximum residence time locations in more than 50% of all ICR samples. The fact that the locations with the highest DBP levels vary in different public water systems indicates that the Stage 1 DBPR monitoring may not accurately represent the high DBP concentrations that actually exist in distribution systems, and that additional monitoring is needed to identify distribution system locations with elevated DBP levels.

These data showed that efforts beyond the Stage 1 DBPR are needed to provide more equitable protection from DBP exposure across the entire distribution system. The incremental regulatory changes made under the Stage 2 DBPR meet this need by reevaluating the locations of DBP monitoring sites and addressing high DBP concentrations that occur at particular locations or in single samples within systems in compliance.

2. Treatment

The analysis of the new treatment study data confirmed that certain technologies are effective at reducing DBP concentrations. Bench- and pilot-scale studies for granular activated carbon (GAC) and membrane technologies required by the Information Collection Rule provided information on the effectiveness of the two technologies. Other studies found UV light to be highly effective for inactivating Cryptosporidium and Giardia at low doses without promoting the formation of DBPs (Malley *et al.* 1996; Zheng *et al.* 1999). This new treatment information adds to the treatment options available to utilities for controlling DBPs beyond the requirements of the Stage 1 DBPR.

E. Conclusions for Regulatory Action

After extensive analysis of available data and rule options considered by the Advisory Committee and review of public comments on the proposed Stage 2 DBPR (USEPA, 2003a), EPA is finalizing a Stage 2 DBPR control strategy consistent with the key elements of the Agreement in Principle signed in September 2000 by the participants in the Stage 2 M–DBP Advisory Committee. EPA believes that exposure to chlorinated drinking water may be associated with cancer, reproductive, and developmental health risks. EPA determined that the risk-targeting measures recommended in the Agreement in Principle will require only those systems with the greatest risk to make treatment and operational changes and will maintain simultaneous protection from potential health concerns from DBPs and microbial contaminants. EPA has carefully evaluated and expanded upon the recommendations of the Advisory Committee and public comments to develop today's rule. EPA also made simplifications where possible to minimize complications for public water systems as they transition to compliance with the Stage 2 DBPR while expanding public health protection. The requirements of the Stage 2 DBPR are described in detail in Section IV of this preamble.

IV. Explanation of Today's Action

A. MCLGs

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 is based on the available evidence of carcinogenicity or noncancer adverse health effects from drinking water exposure using EPA's guidelines for risk assessment. MCLGs are developed to ensure they are protective of the entire population.

Today's rule provides MCLGs for chloroform and two haloacetic acids, monochloroacetic acid (MCAA) and trichloroacetic acid (TCAA).

1. Chloroform MCLG

a. Today's rule. The final MCLG for chloroform is 0.07 mg/L. The MCLG was calculated using toxicological evidence that the carcinogenic effects of chloroform are due to sustained tissue toxicity. EPA is not changing the other THM MCLGs finalized in the Stage 1 DBPR.

b. Background and analysis. The MCLG for chloroform is unchanged from the proposal. The MCLG is calculated using a reference dose (RfD) of 0.01 mg/kg/day and an adult tap water consumption of 2 L per day for a 70 kg adult. A relative source contribution (RSC) of 20% was used in accordance with Office of Water's current approach for deriving RSC through consideration of data that indicate that other routes and sources of exposure may potentially contribute substantially to the overall exposure to chloroform. See the proposed Stage 2 DBPR (USEPA 2003a) for a detailed discussion of the chloroform MCLG.

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

Based on an analysis of the available scientific data on chloroform, EPA believes that the chloroform dose-response is nonlinear and that chloroform is likely to be carcinogenic only under high exposure conditions (USEPA 2001a). This assessment is supported by the principles of the 1999 EPA Proposed Guidelines for Carcinogen Risk Assessment (USEPA 1999a) and reconfirmed by the 2005 final Cancer Guidelines (USEPA 2005i). The science in support of a nonlinear approach for estimating the carcinogenicity of chloroform was affirmed by the Chloroform Risk Assessment Review Subcommittee of the EPA SAB Executive Committee (USEPA 2000d). Since the nonzero MCLG is based on a mode of action consideration specific to chloroform, it does not affect the MCLGs of other trihalomethanes.

c. Summary of major comments. EPA received many comments in support of the proposed MCLG calculation for chloroform, although some commenters disagreed with a non-zero MCLG.

At this time, based on an analysis of all the available scientific data on chloroform, EPA concludes that chloroform is likely to be carcinogenic to humans only under high exposure conditions that lead to cytotoxicity and regenerative hyperplasia and that chloroform is not likely to be carcinogenic to humans under conditions that do not cause cytotoxicity and cell regeneration (USEPA 2001a). Therefore, the dose-response is nonlinear, and the MCLG is set at 0.07 mg/L. This conclusion has been reviewed by the SAB (USEPA 2000d), who agree that nonlinear approach is most appropriate for the risk assessment of chloroform; it also remains consistent with the principles of the 1999 EPA Proposed Guidelines for Carcinogenic Risk Assessment (USEPA 1999a) and the final Cancer Guidelines (USEPA 2005i), which allow for nonlinear extrapolation.

EPA also received some comments requesting a combined MCLG for THMs or HAAs. This is not appropriate because these different chemicals have different health effects.

2. HAA MCLGs: TCAA and MCAA

a. Today's rule. Today's rule finalizes the proposed Stage 2 MCLG for TCAA of 0.02 mg/L (USEPA 2003a) and sets an MCLG for MCAA of 0.07 mg/L. EPA is not changing the other HAA MCLGs finalized in the Stage 1 DBPR (USEPA 1998a).

b. Background and analysis. The Stage 1 DBPR included an MCLG for TCAA of 0.03 mg/L and did not include an MCLG for MCAA (USEPA 1998a). Based on toxicological data published after the Stage 1 DBPR, EPA proposed new MCLGs for TCAA and MCAA of 0.02 mg/L and 0.03 mg/L, respectively, in the Stage 2 proposal (USEPA 2003a). The proposed TCAA MCLG and its supporting analysis is being finalized unchanged in today's final rule. The MCLG calculation for MCAA is revised in this final rule, based on a new reference dose, as discussed later. See the proposed Stage 2 DBPR (USEPA 2003a) for a detailed discussion of the calculation of the MCLGs.

TCAA. The MCLG for TCAA was calculated based on the RfD of 0.03 mg/kg/day using a 70 kg adult body weight, a 2 L/day drinking water intake, and a relative source contribution of 20%. An additional tenfold risk management factor has been applied to account for the possible carcinogenicity of TCAA. This approach is consistent with EPA policy. TCAA induces liver tumors in mice (Ferreira-Gonzalez et al. 1995; Pereira 1996; Pereira and Phelps 1996; Tao et al. 1996; Latendresse and Pereira 1997; Pereira et al. 1997) but not in rats (DeAngelo et al. 1997). Much of the recent data on the carcinogenicity of TCAA have focused on examining the carcinogenic mode(s) of action. However, at this time, neither the bioassay nor the mechanistic data are sufficient to support the development of a slope factor from which to quantify the cancer risk.

$$\text{MCLG for TCAA} = \frac{(0.03\ \text{mg/kg/day})(70\ \text{kg})(0.2)}{(2\ \text{L/day})(10)} = 0.02\ \text{mg/L (rounded)}$$

The chronic bioassay for TCAA by DeAngelo et al. (1997) was selected as the critical study for the development of the RfD. In this chronic drinking water study, a dose-response was noted for several endpoints and both a LOAEL and NOAEL were determined. The data are consistent with the findings in both the Pereira (1996) chronic drinking water study and the Mather et al. (1990) subchronic drinking water study. The RfD of 0.03 mg/kg/day is based on the NOAEL of 32.5 mg/kg/day for liver histopathological changes in rats (DeAngelo et al. 1997). A composite uncertainty factor of 1000 was applied in the RfD determination. A default uncertainty factor of 10 was applied to

the RfD to account for extrapolation from an animal study because data to quantify rat-to-human differences in toxicokinetics or toxicodynamics are not available. The default uncertainty factor of 10 was used to account for human variability in the absence of data on differences in human susceptibility. Although subchronic and chronic studies of TCAA have been reported for multiple species, many studies have focused on liver lesions and a full evaluation of a wide range of potential target organs has not been conducted in two different species. In addition, there has been no multi-generation study of reproductive toxicity and the data from teratology studies in rats provide LOAEL values but no NOAEL for developmental toxicity. Thus, an additional uncertainty factor of 10 was used to account for database insufficiencies.

The MCLG calculation also includes a relative source contribution (RSC) of 20%. The RSC was derived consistent with Office of Water's current approach for deriving RSC. In addition to disinfected water, foods are expected to contribute to daily exposure to TCAA (Raymer et al. 2001, 2004; Reimann et al. 1996). Some of the TCAA in foods comes from cleaning and cooking foods in chlorinated water. Additional TCAA is found in some foods because of the widespread use of chlorine as a sanitizing agent in the food industry (USFDA 1994). EPA was not able to identify any dietary surveys or duplicate diet studies of TCAA in the diet. TCAA also has been identified in rain water, suggesting some presence in the atmosphere (Reimann et al. 1996); however, due to the low volatility (0.5—0.7 mm Hg at 25 °C) of TCAA, exposure from ambient air is expected to be minimal. Dermal exposure to disinfected water is also unlikely to be significant. A study by Xu et al. (2002) reports that dermal exposure from bathing and showering is only 0.01% of that from oral exposure. In addition, the solvents trichloroethylene, tetrachlorethylene, 1,1,1-trichloroethane (often found in ambient air and drinking water), and the disinfection byproduct chloral hydrate all contribute to the body's TCAA load since each of these compounds is metabolized to TCAA (ATSDR 2004; ATSDR 1997a; ATSDR 1997b; USEPA 2000e). Due to the limitations primarily in the dietary data and a clear indication of exposure from other sources, EPA applied a relative source contribution of 20%.

MCAA. The MCLG for MCAA uses the following calculations: An RfD of 0.01 mg/kg/day, a 70 kg adult consuming 2 L/day of tap water, and a relative source contribution of 20%.

The RfD included in the proposal was based on a chronic drinking water study in rats conducted by DeAngelo et al. (1997). In the assessment presented for the proposed rule, the LOAEL from this study was identified as 3.5 mg/kg/day based on increased absolute and relative spleen weight in the absence of histopathologic changes. After reviewing comments and further analysis of the data, EPA concludes that it is more appropriate to identify this change as a NOAEL. Increased spleen weights in the absence of histopathological effects are not necessarily adverse. In addition, spleen weights were decreased, rather than increased in the mid- and high-dose groups in the DeAngelo et al. (1997) study and were accompanied by a significant decrease in body weight, decreased relative and absolute liver weights, decreased absolute kidney weight, and an increase in relative testes weight. Accordingly, the mid-dose in this same study (26.1 mg/kg/day) has been categorized as the LOAEL with the lower 3.5 mg/kg/day dose as a NOAEL.

Based on a NOAEL of 3.5 mg/kg/day (DeAngelo et al. 1997), the revised RfD was calculated as shown below, with a composite uncertainty factor of 300. EPA used a default uncertainty factor of 10 to account for extrapolation from an animal study, since no data on rat-to-human differences in toxicokinetics or toxicodynamics were identified. A default uncertainty factor of 10 was used to account for human variability in the absence of data on the variability in the toxicokinetics of MCAA in humans or in human susceptibility to MCAA. An additional uncertainty factor of three was used to account for database insufficiencies. Although there is no multi-generation reproduction study, the available studies of reproductive and developmental processes suggest that developmental toxicity is unlikely to be the most sensitive endpoint. This led to the following calculation of the Reference Dose (RfD) and MCLG for MCAA:

$$\text{RfD} = \frac{(3.5\ \text{mg/kg/day})}{(300)} = 0.012\ \text{mg/kg/day rounded to } 0.01\ \text{mg/kg/day}$$

Where:

3.5 mg/kg/day = NOAEL for decreased body weight plus decreased liver, kidney and spleen weights in rats exposed to MCA for 104 weeks in drinking water (DeAngelo et al. 1997).

300 = composite uncertainty factor chosen to account for inter species extrapolation, inter-individual variability in humans, and deficiencies in the database.

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

The RSC for MCAA was selected using comparable data to that discussed for TCAA. MCAA, like TCAA, has been found in foods and is taken up by foods during cooking (15% in chicken to 62% in pinto beans) and cleaning (2.5% for lettuce) with water containing 500 ppb MCAA (Reimann et al.1996; Raymer et al. 2001, 2004). Rinsing of cooked foods did not increase the MCAA content of foods to the same extent as was observed for TCAA (Raymer et al. 2004). MCAA was found to be completely stable in water boiled for 60 minutes and is likely to be found in the diet due to the use of chlorinated water in food preparation and the use of chlorine as a sanitizing agent by the food industry (USFDA 1994). As with TCAA, inhalation and dermal exposures are unlikely to be significant. Dermal exposure from bathing and showering was estimated to contribute only 0.03% of that from oral exposure (Xu et al. 2002). As with TCAA, due to the limitations in dietary data and a clear indication of exposure from other

sources, EPA applied a relative source contribution of 20%.

c. *Summary of major comments.* EPA received few comments on MCAA and TCAA. The majority of comments about the MCLGs for TCAA and MCAA were general MCLG questions, including RSC derivation. Some commenters questioned why MCAA, TCAA, and chloroform were calculated using an RSC of 20%. In particular, some commenters compared these calculations to that for DBCM in the Stage 1 DBPR, which uses 80%. Each of the MCLGs set for chloroform, TCAA, and MCAA under this rule is calculated using the best available science and EPA Office of Water's current approach for deriving the RSC. EPA chose an RSC of 20%, not 80%, because of clear indications of exposure from other sources; data limitations preclude the derivation of a specific RSC.

The RSC for DBCM was 80% in the Stage 1 DBPR. The DBCM MCLG is not part of today's rulemaking. Any possible future revision to the DBCM MCLG as a result of an RSC change would not affect the MCL for TTHM finalized in today's rule.

In response to comments received on the RfD for MCAA, EPA has reviewed the critical study regarding the appropriateness of an increase in spleen weight in the absence of histopathology as a LOAEL. EPA has determined that the dose associated with this endpoint is more appropriately categorized as a NOAEL rather than a LOAEL and has revised the RfD and MCLG for MCAA.

B. Consecutive Systems

Today's rule includes provisions for consecutive systems, which are public water systems that receive some or all of their finished water from another water system (a wholesale system). Consecutive systems face particular challenges in providing water that meets regulatory standards for DBPs and other contaminants whose concentration can increase in the distribution system. Moreover, previous regulation of DBP levels in consecutive systems varies widely among States. In consideration of these factors, EPA is finalizing monitoring, compliance schedule, and other requirements specifically for consecutive systems. These requirements are intended to facilitate compliance by consecutive systems with MCLs for TTHM and HAA5 under the Stage 2 DBPR and help to ensure that consumers in consecutive systems receive equivalent public health protection.

1. Today's Rule

As public water systems, consecutive systems must provide water that meets the MCLs for TTHM and HAA5 under the Stage 2 DBPR, use specified analytical methods, and carry out associated monitoring, reporting, recordkeeping, public notification, and other requirements. The following discusses a series of definitions needed for addressing consecutive system requirements in today's rule. Later sections of this preamble provide further details on how rule requirements (e.g., schedule and monitoring) apply to consecutive systems.

A consecutive system is a public water system that receives some or all of its finished water from one or more wholesale systems.

Finished water is water that has been introduced into the distribution system of a public water system and is intended for distribution and consumption without further treatment, except as necessary to maintain water quality in the distribution system (e.g., booster disinfection, addition of corrosion control chemicals).

A wholesale system is a public water system that treats source water as necessary to produce finished water and then delivers finished water to another public water system. Delivery may be through a direct connection or through the distribution system of one or more consecutive systems.

The combined distribution system is defined as the interconnected distribution system consisting of the distribution systems of wholesale systems and of the consecutive systems that receive finished water from those wholesale system(s).

EPA is allowing States some flexibility in defining what systems are a part of a combined distribution system. This provision determines effective dates for requirements in today's rule; see Section IV.E (Compliance Schedules) for further discussion. EPA has consulted with States and deferred to their expertise regarding the nature of the connection in making combined distribution system determinations. In the absence of input from the State, EPA will determine that combined distribution systems include all interconnected systems for the purpose of determining compliance schedules for implementation of this rule.

2. Background and Analysis

The practice of public water systems buying and selling water to each other has been commonplace for many years. Reasons include saving money on pumping, treatment, equipment, and personnel; assuring an adequate supply during peak demand periods; acquiring emergency supplies; selling surplus supplies; and delivering a better product to consumers. EPA estimates that there are more than 10,000 consecutive systems nationally.

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

EPA included requirements specifically for consecutive systems because States have taken widely varying approaches to regulating DBPs in consecutive systems in previous rules. For example, some States have not regulated DBP levels in consecutive systems that deliver disinfected water but do not add a disinfectant. Other States have determined compliance with DBP standards based on the combined distribution system that includes both the wholesaler and consecutive systems. In this case, sites in consecutive systems are treated as monitoring sites within the combined distribution system. Neither of these approaches provide the same level of public health protection as non-consecutive systems receive under the Stage 1 DBPR. Once fully implemented, today's rule will ensure similar protection for consumers in consecutive systems.

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

3. Summary of Major Comments

Commenters generally supported the proposed definitions. However, commenters did express some concerns, especially with including a time period of water delivery that defined whether a system was a consecutive system (proposed to trigger plant-based monitoring requirements) or wholesale system (proposed to allow determination that a combined distribution system existed). EPA has dropped this requirement from the final rule; population-based monitoring requirements in the final rule do not need to define how long a plant must operate in order to be considered a plant, and EPA has provided some flexibility for States to determine which systems comprise a combined distribution system (without presenting a time criterion).

Other commenters expressed concern that the proposed definition of consecutive system was inconsistent with use of the term prior to the rulemaking. EPA acknowledges that the Agency has not previously formally defined the term, but believes that the definition in today's rule best considers all commenters' concerns, while also providing for accountability and public health protection in as simple a manner as is possible given the many consecutive system scenarios that currently exist.

Several States requested flexibility to determine which systems comprised a combined distribution system under this rule; EPA has included that flexibility for situations in which systems have only a marginal association (such as an infrequently used emergency connection) with other systems in the combined distribution system. To prepare for the IDSE and subsequent Stage 2 implementation, EPA has worked with States in identifying all systems that are part of each combined distribution system.

Finally, several commenters requested that the wholesale system definition replace ''public water system'' with ''water system'' so that wholesale systems serving fewer than 25 people would not be considered public water systems. EPA did not change the definition in today's rule; EPA considers any water system to be a public water system (PWS) if it serves 25 or more people either directly (retail) or indirectly (by providing finished water to a consecutive system) or through a combination of retail and consecutive system customers. If a PWS receives water from an unregulated entity, that PWS must meet all compliance requirements (including monitoring and treatment techniques) that any other public water system that uses source water of unknown quality must meet.

C. LRAA MCLs for TTHM and HAA5

1. Today's Rule

This rule requires the use of locational running annual averages (LRAAs) to determine compliance with the Stage 2 MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5. All systems, including consecutive systems, must comply with the MCLs for TTHM and HAA5 using sampling sites identified under the Initial Distribution System Evaluation (IDSE) or using existing Stage 1 DBPR compliance monitoring locations (as discussed in Section IV.F). EPA has dropped the proposed phased approach for LRAA implementation (Stage 2A and Stage 2B) by removing Stage 2A and redesignating Stage 2B as Stage 2.

Details of monitoring requirements and compliance schedules are discussed in preamble Sections IV.G and IV.E, respectively, and may be found in subpart V of today's rule.

2. Background and Analysis

The MCLs for TTHM and HAA5 are the same as those proposed, 0.080 mg/L TTHM and 0.060 mg/L HAA5 as an LRAA. See the proposed rule (68 FR 49584, August 18, 2003) (USEPA 2003a) for a more detailed discussion of the analysis supporting the MCLs. The primary objective of the LRAA is to reduce exposure to high DBP levels. For an LRAA, an annual average must be computed at each monitoring location. The RAA compliance basis of the 1979 TTHM rule and the Stage 1 DBPR allows a system-wide annual average under which high DBP concentrations in one or more locations are averaged with, and dampened by, lower concentrations elsewhere in the distribution system. Figure IV.C–1 illustrates the difference in calculating compliance with the MCLs for TTHM between a Stage 1 DBPR RAA, and the Stage 2 DBPR LRAA.

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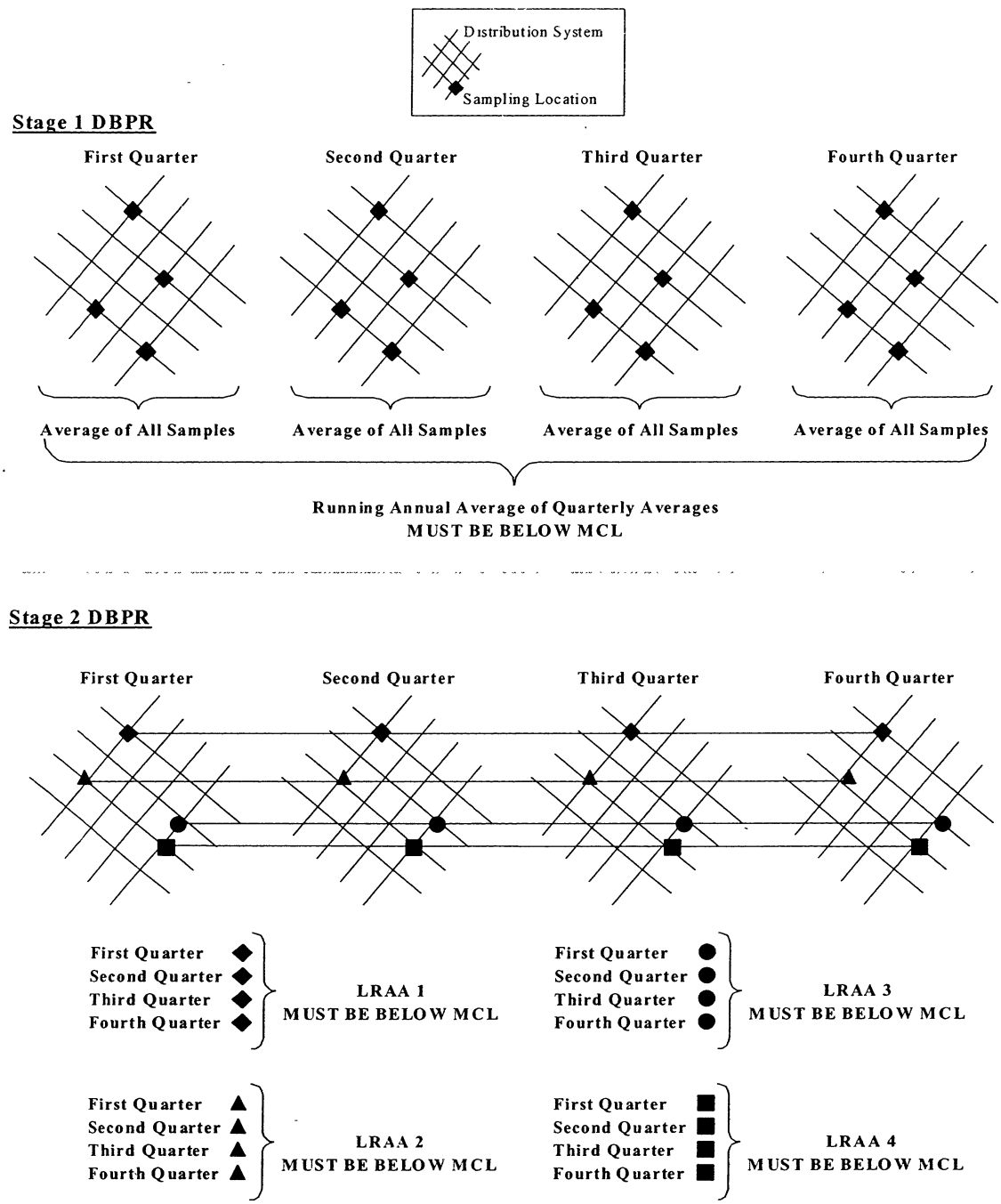
Figure IV.C-1. Comparison of RAA and LRAA compliance calculations[1].



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

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EPA and the Stage 2 M–DBP Advisory Committee considered an array of alternative MCL strategies. The Advisory Committee discussions primarily focused on the relative magnitude of exposure reduction versus the expected impact on the water industry and its customers. Strategies considered included across the board requirements, such as significantly decreasing the MCLs (e.g., 40/30) or single hit MCLs (e.g., all samples must be below 80/60); and risk targeting requirements. In the process of evaluating alternatives, EPA and the Advisory Committee reviewed vast quantities of data and many analyses that addressed health effects, DBP occurrence, predicted reductions in DBP levels, predicted technology changes,

and capital, annual, and household costs. The Advisory Committee recommended and EPA proposed the risk targeting approach of 80/60 as an LRAA preceded by an IDSE. Today's rule finalizes these requirements.

EPA has chosen compliance based on an LRAA due to concerns about levels of DBPs above the MCL in some portions of the distribution system. The LRAA standard will eliminate system-wide averaging of monitoring results from different monitoring locations. The individuals served in areas of the distribution system with above average DBP occurrence levels masked by averaging under an RAA are not receiving the same level of health protection. Although an LRAA standard still allows averaging at a single location over an annual period, EPA concluded that changing the basis of compliance from an RAA to an LRAA will result in decreased exposure to higher DBP levels (see Section VI for predictions of DBP reductions under the LRAA MCLs). This conclusion is based on three considerations:

(1) There is considerable evidence that under the current RAA MCL compliance monitoring requirements, a small but significant proportion of monitoring locations experience high DBP levels at least some of the time. Of systems that collected data under the Information Collection Rule that met the Stage 1 DBPR RAA MCLs, 14 percent had TTHM single sample concentrations greater than the Stage 1 MCL, and 21 percent had HAA5 single sample concentrations above the MCL. Although most TTHM and HAA5 samples were below 100 μg/L, some ranged up to 140 μg/L and 130 μg/L, respectively.

(2) In some situations, the populations served by certain portions of the distribution system consistently receive water that exceeds 0.080 mg/L for TTHM or 0.060 mg/L for HAA5 (both as LRAAs) even though the system is in compliance with Stage 1 MCLs). Of Information Collection Rule systems meeting the Stage 1 DBPR MCLs as RAAs, five percent had monitoring locations that exceeded 0.080 mg/L TTHM and three percent exceeded 0.060 mg/L HAA5 as an annual average (i.e., as LRAAs) by up to 25% (calculated as indicated in Figure IV.C–1). Customers served at these locations consistently received water with TTHM and/or HAA5 concentrations higher than the system-wide average and higher than the MCL.

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

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

3. Summary of Major Comments

Commenters supported the proposed, risk-targeted MCL strategy over the alternative MCL strategies that were considered by the Advisory Committee as the preferred regulatory strategy. Commenters concurred with EPA's analysis that such an approach will reduce peak and average DBP levels. Commenters supported the Stage 2 long-term MCLs of 0.080 mg/L TTHM and 0.060 mg/L HAA5 as LRAAs.

EPA received many comments on today's MCLs specific to consecutive systems. While commenters supported consecutive system compliance with the Stage 2 DBPR in order to provide comparable levels of public health protection, they noted that it would be difficult for many consecutive systems to meet Stage 2 requirements because they have not had to meet the full scope of DBP requirements under previous rules. EPA has developed a training and outreach program to assist these systems and encourages States, wholesale systems, and professional associations to also provide assistance.

Some commenters expressed concern about holding consecutive systems responsible for water quality over which they have no control. Several commenters were concerned about the establishment of contracts between wholesale and consecutive systems, including concern about a strain on their relationship, wholesale system reluctance to commit to keep DBPs at a level suggested by the consecutive systems, and the time and money it could take to work out differences. Although setting up a contract is a prudent business action, commenters noted that small consecutive water systems have few resources to sue for damages should the wholesaler provide water exceeding the MCL.

The purpose of DBPRs is to protect public health from exposure to high DBP levels. Not requiring violations when distributed water exceeds MCLs undermines the intent of the rule. While EPA recognizes consecutive systems do not have full control over the water they receive, agreements between wholesale and consecutive systems may specify water quality and actions required of the wholesaler if those water quality standards are not met.

Finally, commenters recommended that the Stage 2A provisions in the proposed rule be removed. These provisions (compliance with locational running annual average MCLs of 0.120 mg/L for TTHM and 0.100 mg/L for HAA5) required systems to comply with the Stage 1 MCLs (as running annual averages) and the Stage 2A MCLs (as LRAAs) concurrently until systems were required to comply with Stage 2B MCLs. Commenters noted that having two separate MCLs for an individual system to comply with at the same time was confusing to the system and its customers. In addition, State resources needed for compliance determinations and data management for this short-term requirement would be resource-intensive. Finally, resources spent to comply with Stage 2A would be better spent in complying with Stage 2B, especially given that some of the changes for Stage 2A compliance might not provide any benefit for Stage 2B. Since EPA agrees with commenters' concerns, the Stage 2A requirements have been removed from the final rule.

D. BAT for TTHM and HAA5

1. Today's Rule

Today, EPA is identifying the best available technology (BAT) for the TTHM and HAA5 LRAA MCLs (0.080 mg/L and 0.060 mg/L respectively) for systems that treat their own source water as one of the three following technologies:

(1) GAC10 (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 120 days)

(2) GAC20 (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 240 days)

(3) Nanofiltration (NF) using a membrane with a molecular weight cutoff of 1000 Daltons or less.

EPA is specifying a different BAT for consecutive systems than for systems that treat their own source water to meet the TTHM and HAA5 LRAA MCLs. The consecutive system BAT is chloramination with management of hydraulic flow and storage to minimize residence time in the distribution system for systems that serve at least 10,000 people and management of hydraulic flow and storage to minimize residence time in the distribution system for systems that serve fewer than 10,000 people.

2. Background and Analysis

The BATs are the same as was proposed, except that consecutive systems serving fewer than 10,000 people do not have chloramination as part of the consecutive system BAT. See the proposal (68 FR 49588, August 18, 2003) (USEPA 2003a) for more detail on the analysis supporting these requirements. The Safe Drinking Water Act directs EPA to specify BAT for use in achieving compliance with the MCL. Systems unable to meet the MCL after application of BAT can get a variance (see Section IV.K for a discussion of variances). Systems are not required to use BAT in order to comply with the MCL. PWSs may use any State-approved technologies as long as they meet all drinking water standards.

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

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

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

The second method that EPA used to examine alternatives for BAT was the Surface Water Analytical Tool model that was developed to compare alternative regulatory strategies as part of the Stage 1 and Stage 2 M–DBP Advisory Committee deliberations. EPA modeled a number of BAT options. In the model, GAC10 was defined as granular activated carbon with an empty bed contact time of 10 minutes and a reactivation or replacement interval of 90 days or longer. GAC20 was defined as granular activated carbon with an empty bed contact time of 20 minutes and a reactivation or replacement interval of 90 days or longer.

The compliance percentages forecasted by the SWAT model are indicated in Table IV.D–1. EPA estimates that more than 97 percent of large systems will be able to achieve the Stage 2 MCLs with the GAC BAT, regardless of post-disinfection choice (Seidel Memo, 2001). Because the source water quality (e.g., DBP precursor levels) in medium and small systems is expected to be comparable to or better than that for the large system (USEPA 2005f), EPA believes it is conservative to assume that at least 90 percent of medium and small systems will be able to achieve the Stage 2 MCLs if they were to apply one of the proposed GAC BATs. EPA assumes that small systems may adopt GAC20 in a replacement mode (with replacement every 240 days) over GAC10 because it may not be economically feasible for some small systems to install and operate an on-site GAC reactivation facility. Moreover, some small systems may find nanofiltration cheaper than the GAC20 in a replacement mode if their specific geographic locations cause a relatively high cost for routine GAC shipment.

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

Technology	Compliance with 0.080 mg/L TTHM and 0.060 mg/L HAA5 LRAAs			Compliance with 0.064 mg/L TTHM and 0.048 mg/L HAA5 LRAAs (MCLs with 20% Safety factor)		
	Residual disinfectant		All systems (percent)	Residual disinfectant		All systems (percent)
	Chlorine (percent)	Chloramine (percent)		Chlorine (percent)	Chloramine (percent)	
Enhanced Coagulation (EC)	73.5	76.9	74.8	57.2	65.4	60.4
EC (no pre-disinfection)	73.4	88.0	78.4	44.1	62.7	50.5
EC & GAC10	100	97.1	99.1	100	95.7	98.6

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

Technology	Compliance with 0.080 mg/L TTHM and 0.060 mg/L HAA5 LRAAs			Compliance with 0.064 mg/L TTHM and 0.048 mg/L HAA5 LRAAs (MCLs with 20% Safety factor)		
	Residual disinfectant		All systems (percent)	Residual disinfectant		All systems (percent)
	Chlorine (percent)	Chloramine (percent)		Chlorine (percent)	Chloramine (percent)	
EC & GAC20	100	100	100	100	100	100
EC & All Chloramines	NA	83.9	NA	NA	73.6	NA

Note: Enhanced coagulation/softening is required under the Stage 1 DBPR for conventional plants.
Source: Seidel (2001).

The BAT requirements for large consecutive systems are the same as proposed, but the requirements have changed for small consecutive systems. EPA believes that the best compliance strategy for consecutive systems is to collaborate with wholesalers on the water quality they need. For consecutive systems that are having difficulty meeting the MCLs, EPA is specifying a BAT of chloramination with management of hydraulic flow and storage to minimize residence time in the distribution system for systems serving at least 10,000 and management of hydraulic flow and storage to minimize residence time in the distribution system for systems serving fewer than 10,000. EPA believes that small consecutive systems can use this BAT to comply with the Stage 2 DBPR, but if they cannot, then they can apply to the State for a variance.

Chloramination has been used for residual disinfection for many years to minimize the formation of chlorination DBPs, including TTHM and HAA5 (USEPA 2003d). EPA estimates that over 50 percent of large subpart H systems serving at least 10,000 use chloramination for Stage 1. The BAT provision to manage hydraulic flow and minimize residence time in the distribution system is to facilitate the maintenance of the chloramine residual and minimize the likelihood for nitrification. EPA has not included chloramination for consecutive systems as part of the BAT for systems serving fewer than 10,000 due to concerns about their ability to properly control the process, given that many have no treatment capability or expertise and the Agency's concern about such systems having operational difficulties such as distribution system nitrification.

EPA believes that the BATs for nonconsecutive systems are not appropriate for consecutive systems because their efficacy in controlling DBPs is based on precursor removal. Consecutive systems face the unique challenge of receiving waters in which DBPs are already present if the wholesale system has used a residual disinfectant, which the BATs for nonconsecutive systems do not effectively remove. GAC is not cost-effective for removing DBPs. Nanofiltration is only moderately effective at removing THMs or HAAs if membranes with a very low molecular weight cutoff (and very high cost of operation are employed). Therefore, GAC and nanofiltration are not appropriate BATs for consecutive systems.

3. Summary of Major Comments

Commenters concurred with EPA's identification of BATs for nonconsecutive systems but expressed concern about the BAT for consecutive systems. Many commenters agreed that Stage 2 compliance for consecutive systems would usually best be achieved by improved treatment by the wholesale system. However, they noted that the proposed BAT may not be practical for compliance if water delivered to the consecutive system is at or near DBP MCLs. In addition, chloramination requires operator supervision and adjustment and many consecutive systems that buy water may be reluctant to operate chemical feed systems. Therefore, EPA included chloramines as part of the BAT in today's rule only for systems serving at least 10,000 because of the operator attention it requires and concerns with safety and nitrification. While some commenters believed that having a BAT for consecutive systems contradicts the premise of the Stage 1 DBPR that DBPs are best controlled through TOC removal and optimizing disinfection processes, the SDWA requires EPA to identify a BAT for all systems required to meet an MCL. No commenter recommended an alternative BAT. EPA still believes that precursor removal remains a highly effective strategy to reduce DBPs. Thus, EPA encourages States to work with wholesale systems and consecutive systems to identify strategies to ensure compliance, especially those systems with DBP levels close to the MCL.

E. Compliance Schedules

1. Today's Rule

This section specifies compliance dates for the IDSE and MCL compliance requirements in today's rule. As described elsewhere in Section IV of this preamble, today's rule requires PWSs to carry out the following activities:

- Conduct initial distribution system evaluations (IDSEs) on a required schedule. Systems may comply by using any of four approaches for which they qualify (standard monitoring, system specific study, 40/30 certification, or very small system waiver).
- Determine Stage 2 monitoring locations based on the IDSE.
- Comply with Stage 2 MCLs on a required schedule.

Compliance dates for these activities vary by PWS size. Table IV.E–1 and Figure IV.E–1 specify IDSE and Stage 2 compliance dates. Consecutive systems of any size must comply with the requirements of the Stage 2 DBPR on the same schedule as required for the largest system in the combined distribution system.

TABLE IV.E–1.—IDSE AND STAGE 2 COMPLIANCE DATES

Requirement	Compliance dates by PWS size (retail population served) [1]				
	CWSs and NTNCWSs serving at least 100,000	CWSs and NTNCWSs serving 50,000–99,999	CWSs and NTNCWSs serving 10,000–49,999	CWSs serving <10,000	NTNCWSs serving <10,000
Submit IDSE monitoring plan OR Submit IDSE system specific study plan OR. Submit 40/30 certification OR ..... Receive very small system waiver from State.	October 1, 2006	April 1, 2007	October 1, 2007	April 1, 2008	Not applicable.
Complete standard monitoring or system specific study.	September 30, 2008	March 31, 2009	September 30, 2009	March 31, 2010 ..	Not applicable.
Submit IDSE Report	January 1, 2009	July 1, 2009	January 1, 2010	July 1, 2010	Not applicable.
Begin subpart V (Stage 2) compliance monitoring [2].	April 1, 2012	October 1, 2012	October 1, 2013	October 1, 2013 (October 1, 2014 if Cryptosporidium monitoring is required under Subpart W)..	

[1] Wholesale and consecutive systems that are part of a combined distribution system must comply based on the schedule required of the largest system in the combined distribution system.
[2] States may grant up to an additional 2 years for systems making capital improvements.

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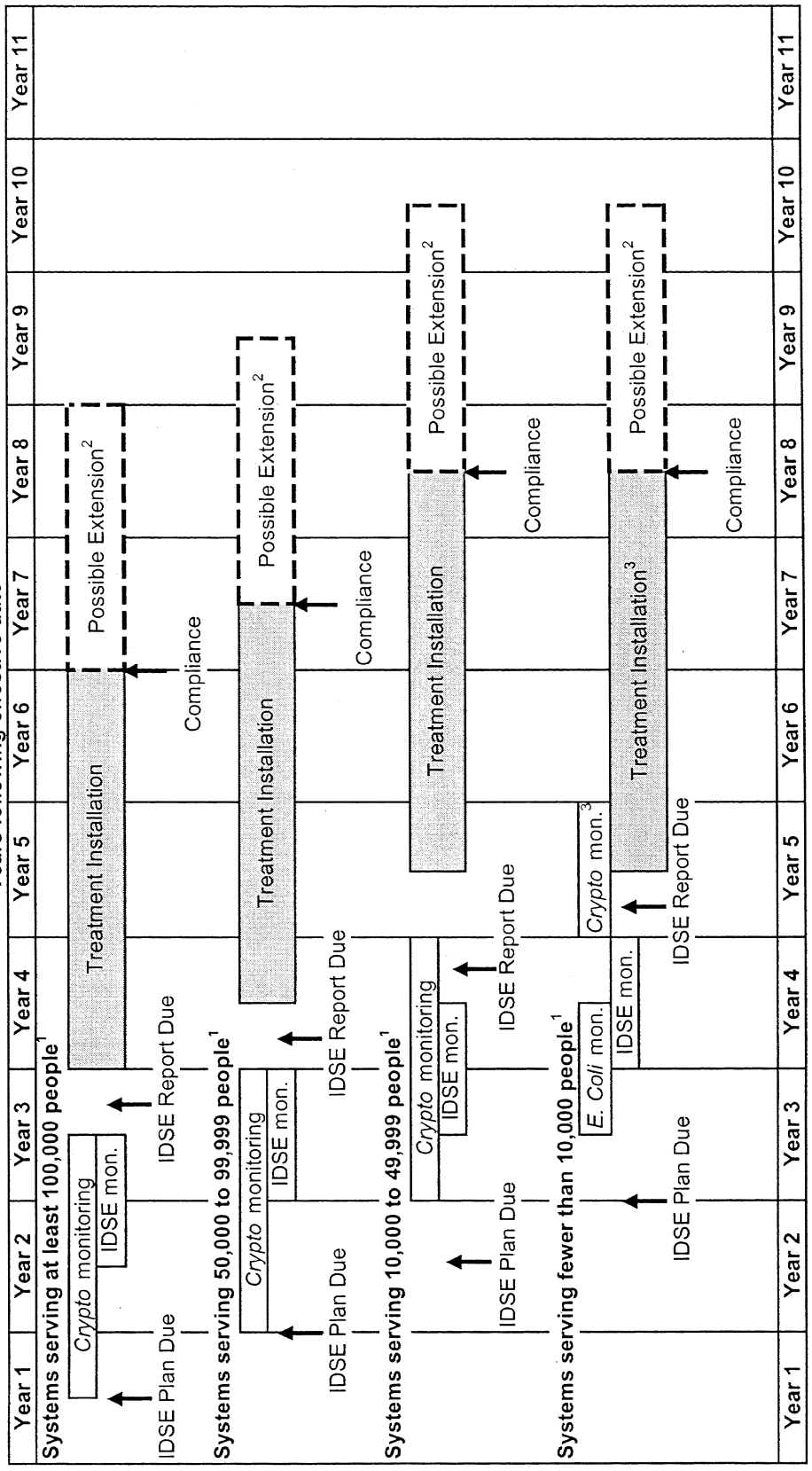
Figure IV.E-1. Final Stage 2 DBPR and LT2ESWTR Implementation Schedule.



[1] Includes all systems that are part of a combined distribution system that has a largest system with this population.

[2] A State may grant up to a two year extension for systems to comply if the State determines that additional time is necessary for capital improvements needed for compliance.

[3] Subpart H systems serving fewer than 10,000 that must conduct *Crypto* monitoring have an additional 12 months to comply with Stage 2 DBPR MCLs.

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2. Background and Analysis

The compliance schedule in today's final rule stems from the risk-targeted approach of the rule, wherein PWSs conduct initial monitoring to determine locations and concentrations of high DBPs. A primary objective of this schedule is to ensure that PWSs identify locations with high DBP concentrations and provide appropriate additional treatment in a timely manner for high risk areas, while not requiring low risk systems to add additional treatment. The compliance schedule balances the objective of early risk-targeted monitoring with adequate time for PWSs and the State or primacy agency to assure full implementation and compliance. EPA is establishing concurrent compliance schedules under the Stage 2 DBPR for all systems (both wholesale systems and consecutive systems) in a particular combined distribution system because this will assure comparable risk-based targeting information being available at the same time for all PWSs that are part of a combined distribution system and thereby allow for more cost-effective compliance with TTHM and HAA5 MCLs.

SDWA section 1412(b)(10) states that a drinking water regulation shall take effect 3 years from the promulgation date unless the Administrator determines that an earlier date is practicable. Today's rule requires PWSs to begin monitoring prior to 3 years from the promulgation date. Based on EPA's assessment and recommendations of the Advisory Committee, as described in this section, EPA has determined that these monitoring start dates are practicable and appropriate.

Systems must submit their IDSE plans (monitoring plans for standard monitoring, study plans for system specific studies) to the primacy agency for review and approval. The State or primacy agency will then have 12 months to review, and, as necessary, consult with the system. A number of PWSs will then conduct one year of distribution system monitoring for TTHM and HAA5 at locations other than those currently used for Stage 1 DBPR compliance monitoring. At the conclusion of this monitoring, these PWSs have three months to evaluate analysis and monitoring results and submit Stage 2 compliance monitoring locations and schedules to the State or primacy agency. Where required, PWSs must provide the necessary level of treatment to comply with the Stage 2 MCLs within three years of the completion of State or primacy agency review of the IDSE report, though States may allow an additional two years for PWSs making capital improvements.

EPA has modified the proposed compliance schedule to stagger monitoring start dates for PWSs serving 10,000 to 99,999 people and to allow more time for development and review of IDSE monitoring plans prior to the start of monitoring. The following discussion addresses these changes from the proposal.

The proposed rule required all PWSs serving at least 10,000 people (plus smaller systems that are part of a combined distribution system with a PWS that serves at least 10,000 people) to complete IDSE monitoring and submit IDSE reports (including recommended Stage 2 compliance monitoring locations) two years after rule promulgation, followed by one year for review of IDSE reports, after which systems had three years to come into compliance with Stage 2B MCLs.

Under today's final rule, PWSs serving at least 100,000 people (plus smaller systems that are part of the combined distribution system) will meet the same Stage 2 compliance deadlines as proposed. However, the timing of the IDSE has been changed to allow for a more even workload and a greater opportunity for primacy agency involvement (*e.g.*, through monitoring plan review and approval). The IDSE plan submission dates for PWSs serving 50,000 to 99,999 people (plus smaller systems that are part of the combined distribution system) will be 12 months after the effective date; for PWSs serving 10,000 to 49,999 (plus smaller systems that are part of the combined distribution system), the IDSE plan submission dates will be 18 months after the effective date. The Stage 2 compliance schedule for systems serving fewer than 10,000 people remains the same as proposed. Stage 2 MCL compliance dates are modified accordingly.

This staggering of IDSE start dates for PWSs serving 10,000 to 99,999 people is advantageous in several respects:

- Provides PWSs greater assurance that IDSEs are properly conducted by requiring IDSE plan review prior to conducting the IDSE.
- Provides additional time to develop budgets and establish contracts with laboratories.
- Spreads out the workload for technical assistance and guidance. The staggered schedule will allow States and EPA to provide more support to individual PWSs as needed.
- Provides time for DBP analytical laboratories to build capacity as needed to accommodate the sample analysis needs of PWSs and extends and smooths the demand for laboratory services.
- Maintains simultaneous rule compliance with the LT2ESWTR as recommended by the Stage 2 M-DBP Advisory Committee and as mandated by the 1996 SDWA Amendments, which require that EPA ''minimize the overall risk of adverse health effects by balancing the risk from the contaminant and the risk from other contaminants the concentrations of which may be affected by the use of a treatment technique or process that would be employed to attain the maximum contaminant level'' (Sec. 1412(b)(5)(B)(i)).

The Advisory Committee recommended the Initial Distribution System Evaluation, as discussed in Section IV.F, and EPA is finalizing an IDSE schedule generally consistent with the Advisory Committee timeframe recommendation, but modified to stagger the schedule for systems serving more than 10,000 but less than 100,000, and to address public comments on the IDSE requirements.

For all systems, the IDSE schedule has been revised to allow systems to submit and States or primacy agencies to review (and revise, if necessary) systems' recommendations for IDSE and Stage 2 monitoring locations, while still allowing systems three years after completion of the State or primacy agency review of Stage 2 compliance monitoring locations to make necessary treatment and operational changes to comply with Stage 2 MCLs.

Figure IV.E–2 illustrates compliance schedules for examples of three combined distribution systems, with the schedule dictated by the retail population served by the largest system.

FIGURE IV.E–2.—SCHEDULE EXAMPLES.

—Wholesale system (pop. 64,000) with three consecutive systems (pops. 21,000; 15,000; 5,000):
  —IDSE monitoring plan due for all systems April 1, 2007 since wholesale system serves 50,000–99,999
  —Stage 2 compliance beginning October 1, 2012 for all systems
—Wholesale system (pop. 4,000) with three consecutive systems (pops. 21,000; 5,000; 5,000):

FIGURE IV.E–2.—SCHEDULE EXAMPLES.—Continued

—IDSE monitoring plan due for all systems October 1, 2007 since the largest system in combined distribution system serves 10,000–49,999
—Stage 2 compliance beginning October 1, 2013 for all systems
—Wholesale system (pop. 4,000) with three consecutive systems (pops. 8,000; 5,000; 5,000):
—IDSE monitoring plan due for all systems April 1, 2008 since no individual system in combined distribution system exceeds 10,000 (even though total population exceeds 10,000)
—Stage 2 compliance beginning October 1, 2013 if no Cryptosporidium monitoring under the LT2ESWTR is required or beginning October 1, 2014 if Cryptosporidium monitoring under the LT2ESWTR is required

This schedule requires wholesale systems and consecutive systems that are part of a combined distribution system with at least one system with an earlier compliance deadline to conduct their IDSE simultaneously so that the wholesale system will be aware of compliance challenges facing the consecutive systems and will be able to implement treatment plant, capital, and operational improvements as necessary to ensure compliance of both the wholesale and consecutive systems. The Advisory Committee and EPA both recognized that DBPs, once formed, are difficult to remove and are generally best addressed by treatment plant improvements, typically through precursor removal or use of alternative disinfectants. For a wholesale system to make the best decisions concerning the treatment steps necessary to meet TTHM and HAA5 LRAAs under the Stage 2 DBPR, both in its own distribution system and in the distribution systems of consecutive systems it serves, the wholesale system must know the DBP levels throughout the combined distribution system. Without this information, the wholesale system may design treatment changes that allow the wholesale system to achieve compliance, but leave the consecutive system out of compliance.

In summary, the compliance schedule for today's rule maintains the earliest compliance dates recommended by the Advisory Committee for PWSs serving at least 100,000 people (plus smaller systems that are part of the combined distribution system). These PWSs serve the majority of people. The schedule also maintains the latest compliance dates the Advisory Committee recommended, which apply to PWSs serving fewer than 10,000 people. EPA has staggered compliance schedules for PWSs between these two size categories in order to facilitate implementation of the rule. This staggered schedule is consistent with the schedule required under the LT2ESWTR promulgated elsewhere in today's **Federal Register**.

3. Summary of Major Comments

EPA received significant public comment on the compliance schedule in the August 18, 2003 proposal. Major issues raised by commenters include providing more time for PWSs to prepare for monitoring, giving States or primacy agencies more time to oversee monitoring, and establishing consistent schedules for consecutive PWSs. A summary of these comments and EPA's responses follows.

Standard monitoring plan and system specific study plan preparation. Many commenters were concerned about the proposed requirement to develop and execute an IDSE monitoring plan without any primacy agency review. PWSs specifically expressed concern about the financial commitment without prior State approval and noted that some PWSs would need more than the time allowed under the proposed rule to develop and implement an IDSE monitoring plan, especially without an opportunity for State or primacy agency review and approval. Smaller PWSs may require substantial time and planning to budget for IDSE expenses, especially for systems that have not previously complied with DBP MCLs.

EPA recognizes these concerns and today's final rule provides time for PWSs to submit IDSE plans (monitoring plans, study plans, or 40/30 certifications) for State or primacy agency review and more time before having to begin monitoring. Specifically, PWSs serving 50,000 to 99,999 people and those serving 10,000 to 49,999 people must submit IDSE plans about 12 months and 18 months after the effective date, respectively, and complete standard monitoring or a system specific study within two years after submitting their IDSE plan. This is significantly more time than was specified under the proposal, where these systems would have had to conduct their IDSE and submit their IDSE report 24 months after the effective date. PWSs serving at least 100,000 people must submit IDSE plans about six months after the effective date and complete standard monitoring or a system specific study about 30 months after the effective date, which also provides more time than was specified under the proposal. PWSs serving fewer than 10,000 people, not associated with a larger system in their combined distribution system, do not begin monitoring until more than 36 months after the effective date.

EPA believes that the final compliance schedule allows PWSs sufficient time to develop IDSE plans with these compliance dates. The schedule also allows 12 months for State or primacy agency review of IDSE plans, which allows additional time for review and for coordination with systems and provides more time to address deficiencies in IDSE plans. This is especially important for smaller PWSs, which are likely to need the most assistance from States. By staggering monitoring start dates, today's rule also eases implementation by reducing the number of PWSs that will submit plans at any one time, when the most assistance from regulatory agencies will be required.

In summary, today's schedule has been modified so that systems are required to submit IDSE plans for primacy agency review and approval prior to conducting their IDSE. Systems can consider that their plan has been approved if they have not heard back from the State by the end of the State review period. Systems are also required to conduct the approved monitoring and submit their IDSE report (including the system's recommended Stage 2 compliance monitoring) for State or primacy agency review on a schedule that allows for systems to still have a minimum of full three years to comply with Stage 2 following State or primacy agency review of the system's Stage 2 recommended monitoring. As with the review of plans, systems can consider that their IDSE report has been approved if they have not heard back from the State by the end of the State review period.

State/primacy agency oversight. EPA is preparing to support implementation of IDSE requirements that must be completed prior to States achieving primacy. Several States have expressed concern about EPA providing guidance and reviewing reports from systems that the State has permitted, inspected, and worked with for a long time. These States believe that their familiarity with

the systems enables them to make the best decisions to implement the rule and protect public health and that the rule requirement should be delayed until States receive primacy. Commenters were concerned that some States will not participate in early implementation activities and indicated that States would prefer monitoring to begin 24 months after rule promulgation. Commenters also noted that States need sufficient time to become familiar with the rule, train their staff, prepare primacy packages, and train PWSs.

EPA agrees that State familiarity is an important component of the review and approval process, looks forward to working closely with the State drinking water program representatives during IDSE implementation, and welcomes proactive State involvement. However, the Agency believes that delaying implementation of risk-based IDSE targeting activities until States receive primacy is an unacceptable delay in public health protection and also inconsistent with the Advisory Committee's recommendations. EPA remains committed to working with States to the greatest extent feasible to implement today's rule, consistent with the schedule promulgated today. For States unable to actively participate in IDSE implementation, however, EPA believes it has an obligation to provide support and guidance to PWSs who are covered and independently responsible for complying with the IDSE requirements of today's rule and is prepared to oversee implementation. Moreover, EPA believes that the staggered compliance schedule in today's final rule will enhance States' ability to help implement the rule.

Consecutive systems. Most commenters supported consecutive systems being on the same IDSE schedule as wholesale systems, recognizing the benefits of treatment plant capital and operational improvements by the wholesale system as the preferred method of DBP compliance, with the timely collection of DBP data throughout the combined distribution system a key component. Several commenters preferred that consecutive systems have a later Stage 2 compliance date to allow for evaluation of whether wholesale system treatment changes are adequate to ensure compliance and to consider changes to water delivery specifications.

EPA disagrees with those commenters recommending a different Stage 2 compliance date and thus has maintained the approach in the proposal, which keeps all systems that are part of a combined distribution system (the interconnected distribution system consisting of the distribution systems of wholesale systems and of the consecutive systems that receive finished water) on the same Stage 2 compliance schedule. Extending the Stage 2 compliance dates would unnecessarily delay the public health protection afforded by this rule. Consecutive systems must be able to evaluate whether wholesale system changes are sufficient to ensure compliance and, if they are not, to make cost-effective changes to ensure compliance where wholesale system efforts address some, but not all, of the concerns with compliance. Public health protection through compliance with Stage 2 MCLs will occur on the schedule of the largest system for all systems in the combined distribution system (regardless of size). If a consecutive system must make capital improvements to comply with this rule, the State may use its existing authority to grant up to an additional 24 months to that system. In addition, implementation and data tracking will be simplified because all systems in a combined distribution system will be on the same IDSE and Stage 2 compliance schedule. EPA believes that this is a better approach from both a public health standpoint and an implementation standpoint.

EPA agrees with many commenters that a high level of coordination among wholesaler, consecutive system, and States will be necessary to ensure compliance. The schedule in today's rule provides more time for planning, reviewing, and conducting the IDSE than the schedule in the proposed rule, which will allow more time for necessary coordination, including small consecutive systems that need help in negotiations with their wholesale system. EPA will work with ASDWA and States to develop guidance to facilitate wholesale/consecutive system cooperation. This additional time and the staggered schedule discussed in this section also lessens the laboratory burden associated with IDSE monitoring.

The staggered schedule also helps address commenter concerns about evaluating combined distribution systems. Other commenters' concerns about time needed for developing contracts between systems and for planning, funding, and implementing treatment changes are addressed by not requiring Stage 2 compliance until at least six years following rule promulgation.

F. Initial Distribution System Evaluation (IDSE)

1. Today's Rule

Today's rule establishes requirements for systems to perform an Initial Distribution System Evaluation (IDSE). The IDSE is intended to identify sample locations for Stage 2 compliance monitoring that represent distribution system sites with high DBP concentrations. Systems will develop an IDSE plan, collect data on DBP levels throughout their distribution system, evaluate these data to determine which sampling locations are most representative of high DBP levels, and compile this information into a report for submission to the State or primacy agency. Systems must complete one IDSE to meet the requirements of today's rule.

a. *Applicability.* This requirement applies to all community water systems, and to large nontransient noncommunity water systems (those serving at least 10,000 people) that use a primary or residual disinfectant other than ultraviolet light, or that deliver water that has been treated with a primary or residual disinfectant other than ultraviolet light. Systems serving fewer than 500 people are covered by the very small system waiver provisions of today's rule and are not required to complete an IDSE if they have TTHM and HAA5 data collected under Subpart L. Consecutive systems are subject to the IDSE requirements of today's rule. Consecutive systems must comply with IDSE requirements on the same schedule as the system serving the largest population in the combined distribution system, as described in section IV.E.

b. Data collection. For those systems not receiving a very small system waiver, there are three possible approaches by which a system can meet the IDSE requirement.

i. Standard monitoring. Standard monitoring requires one year of DBP monitoring throughout the distribution system on a specified schedule. Prior to commencing standard monitoring, systems must prepare a monitoring plan and submit it to the primacy agency for review. The frequency and number of samples required under standard monitoring is determined by source water type and system size. The number of samples does not depend on the number of plants per system. Section IV.G provides a detailed discussion of the specific population-based monitoring requirements for IDSE standard monitoring. Although standard monitoring results are not to be used for determining compliance with MCLs,

systems are required to include individual sample results for the IDSE results when determining the range of TTHM and HAA5 levels to be reported in their Consumer Confidence Report (see section IV.J).

ii. System specific study. Under this approach, systems may choose to perform a system specific study based on earlier monitoring studies or distribution system hydraulic models in lieu of standard monitoring. Prior to commencing a system specific study, systems must prepare a study plan and submit it to the primacy agency for approval. The two options for system specific studies are: (1) TTHM and HAA5 monitoring data that encompass a wide range of sample sites representative of the entire distribution system, including those judged to represent high TTHM and HAA5 concentrations, and (2) extended period simulation hydraulic models that simulate water age in the distribution system, in conjunction with one round of TTHM and HAA5 sampling.

iii. 40/30 certification. Under this approach, systems must certify to their State or primacy agency that every individual compliance sample taken under subpart L during the period specified in Table IV.F–2 were less than or equal to 0.040 mg/L for TTHM and less than or equal to 0.030 mg/L for HAA5, and that there were no TTHM or HAA5 monitoring violations during the same period. The State or primacy agency may require systems to submit compliance monitoring results, distribution system schematics, or recommend subpart V compliance monitoring locations as part of the certification. This certification must be kept on file and submitted to the State or primacy agency for review. Systems that qualify for reduced monitoring for the Stage 1 DBPR during the two years prior to the start of the IDSE may use results of reduced Stage 1 DBPR monitoring to prepare the 40/30 certification. The requirements for the 40/30 certification are listed in Table IV.F–1.

TABLE IV.F–1.—40/30 CERTIFICATION REQUIREMENTS

40/30 Certification Requirements ...	• A certification that every individual compliance sample taken under subpart L during the period specified in Table IV.F–2 were less than or equal to 0.040 mg/L for TTHM and less than or equal to 0.030 mg/L for HAA5, and that there were no TTHM or HAA5 monitoring violations during the same period. • Compliance monitoring results, distribution system schematics, and/or recommended subpart V compliance monitoring locations as required by the State or primacy agency.

TABLE IV.F–2.—40/30 ELIGIBILITY DATES

If your 40/30 Certification Is Due	Then your eligibility for 40/30 certification is based on eight consecutive calendar quarters of subpart L compliance monitoring results beginning no earlier than[1]
(1) October 1, 2006	January 2004.
(2) April 1, 2007	January 2004.
(3) October 1, 2007	January 2005.
(4) April 1, 2008	January 2005.

[1] Unless you are on reduced monitoring under subpart L and were not required to monitor during the specified period. If you did not monitor during the specified period, you must base your eligibility on compliance samples taken during the 12 months preceding the specified period.

c. Implementation. All systems subject to the IDSE requirement under this final rule (except those covered by the very small system waiver) must prepare and submit an IDSE plan (monitoring plan for standard monitoring, study plan for system specific study) or 40/30 certification to the State or primacy agency. IDSE plans and 40/30 certifications must be submitted according to the schedule described in section IV.E and IV.M. The requirements for the IDSE plan depend on the IDSE approach that the system selects and are listed in Tables IV.F–1 and IV.F–3.

TABLE IV.F–3.—IDSE MONITORING PLAN REQUIREMENTS

IDSE data collection alternative	IDSE plan requirements
Standard Monitoring	• Schematic of the distribution system (including distribution system entry points and their sources, and storage facilities), with notes indicating locations and dates of all projected standard monitoring, and all projected subpart L compliance monitoring. • Justification for all standard monitoring locations selected and a summary of data relied on to select those locations. • Population served and system type (subpart H or ground water).
System Specific Study: Hydraulic Model	Hydraulic models must meet the following criteria: • Extended period simulation hydraulic model. • Simulate 24 hour variation in demand and show a consistently repeating 24 hour pattern of residence time. • Represent 75% of pipe volume; 50% of pipe length; all pressure zones; all 12-inch diameter and larger pipes; all 8-inch and larger pipes that connect pressure zones, influence zones from different sources, storage facilities, major demand areas, pumps, and control valves, or are known or expected to be significant conveyors of water; all pipes 6 inches and larger that connect remote areas of a distribution system to the main portion of the system; all storage facilities with standard operations represented in the model; all active pump stations with controls represented in the model; and all active control valves.

TABLE IV.F–3.—IDSE MONITORING PLAN REQUIREMENTS—Continued

IDSE data collection alternative	IDSE plan requirements
	• The model must be calibrated, or have calibration plans, for the current configuration of the distribution system during the period of high TTHM formation potential. All storage facilities must be evaluated as part of the calibration process. • All required calibration must be completed no later than 12 months after plan submission. Submission must include: • Tabular or spreadsheet data demonstrating percent of total pipe volume and pipe length represented in the model, broken out by pipe diameter, and all required model elements. • A description of all calibration activities undertaken, and if calibration is complete, a graph of predicted tank levels versus measured tank levels for the storage facility with the highest residence time in each pressure zone, and a time series graph of the residence time at the longest residence time storage facility in the distribution system showing the predictions for the entire simulation period (i.e., from time zero until the time it takes for the model to reach a consistently repeating pattern of residence time). • Model output showing preliminary 24 hour average residence time predictions throughout the distribution system. • Timing and number of samples planned for at least one round of TTHM and HAA5 monitoring at a number of locations no less than would be required for the system under standard monitoring in § 141.601 during the historical month of high TTHM. These samples must be taken at locations other than existing subpart L compliance monitoring locations. • Description of how all requirements will be completed no later than 12 months after submission of the system specific study plan. • Schematic of the distribution system (including distribution system entry points and their sources, and storage facilities), with notes indicating the locations and dates of all completed system specific study monitoring (if calibration is complete) and all subpart L compliance monitoring. • Population served and system type (subpart H or ground water). • If the model submitted does not fully meet the requirements, the system must correct the deficiencies and respond to State inquiries on a schedule the State approves, or conduct standard monitoring.
System Specific Study: Existing Monitoring Results	Existing monitoring results must meet the following criteria: • TTHM and HAA5 results must be based on samples collected and analyzed in accordance with § 141.131. Samples must be collected within five years of the study plan submission date. • The sampling locations and frequency must meet the requirements identified in Table IV.F–4. Each location must be sampled once during the peak historical month for TTHM levels or HAA5 levels or the month of warmest water temperature for every 12 months of data submitted for that location. Monitoring results must include all subpart L compliance monitoring results plus additional monitoring results as necessary to meet minimum sample requirements. Submission must include: • Previously collected monitoring results • Certification that the reported monitoring results include all compliance and non-compliance results generated during the time period beginning with the first reported result and ending with the most recent subpart L results. • Certification that the samples were representative of the entire distribution system and that treatment and distribution system have not changed significantly since the samples were collected. • Schematic of the distribution system (including distribution system entry points and their sources, and storage facilities), with notes indicating the locations and dates of all completed or planned system specific study monitoring. • Population served and system type (subpart H or ground water). • If a system submits previously collected data that fully meet the number of samples required for IDSE monitoring in Table IV.F–4 and some of the data are rejected due to not meeting the additional requirements, the system must either conduct additional monitoring to replace rejected data on a schedule the State approves, or conduct standard monitoring.

TABLE IV.F–4.—SSS EXISTING MONITORING DATA SAMPLE REQUIREMENTS.

System type	Population size category	Number of monitoring locations	Number of samples	
			TTHM	HAA5
Subpart H:				
	<500	3	3	3
	500–3,300	3	9	9
	3,301–9,999	6	36	36
	10,000–49,999	12	72	72
	50,000–249,999	24	144	144
	250,000–999,999	36	216	216

TABLE IV.F–4.—SSS EXISTING MONITORING DATA SAMPLE REQUIREMENTS.—Continued

System type	Population size category	Number of monitoring locations	Number of samples	
			TTHM	HAA5
	1,000,000–4,999,999	48	288	288
	≥ 5,000,000	60	360	360
Ground Water:	<500	3	3	3
	500–9,999	3	9	9
	10,000–99,999	12	48	48
	100,000–499,999	18	72	72
	≥ 500,000	24	96	96

The State or primacy agency will approve the IDSE plan or 40/30 certification, or request modifications. If the State or primacy agency has not taken action by the date specified in section IV.E or has not notified the system that review is not yet complete, systems may consider their submissions to be approved. Systems must implement the IDSE option described in the IDSE plan approved by the State or primacy agency according to the schedule described in section IV.E.

All systems completing standard monitoring or a system specific study must submit a report to the State or primacy agency according to the schedule described in section IV.E. Systems that have completed their system specific study at the time of monitoring plan submission may submit a combined monitoring plan and report on the required schedule for IDSE plan submissions. The requirements for the IDSE report are listed in Table IV.F–5. Some of these reporting requirements have changed from the proposal to reduce reporting and paperwork burden on systems.

TABLE IV.F–5.—IDSE REPORT REQUIREMENTS

IDSE data collection alternative	IDSE report requirements
Standard Monitoring	• All subpart L compliance monitoring and standard monitoring TTHM and HAA5 analytical results in a tabular format acceptable to the State. • If changed from the monitoring plan, a schematic of the distribution system, population served, and system type. • An explanation of any deviations from the approved monitoring plan. • Recommendations and justifications for subpart V compliance monitoring locations and timing.
System Specific Study	• All subpart L compliance monitoring and all system specific study monitoring TTHM and HAA5 analytical results conducted during the period of the system specific study in a tabular or spreadsheet form acceptable to the State. • If changed from the study plan, a schematic of the distribution system, population served, and system type. • If using the modeling provision, include final information for required plan submissions and a 24-hour time series graph of residence time for each subpart V compliance monitoring location selected. • An explanation of any deviations from the original study plan. • All analytical and modeling results used to select subpart V compliance monitoring locations that show that the system specific study characterized TTHM and HAA5 levels throughout the entire distribution system. • Recommendations and justifications for subpart V compliance monitoring locations and timing.

All systems must prepare Stage 2 compliance monitoring recommendations. All IDSE reports must include recommendations for Stage 2 compliance monitoring locations and sampling schedule. Systems submitting a 40/30 certification must include their Stage 2 compliance monitoring recommendations in their Stage 2 (Subpart V) monitoring plan unless the State requests Subpart V site recommendations as part of the 40/30 certification. The number of sampling locations and the criteria for their selection are described in § 141.605 of today's final rule, and in section IV.G. Generally, a system must recommend locations with the highest LRAAs unless it provides a rationale (such as ensuring geographical coverage of the distribution system instead of clustering all sites in a particular section of the distribution system) for selecting other locations. In evaluating possible Stage 2 compliance monitoring locations, systems must consider both Stage 1 DBPR compliance data and IDSE data.

The State or primacy agency will approve the IDSE report or request modifications. If the State or primacy agency has not taken action by the date specified in section IV.E or has not notified the system that review is not yet complete, systems may consider their submission to be approved and prepare to begin Stage 2 compliance monitoring.

EPA has developed the Initial Distribution System Evaluation Guidance Manual for the Final Stage 2 Disinfectants and Disinfection Byproducts Rule (USEPA 2006) to assist systems with implementing each of these requirements. This guidance may be requested from EPA's Safe Drinking

Water Hotline, which may be contacted as described under **FOR FURTHER INFORMATION CONTACT** in the beginning of this notice. This guidance manual is also available on the EPA Web site at *http://www.epa.gov/safewater/stage2/index.html*.

2. Background and Analysis

In the Stage 2 DBPR proposal (USEPA, 2003a), EPA proposed requirements for systems to complete an IDSE. The Agency based its proposal upon the Stage 2 M–DBP Advisory Committee recommendations in the Agreement in Principle. The Advisory Committee believed and EPA concurs that maintaining Stage 1 DBPR monitoring sites for the Stage 2 DBPR would not accomplish the risk-targeting objective of minimizing high DBP levels and providing consistent and equitable protection across the distribution system. Most of these requirements have not changed from the proposed rule.

The data collection requirements of the IDSE are designed to find both high TTHM and high HAA5 sites (see section IV.G for IDSE monitoring requirements). High TTHM and HAA5 concentrations often occur at different locations in the distribution system. The Stage 1 DBPR monitoring sites identified as the maximum location are selected according to residence time. HAAs can degrade in the distribution system in the absence of sufficient disinfectant residual (Baribeau et al. 2000). Consequently, residence time is not an ideal criterion for identifying high HAA5 sites. In addition, maximum residence time locations that are associated with high TTHM levels may not be constant due to daily or seasonal changes in demand. The analysis of maximum residence time completed for the selection of Stage 1 monitoring sites may not have been capable of detecting these variations. The Information Collection Rule data show that over 60 percent of the highest HAA5 LRAAs and 50 percent of the highest TTHM LRAAs were found at sampling locations in the distribution system other than the maximum residence time compliance monitoring location (USEPA 2003a). Therefore, the method and assumptions used to select the Information Collection Rule monitoring sites and the Stage 1 DBPR compliance monitoring sites may not reliably capture high DBP levels for Stage 2 DBPR compliance monitoring sites.

a. Standard monitoring. The Advisory Committee recommended that systems sample throughout the distribution system at twice the number of locations as required under Stage 1 and, using these results in addition to Stage 1 compliance data, identify high DBP locations. Monitoring at additional sites increases the chance of finding sites with high DBP levels and targets both DBPs that degrade and DBPs that form as residence time increases in the distribution system. EPA believes that the required number of standard monitoring locations plus Stage 1 monitoring results will provide an adequate characterization of DBP levels throughout the distribution system at a reasonable cost. By revising Stage 2 compliance monitoring plans to target locations with high DBPs, systems will be required to take steps to address high DBP levels at locations that might otherwise have gone undetected.

The Advisory Committee recommended that an IDSE be performed by all community water systems, unless the system had sufficiently low DBP levels or is a very small system with a simple distribution system. EPA believes that large nontransient noncommunity water systems (NTNCWS) (those serving at least 10,000 people) also have distribution systems that require further evaluation to determine the locations most representative of high DBP levels and proposed that they be required to conduct an IDSE. Therefore, large NTNCWS and all community water systems are required to comply with IDSE requirements under today's final rule, unless they submit a 40/30 certification or they are covered by the very small system waiver provisions.

b. Very small system waivers. Systems serving fewer than 500 people that have taken samples under the Stage 1 DBPR will receive a very small system waiver. EPA proposed and the Advisory Committee recommended a very small system waiver following a State determination that the existing Stage 1 compliance monitoring location adequately characterizes both high TTHM and high HAA5 for the distribution system because many very small systems have small or simple distribution systems. The final rule grants the very small system waiver to all systems serving fewer than 500 that have Stage 1 DBPR data. This provision was changed from the proposal to reflect that most very small systems that sample under the Stage 1 DBPR have sampling locations that are representative of both high TTHM and high HAA5 because most very small systems have small and simple distribution systems. In addition, many very small systems are ground water systems that typically have stable DBP levels that tend to be lower than surface water DBP levels. NRWA survey data show that free chlorine residual in very small systems (serving <500) at both average residence time and maximum residence time locations are lower than levels at both of those locations in larger systems, and the change in residual concentration between those two locations is smaller in very small systems compared to larger sized systems. The magnitude of the reduction in residual concentration gives an indication of how much disinfectant has reacted to form DBPs, including TTHM and HAA5. The smaller reduction in disinfectant concentration between average residence time and maximum residence time in very small systems compared to larger systems indicates that DBP formation potential is probably lower in very small systems compared to larger systems, and the likelihood for significant DBP variation within the distribution system of very small systems is low if the distribution system is small and not complex. However, there may be some small systems with extended or complex distribution systems that should be studied further to determine new sampling locations. For this reason, States or primacy agencies can require any particular very small system to conduct an IDSE. Very small systems subject to the Stage 2 DBPR that do not have a Stage 1 compliance monitoring location may monitor in accordance with the Stage 1 DBPR provisions to be eligible for this waiver.

c. 40/30 certifications. Systems that certify to their State or primacy agency that all compliance samples taken during eight consecutive calendar quarters prior to the start of the IDSE were ≤0.040 mg/L TTHM and ≤0.030 mg/L HAA5 are not required to collect additional DBP monitoring data under the IDSE requirements as long as the system has no TTHM or HAA5 monitoring violations. These criteria were developed because both EPA and the AdvisoryCommittee determined that these systems most likely would not have DBP levels that exceed the MCLs. Systems must have qualifying TTHM and HAA5 data for eight consecutive calendar quarters according to the schedule in Table IV.F–2 to be eligible for this option. Systems on reduced monitoring that did not monitor during the specified time period may use data from the prior year to meet the 40/30 certification criteria. Systems that have not previously conducted Stage 1 DBPR compliance monitoring may begin such monitoring to collect the data necessary to qualify for 40/30 certification. The certification and data supporting it must be available to the public upon request.

The qualifying time period for the 40/30 certification has changed from the proposed rule.

Under the proposed rule, the rule language identified a specific two year window with start and end dates. In today's final rule, the qualifying time period has been changed to ''eight consecutive calendar quarters of subpart L compliance monitoring results beginning no earlier than * * *'' (see Table IV.F–2). This change was made so that systems that have made a treatment change within the two years prior to rule promulgation and have collected initial data that meet the 40/30 criteria might have the opportunity to collect eight consecutive quarters of qualifying data and apply for a 40/30 certification. This schedule change also allows systems that have not previously monitored under Stage 1 an opportunity to qualify for a 40/30 certification.

Under the proposed Stage 2 DBPR, systems that missed the deadline for submitting a 40/30 certification would be required to conduct either standard monitoring or a system specific study even if the system otherwise qualified for the 40/30 certification. Under today's final rule, systems that do not make any submission by the IDSE plan submission deadline will still receive a violation, but may submit a late 40/30 certification if their data meet the requirements. This change was made so that systems and primacy agencies do not spend time preparing and reviewing standard monitoring plans and IDSE reports for systems with a low likelihood of finding high TTHM and HAA5 levels.

The reporting requirements for this provision have been reduced from the requirements in the proposed rulemaking. In the proposal, systems qualifying for the 40/30 certification were required to submit all qualifying data and provide recommendations for Stage 2 compliance monitoring locations. The final rule requires systems to submit a certification that their data meet all the requirements of the 40/30 certification and to include their Stage 2 compliance monitoring recommendations in their Stage 2 monitoring plan. These changes were made to reduce the reporting burden on systems that qualify for the 40/30 certification and to maintain consistency with monitoring plan requirements under the Stage 1 DBPR. This approach also gives systems more time to select appropriate monitoring sites for Stage 2 compliance monitoring. The State or primacy agency may request systems to submit the data, a distribution system schematic, and/or recommendations for Stage 2 compliance monitoring as part of the 40/30 certification. This provision was included to facilitate primacy agency review of 40/30 certifications; the additional information is only required if requested by the primacy agency.

d. System specific studies. Advisory Committee members recognized that some systems have detailed knowledge of their distribution systems by way of ongoing hydraulic modeling and/or existing widespread monitoring plans (beyond that required for compliance monitoring) that would provide equivalent or superior monitoring site selection information compared to standard monitoring. Therefore, the Advisory Committee recommended that such systems be allowed to determine new monitoring sites using system-specific data such as hydraulic model results or existing monitoring data; this provision remains in the final rule. In the proposed rule, the only specification for SSSs was to identify monitoring sites that would be equivalent or superior to those identified under Standard Monitoring. The final rule includes more specific requirements on how these studies should be completed. The requirements in the final rule were developed to be consistent with the proposal, yet more specific to help systems better understand expectations under this provision and lessen the chances of a study plan not being approved.

The new modeling requirements were developed to reflect that hydraulic models can identify representative high TTHM monitoring locations by predicting hydraulic residence time in the distribution system. Water age has been found to correlate with TTHM formation in the distribution system. Consequently, for this system specific study approach, hydraulic residence time predicted by the model is used as a surrogate for TTHM formation to locate appropriate Stage 2 compliance monitoring locations. To predict hydraulic residence time in the distribution system, the model must represent most of the distribution system and must have been calibrated recently and appropriately to reflect water age in the distribution system. Requirements to reflect this are in today's rule. All storage facilities must be evaluated for the calibration, and systems using this option must submit a graph of predicted tank levels versus measured tank levels for the storage facility with the highest residence time in each pressure zone. These calibration requirements are focused on storage facilities because they are the largest controlling factor for water age in the distribution system. The calibration requirements reflect the fact that the purpose of the model is to predict water age. ICR data show that HAA5 data do not necessarily correlate well with water age (USEPA 2003a). Because the purpose of the IDSE is to locate representative high locations for both TTHM and HAA5, one round of monitoring must be completed at potential Stage 2 compliance monitoring locations to determine appropriate HAA5 monitoring locations during the historical high month of TTHM concentrations. The number of locations must be no less than would be required under standard monitoring.

Preliminary average residence time data are required as a part of the study plan for systems to demonstrate that their distribution system hydraulic model is able to produce results for water age throughout the distribution system, even though calibration may not be complete. Systems also need to describe their plans to complete the modeling requirements within 12 months of submitting the study plan. These last two requirements were developed so that States can be assured that systems have the technical capacity to complete their modeling requirements by the IDSE report deadline. If systems cannot demonstrate that they are in a position to complete the modeling requirements according to the required schedule, they will be required to complete standard monitoring.

All new modeling requirements were added to help systems demonstrate how their model will fulfill the purpose and requirements of the IDSE and to assist primacy agencies with approval determinations. The associated reporting requirements were developed to balance the needs of systems to demonstrate that they have fulfilled the requirements and the needs of primacy agency reviewers to be able to understand the work completed by the system.

EPA has specified new requirements for systems complete an SSS using existing monitoring data to help systems understand the extent of historical data that would meet the requirements of the IDSE. The number of required sample locations and samples are consistent with sampling requirements under standard monitoring and the recommendations made by the Advisory Committee. The Advisory Committee recommended that systems complete an IDSE sample at twice the number of sites required by the Stage 1 DBPR in addition to Stage 1 DBPR sampling. Because the number of required Stage 1 DBPR monitoring locations varies within each population category under

the Stage 1 plant-based monitoring approach (since systems have different numbers of plants), EPA used the number of required Standard Monitoring locations plus the number of Stage 2 compliance monitoring locations to develop minimum requirements for the use of existing monitoring data for the SSS. The number of required locations and samples are shown in Table IV.F–4. Systems will use their Stage 1 monitoring results plus additional non-compliance or operational samples to fulfill these requirements. Small systems with many plants may have been collecting a disproportionate number of samples under the Stage 1 DBPR compared to the population based monitoring requirements presented in today's rule and may have sufficient historical data to characterize the entire distribution system. These requirements allow those systems to submit an SSS based on existing Stage 1 monitoring results, and they also accommodate systems that have been completing additional monitoring throughout the distribution system.

The requirement to sample during the historical month of high TTHM, high HAA5, or warmest water temperature during each year for which data were collected was added to maintain consistency with the standard monitoring requirements where each location must be sampled one time during the peak historical month. Samples that qualify for this SSS must have been collected within five years of the study plan submission date and must reflect the current configuration of treatment and the distribution system. Five years was selected as a cut off for eligible data so that all data submitted would be reasonably representative of current source water conditions and DBP formation within the distribution system. Data that are older may not reflect current DBP formation potential in the distribution system. Five years prior to the submission of the study plan also correlates with the signing of the Agreement in Principle where the Advisory Committee made the recommendation for this provision. Systems interested in using this provision would have started eligible monitoring after the agreement was signed.

Systems that submit existing monitoring data must submit all Stage 1 sample results from the beginning of the SSS to the time when the SSS plan is submitted. The purpose of this requirement is to demonstrate that there have been no significant changes in source water quality since the first samples were collected, especially if all existing monitoring results were taken during the earliest eligible dates. Again, these clarifications were made so that systems could better understand the extent of data necessary for a monitoring plan to be deemed acceptable and be confident that efforts to complete an SSS would be found acceptable to the State or primacy agency.

e. Distribution System Schematics. EPA has considered security concerns that may result from the requirement for systems to submit a distribution system schematic as part of their IDSE plan. EPA believes that the final rule strikes an appropriate balance between security concerns and the need for States and primacy agencies to be able to review IDSE plans. EPA has developed guidance for systems on how to submit a distribution system schematic that does not include sensitive information.

3. Summary of Major Comments

The Agency received significant comments on the following issues related to the proposed IDSE requirements: Waiver limitations, and State or primacy agency review of IDSE plans.

In the proposed rule, EPA requested comment on what the appropriate criteria should be for States or primacy agencies to grant very small system waivers. Commenters responded with a wide range of suggestions including support for the proposal as written, different population cut-offs, State or primacy agency discretion on what system size should qualify for the waiver, and alternative waiver criteria such as pipe length or number of booster stations. There was no consensus among the commenters on what changes should be made to the proposal for the very small system waiver requirements. EPA did not change the population cutoff for the very small system waiver because analysis of NRWA survey data also showed that systems serving fewer than 500 had different residence times and lower free chlorine residual concentrations compared to other population categories, indicating that larger systems have different DBP formation characteristics compared to very small systems. Some of the suggested changes for very small system waiver criteria may require data that are not readily available to systems (such as pipe length in service) and for which there were no specific criteria proposed or recommended by the commenters. Implementation of subjective very small system waiver criteria would result in reduced public health protection from the rule by allowing higher DBP levels to go undetected.

In addition to addressing the very small system waivers, commenters suggested that different criteria should be used for the 40/30 certification, such as higher minimum DBP levels, cut-offs of 40/30 as LRAAs or RAAs rather than single sample maximums, or State or primacy agency discretion on which systems should qualify for 40/30 certification. There was no consensus among the commenters on what changes should be made to the proposal for the 40/30 certification requirements. EPA did not change the requirements for the 40/30 certification eligibility because the recommended alternatives were not technically superior to the requirements of the proposed rule. Implementation of 40/30 criteria using an LRAA or RAA would result in reduced public health protection from the rule by allowing higher DBP levels to go undetected. EPA did change the eligibility dates and reporting requirements for the 40/30 certification to reduce the burden on the system. Under today's final rule, States or primacy agencies can request TTHM and HAA5 data as desired for a more in-depth review of a system's qualifications.

Many commenters expressed concern over the implementation schedule for the IDSE. Commenters were especially concerned that IDSE plans would be developed and implemented prior to State primacy, and once States receive primacy, they might not support the IDSE plan and would reject the results of the completed IDSE. To address this issue, commenters requested the opportunity for States to review the IDSE plans prior to systems completing their IDSEs. In today's rule EPA has modified the compliance schedule for the Stage 2 DBPR so that systems have the opportunity to complete their IDSE plan and have it reviewed by the primacy agency prior to completing the IDSE to address the concern that States or primacy agencies may reject the results of the completed IDSE. The changes to the compliance schedule are discussed further in section IV.E.

G. Monitoring Requirements and Compliance Determination for TTHM and HAA5 MCLs

EPA is finalizing monitoring requirements under a population-based approach described in this section. EPA believes the population-based approach will provide more representative high DBP concentrations throughout distribution systems than would plant-based monitoring, is equitable, and will simplify implementation for both States and systems. For these reasons, EPA believes this approach is more appropriate than the proposed plant-

based monitoring. Detailed discussion of the two approaches is presented in the preamble of the proposed rule (USEPA 2003a) and EA for today's rule (USEPA 2005a).

1. Today's Rule

Today's rule establishes TTHM and HAA5 monitoring requirements for all systems based on a population-based monitoring approach instead of a plant-based approach. Under the population-based approach, monitoring requirements are based solely on the retail population served and the type of source water used and not influenced by the number of treatment plants or entry points in the distribution system as in previous rules (i.e., TTHM Rule (USEPA 1979) and Stage 1 DBPR (USEPA 1998a)).

a. IDSE Monitoring. All systems conducting IDSE standard monitoring must collect samples during the peak historical month for DBP levels or water temperature; this will determine their monitoring schedule. Table IV.G–1 contains the IDSE monitoring frequencies and locations for all source water and size category systems. Section IV.F identifies other approaches by which systems can meet IDSE requirements.

TABLE IV.G–1.—IDSE MONITORING FREQUENCIES AND LOCATIONS

Source water type	Population size category	Monitoring periods and frequency of sampling	Distribution system monitoring locations [1]				
			Total per monitoring period	Near entry points	Average residence time	High TTHM locations	High HAA5 locations
Subpart H	<500 consecutive systems.	one (during peak historical month) [2].	2	1	.....	1	
	<500 non-consecutive systems.	.....	2	.....	.....	1	1
	500–3,300 non-consecutive systems.	four (every 90 days)	2	1	.....	1	.....
	500–3,300 consecutive systems.	.....	2	.....	.....	1	1
	3,301–9,999	.....	4	.....	1	2	1
	10,000–49,999	six (every 60 days)	8	1	2	3	2
	50,000–249,999	.....	16	3	4	5	4
	250,000–999,999	.....	24	4	6	8	6
	1,000,000–4,999,999	.....	32	6	8	10	8
	≥5,000,000	.....	40	8	10	12	10
Ground Water	<500 consecutive systems.	one (during peak historical month) [2].	2	1	.....	1	.....
	<500 non-consecutive systems.	.....	2	.....	.....	1	1
	500–9,999	four (every 90 days)	2	.....	.....	1	1
	10,000–99,999	.....	6	1	1	2	2
	100,000–499,999	.....	8	1	1	3	3
	≥500,000	.....	12	2	2	4	4

[1] A dual sample set (i.e., a TTHM and an HAA5 sample) must be taken at each monitoring location during each monitoring period.
[2] The peak historical month is the month with the highest TTHM or HAA5 levels or the warmest water temperature.

b. Routine Stage 2 Compliance Monitoring. For all systems conducting either standard monitoring or a system specific study, initial Stage 2 compliance monitoring locations are based on the system's IDSE results, together with an analysis of a system's Stage 1 DBPR compliance monitoring results. Systems receiving 40/30 certification or a very small system waiver, and nontransient noncommunity water systems serving <10,000 not required to conduct an IDSE, base Stage 2 initial compliance monitoring locations on the system's Stage 1 DBPR compliance monitoring results. Some of these systems may also need an evaluation of distribution system characteristics to identify additional monitoring locations, if required by the transition from plant-based monitoring to population-based monitoring.

Systems recommend Stage 2 monitoring locations generally by arraying results of IDSE standard monitoring (or system specific study results) and Stage 1 compliance monitoring by monitoring location (from highest to lowest LRAA for both TTHM and HAA5). Using the protocol in § 141.605(c) of today's rule, systems then select the required number of locations. Larger systems include existing Stage 1 monitoring locations in order to be able to have historical continuity for evaluating how changes in operations or treatment affect DBP levels. Systems may also recommend locations with lower levels of DBPs that would not be picked up by the protocol if they provide a rationale for the recommendation. Examples of rationales include ensuring better distribution system or population coverage (not having all locations in the same area) or maintaining existing locations with DBP levels that are nearly as high as those that would otherwise be selected. The State or primacy agency will review these recommendations as part of the review of the IDSE report submitted by systems that conducted standard monitoring or a system specific study.

Table IV.G–2 contains the routine Stage 2 TTHM and HAA5 compliance

monitoring requirements for all systems (both non-consecutive and consecutive systems), as well as the protocol for Stage 2 compliance monitoring location selection in the IDSE report. Systems that do not have to submit an IDSE report (those receiving a 40/30 certification or very small system waiver and nontransient noncommunity water systems serving <10,000) must conduct Stage 2 compliance monitoring as indicated in the ''Total per monitoring period'' column at current Stage 1 compliance monitoring locations, unless the State or primacy agency specifically directs otherwise. All systems are then required to maintain and follow a Stage 2 compliance monitoring plan.

TABLE IV.G–2. ROUTINE COMPLIANCE MONITORING FREQUENCIES AND LOCATIONS

Source water type	Population size category	Monitoring frequency[1]	Distribution system monitoring location			
			Total per monitoring period[2]	Highest TTHM locations	Highest HAA5 locations	Existing Subpart L compliance locations
Subpart H:						
	<500	per year	2	1	1	.....
	500–3,300	per quarter	2	1	1	.....
	3,301–9,999	per quarter	2	1	1	.....
	10,000–49,999	per quarter	4	2	1	1
	50,000–249,999	per quarter	8	3	3	2
	250,000–999,999	per quarter	12	5	4	3
	1,000,000–4,999,999	per quarter	16	6	6	4
	≥ 5,000,000	per quarter	20	8	7	5
Ground water:						
	<500	per year	2	1	1	.....
	500–9,999	per year	2	1	1	.....
	10,000–99,999	per quarter	4	2	1	1
	100,000–499,999	per quarter	6	3	2	1
	≥ 500,000	per quarter	8	3	3	2

[1] All systems must monitor during month of highest DBP concentrations.
[2] Systems on quarterly monitoring must take dual sample sets every 90 days at each monitoring location, except for subpart H systems serving 500–3,300. Systems on annual monitoring and subpart H systems serving 500–3,300 are required to take individual TTHM and HAA5 samples (instead of a dual sample set) at the locations with the highest TTHM and HAA5 concentrations, respectively. Only one location with a dual sample set per monitoring period is needed if highest TTHM and HAA5 concentrations occur at the same location, and month, if monitored annually).

Today's rule provides States the flexibility to specify alternative Stage 2 compliance monitoring requirements (but not alternative IDSE monitoring requirements) for multiple consecutive systems in a combined distribution system. As a minimum under such an approach, each consecutive system must collect at least one sample among the total number of samples required for the combined distribution system and will base compliance on samples collected within its distribution system. The consecutive system is responsible for ensuring that required monitoring is completed and the system is in compliance. It also must document its monitoring strategy as part of its subpart V monitoring plan.

Consecutive systems not already conducting disinfectant residual monitoring under the Stage 1 DBPR must comply with the monitoring requirements and MRDLs for chlorine and chloramines. States may use the provisions of § 141.134(c) to modify reporting requirements. For example, the State may require that only the consecutive system distribution system point-of-entry disinfectant concentration be reported to demonstrate MRDL compliance, although monitoring requirements may not be reduced.

i. Reduced monitoring. Systems can qualify for reduced monitoring, as specified in Table IV.G–3, if the LRAA at each location is ≤0.040 mg/L for TTHM and ≤0.030 mg/L for HAA5 based on at least one year of monitoring at routine compliance monitoring locations. Systems may remain on reduced monitoring as long as the TTHM LRAA is ≤0.040 mg/L and the HAA5 LRAA is ≤0.030 mg/L at each monitoring location for systems with quarterly reduced monitoring. If the LRAA at any location exceeds either 0.040 mg/L for TTHM or 0.030 mg/L for HAA5 or if the source water annual average TOC level, before any treatment, exceeds 4.0 mg/L at any of the system's treatment plants treating surface water or ground water under the direct influence of surface water, the system must resume routine monitoring. For systems with annual or less frequent reduced monitoring, systems may remain on reduced monitoring as long as each TTHM sample is ≤0.060 mg/L and each HAA5 sample is ≤0.045 mg/L. If the annual (or less frequent) sample at any location exceeds either 0.060 mg/L for TTHM or 0.045 mg/L for HAA5, or if the source water annual average TOC level, before any treatment, exceeds 4.0 mg/L at any treatment plant treating surface water or ground water under the direct influence of surface water, the system must resume routine monitoring.

TABLE IV.G–3.—REDUCED MONITORING FREQUENCY

Source water type	Population size category	Monitoring frequency[1]	Distribution system monitoring location per monitoring period
Subpart H:			
	<500	.....	Monitoring may not be reduced.

TABLE IV.G–3.—REDUCED MONITORING FREQUENCY—Continued

Source water type	Population size category	Monitoring frequency [1]	Distribution system monitoring location per monitoring period
	500–3,300	per year	1 TTHM and 1 HAA5 sample: one at the location and during the quarter with the highest TTHM single measurement, one at the location and during the quarter with the highest HAA5 single measurement; 1 dual sample set per year if the highest TTHM and HAA5 measurements occurred at the same location and quarter.
	3,301–9,999	per year	2 dual sample sets: one at the location and during the quarter with the highest TTHM single measurement, one at the location and during the quarter with the highest HAA5 single measurement.
	10,000–49,999	per quarter	2 dual sample sets at the locations with the highest TTHM and highest HAA5 LRAAs.
	50,000–249,999	per quarter	4 dual sample sets—at the locations with the two highest TTHM and two highest HAA5 LRAAs.
	250,000–999,999	per quarter	6 dual sample sets—at the locations with the three highest TTHM and three highest HAA5 LRAAs
	1,000,000–4,999,999.	per quarter	8 dual sample sets—at the locations with the four highest TTHM and four highest HAA5 LRAAs.
	≥5,000,000	per quarter	10 dual sample sets—at the locations with the five highest TTHM and five highest HAA5 LRAAs.
Ground Water:			
	<500	every third year	1 TTHM and 1 HAA5 sample: one at the location and during the quarter with the highest TTHM single measurement, one at the location and during the quarter with the highest HAA5 single measurement; 1 dual sample set per year if the highest TTHM and HAA5 measurements occurred at the same location and quarter.
	500–9,999	per year	1 TTHM and 1 HAA5 sample: one at the location and during the quarter with the highest TTHM single measurement, one at the location and during the quarter with the highest HAA5 single measurement; 1 dual sample set per year if the highest TTHM and HAA5 measurements occurred at the same location and quarter.
	10,000–99,999	per year	2 dual sample sets: one at the location and during the quarter with the highest TTHM single measurement, one at the location and during the quarter with the highest HAA5 single measurement.
	100,000–499,999	per quarter	2 dual sample sets; at the locations with the highest TTHM and highest HAA5 LRAAs.
	≥500,000	per quarter	4 dual sample sets at the locations with the two highest TTHM and two highest HAA5 LRAAs.

[1] Systems on quarterly monitoring must take dual sample sets every 90 days.

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

Monitoring and MCL violations are assigned to the PWS where the violation occurred. Several examples are as follows:

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

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

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

2. Background and Analysis

EPA proposed the plant-based approach for all systems that produce some or all of their finished water and the population-based monitoring approach for systems purchasing all of their finished water year-round. As part of the proposal, EPA presented a monitoring cost analysis for applying this approach to all systems in the Economic Analysis to better understand the impacts of using the population-based approach.

The plant-based approach was adopted from the 1979 TTHM rule and the Stage 1 DBPR and was derived from the generally valid assumption that, as systems increase in size, they tend to have more plants and increased complexity. During the development of the Stage 2 proposal, EPA identified a number of issues associated with the use of the plant-based monitoring approach. These included: (1) Plant-based monitoring is not as effective as population-based monitoring in targeting locations with the highest risk; (2) a plant-based approach can result in disproportionate monitoring requirements for systems serving the same number of people (due to widely varying numbers of plants per system); (3) it cannot be adequately applied to plants or consecutive system entry points that are operated seasonally or intermittently if an LRAA is used for compliance due to complex implementation and a need for repeated transactions between the State and

system to determine whether and how compliance monitoring requirements may need to be changed; (4) State determinations of monitoring requirements for consecutive systems would be complicated, especially in large combined distribution systems with many connections between systems; and (5) systems with multiple disinfecting wells would have to conduct evaluation of common aquifers in order to avoid taking unnecessary samples for compliance (if they did not conduct such evaluations under Stage 1). EPA requested comment on two approaches to address these issues: (1) keep the plant-based monitoring approach and add new provisions to address specific concerns; and (2) base monitoring requirements on source water type and population served, in lieu of plant-based monitoring.

The final rule's requirements of population-based monitoring for all systems are based on improved public health protection, flexibility, and simplified implementation. For determining monitoring requirements, EPA's objective was to maintain monitoring loads consistent with Stage 1 and similar to monitoring loads proposed for Stage 2 under a plant-based approach, using a population-based approach to facilitate implementation, better target high DBP levels, and protect human health. This leads to a more cost-effective characterization of where high levels occur. For the proposed rule, EPA used 1995 CWSS data to derive the number of plants per system for calculating the number of proposed monitoring sites per system. During the comment period, 2000 CWSS data became available. Compared to the 1995 CWSS, the 2000 CWSS contained questions more relevant for determining the number of plants in each system. Based on 2000 CWSS data, EPA has modified the number of monitoring sites per system for several categories (particularly for the larger subpart H systems) to align the median population-based monitoring requirements with the median monitoring requirements under plant-based monitoring, as was proposed.

EPA also believes that more samples are necessary to characterize larger systems (as defined by population) than for smaller systems. This progressive approach is included in Table IV.G–4. As system size increases, the number of samples increases to better reflect the hydraulic complexity of these systems. While the national monitoring burden under the population-based approach is slightly less than under a plant-based approach, some larger systems with few plants relative to system population will take more samples per system than they had under plant-based monitoring. However, EPA believes that many of these large systems with few plants have traditionally been undermonitored (as noted in the proposal). Systems with more plants will see a reduction in monitoring (e.g., small ground water systems with multiple wells).

While population-based monitoring requirements for ground water systems in today's rule remain the same as those in the proposed rule, the final rule consolidates ten population categories for subpart H systems into eight categories for ease of implementation. As indicated in Table IV.G–4, EPA has gone from four to three population size categories for smaller subpart H systems (serving fewer than 10,000 people) and the ranges have been modified to be consistent with those for other existing rules (such as the Lead and Copper Rule). This change will reduce implementation transactional costs. For medium and large subpart H systems (serving at least 10,000 people), EPA has gone from seven categories in the proposal to five categories in final rule. The population groups are sized so that the ratio of maximum population to minimum population for each of the categories is consistent. EPA believes that this will allow most systems to remain in one population size category and maintain the same monitoring requirements within a reasonable range of population variation over time. In addition, it assures that systems within a size category will not have disparate monitoring burdens as could occur if there were too few categories. Overall, EPA believes that the population-based monitoring approach allows systems to have more flexibility to designate their monitoring sites within the distribution system to better target high DBP levels and is more equitable.

To derive the number of monitoring sites for IDSE standard monitoring, EPA doubled the number of routine compliance monitoring sites per system for each size category. This is consistent with the advice and recommendations of the M-DBP Advisory Committee for the IDSE. EPA has developed the Initial Distribution System Evaluation Guidance Manual for the Final Stage 2 Disinfectants and Disinfection Byproducts Rule (USEPA 2006) to assist systems in choosing IDSE monitoring locations, including criteria for selecting monitoring.

TABLE IV.G–4.—COMPARISON OF MONITORING LOCATIONS PER SYSTEM FOR STAGE 2 ROUTINE COMPLIANCE MONITORING WITH PLANT-BASED AND POPULATION-BASED APPROACHES

Population category	Ratio of maximum population to minimum population	Number of sampling periods per year	Plant-based approach*	Number of plants per system (Based on 2000 CWSS data)		Calculated number of sites per system for plant-based approach		Number of monitoring sites per system for pop-based approach
			# Sites per plant	Median	Mean	Based on median # plants per system	Based on mean # plants per system	
		A	B	C	D	E=B*C	F=B*D	G
<500	.....	1	**1	1	1.21	1	1.2	**1
500–3,300	6.6	4	**1	1	1.22	1	1.2	**1
3,301–9,999	3	4	2	1	1.56	2	3.1	2
10,000–49,999	5	4	4	1	1.37	4	5.5	4
50,000–249,999	5	4	4	1	1.83	4	7.3	8
250,000–<1 million	4	4	4	2	2.53	8	10.1	12
1 million–<5 million	5	4	4	4	3.62	16	14.5	16
≥5 million	.....	4	4	4	4.33	16	17.3	20

* As in the proposal.

** System is required to take individual TTHM and HAA5 samples at the locations with the highest TTHM and HAA5 concentrations, respectively, if highest TTHM and HAA5 concentrations do not occur at the same location.

Note: To determine the number of routine compliance monitoring sites per population category, EPA took these steps: (1) Maintaining about the same sampling loads in the nation as required under the plant-based approach, but basing on population rather than number of plants to better target high DBP levels in distribution systems and facilitate implementation; (2) The number of monitoring sites per plant under the plant-based approach (Column B) were multiplied by the number of plants per system (Columns C and D) to calculate the number of monitoring sites per system under the plant-based approach (Columns E and F in terms of median and mean, respectively); and (3) The number of monitoring sites per system under the population-based approach were derived with adjustments to keep categories consistent and to maintain an even incremental trend as the population size category increases (Column G).

3. Summary of Major Comments

EPA received significant support for applying the population-based approach to all systems. EPA also received comments concerning the specific requirements in a population-based approach.

Excessive Sampling Requirements. Several commenters believed that the proposed sampling requirements were excessive (especially in the larger population categories for subpart H systems) and that some individual systems would be required to sample more under the population-based approach than the plant-based approach. EPA recognizes that a small fraction of systems in some categories will have to take more samples under the population-based approach than the plant-based approach because their number of plants is substantially less than the national median or mean. However, the number of samples required under the Stage 1 DBPR for these systems may not have been sufficient to determine the concentrations of DBPs throughout the distribution system of these systems. On the other hand, systems with many plants may have taken excessive samples under the Stage 1 DBPR that were not necessary to appropriately determine DBP levels throughout the distribution system. Consequently, the total number of samples taken nationally will be comparable to the Stage 1 DBPR, but will better target DBP risks in individual distribution systems.

Consecutive systems. Some commenters noted that a consecutive system may need to take more samples than its associated wholesale system. Under today's rule, all systems, including consecutive systems, must monitor based on retail population served. Thus, large consecutive systems will take more samples than a smaller wholesale system. The population-based monitoring approach will allow the samples to better represent the DBP concentrations consumed by the population associated with the sampling locations and to understand the DBP concentrations reaching consumers. There is also a provision that allows States to specify alternative monitoring requirements for a consecutive system in a combined distribution system (40 CFR 142.16(m)(3)). This special primacy condition allows the State to establish monitoring requirements that account for complicated distribution system relationships, such as where neighboring systems buy from and sell to each other regularly throughout the year. In this case, water may pass through multiple consecutive systems before it reaches a user. Another example would be a large group of interconnected systems that have a complicated combined distribution system. This approach also allows the combined distribution system to concentrate IDSE and Stage 2 monitoring sites in the system with the highest known DBP concentrations, while assigning fewer sample sites to systems with low DBP concentrations.

Population Size Categories. Some commenters recommended fewer population categories for subpart H systems (those using surface water or ground water under the direct influence of surface water as a source) than proposed while others recommended more. Today's rule has fewer categories than proposed. However, EPA believes that further reduction of the number of population size categories will not reflect the fact that the number of plants and complexity of distribution systems (and DBP exposure) tend to increase as the population served increases. As a result, the population served by a large system in one particular category would receive much less protection from the DBP risks than a smaller system in the same size category. On the other hand, too many categories with smaller population ranges would result in frequent category and requirement shifts as population fluctuates. Much greater implementation effort would be needed for those systems without much benefit in DBP exposure knowledge.

Population Definition. Some commenters supported use of the population of a combined distribution system (i.e., the wholesale and consecutive systems should be considered a single system for monitoring purposes) while others preferred use of the retail population for each individual system (i.e., wholesale systems and consecutive systems are considered separately). Today's final rule uses the retail population for each individual system. EPA chose this approach for today's rule because of the complexity involved in making implementation decisions for consecutive systems. Using the retail population to determine requirements eases the complexity by specifying minimum system-level requirements; simplicity is essential for meeting the implementation schedule in today's rule. If monitoring requirements were determined by the combined distribution system population, many implementation problems would occur. Some of these problems would have the potential to impact public health protection. For example, States or primacy agencies would have to decide how to allocate IDSE distribution system samples (where and how much to monitor in individual PWSs) in a complicated combined distribution system with many systems, multiple sources, multiple treatment plants, and varying water demand and with limited understanding of DBP levels throughout the combined distribution system. This would have to happen shortly after rule promulgation in order to meet the schedule. For example, some consecutive systems buy water seasonally (in times of high water demand) or buy from more than one wholesale system (with the volume purchased based on many factors). The State or primacy agency would find it difficult to properly assign a limited number of IDSE monitoring locations (especially since there are States where many consecutive systems have no DBP data) to adequately reflect DBP levels in such a system, as well as throughout the combined distribution system.

EPA believes that assigning compliance monitoring requirements appropriately throughout the combined distribution system requires a case-by-case determination based on factors such as amount and percentage of finished water provided; whether finished water is provided seasonally, intermittently, or full-time; and improved DBP occurrence information. Since the IDSE will provide improved DBP occurrence information throughout the combined distribution system, States may consider modifications to Stage 2 compliance monitoring requirements for consecutive systems on a case-by-case basis as allowed by § 141.29 or under the special primacy condition at § 142.16(m)(3) by taking all these factors into consideration. In making these case-by-case determinations, the State will be able to use its system-specific knowledge, along with the IDSE results, to develop an appropriate monitoring plan for each

system within the combined distribution system.

Changes to monitoring plans. Commenters requested more specific language regarding how IDSE and Stage 2 monitoring plans should be updated as a result of treatment or population changes in the distribution system. Changes to IDSE plans should not be necessary since the State or primacy agency will have reviewed those plans shortly before the system must conduct the IDSE and the reviewed plan should identify such issues. EPA provided a process in the Stage 2 DBPR proposal for updating monitoring plans for systems that have significant changes to treatment or in the distribution system after they complete their IDSE. This process remains in today's rule, with an added requirement that systems must consult with the State or primacy agency to determine whether the changes are necessary and appropriate prior to implementing changes to their Stage 2 monitoring plan.

In addition, the State or primacy agency may require a system to revise its IDSE plan, IDSE report, or Stage 2 monitoring plan at any time. This change was made so that systems could receive system-specific guidance from the State or primacy agency on the appropriate revisions to the Stage 2 monitoring plan. Regulatory language regarding changes that might occur is not appropriate because any modifications would be system-specific and a national requirement is not capable of addressing these system-specific issues.

H. Operational Evaluation Requirements Initiated by TTHM and HAA5 Levels

A system that is in full compliance with the Stage 2 DBPR LRAA MCL may still have individual DBP measurements that exceed the Stage 2 DBPR MCLs, since compliance is based on individual DBP measurements at a location averaged over a four-quarter period. EPA and the Advisory Committee were concerned about these higher levels of DBPs. This concern was clearly reflected in the Agreement in Principle, which states, ''. . . significant excursions of DBP levels will sometimes occur, even when systems are in full compliance with the enforceable MCL. . .''.

Today's final rule addresses this concern by requiring systems to conduct operational evaluations that are initiated by operational evaluation levels identified in Stage 2 DBPR compliance monitoring and to submit an operational evaluation report to the State.

1. Today's Rule

Today's rule defines the Stage 2 DBP operational evaluation levels that require systems to conduct operational evaluations. The Stage 2 DBP operational evaluation levels are identified using the system's Stage 2 DBPR compliance monitoring results. The operational evaluation levels for each monitoring location are determined by the sum of the two previous quarters' TTHM results plus twice the current quarter's TTHM result, at that location, divided by 4 to determine an average and the sum of the two previous quarters' HAA5 results plus twice the current quarter's HAA5 result, at that location, divided by 4 to determine an average. If the average TTHM exceeds 0.080 mg/L at any monitoring location or the average HAA5 exceeds 0.060 mg/L at any monitoring location, the system must conduct an operational evaluation and submit a written report of the operational evaluation to the State.

Operational evaluation levels (calculated at each monitoring location)

IF $(Q_1 + Q_2 + 2Q_3)/4 >$ MCL, then the system must conduct an operational evaluation

where:

Q_3 = current quarter measurement
Q_2 = previoius quarter measurement
Q_1 = quarter before previous quarter measurement

MCL = Stage 2 MCL for TTHM (0.080 mg/l) *or* Stage 2 MCL for HAA5 (0.060 mg/L)

The operational evaluation includes an examination of system treatment and distribution operational practices, including changes in sources or source water quality, storage tank operations, and excess storage capacity, that may contribute to high TTHM and HAA5 formation. Systems must also identify what steps could be considered to minimize future operational evaluation level exceedences. In cases where the system can identify the cause of DBP levels that resulted in the operational evaluation, based on factors such as water quality data, plant performance data, and distribution system configuration the system may request and the State may allow limiting the evaluation to the identified cause. The State must issue a written determination approving limiting the scope of the operational evaluation. The system must submit their operational evaluation report to the State for review within 90 days after being notified of the analytical result that initiates the operational evaluation. Requesting approval to limit the scope of the operational evaluation does not extend the schedule (90 days after notification of the analytical result) for submitting the operational evaluation report.

2. Background and Analysis

The Stage 2 DBPR proposal outlined three components of the requirements for significant excursions (definition, system evaluation and excursion report). In response to public comments, the term ''significant excursion'' has been replaced by the term ''operational evaluation level'' in today's rule. The evaluation and report components remain the same as those outlined in the proposed rule for significant excursions. However, the scope of the evaluation and report components of the operational evaluation has also been modified from the proposed significant excursion evaluation components based on public comments.

In the Stage 2 DBPR proposal, States were to define criteria to identify significant excursions rather than using criteria defined by EPA. Concurrent with the Stage 2 DBPR proposal, EPA issued draft guidance (USEPA 2003e) for systems and States that described how to determine whether a significant excursion has occurred, using several different options. The rule proposal specifically requested public comment on the definition of a significant excursion, whether it should be defined by the State or nationally, and the scope of the evaluation.

After reviewing comments on the Stage 2 DBPR proposal, EPA determined that DBP levels initiating an operational evaluation should be defined in the regulation to ensure national consistency. Systems were concerned with the evaluation requirements being initiated based on criteria that might not be consistent nationally. Also, many States believed the requirement for States to define criteria to initiate an evaluation would be difficult for States to implement.

Under today's rule, EPA is defining operational evaluation levels with an algorithm based on Stage 2 DBPR compliance monitoring results. These operational evaluation levels will act as an early warning for a possible MCL violation in the following quarter. This early warning is accomplished because the operational evaluation requirement is initiated when the system assumes that the current quarter's result is repeated and this will result in an MCL violation. This early identification allows the system to act to prevent the violation.

Today's rule also modifies the scope of an operational evaluation. EPA has concluded that the source of DBP levels

that would initiate an operational evaluation can potentially be linked to a number of factors that extend beyond distribution system operations. Therefore, EPA believes that evaluations must include a consideration of treatment plant and other system operations rather than limiting the operational evaluation to only the distribution system, as proposed. Because the source of the problem could be associated with operations in any of these system components (or more than one), an evaluation that provides systems with valuable information to evaluate possible modifications to current operational practices (e.g. water age management, source blending) or in planning system modifications or improvements (e.g. disinfection practices, tank modifications, distribution looping) will reduce DBP levels initiating an operational evaluation. EPA also believes that State review of operational evaluation reports is valuable for both States and systems in their interactions, particularly when systems may be in discussions with or requesting approvals from the State for system improvements. Timely reviews of operational evaluation reports will be valuable for States in reviewing other compliance submittals and will be particularly valuable in reviewing and approving any proposed source, treatment or distribution system modifications for a water system. Under today's rule, systems must submit a written report of the operational evaluation to the State no later than 90 days after being notified of the DBP analytical result initiating an operational evaluation. The written operational evaluation report must also be made available to the public upon request.

3. Summary of Major Comments

EPA received comments both in favor of and opposed to the proposed evaluation requirements. While some commenters felt that the evaluation requirements should not be a part of the Stage 2 DBPR until there was more information regarding potential health effects correlated to specific DBP levels, other commenters felt that the existing health effects data were sufficient to warrant strengthening the proposed requirements for an evaluation. Today's final rule requirements are consistent with the Agreement in Principle recommendations.

Some commenters noted that health effects research on DBPs is insufficient to identify a level at which health effects occur and were concerned that the proposed significant excursion requirements placed an emphasis on DBP levels that might not be warranted rather than on system operational issues and compliance with Stage 2 DBPR MCLs.

Basis. The proposed requirements for significant excursion evaluations were not based upon health effects, but rather were intended to be an indicator of operational performance. To address commenter's concerns and to emphasize what EPA believes should initiate a comprehensive evaluation of system operations that may result in elevated DBP levels and provide a proactive procedure to address compliance with Stage 2 DBP LRAA MCLs , EPA has replaced the term ''significant excursion'' used in the Stage 2 DBPR proposal with the term ''operational evaluation level'' in today's rule.

Definition of the operational evaluation levels. The majority of commenters stated that EPA should define the DBP levels initiating an operational evaluation (''significant excursion'' in the proposal) in the regulation to ensure national consistency rather than requiring States to develop their own criteria (as was proposed). Commenters suggested several definitions, including a single numerical limit and calculations comparing previous quarterly DBP results to the current quarter's result. Commenters that recommended a single numerical limit felt that such an approach was justified by the available health effects information, while other commenters felt available heath effects information did not support a single numerical limit. Commenters recommended that any definition be easy to understand and implement.

EPA agrees with commenter preference for national criteria to initiate an operational evaluation. The DBP levels initiating an operational evaluation in today's rule consider routine operational variations in distribution systems, are simple for water systems to calculate, and minimize the implementation burden on States. They also provide an early warning to help identify possible future MCL violations and allow the system to take proactive steps to remain in compliance. EPA emphasizes, as it did in the proposal and elsewhere in this notice, that health effects research is insufficient to identify a level at which health effects occur, and thus today's methodology for initiating operational evaluation is not based upon health effects, but rather is intended as an indicator of operational performance.

Scope of an evaluation. Some commenters felt that the scope of an evaluation initiated by locational DBP levels should be limited to the distribution systems, as in the proposal. Others felt that the treatment processes should be included in the evaluation, noting that these can be significant in the formation of DBPs.

The Agency agrees with commenters that treatment processes can be a significant factor in DBP levels initiating an operational evaluation and that a comprehensive operational evaluation should address treatment processes. In cases where the system can clearly identify the cause of the DBP levels initiating an operational evaluation (based on factors such as water quality data, plant performance data, distribution system configuration, and previous evaluations) the State may allow the system to limit the scope of the evaluation to the identified cause. In other cases, it is appropriate to evaluate the entire system, from source through treatment to distribution system configuration and operational practices.

Timing for completion and review of the evaluation report. While some commenters agreed that the evaluation report should be reviewed as part of the sanitary survey process (as proposed), many commenters felt that the time between sanitary surveys (up to five years) minimized the value of the evaluation report in identifying both the causes of DBP levels initiating an operational evaluation and in possible changes to prevent recurrence. Moreover, a number of commenters felt that the evaluation report was important enough to warrant a separate submittal and State review rather than have the evaluation report compete with other priorities during a sanitary survey.

The Agency agrees that completion and State review of evaluation reports on a three or five year sanitary survey cycle, when the focus of the evaluation is on what may happen in the next quarter, would allow for an unreasonable period of time to pass between the event initiating the operational evaluation and completion and State review of the report. This would diminish the value of the evaluation report for both systems and States, particularly when systems may be in discussions with or requesting approval for treatment changes from States, and as noted above, the focus of the report is on what may occur in the next quarter. EPA believes that timely reviews of evaluation reports by States is important, would be essential for States in understanding system operations and reviewing other compliance submittals, and would be extremely valuable in reviewing and approving any proposed source, treatment or distribution system modifications for a water system.

Having the evaluation information on an ongoing basis rather than a delayed basis would also allow States to prioritize their resources in scheduling and reviewing particular water system operations and conditions as part of any on-site system review or oversight. Therefore, today's rule requires that systems complete the operational evaluation and submit the evaluation report to the State within 90 days of the occurrence.

I. MCL, BAT, and Monitoring for Bromate

1. Today's Rule

Today EPA is confirming that the MCL for bromate for systems using ozone remains at 0.010 mg/L as an RAA for samples taken at the entrance to the distribution system as established by the Stage 1 DBPR. Because the MCL remains the same, EPA is not modifying the existing bromate BAT. EPA is changing the criterion for a system using ozone to qualify for reduced bromate monitoring from demonstrating low levels of bromide to demonstrating low levels of bromate.

2. Background and Analysis

a. Bromate MCL. Bromate is a principal byproduct from ozonation of bromide-containing source waters. As described in more detail in the Stage 2 DBPR proposal (USEPA 2003a), more stringent bromate MCL has the potential to decrease current levels of microbial protection, impair the ability of systems to control resistant pathogens like Cryptosporidium, and increase levels of DBPs from other disinfectants that may be used instead of ozone. EPA considered reducing the bromate MCL from 0.010 mg/L to 0.005 mg/L as an annual average but concluded that many systems using ozone to inactivate microbial pathogens would have significant difficulty maintaining bromate levels at or below 0.005 mg/L. In addition, because of the high doses required, the ability of systems to use ozone to meet Cryptosporidium treatment requirements under the LT2ESWTR would be diminished if the bromate MCL was decreased from 0.010 to 0.005 mg/L; higher doses will generally lead to greater bromate formation. After evaluation under the risk-balancing provisions of section 1412(b)(5) of the SDWA, EPA concluded that the existing MCL was justified. EPA will review the bromate MCL as part of the six-year review process and determine whether the MCL should remain at 0.010 mg/L or be reduced to a lower level. As a part of that review, EPA will consider the increased utilization of alternative technologies, such as UV, and whether the risk/risk concerns reflected in today's rule, as well as in the LT2ESWTR, remain valid.

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

EPA approved several new analytical methods for bromate that are far more sensitive than the existing method as part of today's rule. Since these methods can measure bromate to levels of 0.001 mg/L or lower, EPA is replacing the criterion for reduced bromate monitoring (source water bromide running annual average not to exceed 0.05 mg/L) with a bromate running annual average not to exceed 0.0025 mg/L.

In the past, EPA has often set the criterion for reduced monitoring eligibility at 50% of the MCL, which would be 0.005 mg/L. However, the MCL for bromate will remain at 0.010 mg/L, representing a risk level of 2×10/b 2×10^{-4}, 10^{-4} and 10^{-6} (higher than EPA's usual excess cancer risk range of 10^{-4} to 10^{-6}) because of risk tradeoff considerations) (USEPA 2003a).

EPA believes that the decision for reduced monitoring is separate from these risk tradeoff considerations. Risk tradeoff considerations influence the selection of the MCL, while reduced monitoring requirements are designed to ensure that the MCL, once established, is reliably and consistently achieved. Requiring a running annual average of 0.0025 mg/L for the reduced monitoring criterion allows greater confidence that the system is achieving the MCL and thus ensuring public health protection.

3. Summary of Major Comments

Commenters supported both the retention of the existing bromate MCL and the modified reduced monitoring criterion.

J. Public Notice Requirements

1. Today's Rule

Today's rule does not alter existing public notification language for TTHM, HAA5 or TOC, which are listed under 40 CFR 141.201–141.210 (Subpart Q).

2. Background and Analysis

EPA requested comment on including language in the proposed rule concerning potential reproductive and developmental health effects. EPA believes this is an important issue because of the large population exposed (58 million women of child-bearing age; USEPA 2005a) and the number of studies that, while not conclusive, point towards a potential risk concern. While EPA is not including information about reproductive and developmental health effects in public notices at this time, the Agency plans to reconsider whether to include this information in the future. As part of this effort, EPA intends to support research to assess communication strategies on how to best provide this information.

The responsibilities for public notification and consumer confidence reports rest with the individual system. Under the Public Notice Rule (Part 141 subpart Q) and Consumer Confidence Report Rule (Part 141 subpart O), the wholesale system is responsible for notifying the consecutive system of analytical results and violations related to monitoring conducted by the wholesale system. Consecutive systems are required to conduct appropriate public notification after a violation (whether in the wholesale system or the consecutive system). In their consumer confidence report, consecutive systems must include results of the testing conducted by the wholesale system unless the consecutive system conducted equivalent testing (as required in today's rule) that indicated the consecutive system was in compliance, in which case the consecutive system reports its own compliance monitoring results.

3. Summary of Major Comments

EPA requested and received many comments on the topic of including public notification language regarding potential reproductive and developmental effects. A number of comments called for including reproductive and developmental health effects language to address the potential health concerns that research has shown. Numerous comments also opposed such language due to uncertainties in the underlying science and the implications such language could have on public trust of utilities.

EPA agrees on the importance of addressing possible reproductive and developmental health risks. However, given the uncertainties in the science and our lack of knowledge of how to best communicate undefined risks, a general statement about reproductive

and developmental health effects is premature at this time. The Agency needs to understand how best to characterize and communicate these risks and what to do to follow up any such communication. The public deserves accurate, timely, relevant, and understandable communication. The Agency will continue to follow up on this issue with additional research, possibly including a project to work with stakeholders to assess risk communication strategies.

Some comments also suggested leaving the choice of language up to the water server. EPA believes that this strategy would cause undue confusion to both the PWS and the public.

Commenters generally agreed that both wholesale and consecutive systems that conduct monitoring be required to report their own analytical results as part of their CCRs. One commenter requested clarification of consecutive system public notification requirements when there is a violation in the wholesale system but the consecutive system data indicate that it meets DBP MCLs.

Although EPA requires consecutive systems to conduct appropriate public notification of violations (whether in the wholesale or consecutive system), there may be cases where the violation may only affect an isolated portion of the distribution system. Under the public notification rule, the State may allow systems to limit distribution of the notice to the area that is out of compliance if the system can demonstrate that the violation occurred in a part of the distribution system that is ''physically or hydraulically isolated from other parts of the distribution system.'' This provision remains in place. As for a consecutive system whose wholesale system is in violation, the consecutive system is not required to conduct public notification if DBP levels in the consecutive system are in compliance.

K. Variances and Exemptions

1. Today's Rule

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

2. Background and Analysis

a. Variances. The SDWA provides for two types of variances—general variances and small system variances. Under section 1415(a)(1)(A) of the SDWA, a State that has primary enforcement responsibility (primacy), or EPA as the primacy agency, may grant general variances from MCLs to those public water systems of any size that cannot comply with the MCLs because of characteristics of the raw water sources. The primacy agency may grant general variances to a system on condition that the system install the best technology, treatment techniques, or other means that EPA finds available and based upon an evaluation satisfactory to the State that indicates that alternative sources of water are not reasonably available to the system. At the time this type of variance is granted, the State must prescribe a compliance schedule and may require the system to implement additional control measures. Furthermore, before EPA or the State may grant a general variance, it must find that the variance will not result in an unreasonable risk to health (URTH) to the public served by the public water system. In today's final rule, EPA is specifying BATs for general variances under section 1415(a) (see section IV.D).

Section 1415(e) authorizes the primacy agency to issue variances to small public water systems (those serving fewer than 10,000 people) where the primacy agent determines (1) that the system cannot afford to comply with an MCL or treatment technique and (2) that the terms of the variances will ensure adequate protection of human health (63 FR 43833, August 14, 1998) (USEPA 1998c). These variances may only be granted where EPA has determined that there is no affordable compliance technology and has identified a small system variance technology under section 1412(b)(15) for the contaminant, system size and source water quality in question. As discussed below, small system variances under section 1415(e) are not available because EPA has determined that affordable compliance technologies are available.

The 1996 Amendments to the SDWA identify three categories of small public water systems that need to be addressed: (1) Those serving a population of 3301–10,000; (2) those serving a population of 500–3300; and (3) those serving a population of 25–499. The SDWA requires EPA to make determinations of available compliance technologies for each size category. A compliance technology is a technology that is affordable and that achieves compliance with the MCL and/or treatment technique. Compliance technologies can include point-of-entry or point-of-use treatment units. Variance technologies are only specified for those system size/source water quality combinations for which there are no listed affordable compliance technologies.

Using its current National Affordability Criteria, EPA has determined that multiple affordable compliance technologies are available for each of the three system sizes (USEPA 2005a), and therefore did not identify any variance treatment technologies. The analysis was consistent with the current methodology used in the document ''National-Level Affordability Criteria Under the 1996 Amendments to the Safe Drinking Water Act'' (USEPA 1998d) and the ''Variance Technology Findings for Contaminants Regulated Before 1996'' (USEPA 1998e). However, EPA is currently reevaluating its national-level affordability criteria and has solicited recommendations from both the NDWAC and the SAB as part of this review. EPA intends to apply the revised criteria to the Stage 2 DBPR once they have been finalized for the purpose of determining whether to enable States to give variances. Thus, while the analysis of Stage 2 household costs will not change, EPA's determination regarding the availability of affordable compliance technologies for the different categories of small systems may.

b. Affordable Treatment Technologies for Small Systems. The treatment trains considered and predicted to be used in EPA's compliance forecast for systems serving under 10,000 people, are listed in Table IV.K–1.

TABLE IV.K–1.—TECHNOLOGIES CONSIDERED AND PREDICTED TO BE USED IN COMPLIANCE FORECAST FOR SMALL SYSTEMS

SW Water Plants	GW Water Plants
• Switching to chloramines as a residual disinfectant	• Switching to chloramines as a residual disinfectant
• Chlorine dioxide (not for systems serving fewer than 100 people)	• UV
• UV	• Ozone (not for systems serving fewer than 100 people)
• Ozone (not for systems serving fewer than 100 people)	• GAC20
• Micro-filtration/Ultra-filtration	• Nanofiltration

TABLE IV.K–1.—TECHNOLOGIES CONSIDERED AND PREDICTED TO BE USED IN COMPLIANCE FORECAST FOR SMALL SYSTEMS—Continued

SW Water Plants	GW Water Plants
• GAC20. • GAC20 + Advanced disinfectants. • Integrated Membranes.	

Note: Italicized technologies are those predicted to be used in the compliance forecast.
Source: Exhibits 5.11b and 5.14b, USEPA 2005a.

The household costs for these technologies were compared against the EPA's current national-level affordability criteria to determine the affordable treatment technologies. The Agency's national level affordability criteria were published in the August 6, 1998 **Federal Register** (USEPA 1998d). A complete description of how this analysis was applied to Stage 2 DBPR is given in Section 8.3 of the Economic Analysis (USEPA 2005a).

Of the technologies listed in Table IV.K–1, integrated membranes with chloramines, GAC20 with advanced oxidants, and ozone are above the affordability threshold in the 0 to 500 category. No treatment technologies are above the affordability threshold in the 500 to 3,300 category or the 3,300 to 10,000 category. As shown in the Economic Analysis for systems serving fewer than 500 people, 14 systems are predicted to use GAC20 with advanced disinfectants, one system is predicted to use integrated membranes, and no systems are predicted to use ozone to comply with the Stage 2 DBPR (USEPA 2005a). However, several alternate technologies are affordable and likely available to these systems. In some cases, the compliance data for these systems under the Stage 2 DBPR will be the same as under the Stage 1 DBPR (because many systems serving fewer than 500 people will have the same single sampling site under both rules); these systems will have already installed the necessary compliance technology to comply with the Stage 1 DBPR. It is also possible that less costly technologies such as those for which percentage use caps were set in the decision tree may actually be used to achieve compliance (e.g., chloramines, UV). Thus, EPA believes that compliance by these systems will be affordable.

As shown in Table IV.K–2, the cost model predicts that some households served by very small systems will experience household cost increases greater than the available expenditure margins as a result of adding advanced technology for the Stage 2 DBPR (USEPA 2005a). This prediction may be overestimated because small systems may have other compliance alternatives available to them besides adding treatment, which were not considered in the model. For example, some of these systems currently may be operated on a part-time basis; therefore, they may be able to modify the current operational schedule or use excessive capacity to avoid installing a costly technology to comply with the Stage 2 DBPR. The system also may identify another water source that has lower TTHM and HAA5 precursor levels. Systems that can identify such an alternate water source may not have to treat that new source water as intensely as their current source, resulting in lower treatment costs. Systems may elect to connect to a neighboring water system. While connecting to another system may not be feasible for some remote systems, EPA estimates that more than 22 percent of all small water systems are located within metropolitan regions (USEPA 2000f) where distances between neighboring systems will not present a prohibitive barrier. Low-cost alternatives to reduce total trihalomethanes (TTHM) and haloacetic acid (HAA5) levels also include distribution system modifications such as flushing distribution mains more frequently, looping to prevent dead ends, and optimizing storage to minimize retention time. More discussion of household cost increases is presented in Section VI.E and the Economic Analysis (USEPA 2005a).

TABLE IV.K–2.—DISTRIBUTION OF HOUSEHOLD UNIT TREATMENT COSTS FOR PLANTS ADDING TREATMENT

Systems size (population seved)	Number of households served by plants adding treatment (Percent of all households subject to the Stage 2 DBPR)	Mean annual household cost increase	Median annual household cost increase	90th Percentile annual household cost increase	95th Percentile annual household cost increase	Available expenditure margin ($/hh/yr)	Number of households with annual cost increases greater than the available expenditure margin	Number of surface water plants with annual cost increases greater than the available expenditure margin	Number of groundwater plants with annual cost increases greater than the available expenditure margin	Total number of plants with annual cost increases greater than the available expenditure margin
	A	B	C	D	E	F	G	H	I	J = H + I
0–500	43045(3)	$201.55	$299.01	$299.01	$414.74	$733	964	15	0	15
501–3,300	205842 (4)	$58.41	$29.96	$75.09	$366.53	$724	0	9	0	0
3,301–10,000	342525 (5)	$37.05	$14.59	$55.25	$200.05	$750	0	0	0	0

Notes: Household unit costs represent treatment costs only. All values in year 2003 dollars.
Source: Exhibit 8.4c, USEPA 2005a.

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

drinking water. If EPA or the State grants an exemption to a public water system, it must at the same time prescribe a schedule for compliance (including increments of progress or measures to develop an alternative source of water supply) and implementation of appropriate control measures that the State requires the system to meet while the exemption is in effect. Under section 1416(b)(2)(A), the schedule prescribed shall require compliance as expeditiously as practicable (to be determined by the State), but no later than 3 years after the effective date for the regulations established pursuant to section 1412(b)(10). For public water systems which do not serve more than a population of 3,300 and which need financial assistance for the necessary improvements, EPA or the State may renew an exemption for one or more additional two-year periods, but not to exceed a total of 6 years, if the system establishes that it is taking all practicable steps to meet the requirements above. A public water system shall not be granted an exemption unless it can establish that either: (1) the system cannot meet the standard without capital improvements that cannot be completed prior to the date established pursuant to section 1412(b)(10); (2) in the case of a system that needs financial assistance for the necessary implementation, the system has entered into an agreement to obtain financial assistance pursuant to section 1452 or any other Federal or state program; or (3) the system has entered into an enforceable agreement to become part of a regional public water system.

3. Summary of Major Comments

Several commenters agreed with the proposal not to list variances technologies for the Stage 2 DBPR. One commenter requested that EPA modify the methodology used to assess affordability. As mentioned earlier, EPA is currently reevaluating its national-level affordability criteria and has solicited recommendations from both the NDWAC and the SAB as part of this review. EPA intends to apply the revised criteria to the Stage 2 DBPR for the purpose of determining whether to enable States to give variances.

L. Requirements for Systems to Use Qualified Operators

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

M. System Reporting and Recordkeeping Requirements

1. Today's Rule

Today's Stage 2 DBPR, consistent with the existing system reporting and recordkeeping regulations under 40 CFR 141.134 (Stage 1 DBPR), requires public water systems (including consecutive systems) to report monitoring data to States within ten days after the end of the compliance period. In addition, systems are required to submit the data required in § 141.134. These data are required to be submitted quarterly for any monitoring conducted quarterly or more frequently, and within ten days of the end of the monitoring period for less frequent monitoring. As with other chemical analysis data, the system must keep the results for 10 years.

In addition to the existing Stage 1 reporting requirements, today's rule requires systems to perform specific IDSE-related reporting to the primacy agency, except for systems serving fewer than 500 for which the State or primacy agency has waived this requirement. Required reporting includes submission of IDSE monitoring plans, 40/30 certification, and IDSE reports. This reporting must be accomplished on the schedule specified in the rule (see § 141.600(c)) and discussed in section IV.E of today's preamble. System submissions must include the elements identified in subpart U and discussed further in section IV.F of today's preamble. These elements include recommended Stage 2 compliance monitoring sites as part of the IDSE report.

Systems must report compliance with Stage 2 TTHM and HAA5 MCLs (0.080 mg/LTTHM and 0.060 mg/L HAA5, as LRAAs) according to the schedules specified in §§ 141.620 and 141.629 and discussed in section IV.E of today's preamble. Reporting for DBP monitoring, as described previously, will remain generally consistent with current public water system reporting requirements (§ 141.31 and § 141.134); systems will be required to calculate and report each LRAA (instead of the system's RAA) and each individual monitoring result (as required under the Stage 1 DBPR). Systems will also be required to provide a report to the State about each operational evaluation within 90 days, as discussed in section IV.H. Reports and evaluations must be kept for 10 years and may prove valuable in identifying trends and recurring issues.

2. Summary of Major Comments

EPA requested comment on all system reporting and recordkeeping requirements. Commenters generally supported EPA's proposed requirements, but expressed concern about two specific issues. The first issue was the data management and tracking difficulties that States would face if EPA finalized a monitoring approach which had both plant-based and population-based requirements, as was proposed. Since today's rule contains only population-based monitoring requirements, this concern is no longer an issue. See section IV.G in today's preamble for further discussion.

The second concern related to reporting associated with the IDSE. Commenters who supported an approach other than the IDSE for determining Stage 2 compliance monitoring locations did not support IDSE-related reporting. The IDSE remains a key component of the final rule; thus, EPA has retained IDSE-related reporting. However, the Agency has modified both the content and the timing of the reporting to reduce the burden. See sections IV.F and IV.E, respectively, of today's preamble for further discussion.

N. Approval of Additional Analytical Methods

1. Today's Rule

EPA is taking final action to:

(1) allow the use of 13 methods published by the Standard Methods Committee in Standard Methods for the Examination of Water and Wastewater,

20th edition, 1998 (APHA 1998) and 12 methods in Standard Methods Online.

(2) approve three methods published by American Society for Testing and Materials International.

(3) approve EPA Method 327.0 Revision 1.1 (USEPA 2005h) for daily monitoring of chlorine dioxide and chlorite, EPA Method 552.3 (USEPA 2003f) for haloacetic acids (five) (HAA5), EPA Methods 317.0 Revision 2 (USEPA 2001c) and 326.0 (USEPA 2002) for bromate, chlorite, and bromide, EPA Method 321.8 (USEPA 2000g) for bromate only, and EPA Method 415.3 Revision 1.1 (USEPA 2005l) for total organic carbon (TOC) and specific ultraviolet absorbance (SUVA).

(4) update the citation for EPA Method 300.1 (USEPA 2000h) for bromate, chlorite, and bromide.

(5) standardize the HAA5 sample holding times and the bromate sample preservation procedure and holding time.

(6) add the requirement to remove inorganic carbon prior to determining TOC or DOC, remove the specification of type of acid used for TOC/DOC sample preservation; and require that TOC samples be preserved at the time of collection.

(7) clarify which methods are approved for magnesium hardness determinations (40 CFR 141.131 and 141.135).

2. Background and Analysis

The Stage 1 Disinfectants and Disinfection Byproducts Rule (Stage 1 DBPR) was promulgated on December 16, 1998 (USEPA 1998a) and it included approved analytical methods for DBPs, disinfectants, and DBP precursors. Additional analytical methods became available subsequent to the rule and were proposed in the Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBPR) (USEPA 2003a). These methods are applicable to monitoring that is required under the Stage 1 DBPR. After the Stage 2 DBPR proposal, analytical methods for additional drinking water contaminants were proposed for approval in a Methods Update Rule proposal (USEPA 2004). The Stage 2 DBPR and Methods Update Rule proposals both included changes in the same sections of the CFR. EPA decided to make all the changes to § 141.131 as part of the Stage 2 DBPR and the remainder of the methods that were proposed with the Stage 2 DBPR will be considered as part of the Methods Update Rule, which will be finalized at a later date. Two ASTM methods, D 1253–86(96) and D 1253–03, that were proposed in the Methods Update Rule, are being approved for measuring chlorine residual as part of today's action.

Minor corrections have been made in two of the methods that were proposed in the Stage 2 DBPR. In today's rule, the Agency is approving EPA Method 327.0 (Revision 1.1, 2005) which corrects three typographical errors in the proposed method.

EPA is also approving EPA Method 415.3 (Revision 1.1, 2005), which does not contain the requirement that samples for the analysis of TOC must be received within 48 hours of sample collection.

A summary of the methods that are included in today's rule is presented in Table IV.N–1.

TABLE IV.N–1. ANALYTICAL METHODS APPROVED IN TODAY'S RULE

Analyte	EPA method	Standard methods 20th edition	Standard methods online	Other
§ 141.131—Disinfection Byproducts				
HAA5	552.3	6251 B	6251 B–94	
Bromate	317.0, Revision 2.0			ASTM D 6581–00
	321.8			
	326.0			
Chlorite (monthly or daily)	317.0, Revision 2.0			ASTM D 6581–00
	326.0			
Chlorite (daily)	327.0, Revision 1.1	4500–ClO_2 E	4500–ClO_2 E–00	
§ 141.131—Disinfectants				
Chlorine (free, combined, total).		4500–Cl D	4500–Cl D–00	ASTM D 1253–86(96)
		4500–Cl F	4500–Cl F–00	ASTM D 1253–03
		4500–Cl G	4500–Cl G–00	
Chlorine (total)		4500–Cl E	4500–Cl E–00	
		4500–Cl I	4500–Cl I–00	
Chlorine (free)		4500–Cl H	4500–Cl H–00	
Chlorine Dioxide	327.0, Revision 1.1	4500–ClO_2 D	4500–ClO_2 E–00	
		4500–ClO_2 E		
§ 141.131—Other parameters				
Bromide	317.0, Revision 2.0			ASTM D 6581–00
	326.0			
TOC/DOC	415.3, Revision 1.1	5310 B	5310 B–00	
		5310 C	5310 C–00	
		5310 D	5310 D–00	
UV_{254}	415.3, Revision 1.1	5910 B	5910 B–00	
SUVA	415.3, Revision 1.1			

O. Laboratory Certification and Approval

1. PE Acceptance Criteria

a. Today's rule. Today's rule maintains the requirements of laboratory certification for laboratories performing analyses to demonstrate compliance with MCLs and all other analyses to be conducted by approved parties. It revises the acceptance criteria for performance evaluation (PE) studies which laboratories must pass as part of the certification program. The new acceptance limits are effective 60 days after promulgation. Laboratories that were certified under the Stage 1 DBPR PE acceptance criteria will be subject to the new criteria when it is time for them to analyze their annual DBP PE sample(s). Today's rule also requires that TTHM and HAA5 analyses that are performed for the IDSE or system-specific study be conducted by laboratories certified for those analyses.

TABLE IV.O–1.—PERFORMANCE EVALUATION (PE) ACCEPTANCE CRITERIA

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

b. Background and analysis. The Stage 1 DBPR (USEPA 1998a) specified that in order to be certified the laboratory must pass an annual performance evaluation (PE) sample approved by EPA or the State using each method for which the laboratory wishes to maintain certification. The acceptance criteria for the DBP PE samples were set as statistical limits based on the performance of the laboratories in each study. This was done because EPA did not have enough data to specify fixed acceptance limits.

Subsequent to promulgation of the Stage 1 DBPR, EPA was able to evaluate data from PE studies conducted during the Information Collection Rule (USEPA 1996) and during the last five general Water Supply PE studies. Based on the evaluation process as described in the proposed Stage 2 DBPR (USEPA 2003a), EPA determined that fixed acceptance limits could be established for the DBPs. Today's action replaces the statistical PE acceptance limits with fixed limits effective one year after promulgation.

c. Summary of major comments. Four commenters supported the fixed acceptance criteria as presented in the proposed rule. One requested that a minimum concentration be set for each DBP in the PE studies, so that laboratories would not be required to meet tighter criteria in the PE study than they are required to meet with the minimum reporting level (MRL) check standard. EPA has addressed this concern by directing the PE sample suppliers to use concentrations no less than 10 μg/L for the individual THM and HAAs, 100 μg/L for chlorite, and 7 μg/L for bromate in PE studies used for certifying drinking water laboratories.

Two commenters requested that the effective date for the new PE acceptance criteria be extended from 60 days to 180 days, because they felt that 60 days was not enough time for laboratories to meet the new criteria. EPA realized from those comments that the original intent of the proposal was not clearly explained; the 60 days was to be the deadline for when the PE providers must change the acceptance criteria that are used when the studies are conducted. Laboratories would have to meet the criteria when it is time for them to analyze their annual PE samples in order to maintain certification. Depending upon when the last PE sample was analyzed, laboratories could have up to one year to meet the new criteria. In order to eliminate this confusion, EPA has modified the rule language to allow laboratories one year from today's date to meet the new PE criteria.

2. Minimum Reporting Limits

a. Today's rule. EPA is establishing regulatory minimum reporting limits (MRLs) for compliance reporting of DBPs by Public Water Systems. These regulatory MRLs (Table IV.O–2) also define the minimum concentrations that must be reported as part of the Consumer Confidence Reports (40 CFR § 141.151(d)). EPA is incorporating MRLs into the laboratory certification program for DBPs by requiring laboratories to include a standard near the MRL concentration as part of the calibration curve for each DBP and to verify the accuracy of the calibration curve at the MRL concentration by analyzing an MRL check standard with a concentration less than or equal to 110% of the MRL with each batch of samples. The measured DBP concentration for the MRL check standard must be ±50% of the expected value, if any field sample in the batch has a concentration less than 5 times the regulatory MRL.

TABLE IV.O–2.—REGULATORY MINIMUM REPORTING LEVELS

DBP	Minimum reporting level (mg/L) [1]	Comments
TTHM [2]		
Chloroform	0.0010	
Bromodichloromethane	0.0010	
Dibromochloromethane	0.0010	
Bromoform	0.0010	
HAA5 [2]		
Monochloroacetic Acid	0.0020	
Dichloroacetic Acid	0.0010	
Trichloroacetic Acid	0.0010	
Monobromoacetic Acid	0.0010	
Dibromoacetic Acid	0.0010	
Chlorite	0.020	Applicable to monitoring as prescribed in § 141.132(b)(2)(i)(B) and (b)(2)(ii).
Bromate	0.0050 or 0.0010	Laboratories that use EPA Methods 317.0 Revision 2.0, 326.0 or 321.8 must meet a 0.0010 mg/L MRL for bromate.

[1] The calibration curve must encompass the regulatory minimum reporting level (MRL) concentration. Data may be reported for concentrations lower than the regulatory MRL as long as the precision and accuracy criteria are met by analyzing an MRL check standard at the lowest reporting limit chosen by the laboratory. The laboratory must verify the accuracy of the calibration curve at the MRL concentration by analyzing an MRL check standard with a concentration less than or equal to 110% of the MRL with each batch of samples. The measured concentration for the MRL check standard must be ±50% of the expected value, if any field sample in the batch has a concentration less than 5 times the regulatory MRL. Method requirements to analyze higher concentration check standards and meet tighter acceptance criteria for them must be met in addition to the MRL check standard requirement.

[2] When adding the individual trihalomethane or haloacetic acid concentrations to calculate the TTHM or HAA5 concentrations, respectively, a zero is used for any analytical result that is less than the MRL concentration for that DBP, unless otherwise specified by the State.

b. Background and analysis. EPA proposed to establish regulatory MRLs for DBPs in order to define expectations for reporting compliance monitoring data to the Primacy Agencies and in the Consumer Confidence Reports. The proposed MRLs were generally based on those used during the Information Collection Rule (USEPA 1996), because an analysis of the quality control data set from the Information Collection Rule (Fair et al. 2002) indicated that laboratories are able to provide quantitative data down to those concentrations.

EPA also proposed that laboratories be required to demonstrate ability to quantitate at the MRL concentrations by analyzing an MRL check standard and meeting accuracy criteria on each day that compliance samples are analyzed. Three public commenters noted that meeting the accuracy requirement for the MRL check standard did not contribute to the quality of the data in cases in which the concentration of a DBP in the samples was much higher than the MRL. For example, if chloroform concentrations are always greater than 0.040 mg/L in a water system's samples, then verifying accurate quantitation at 0.0010 mg/L is unnecessary and may require the laboratory to dilute samples or maintain two calibration curves in order to comply with the requirement. EPA has taken this into consideration in today's rule and has adjusted the requirement accordingly. EPA is maintaining the requirement for all laboratories to analyze the MRL check standard, but the laboratory is only required to meet the accuracy criteria (±50%) if a field sample has a concentration less than five times the regulatory MRL concentration.

EPA proposed a regulatory MRL of 0.200 mg/L for chlorite, because data from the Information Collection Rule indicated that most samples would contain concentrations greater than 0.200 mg/L (USEPA 2003c). EPA also took comment on a lower MRL of 0.020 mg/L. Commenters were evenly divided concerning which regulatory MRL concentration should be adopted in the final rule. EPA has decided to set the chlorite regulatory MRL at 0.020 mg/L in today's rule. This decision was based on two factors. First, the approved analytical methods for determining compliance with the chlorite MCL can easily support an MRL of 0.020 mg/L. More importantly, since the proposal, EPA has learned that water systems that have low chlorite concentrations in their water have been obtaining data on these low concentrations from their laboratories and have been using these data in their Consumer Confidence Reports. Setting the MRL at 0.020 mg/L is reflective of current practices in laboratories and current data expectations by water systems.

c. Summary of major comments. There were no major comments.

P. Other Regulatory Changes

As part of today's action, EPA has included several ''housekeeping'' actions to remove sections of Part 141 that are no longer effective. These sections have been superceded by new requirements elsewhere in Part 141.

Sections 141.12 (Maximum contaminant levels for total trihalomethanes) and 141.30 (Total trihalomethanes sampling, analytical and other requirements) were promulgated as part of the 1979 TTHM Rule. These sections have been superceded in their entirety by § 141.64 (Maximum contaminant levels for disinfection byproducts) and subpart L (Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors), respectively, as of December 31, 2003. Also, § 141.32 (Public notification) has been superceded by subpart Q (Public Notification of Drinking Water Violations), which is now fully in effect.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing prior notice and an opportunity for public comment. In addition to updating methods, this rule also makes minor corrections to the National Primary Drinking Water Regulations, specifically the Public Notification tables (Subpart Q, Appendices A and B). Two final drinking water rules (66 FR 6976 and 65 FR 76708) inadvertently added new endnotes to two existing tables using the same endnote numbers. This rule corrects this technical drafting error by

renumbering the endnote citations in these two tables. Thus, additional notice and public comment is not necessary. EPA finds that this constitutes ''good cause'' under 5 U.S.C. 553(b)(B). For the same reasons, EPA is making this rule change effective upon publication. 5 U.S.C. 553(d)(3).

V. State Implementation

A. Today's Rule

This section describes the regulations and other procedures and policies States must adopt to implement today's rule. States must continue to meet all other conditions of primacy in 40 CFR Part 142. To implement the Stage 2 DBPR, States must adopt revisions to the following:

—§ 141.2—Definitions
—§ 141.33—Record maintenance;
—§ 141.64—Maximum contaminant levels for disinfection byproducts;
—subpart L—Disinfectant Residuals, Disinfection Byproducts, and Disinfection Byproduct Precursors;
—subpart O, Consumer Confidence Reports;
—subpart Q, Public Notification of Drinking Water Violations;
—new subpart U, Initial Distribution System Evaluation; and
—new subpart V, Stage 2 Disinfection Byproducts Requirements.

1. State Primacy Requirements for Implementation Flexibility

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

To ensure that a State program includes all the elements necessary for an effective and enforceable program under today's rule, a State primacy application must include a description of how the State will implement a procedure for modifying consecutive system and wholesale system monitoring requirements on a case-by-case basis, if a State will use the authority to modify monitoring requirements under this special primacy condition.

2. State Recordkeeping Requirements

Today's rule requires States to keep additional records of the following, including all supporting information and an explanation of the technical basis for each decision:

—very small system waivers.
—IDSE monitoring plans.
—IDSE reports and 40/30 certifications, plus any modifications required by the State.
—operational evaluations conducted by the system.

3. State Reporting Requirements

Today's rule has no new State reporting requirements.

4. Interim Primacy

States that have primacy for every existing NPDWR already in effect may obtain interim primacy for this rule, beginning on the date that the State submits the application for this rule to USEPA, or the effective date of its revised regulations, whichever is later. A State that wishes to obtain interim primacy for future NPDWRs must obtain primacy for today's rule. As described in Section IV.F, EPA expects to work with States to oversee the individual distribution system evaluation process that begins shortly after rule promulgation.

5. IDSE Implementation

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

B. Background and Analysis

SDWA establishes requirements that a State or eligible Indian Tribe must meet to assume and maintain primary enforcement responsibility (primacy) for its PWSs. These requirements include the following activities: (1) Adopting drinking water regulations that are no less stringent than Federal drinking water regulations; (2) adopting and implementing adequate procedures for enforcement; (3) keeping records and making reports available on activities that EPA requires by regulation; (4) issuing variances and exemptions (if allowed by the State), under conditions no less stringent than allowed under SDWA; and (5) adopting and being capable of implementing an adequate plan for the provisions of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the public water supply supervision program as authorized under SDWA section 1413. In addition to adopting basic primacy requirements specified in 40 CFR Part 142, States may be required to adopt special primacy provisions pertaining to specific regulations where implementation of the rule involves activities beyond general primacy provisions. States must include these regulation specific provisions in an application for approval of their program revision.

The current regulations in 40 CFR 142.14 require States with primacy to keep various records, including the following: analytical results to determine compliance with MCLs, MRDLs, and treatment technique requirements; PWS inventories; State approvals; enforcement actions; and the issuance of variances and exemptions. Today's final rule requires States to keep additional records, including all supporting information and an explanation of the technical basis for decisions made by the State regarding today's rule requirements. The State may use these records to identify trends and determine whether to limit the scope of operational evaluations. EPA currently requires in 40 CFR 142.15 that States report to EPA information such as violations, variance and exemption status, and enforcement actions; today's rule does not add additional reporting requirements or modify existing requirements.

On April 28, 1998, EPA amended its State primacy regulations at 40 CFR 142.12 to incorporate the new process identified in the 1996 SDWA Amendments for granting primary enforcement authority to States while their applications to modify their primacy programs are under review (63 FR 23362, April 28, 1998) (USEPA 1998f). The new process grants interim primary enforcement authority for a new or revised regulation during the period in which EPA is making a determination with regard to primacy for that new or revised regulation. This interim enforcement authority begins on the date of the primacy application submission or the effective date of the

new or revised State regulation, whichever is later, and ends when EPA makes a final determination. However, this interim primacy authority is only available to a State that has primacy (including interim primacy) for every existing NPDWR in effect when the new regulation is promulgated. States that have primacy for every existing NPDWR already in effect may obtain interim primacy for this rule and a State that wishes to obtain interim primacy for future NPDWRs must obtain primacy for this rule.

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

C. Summary of Major Comments

Public comment generally supported the special primacy requirements in the August 11, 2003 proposal, and many commenters expressed appreciation for the flexibility the special primacy requirements provided to States.

Many commenters expressed concern about EPA as the implementer instead of the State, given the existing relationship between the State and system. EPA agrees that States perform an essential role in rule implementation and intends to work with States to the greatest extent possible, consistent with the rule schedule promulgated today. EPA believes that pre-promulgation coordination with States, changes in the final rule strongly supported by States (e.g., population-based monitoring instead of plant-based monitoring), and the staggered rule schedule will facilitate State involvement in pre-primacy implementation.

Many commenters also requested that the State have more flexibility to grant sampling waivers and exemptions. EPA believes that it has struck a reasonable balance among competing objectives in granting State flexibility. State flexibility comes at a resource cost and excessive system-by-system flexibility could overwhelm State resources. Also, EPA believes that much of the monitoring and water quality information a State would need to properly consider whether a waiver is appropriate is generally not available and, if available, difficult to evaluate.

VI. Economic Analysis

This section summarizes the Economic Analysis for the Final Stage 2 Disinfectants and Disinfection Byproducts Rule (Economic Analysis (EA)) (USEPA 2005a). The EA is an evaluation of the benefits and costs of today's final rule and other regulatory alternatives the Agency considered. Specifically, this evaluation addresses both quantified and non-quantified benefits to PWS consumers, including the general population and sensitive subpopulations. Costs are presented for PWSs, States, and consumer households. Also included is a discussion of potential risks from other contaminants, uncertainties in benefit and cost estimates, and a summary of major comments on the EA for the proposed Stage 2 DBPR.

EPA relied on data from several epidemiologic and toxicologic studies, the Information Collection Rule (ICR), and other sources, along with analytical models and input from technical experts, to understand DBP risk, occurrence, and PWS treatment changes that will result from today's rule. Benefits and costs are presented as annualized values using social discount rates of three and seven percent. The time frame used for benefit and cost comparisons is 25 years—approximately five years account for rule implementation and 20 years for the average useful life of treatment technologies.

EPA has prepared this EA to comply with the requirements of SDWA, including the Health Risk Reduction and Cost Analysis required by SDWA section 1412(b)(3)(C), and Executive Order 12866, Regulatory Planning and Review. The full EA is available in the docket for today's rule, which is available online as described in the **ADDRESSES** section. The full document provides detailed explanations of the analyses summarized in this section and additional analytical results.

A. Regulatory Alternatives Considered

The Stage 2 DBPR is the second in a set of rules that address public health risks from DBPs. EPA promulgated the Stage 1 DBPR to decrease average exposure to DBPs and mitigate associated health risks—compliance with TTHM and HAA5 MCLs is based on averaging concentrations across the distribution system. In developing the Stage 2 DBPR, EPA sought to identify and further reduce remaining risks from exposure to chlorinated DBPs.

The regulatory options EPA considered for the Stage 2 DBPR are the direct result of a consensus rulemaking process (Federal Advisory Committee Act (FACA) process) that involved various drinking water stakeholders (see Section III for a description of the FACA process). The Advisory Committee considered the following key questions during the negotiation process for the Stage 2 DBPR:

- What are the remaining health risks after implementation of the Stage 1 DBPR?
- What are approaches to addressing these risks?
- What are the risk tradeoffs that need to be considered in evaluating these approaches?
- How do the estimated costs of an approach compare to reductions in peak DBP occurrences and overall DBP exposure for that approach?

The Advisory Committee considered DBP occurrence estimates to be important in understanding the nature of public health risks. Although the ICR data were collected prior to promulgation of the Stage 1 DBPR, they were collected under a similar sampling strategy. The data support the concept that a system could be in compliance with the RAA Stage 1 DBPR MCLs of 0.080 mg/L and 0.060 mg/L for TTHM and HAA5, respectively, and yet have points in the distribution system with either periodically or consistently higher DBP levels.

Based on these findings, the Advisory Committee discussed an array of alternatives to address disproportionate risk within distribution systems. Alternative options included lowering DBP MCLs, revising the method for MCL compliance determination e.g., requiring individual sampling locations to meet the MCL as an LRAA or requiring that no samples exceed the MCL), and combinations of both. The Advisory Committee also considered the associated technology changes and costs for these alternatives. After narrowing down options, the Advisory Committee

primarily focused on four types of alternative MCL scenarios. These are the alternatives EPA evaluated in the EA, as follows:

Preferred Alternative
- —MCLs of 0.080 mg/L for TTHM and 0.060 mg/L for HAA5 as LRAAs
- —Bromate MCL remaining at 0.010 mg/L

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

Alternative 2
- —MCLs of 0.080 mg/L for TTHM and 0.060 mg/L for HAA5 as absolute maximums for individual measurements
- —Bromate MCL remaining at 0.010 mg/L

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

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

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

Basis of Compliance

Violation of MCL

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

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

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

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

[1]The Preferred Alternative and Alternative 1 have the same TTHM MCL; they differ only in regard to the bromate MCL.
[2]Based on the IDSE, new locations targeted for high DBPs.

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

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

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

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

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B. Analyses That Support Today's Final Rule

EPA's goals in designing the Stage 2 DBPR were to protect public health by reducing peak DBP levels in the distribution system while maintaining microbial protection. As described earlier, the Stage 1 DBPR reduces overall average DBP levels, but specific locations within distribution systems can still experience relatively high DBP concentrations. EPA believes that high DBP concentrations should be reduced due to the potential association of DBPs with cancer, as well as reproductive and developmental health effects.

EPA analyzed the benefits and costs of the four regulatory alternatives presented in the previous section. Consistent with the recommendations of the Advisory Committee, EPA is establishing the preferred alternative to achieve the Agency's goals for the Stage 2 DBPR. The following discussion summarizes EPA's analyses that support today's final rule. This discussion explains how EPA predicted water quality and treatment changes, estimated benefits and costs, and assessed the regulatory alternatives.

1. Predicting Water Quality and Treatment Changes

Water quality and treatment data from the ICR were used in predicting treatment plant technology changes (i.e. compliance forecasts) and reductions in DBP exposure resulting from the Stage 2 DBPR. Because ICR data were gathered prior to Stage 1 DBPR compliance deadlines, EPA first accounted for treatment changes resulting from the Stage 1 DBPR. Benefit and cost estimates for the Stage 2 DBPR reflect changes following compliance with the Stage 1 DBPR.

The primary model used to predict changes in treatment and reductions in DBP levels was the Surface Water Analytical Tool (SWAT), which EPA developed using results from the ICR. SWAT results were applied directly for large and medium surface water systems and were adjusted for small surface water systems to account for differences in source water DBP precursor levels and operational constraints in small systems. EPA used ICR data and a Delphi poll process (a group of drinking water experts who provided best professional judgment in a structured format) to project technologies selected by ground water systems.

To address uncertainty in SWAT predictions, EPA also predicted treatment changes using a second methodology, called the ''ICR Matrix Method.'' Rather than a SWAT-predicted pre-Stage 1 baseline, the ICR Matrix Method uses unadjusted ICR TTHM and HAA5 pre-Stage 1 data to estimate the percent of plants changing technology to comply with the Stage 2 DBPR. EPA gives equal weight to SWAT and ICR Matrix Method predictions in estimating Stage 2 compliance forecasts and resultant reductions in DBP exposure. The ICR Matrix Method is also used to estimate reductions in the occurrence of peak TTHM and HAA5 concentrations because SWAT-predicted TTHM and HAA5 concentrations are valid only when considering national averages, not at the plant level.

When evaluating compliance with a DBP MCL, EPA assumed that systems would maintain DBP levels at least 20 percent below the MCL. This safety margin represents the level at which systems typically take action to ensure they meet a drinking water standard and reflects industry practice. In addition, the safety margin accounts for year-to-year fluctuations in DBP levels. To address the impact of the IDSE, EPA also analyzed compliance using a safety margin of 25 percent based on an analysis of spatial variability in TTHM and HAA5 occurrence. EPA assigned equal probability to the 20 and 25 percent safety margin for large and medium surface water systems for the final analysis because both alternatives are considered equally plausible. EPA assumes the 20 percent operational safety margin accounts for variability in small surface water systems and all groundwater systems.

2. Estimating Benefits

Quantified benefits estimates for the Stage 2 DBPR are based on potential reductions in fatal and non-fatal bladder cancer cases. In the EA, EPA included a sensitivity analysis for benefits from avoiding colon and rectal cancers. EPA believes additional benefits from this rule could come from reducing potential reproductive and developmental risks. EPA has not included these potential risks in the primary benefit analysis because of the associated uncertainty.

The major steps in deriving and characterizing potential cancer cases avoided include the following: (1) estimate the current and future annual cases of illness from all causes; (2) estimate how many cases can be attributed to DBP occurrence and exposure; and (3) estimate the reduction in future cases corresponding to anticipated reductions in DBP occurrence and exposure due to the Stage 2 DBPR.

EPA used results from the National Cancer Institute's Surveillance, Epidemiology, and End Results program in conjunction with data from the 2000 U.S. Census to estimate the number of new bladder cancer cases per year (USEPA 2005a). Three approaches were then used to gauge the percentage of cases attributable to DBP exposure (i.e., population attributable risk (PAR)). Taken together, the three approaches provide a reasonable estimate of the range of potential risks. EPA notes that the existing epidemiological evidence has not conclusively established causality between DBP exposure and any health risk endpoints, so the lower bound of potential risks may be as low as zero.

The first approach used the range of PAR values derived from consideration of five individual epidemiology studies. This range was used at the basis for the Stage 1 and the proposed Stage 2 economic analyses (i.e., 2 percent to 17 percent) (USEPA 2003a).

The second approach used results from the Villanueva et al. (2003) meta-analysis. This study develops a combined Odds Ratio (OR) of 1.2 that reflects the ever-exposed category for both sexes from all studies considered in the meta-analysis and yields a PAR value of approximately 16 percent.

The third approach used the Villanueva et al. (2004) pooled data analysis to develop a dose-response relationship for OR as a function of average TTHM exposure. Using the results from this approach, EPA estimates a PAR value of approximately 17 percent.

EPA used the PAR values from all three approaches to estimate the number of bladder cancer cases ultimately avoided annually as a result of the Stage 2 DBPR. To quantify the reduction in cases, EPA assumed a linear relationship between average DBP concentration and relative risk of bladder cancer. Because of this, EPA considers these estimates to be an upper bound on the annual reduction in bladder cancer cases due to the rule.

A lag period (i.e., cessation lag) exists between when reduction in exposure to a carcinogen occurs and when the full risk reduction benefit of that exposure reduction is realized by exposed individuals. No data are available that address the rate of achieving bladder cancer benefits resulting from DBP reductions. Consequently, EPA used data from epidemiological studies that address exposure reduction to cigarette smoke and arsenic to generate three possible cessation lag functions for bladder cancer and DBPs. The cessation lag functions are used in conjunction

with the rule implementation schedule to project the number of bladder cancer cases avoided each year as a result of the Stage 2 DBPR.

Although EPA used three approaches for estimating PAR, for simplicity's sake, EPA used the Villanueva et al. (2003) study to calculate the annual benefits of the Stage 2 DBPR. The benefits estimates derived from Villanueva et al. (2003) capture a substantial portion of the overall range of results, reflecting the uncertainty in both the underlying OR and PAR values, as well as the uncertainty in DBP reductions for Stage 2.

To assign a monetary value to avoided bladder cancer cases, EPA used the value of a statistical life (VSL) for fatal cases and used two alternate estimates of willingness-to-pay to avoid non-fatal cases (one based on curable lymphoma and the other based on chronic bronchitis). EPA believes additional benefits from this rule could come from a reduction in potential reproductive and developmental risks. See Chapter 6 of the EA for more information on estimating benefits (USEPA 2005a).

3. Estimating Costs

Analyzing costs for systems to comply with the Stage 2 DBPR included identifying and costing treatment process improvements that systems will make, as well as estimating the costs to implement the rule, conduct IDSEs, prepare monitoring plans, perform additional routine monitoring, and evaluate significant DBP excursion events. The cost analysis for States/Primacy Agencies included estimates of the labor burdens for training employees on the requirements of the Stage 2 DBPR, responding to PWS reports, and record keeping.

All treatment costs are based on mean unit cost estimates for advanced technologies and chloramines. Derivation of unit costs are described in detail in Technologies and Costs for the Final Long Term 2 Enhanced Surface Water Treatment Rule and Final Stage 2 Disinfectants and Disinfection Byproducts Rule (USEPA 2005g). Unit costs (capital and O&M) for each of nine system size categories are calculated using mean design and average daily flows values. The unit costs are then combined with the predicted number of plants selecting each technology to produce national treatment cost estimates.

Non-treatment costs for implementation, the IDSE, monitoring plans, additional routine monitoring, and operational evaluations are based on estimates of labor hours for performing these activities and on laboratory costs.

While systems vary with respect to many of the input parameters to the Stage 2 DBPR cost analysis (e.g., plants per system, population served, flow per population, labor rates), EPA believes that mean values for the various input parameters are appropriate to generate the best estimate of national costs for the rule. Uncertainty in the national average unit capital and O&M costs for the various technologies has been incorporated into the cost analysis (using Monte Carlo simulation procedures). Costs of the Stage 2 DBPR are estimated at both mean and 90 percent confidence bound values.

EPA assumes that systems will, to the extent possible, pass cost increases on to their customers through increases in water rates. Consequently, EPA has also estimated annual household cost increases for the Stage 2 DBPR. This analysis includes costs for all households served by systems subject to the rule, costs just for those households served by systems actually changing treatment technologies to comply with the rule, costs for households served by small systems, and costs for systems served by surface water and ground water sources.

4. Comparing Regulatory Alternatives

Through the analyses summarized in this section, EPA assessed the benefits and costs of the four regulatory alternatives described previously. Succeeding sections of this preamble present the results of these analyses. As recommended by the Advisory Committee, EPA is establishing the preferred regulatory alternative for today's Stage 2 DBPR. This regulation will reduce peak DBP concentrations in distribution systems through requiring compliance determinations with existing TTHM and HAA5 MCLs using the LRAA. Further, the IDSE will ensure that systems identify compliance monitoring sites that reflect high DBP levels. EPA believes that these provision are appropriate given the association of DBPs with cancer, as well as potential reproductive and developmental health effects.

Alternative 1 would have established the same DBP regulations as the preferred alternative, and would have lowered the bromate MCL from 0.010 to 0.005 mg/L. The Advisory Committee did not recommend and EPA did not establish this alternative because it could have an adverse effect on microbial protection. The lower bromate MCL could cause many systems to reduce or eliminate the use of ozone, which is an effective disinfectant for a broad spectrum of microbial pathogens, including microorganisms like Cryptosporidium that are resistant to chlorine.

Alternative 2 would have prohibited any single sample from exceeding the TTHM or HAA5 MCL. This is significantly more stringent than the preferred alternative and would likely require a large fraction of surface water systems to switch from their current treatment practices to more expensive advanced technologies. Consistent with the Advisory Committee, EPA does not believe such a drastic shift is warranted at this time.

Similarly, Alternative 3, which would decrease TTHM and HAA5 MCLs to 0.040 mg/L and 0.030 mg/L, respectively, and would require a significant portion of surface water systems to implement expensive advanced technologies in place of their existing treatment. Further, compliance with TTHM and HAA5 MCLs under this alternative would be based on the RAA, which does not specifically address DBP peaks in the distribution system as the LRAA, in conjunction with the IDSE, are designed to do. Based on these considerations, EPA and the Advisory Committee did not favor this alternative.

C. Benefits of the Stage 2 DBPR

The benefits analysis for the Stage 2 DBPR includes a description of non-quantified benefits, calculations of quantified benefits, and a discussion of when benefits will occur after today's final rule is implemented. An overview of the methods used to determine benefits is provided in Section VI.B. More detail can be found in the final EA. A summary of benefits for the Stage 2 DBPR is given in this section.

1. Nonquantified Benefits

Non-quantified benefits of the Stage 2 DBPR include potential benefits from reduced reproductive and developmental risks, reduced risks of cancers other than bladder cancer, and improved water quality. EPA believes that additional benefits from this rule could come from a reduction in potential reproductive and developmental risks. However, EPA does not believe the available evidence provides an adequate basis for quantifying these potential risks in the primary analysis.

Both toxicology and epidemiology studies indicate that other cancers may be associated with DBP exposure but currently there is not enough data to include them in the primary analysis. However, EPA believes that the association between exposure to DBPs and colon and rectal cancer is possibly

significant, so an analysis of benefits is presented as a sensitivity analysis.

To the extent that the Stage 2 DBPR changes perceptions of the health risks associated with drinking water and improves taste and odor, it may reduce actions such as buying bottled water or installing filtration devices. Any resulting cost savings would be a regulatory benefit. Also, as PWSs move away from conventional treatment to more advanced technologies, other non-health benefits are anticipated besides better tasting and smelling water. For example, GAC lowers nutrient availability for bacterial growth, produces a biologically more stable finished water, and facilitates management of water quality in the distribution system. Since GAC also removes synthetic organic chemicals (SOCs), it provides additional protection from exposure to chemicals associated with accidental spills or environmental runoff.

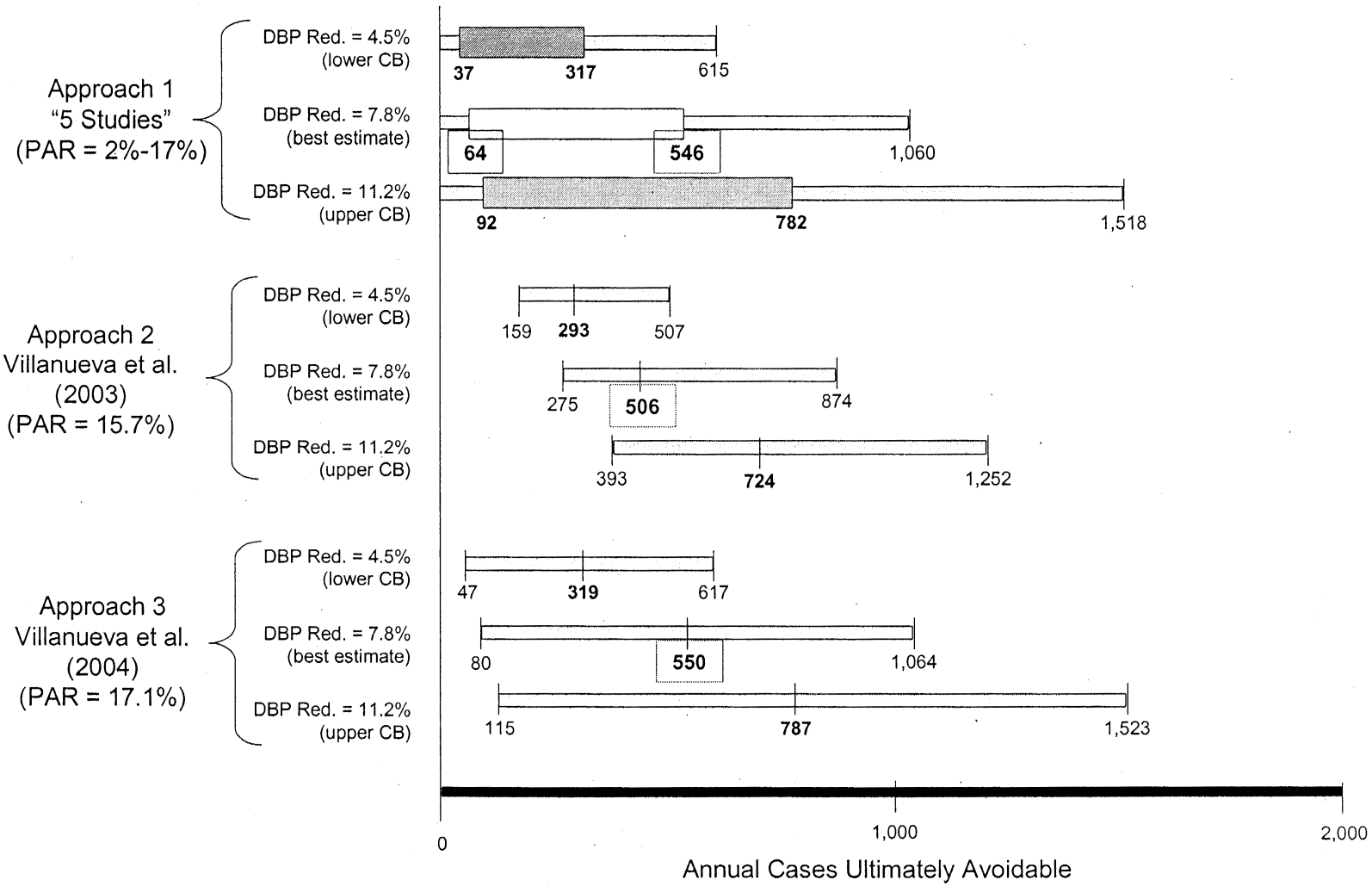
2. Quantified Benefits

EPA has quantified the benefits associated with the expected reductions in the incidence of bladder cancer. As discussed in Section VI.B, EPA used the PAR values from all three approaches to estimate the number of bladder cancer cases ultimately avoided annually as a result of the Stage 2 DBPR, shown in Figure VI.C–1.

Table VI.C–1 summarizes the estimated number of bladder cancer cases avoided as a result of the Stage 2 DBPR, accounting for cessation lag and the rule implementation schedule, and the monetized value of those cases. The benefits in Table VI.C–1 were developed using the PAR value from Villanueva et al. (2003), as described in Section VI.B. Table VI.C–1 summarizes the benefits for the Preferred Regulatory Alternative for the Stage 2 DBPR. Benefits estimates for the other regulatory alternatives were derived using the same methods as for the Preferred Regulatory Alternative and are presented in the EA.

The confidence bounds of the results in Table VI.C–1 reflect uncertainty in PAR, uncertainty in the compliance forecast and resulting reduction in DBP concentrations, and cessation lag. Confidence bounds of the monetized benefits also reflect uncertainty in valuation parameters. An estimated 26 percent of bladder cancer cases avoided are fatal, and 74 percent are non-fatal (USEPA 1999b). The monetized benefits therefore reflect the estimate of avoiding both fatal and non-fatal cancers in those proportions.

Figure VI.C-1. Comparison of Estimates of Annual Bladder Cancer Cases Ultimately Avoidable from Stage 1 to Stage 2.



Abbreviation: PAR = Population Attributable Risk (values shown are best estimates). CB = Confidence Bound

Notes: Estimated annual cases ultimately avoidable are based on predicted DBP reduction from Stage 1 to Stage 2. Results shown assume that percent reduction in average TTHM concentrations is an indicator of percent reduction in concentrations of all DBPs. Three contributions to the uncertainty in the estimate of the annual cases ultimately avoidable by Stage 2 are displayed in this exhibit: (1) uncertainty in the approach used to estimate PAR; (2) uncertainty in the underlying data used to derive the PAR estimates for each approach, represented by the 95 percent confidence intervals displayed in each horizontal bar; and (3) uncertainty in the percent reduction in the national average DBP levels achieved by Stage 2 is represented by the lower 90 percent CB, best estimate, and upper 90 percent CB values shown for each approach. For Approach 1, the hatched boxes represent the 2 percent to 17 percent range of best estimates from the five separate studies considered.in the Odds Ratios underlying the PAR values. The estimates in boxes are the overall mean (best) estimates for each approach.

TABLE VI.C–1.—SUMMARY OF QUANTIFIED BENEFITS FOR THE STAGE 2 DBPR (MILLIONS OF $2003)

Annual average cases avoided			Discount rate, WTP for non-fatal cases	Annualized benefits of cases avoided			Cessation lag model
Mean	5th	95th		Mean	5th	95th	
279	103	541	3%, Lymphoma	$1,531	$233	$3,536	Smoking/Lung Cancer
			7% Lymphoma	1,246	190	2,878	
			3% Bronchitis	763	165	1,692	
			7% Bronchitis	621	135	1,376	
188	61	399	3%, Lymphoma	1,032	157	2,384	Smoking/Bladder Cancer
			7% Lymphoma	845	129	1,950	
			3% Bronchitis	514	111	1,141	
			7% Bronchitis	420	91	932	
333	138	610	3%, Lymphoma	1,852	282	4,276	Arsenic/Bladder Cancer
			7% Lymphoma	1,545	235	3,566	
			3% Bronchitis	922	200	2,045	
			7% Bronchitis	769	167	1,704	

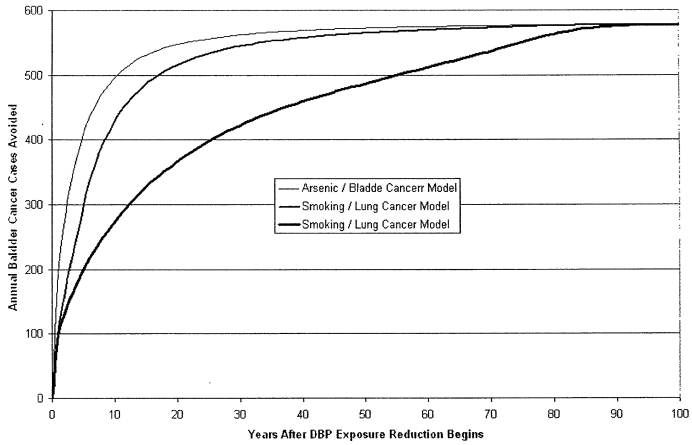
Notes: Values are discounted and annualized in 2003$. The 90 percent confidence interval for cases incorporates uncertainty in PAR, reduction in average TTHM and HAA5 concentrations, and cessation lag. The 90 percent confidence bounds for monetized benefits reflect uncertainty in monetization inputs relative to mean cases. Based on TTHM as an indicator, benefits were calculated using the Villanueva et al. (2003) PAR. EPA recognizes that benefits may be as low as zero since causality has not yet been established between exposure to chlorinated water and bladder cancer. Assumes 26 percent of cases are fatal, 74 percent are non-fatal (USEPA 1999b).

Source: Exhibit 6.1, USEPA 2005a.

3. Timing of Benefits Accrual

EPA recognizes that it is unlikely that all cancer reduction benefits would be realized immediately upon exposure reduction. Rather, it is expected that there will likely be some transition period as individual risks reflective of higher past exposures at the time of rule implementation become, over time, more reflective of the new lower exposures. EPA developed cessation lag models for DBPs from literature to describe the delayed benefits, in keeping with the recommendations of the SAB (USEPA 2001d). Figure VI.C–2 illustrates the effects of the cessation lag models. The results from the cessation lag models show that the majority of the potential cases avoided occur within the first fifteen years after initial reduced exposure to DBPs. For example, fifteen years after the exposure reduction has occurred, the annual cases avoided will be 489 for the smoking/lung cancer cessation lag model, 329 for the smoking/bladder cancer cessation lag model, and 534 cases for the arsenic/bladder cancer cessation lag model. These represent approximately 84%, 57%, and 92%, respectively, of the estimated 581 annual cases ultimately avoidable by the Stage 2 DBPR.

Figure VI.C-2. Comparison of Alternative Cessation Lag Models: Estimates of Annual Cases Avoided by Year Following Exposure Reduction (Excluding Implementation Schedule).



In addition to the delay in reaching a steady-state level of risk reduction as a result of cessation lag, there is a delay in attaining maximum exposure reduction across the entire affected population that results from the Stage 2 DBPR implementation schedule. For example, large surface water PWSs have six years from rule promulgation to meet the new Stage 2 MCLs, with up to a two-year extension possible for capital improvements. In general, EPA assumes that a fairly constant increment of systems will complete installation of new treatment technologies each year, with the last systems installing treatment by 2016. The delay in exposure reduction resulting from the rule implementation schedule is incorporated into the benefits model by adjusting the cases avoided for the given year and is illustrated in Table VI.C–2.

TABLE VI.C–2.—BLADDER CANCER CASES AVOIDED (TTHM AS INDICATOR) EACH YEAR USING THREE CESSATION LAG MODELS

Year	Smoking/lung cancer cessation lag model		Smoking/bladder cancer cessation lag model		Arsenic/bladder cancer cessation lag model	
	Total	Percent	Total	Percent	Total	Percent
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0
6	24	4	23	4	45	8
7	62	11	54	9	110	19
8	111	19	90	16	187	32
9	170	29	132	23	275	48
10	220	38	161	28	334	58
11	265	46	184	32	379	65
12	305	53	204	35	412	71
13	341	59	221	38	438	76
14	371	64	237	41	458	79
15	396	68	251	43	475	82
16	416	72	265	46	488	84
17	433	75	278	48	499	86
18	448	77	289	50	509	88
19	460	79	301	52	516	89
20	471	81	311	54	523	90
21	481	83	321	55	528	91
22	489	84	330	57	533	92
23	496	86	339	59	537	93
24	503	87	347	60	541	93
25	509	88	355	61	544	94

Notes: Percent of annual cases ultimately avoidable achieved during each of the first 25 years. The benefits model estimates 581 (90% CB = 229–1,079) annual cases ultimately avoidable using the Villanueva et al. (2003) PAR inputs and including uncertainty in these and DBP reductions. EPA recognizes that benefits may be as low as zero since causality has not yet been established between exposure to chlorinated water and bladder cancer.

Source: Summarized from detailed results presented in Exhibits E.38a, E.38e and E.38i, USEPA 2005a.

D. Costs of the Stage 2 DBPR

National costs include those of treatment changes to comply with the rule as well as non-treatment costs such as for Initial Distribution System Evaluations (IDSEs), additional routine monitoring, and operational evaluations. The methodology used to estimate costs is described in Section VI.B. More detail is provided in the EA (USEPA 2005a). The remainder of this section presents summarized results of EPA's cost analysis for total annualized present value costs, PWS costs, State/Primacy agency costs, and non-quantified costs.

1. Total Annualized Present Value Costs

Tables VI.D–1 and VI.D–2 summarize the average annualized costs for the Stage 2 DBPR Preferred Regulatory Alternative at 3 and 7 percent discount rates, respectively. System costs range from approximately $55 to $101 million annually at a 3 percent discount rate, with a mean estimate of approximately $77 million per year. The mean and range of annualized costs are similar at a 7 percent discount rate. State costs are estimated to be between $1.70 and $1.71 million per year depending on the discount rate. These estimates are annualized starting with the year of promulgation. Actual dollar costs during years when most treatment changes are expected to occur would be somewhat higher (the same is true for benefits that occur in the future).

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Table VI.D-1. Total Annualized Costs for Stage 2 DBPR Activities ($Millions/Year, 3 Percent Discount Rate).

System Size (Population Served)	System Costs														State Costs	Total Costs of the Rule		
	Capital Costs			O&M Costs			Non-Treatment Costs (Point Estimate)					Total System Costs						
	Mean Value	90 Percent Confidence Bound		Mean Value	90 Percent Confidence Bound		Implement-ation	IDSE	Monitoring Plans	Moni-toring	Significant Excursion	Mean Value	90 Percent Confidence Bound			Mean Value	90 Percent Confidence Bound	
		Lower (5th %tile)	Upper (95th %tile)		Lower (5th %tile)	Upper (95th %tile)							Lower (5th %tile)	Upper (95th %tile)			Lower (5th %tile)	Upper (95th %tile)
Surface Water CWSs																		
< 10,000	$4.21	$2.32	$6.23	$6.10	$3.41	$8.83	$0.12	$0.93	$0.05	-$0.07	$0.02	$11.34	$6.76	$16.10				
≥ 10,000	$20.60	$11.22	$28.75	$14.33	$9.03	$21.55	$0.09	$1.59	$0.03	-$1.14	$0.11	$35.61	$20.93	$50.97				
Surface Water NTNCWSs																		
< 10,000	$0.27	$0.15	$0.40	$0.57	$0.32	$0.82	$0.01	$0.00	$0.00	$0.02	$0.00	$0.86	$0.49	$1.25				
≥ 10,000	$0.04	$0.02	$0.06	$0.03	$0.02	$0.04	$0.00	$0.00	$0.00	$0.00	$0.00	$0.08	$0.05	$0.11				
Ground Water CWSs																		
< 10,000	$7.41	$6.13	$8.70	$7.20	$6.60	$7.79	$0.30	$0.29	$0.08	$1.05	$0.00	$16.33	$14.45	$18.21				
≥ 10,000	$4.87	$4.37	$5.36	$6.00	$5.64	$6.37	$0.05	$0.10	$0.02	$0.00	$0.00	$11.04	$10.18	$11.90				
Ground Water NTNCWSs																		
< 10,000	$0.57	$0.48	$0.65	$0.75	$0.69	$0.81	$0.06	$0.00	$0.01	$0.42	$0.00	$1.80	$1.65	$1.95				
≥ 10,000	$0.01	$0.01	$0.01	$0.01	$0.01	$0.01	$0.00	$0.00	$0.00	$0.01	$0.00	$0.03	$0.02	$0.03				
TOTAL	**$37.97**	**$24.69**	**$50.17**	**$34.98**	**$25.72**	**$46.22**	**$0.62**	**$2.91**	**$0.19**	**$0.28**	**$0.12**	**$77.08**	**$54.53**	**$100.51**	**$1.71**	**$78.80**	**$56.24**	**$102.22**

Notes: Detail may not add due to independent rounding. 90 percent confidence bound reflects uncertainty in technology compliance forecast and unit treatment costs.
Estimates are discounted to 2003 and given in 2003 dollars.

Source: Exhibit 7.5a, USEPA 2005a.

Table VI.D-2. Total Annualized Costs for Stage 2 DBPR Activities ($Millions/Year, 7 Percent Discount Rate).

System Size (Population Served)	System Costs														State Costs	Total Costs of the Rule		
	Capital Costs			O&M Costs			Non-Treatment Costs (Point Estimate)					Total System Costs						
	Mean Value	90 Percent Confidence Bound		Mean Value	90 Percent Confidence Bound		Implement-ation	IDSE	Monitoring Plans	Moni-toring	Significant Excursion	Mean Value	90 Percent Confidence Bound			Mean Value	90 Percent Confidence Bound	
		Lower (5th %tile)	Upper (95th %tile)		Lower (5th %tile)	Upper (95th %tile)							Lower (5th %tile)	Upper (95th %tile)			Lower (5th %tile)	Upper (95th %tile)
Surface Water CWSs																		
< 10,000	$4.53	$2.50	$6.71	$4.86	$2.72	$7.04	$0.15	$1.16	$0.06	-$0.06	$0.01	$10.72	$6.54	$15.08				
≥ 10,000	$23.00	$12.53	$32.10	$11.66	$7.35	$17.54	$0.11	$2.06	$0.04	-$0.90	$0.08	$36.06	$21.27	$51.03				
Surface Water NTNCWSs																		
< 10,000	$0.29	$0.16	$0.43	$0.45	$0.25	$0.66	$0.01	$0.00	$0.00	$0.01	$0.00	$0.76	$0.43	$1.11				
≥ 10,000	$0.05	$0.03	$0.07	$0.02	$0.01	$0.03	$0.00	$0.00	$0.00	$0.00	$0.00	$0.08	$0.05	$0.11				
Ground Water CWSs																		
< 10,000	$7.98	$6.60	$9.37	$5.74	$5.26	$6.21	$0.38	$0.36	$0.09	$0.84	$0.00	$15.38	$13.53	$17.24				
≥ 10,000	$5.39	$4.84	$5.94	$4.87	$4.57	$5.16	$0.06	$0.13	$0.02	$0.00	$0.00	$10.46	$9.62	$11.31				
Ground Water NTNCWSs																		
< 10,000	$0.61	$0.51	$0.70	$0.60	$0.55	$0.65	$0.07	$0.00	$0.01	$0.33	$0.00	$1.62	$1.48	$1.77				
≥ 10,000	$0.01	$0.01	$0.01	$0.01	$0.01	$0.01	$0.00	$0.00	$0.00	$0.01	$0.00	$0.02	$0.02	$0.02				
TOTAL	**$41.86**	**$27.16**	**$55.33**	**$28.21**	**$20.73**	**$37.29**	**$0.78**	**$3.71**	**$0.23**	**$0.23**	**$0.10**	**$75.11**	**$52.94**	**$97.67**	**$1.70**	**$76.81**	**$54.64**	**$99.36**

Notes: Detail may not add due to independent rounding. 90 percent confidence bound reflects uncertainty in technology compliance forecast and unit treatment costs.

Estimates are discounted to 2003 and given in 2003 dollars.

Source: Exhibit 7.5b, USEPA 2005a.

2. PWS costs

PWS costs for the Stage 2 DBPR include non-treatment costs of rule implementation, Initial Distribution System Evaluations (IDSEs), Stage 2 DBPR monitoring plans, additional routine monitoring, and operational evaluations. Systems required to install treatment to comply with the MCLs will accrue the additional costs of treatment installation as well as operation and maintenance. Significant PWS costs for IDSEs, treatment, and monitoring are described in this section, along with a sensitivity analysis.

a. IDSE costs. Costs and burden associated with IDSE activities differ depending on whether or not the system performs the IDSE and, if so, which option a system chooses. All systems performing the IDSE are expected to incur some costs. EPA's analysis allocated systems into five categories to determine the costs of the IDSE—those conducting standard monitoring, SSS, VSS, 40/30, and NTNCWS not required to do an IDSE. EPA then developed cost estimates for each option. Tables VI.D–3, VI.D–4, and VI.D–5 illustrate PWS costs for IDSE for systems conducting an SMP, SSS, and 40/30, respectively.

Table VI.D-3. IDSE Costs for Systems Using Standard Monitoring.

Size Category	Total Number of Systems That Monitor	Develop IDSE monitoring plan and report			Sampling				Total Cost	Total Burden (Hours)	Total Burden (FTEs)
		Preparation of IDSE Monitoring Plan	Preparation of IDSE Report	Reporting Cost per Labor Hour	Number of Dual Sample Sets per System	Hours per Sample	Sampling Cost per Labor Hour	Laboratory Cost per Sample			
	A	B	C	D	E	F	G	H	I=A*((B+C)*D+E*(F*G+H))	J=A*(B+C+E*F)	K=J/2,080
Surface Water and Mixed CWSs											
<500	2,060	4	2	$ 22.55	2	1	$ 22.55	$ 240	$ 1,360,071	16,476	7.9
500-3,299	3,823	4	2	$ 24.74	8	1	$ 24.74	$ 240	$ 8,664,294	53,522	25.7
3,300-9,999	1,888	4	2	$ 30.51	16	1	$ 25.34	$ 240	$ 8,361,031	41,536	20.0
10,000-49,999	1,524	8	4	$ 31.08	48	1	$ 26.05	$ 210	$ 17,835,921	91,440	44.0
50,000-249,999	436	8	8	$ 32.64	96	1	$ 28.00	$ 210	$ 10,189,487	48,832	23.5
250,000-999,999	63	12	12	$ 35.25	144	1	$ 31.26	$ 210	$ 2,242,006	10,584	5.1
1,000,000-4,999,999	14	16	24	$ 35.25	192	1	$ 31.26	$ 210	$ 668,246	3,248	1.6
≥5 M	1	24	24	$ 35.25	240	1	$ 31.26	$ 210	$ 59,594	288	0.1
National Totals	**9,809**								**$ 49,380,649**	**265,926**	**127.8**
Disinfecting Ground Water Only CWSs											
<500	752	4	2	$ 22.35	2	1	$ 22.35	$ 240	$ 495,114	6,012	2.9
500-9,999	1,956	4	2	$ 24.86	8	1	$ 24.86	$ 240	$ 4,435,321	27,378	13.2
10,000-99,999	240	8	8	$ 31.08	24	1	$ 26.05	$ 210	$ 1,477,430	9,590	4.6
100,000-499,999	18	12	12	$ 35.25	32	1	$ 31.26	$ 210	$ 152,514	997	0.5
> 500,000	1	16	24	$ 35.25	48	1	$ 31.26	$ 210	$ 11,576	78	0.0
National Totals	**2,966**								**$ 6,571,956**	**44,056**	**21.2**
Surface Water and Mixed NTNCWSs											
<500	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
500-3,299	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3,300-9,999	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10,000-49,999	4	8	4	$ 31.08	48	1	$ 26.05	$ 210	$ 46,813	240	0.1
50,000-249,999	1	8	8	$ 35.25	96	1	$ 31.26	$ 210	$ 23,725	112	0.1
250,000-999,999	0	12	12	N/A	144	1	N/A	$ 210	$ -	-	-
1,000,000-4,999,999	0	16	24	N/A	192	1	N/A	$ 210	$ -	-	-
≥5 M	0	24	24	N/A	240	1	N/A	$ 210	$ -	-	-
National Totals	**5**								**$ 70,538**	**352**	**0.2**
Disinfecting Ground Water Only NTNCWSs											
<500	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
500-9,999	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10,000-99,999	1	8	8	$ 31.08	24	1	$ 26.05	$ 210	$ 3,759	24	0.0
100,000-499,999	0	12	12	$ 35.25	32	1	$ 31.26	$ 210	$ 2,484	16	0.0
> 500,000	0	16	24	N/A	48	1	N/A	$ 210	$ -	-	-
National Totals	**1**								**$ 6,243**	**41**	**0.0**
Grand Totals	**12,780**								**$ 56,029,386**	**310,375**	**149.2**

Notes: Detail my not add due to independent rounding.
Shaded areas represent systems that are not subject to IDSE requirements.
1 FTE = 2,080 hours (40 hours/week, 52 weeks/year)

Source: Exhibit H.4, USEPA 2005a.

Table VI.D-5. IDSE Costs Systems Qualifying for the 40/30 Certification.

	Selecting Additional Sites		Preparing IDSE Certification					
Size Category	Systems Receiving 40/30 Certification but Adding Stage 2 site(s)	Hours per System	Number of Systems Receiving 40/30 Certification	Reporting Hours per System	Cost per Labor Hour	Total Cost	Total Burden (Hours)	Total Burden (FTEs)
	A	B	C	D	E	F = (A*B+C*D)*E	G = A*B+C*D	H = G/2,080
Surface Water and Mixed CWSs								
<500	-	1	-	1	$ 22.55	$ -	-	-
500-3,299	-	3	235	1	$ 24.74	$ 5,814	235	0.1
3,300-9,999	154	3	154	1	$ 30.51	$ 18,795	616	0.3
10,000-49,999	-	8	249	2	$ 31.08	$ 15,478	498	0.2
50,000-249,999	75	8	75	2	$ 32.64	$ 24,481	750	0.4
250,000-999,999	11	8	11	2	$ 35.25	$ 3,877	110	0.1
1,000,000-4,999,999	2	8	2	2	$ 35.25	$ 705	20	0.0
≥5 M	-	8	-	2	$ 35.25	$ -	-	-
National Total	**242**		**726**			**$ 69,150**	**2,229**	**1.1**
Disinfecting Ground Water Only CWSs								
<500	-	1	-	1	$ 22.35	$ -	-	-
500-9,999	9,094	3	9,094	1	$ 24.86	$ 904,287	36,376	17.5
10,000-99,999	1,118	8	1,118	2	$ 31.08	$ 347,474	11,180	5.4
100,000-499,999	-	8	40	2	$ 35.25	$ 2,820	80	0.0
> 500,000	-	8	5	2	$ 35.25	$ 352	10	0.0
National Total	**10,212**		**10,257**			**$ 1,254,934**	**47,646**	**22.9**
Surface Water and Mixed NTNCWSs								
<500	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
500-3,299	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3,300-9,999	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10,000-49,999	-	8	1	2	$ 31.08	$ 62	2	0.0
50,000-249,999	-	8	-	2	$ 35.25	$ -	-	-
250,000-999,999	-	8	-	2	N/A	$ -	-	-
1,000,000-4,999,999	-	8	-	2	N/A	$ -	-	-
≥5 M	-	8	-	2	N/A	$ -	-	-
National Total	**-**		**1**			**$ 62**	**2**	**0.0**
Disinfecting Ground Water Only NTNCWSs								
<500	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
500-9,999	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10,000-99,999	3	8	3	2	$ 31.08	$ 932	30	0.0
100,000-499,999	-	8	-	3	$ 35.25	$ -	-	-
> 500,000	-	8	-	6	N/A	$ -	-	-
National Total	**3**		**3**			**$ 932**	**30**	**0.0**
Grand Totals	**10,457**		**10,987**			**$ 1,325,079**	**49,907**	**24.0**

Notes: Shaded areas represent systems that are not subject to IDSE requirements.
Source: Exhibit H.6, USEPA 2005a.

Table VI.D-4. IDSE Costs for Systems Using SSSs.

Size Category	Number of Systems Qualifying for SSS	Preparation of IDSE Study Plan	Conduct Study	Preparation of IDSE Study Report	Cost per Labor Hour	Total Cost	Total Burden (Hours)	Total Burden (FTEs)
	A	B	C	D	E	F = A*(B+C+D)*E	G = A*(B+C+D)	H = G/2,080
Surface Water and Mixed CWSs								
<500	-	-	-	-	$ -	$ -	-	-
500-3,299	-	-	-	-	$ -	$ -	-	-
3,300-9,999	-	-	-	-	$ -	$ -	-	-
10,000-49,999	-	-	-	-	$ -	$ -	-	-
50,000-249,999	23	20	40	20	$ 32.64	$ 60,060	1,840	0.9
250,000-999,999	7	20	40	20	$ 35.25	$ 19,739	560	0.3
1,000,000-4,999,999	1	20	40	20	$ 35.25	$ 2,820	80	0.0
≥5 M	-	-	-	-	$ -	$ -	-	-
National Total	**31**					**$ 82,618**	**2,480**	**1.2**
Disinfecting Ground Water Only CWSs								
<500	-	-	-	-	$ -	$ -	-	-
500-9,999	-	-	-	-	$ -	$ -	-	-
10,000-99,999	-	-	-	-	$ -	$ -	-	-
100,000-499,999	2	20	40	20	$ 35.25	$ 5,640	160	0.1
> 500,000	-	-	-	-	$ -	$ -	-	-
National Total	**2**					**$ 5,640**	**160**	**0.1**
Surface Water and Mixed NTNCWSs								
<500	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
500-3,299	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3,300-9,999	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10,000-49,999	-	-	-	-	$ -	$ -	-	-
50,000-249,999	-	-	-	-	$ -	$ -	-	-
250,000-999,999	-	-	-	-	$ -	$ -	-	-
1,000,000-4,999,999	-	-	-	-	$ -	$ -	-	-
≥5 M	-	-	-	-	$ -	$ -	-	-
National Total	**-**					**$ -**	**-**	**-**
Disinfecting Ground Water Only NTNCWSs								
<500	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
500-9,999	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10,000-99,999	-	-	-	-	$ -	$ -	-	-
100,000-499,999	-	-	-	-	$ -	$ -	-	-
> 500,000	-	-	-	-	$ -	$ -	-	-
National Total	**-**					**$ -**	**-**	**-**
Grand Totals	**33**					**$ 88,258**	**2,640**	**1.3**

Notes: Detail my not add due to independent rounding.
Shaded areas represent systems that are not subject to IDSE requirements.
SSS = System Specific Study.
Source: Exhibit H.5, USEPA 2005a.

b. PWS treatment costs. The number of plants changing treatment as a result of the Stage 2 DBPR and which technology various systems will install are determined from the compliance forecast. The percent of systems predicted to make treatment technology changes and the technologies predicted to be in place after implementation of the Stage 2 DBPR are shown in Table VI.D–6. The cost model includes estimates for the cost of each technology; the results of the cost model for PWS treatment costs are summarized in Table VI.D–7.

Table VI.D-6. Percent of Plants Changing to Various Treatment Technologies as a Result of the Stage 2 DBPR.

Source	System Classification	System Size (Population Served)	CLM Only	Chlorine Dioxide	UV	Ozone	MF/UF	GAC10	GAC 10 + Alternative Disinfectants	GAC 20	GAC 20 + Alternative Disinfectants	Membranes	Total Converting to CLM	Total Percent of Plants Changing Technology
Surface Water	CWSs	<100	1.9%		7.1%		0.0%			0.0%	1.2%	0.0%	5.4%	10.2%
		100-499	4.1%	0.5%	2.5%	0.0%	0.0%			0.0%	1.3%	0.1%	6.5%	8.4%
		500-999	4.1%	0.5%	2.5%	0.0%	0.0%			0.0%	1.3%	0.1%	6.5%	8.4%
		1,000-3,300	4.2%	1.1%	2.2%	0.0%	0.0%			0.0%	1.3%	0.0%	7.2%	8.8%
		3,301-9,999	4.2%	1.1%	2.2%	0.0%	0.0%			0.0%	1.3%	0.0%	7.2%	8.8%
		10,000-49,999	8.6%	0.3%	3.6%	0.0%	0.0%	0.0%	1.7%	0.3%	0.0%	0.0%	10.3%	14.6%
		50,000-99,999	8.6%	0.3%	3.6%	0.0%	0.0%	0.0%	1.7%	0.3%	0.0%	0.0%	10.3%	14.6%
		100,000-999,999	8.6%	0.3%	3.6%	0.0%	0.0%	0.0%	1.7%	0.3%	0.0%	0.0%	10.3%	14.6%
		1,000,000+	8.6%	0.3%	3.6%	0.0%	0.0%	0.0%	1.7%	0.3%	0.0%	0.0%	10.3%	14.6%
		All Sizes	5.8%	0.6%	3.1%	0.0%	0.0%	0.0%	0.6%	0.1%	0.8%	0.0%	8.2%	11.1%
	NTNCWSs	<100	1.9%		7.1%		0.0%			0.0%	1.2%	0.0%	5.4%	10.2%
		100-499	4.1%	0.5%	2.5%	0.0%	0.0%			0.0%	1.3%	0.1%	6.5%	8.4%
		500-999	4.1%	0.5%	2.5%	0.0%	0.0%			0.0%	1.3%	0.1%	6.5%	8.4%
		1,000-3,300	4.2%	1.1%	2.2%	0.0%	0.0%			0.0%	1.3%	0.0%	7.2%	8.8%
		3,301-9,999	4.2%	1.1%	2.2%	0.0%	0.0%			0.0%	1.3%	0.0%	7.2%	8.8%
		10,000-49,999	8.6%	0.3%	3.6%	0.0%	0.0%	0.0%	1.7%	0.3%	0.0%	0.0%	10.3%	14.6%
		50,000-99,999	- %	- %	- %	- %	- %	- %	- %	- %	- %	- %	- %	- %
		100,000-999,999	8.6%	0.3%	3.6%	0.0%	0.0%	0.0%	1.7%	0.3%	0.0%	0.0%	10.3%	14.6%
		1,000,000+	- %	- %	- %	- %	- %	- %	- %	- %	- %	- %	- %	- %
		All Sizes	3.5%	0.4%	3.8%	0.0%	0.0%	0.0%	0.0%	0.0%	1.2%	0.0%	6.3%	9.0%
Ground Water	CWSs	<100	1.0%		1.1%	0.0%				0.4%		0.0%	2.1%	2.4%
		100-499	1.4%		1.6%	0.0%				0.2%		0.0%	3.0%	3.2%
		500-999	1.4%		1.6%	0.0%				0.2%		0.0%	3.0%	3.2%
		1,000-3,300	1.1%		1.6%	0.0%				0.0%		0.0%	2.7%	2.7%
		3,301-9,999	1.1%		1.6%	0.0%				0.0%		0.0%	2.7%	2.7%
		10,000-49,999	1.4%			0.3%				0.2%		0.2%	2.0%	2.1%
		50,000-99,999	1.4%			0.3%				0.2%		0.2%	2.0%	2.1%
		100,000-999,999	1.3%			0.3%				0.1%		0.2%	1.9%	2.0%
		1,000,000+	1.4%			0.3%				0.1%		0.2%	2.0%	2.1%
		All Sizes	1.3%		1.3%	0.0%				0.2%		0.0%	2.6%	2.8%
	NTNCWSs	<100	1.0%		1.1%	0.0%				0.4%		0.0%	2.1%	2.4%
		100-499	1.4%		1.6%	0.0%				0.2%		0.0%	3.0%	3.2%
		500-999	1.4%		1.6%	0.0%				0.2%		0.0%	3.0%	3.2%
		1,000-3,300	1.1%		1.6%	0.0%				0.0%		0.0%	2.7%	2.7%
		3,301-9,999	1.1%		1.6%	0.0%				0.0%		0.0%	2.7%	2.7%
		10,000-49,999	1.4%			0.3%				0.2%		0.2%	2.0%	2.1%
		50,000-99,999	1.4%			0.3%				0.2%		0.2%	2.0%	2.1%
		100,000-999,999	1.3%			0.3%				0.1%		0.2%	1.9%	2.0%
		1,000,000+	- %			- %				- %		- %	- %	- %
		All Sizes	1.2%		1.4%	0.0%				0.3%		0.0%	2.5%	2.8%

Notes: Detail may not add due to independent rounding.

Source: Summarized from detailed results presented in Exhibits 5.11a-d and 5.14a-d, USEPA 2005a.

Table VI.D-7. Total Initial Capital Costs and Steady-State O&M Costs ($Millions/Year).

Source	System Classification	System Size (population served)	Capital Costs				O&M Costs			
			Mean Value	Median Value	90 Percent Confidence Bound Lower (5th %tile)	90 Percent Confidence Bound Upper (95th %tile)	Mean Value	Median Value	90 Percent Confidence Bound Lower (5th %tile)	90 Percent Confidence Bound Upper (95th %tile)
Surface Water	CWSs	<100	$ 1 09	$ 1.07	$ 0 58	$ 1.68	$ 0.20	$ 0.20	$ 0.11	$ 0.29
		100-499	$ 3.27	$ 3.22	$ 1 77	$ 4 94	$ 0 82	$ 0.82	$ 0.46	$ 1.19
		500-999	$ 3 86	$ 3.78	$ 2.08	$ 5 89	$ 0.61	$ 0.61	$ 0.34	$ 0.88
		1,000-3,299	$ 24.39	$ 24.27	$ 13.37	$ 36.07	$ 3.36	$ 3.36	$ 1 88	$ 4.86
		3,300-9,999	$ 62.23	$ 61 92	$ 34.42	$ 91.81	$ 5 32	$ 5.34	$ 2.97	$ 7.70
		10,000-49,999	$ 113.20	$ 113.98	$ 62 72	$ 157 05	$ 6 04	$ 6.00	$ 3 74	$ 8.66
		50,000-99,999	$ 67.40	$ 68 08	$ 37.41	$ 93.50	$ 3.41	$ 3.36	$ 2.13	$ 4.95
		100,000-999,999	$ 183 98	$ 186 24	$ 98 21	$ 257 75	$ 8.17	$ 7.87	$ 5.21	$ 12.52
		1,000,000+	$ 86.04	$ 86.46	$ 47.14	$ 120 41	$ 4.91	$ 4.65	$ 3.11	$ 7.73
		All Sizes	$ 545.44	$ 549 03	$ 297.70	$ 769.10	$ 32.84	$ 32.21	$ 19 95	$ 48.78
	NTNCWSs	<100	$ 0.67	$ 0 66	$ 0 36	$ 1.03	$ 0.12	$ 0.12	$ 0.07	$ 0.17
		100-499	$ 1.32	$ 1 31	$ 0.72	$ 2.00	$ 0.33	$ 0.33	$ 0.19	$ 0.48
		500-999	$ 0.85	$ 0 84	$ 0.46	$ 1 30	$ 0.13	$ 0.13	$ 0.07	$ 0.20
		1,000-3,299	$ 1.89	$ 1.88	$ 1 04	$ 2 80	$ 0.26	$ 0.26	$ 0.15	$ 0.38
		3,300-9,999	$ 1.29	$ 1 28	$ 0.71	$ 1.90	$ 0.11	$ 0.11	$ 0.06	$ 0.16
		10,000-49,999	$ 0.55	$ 0 55	$ 0.30	$ 0 76	$ 0.03	$ 0.03	$ 0.02	$ 0.04
		50,000-99,999	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
		100,000-999,999	$ 0 41	$ 0 41	$ 0.22	$ 0.57	$ 0.02	$ 0.02	$ 0.01	$ 0.03
		1,000,000+	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
		All Sizes	$ 6.99	$ 6 95	$ 3.82	$ 10 36	$ 1.00	$ 1.00	$ 0.56	$ 1.46
		Subtotal	**$ 552.43**	**$ 555.97**	**$ 301.52**	**$ 779.46**	**$ 33.85**	**$ 33.22**	**$ 20.52**	**$ 50.24**
Ground Water	CWSs	<100	$ 8 34	$ 8 34	$ 7.19	$ 9.53	$ 0.98	$ 0.98	$ 0.91	$ 1.05
		100-499	$ 33.19	$ 33.18	$ 28 04	$ 38 38	$ 3 68	$ 3.68	$ 3.38	$ 3.98
		500-999	$ 20.18	$ 20.18	$ 17.00	$ 23 34	$ 1.96	$ 1 96	$ 1 80	$ 2.12
		1,000-3,299	$ 39.43	$ 39 42	$ 32.35	$ 46.54	$ 3.00	$ 3 00	$ 2.73	$ 3.26
		3,300-9,999	$ 65.91	$ 65.86	$ 53.53	$ 78.34	$ 2.55	$ 2 55	$ 2 33	$ 2 76
		10,000-49,999	$ 59.09	$ 59.08	$ 53.39	$ 64.79	$ 5.03	$ 5 03	$ 4.76	$ 5.30
		50,000-99,999	$ 14.96	$ 14.96	$ 13.38	$ 16.53	$ 1.28	$ 1 28	$ 1.20	$ 1.36
		100,000-999,999	$ 29.70	$ 29.71	$ 26.43	$ 32.95	$ 2.83	$ 2 83	$ 2.64	$ 3.02
		1,000,000+	$ 3.38	$ 3.38	$ 2.97	$ 3.79	$ 0.43	$ 0.43	$ 0.40	$ 0.46
		All Sizes	$ 274.18	$ 274.11	$ 234.29	$ 314.20	$ 21 73	$ 21.73	$ 20.16	$ 23.31
	NTNCWSs	<100	$ 3.17	$ 3.17	$ 2.73	$ 3 62	$ 0.37	$ 0.37	$ 0.35	$ 0.40
		100-499	$ 5 04	$ 5.04	$ 4.25	$ 5.81	$ 0.55	$ 0.55	$ 0.51	$ 0.60
		500-999	$ 2.47	$ 2.47	$ 2.07	$ 2.87	$ 0 23	$ 0.23	$ 0.21	$ 0.25
		1,000-3,299	$ 1.61	$ 1.61	$ 1.32	$ 1.90	$ 0.10	$ 0.10	$ 0.09	$ 0.11
		3,300-9,999	$ 0 46	$ 0.46	$ 0 38	$ 0.55	$ 0.01	$ 0.01	$ 0.01	$ 0.02
		10,000-49,999	$ 0.10	$ 0.10	$ 0.09	$ 0.11	$ 0.01	$ 0.01	$ 0.01	$ 0.01
		50,000-99,999	$ 0.02	$ 0.02	$ 0.02	$ 0.02	$ 0.00	$ 0.00	$ 0.00	$ 0.00
		100,000-999,999	$ 0.03	$ 0.03	$ 0.03	$ 0.03	$ 0.00	$ 0.00	$ 0.00	$ 0.00
		1,000,000+	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
		All Sizes	$ 12.90	$ 12.90	$ 10.87	$ 14.91	$ 1.29	$ 1.29	$ 1.18	$ 1.39
		Subtotal	**$ 287.08**	**$ 287.01**	**$ 245.16**	**$ 329.11**	**$ 23.02**	**$ 23.02**	**$ 21.34**	**$ 24.70**
		Total	**$ 839.51**	**$ 842.98**	**$ 546.68**	**$ 1,108.57**	**$ 56.86**	**$ 56.23**	**$ 41.86**	**$ 74.94**

Notes: Estimates are discounted to 2003 and given in 2003 dollars.
Detail may not add to totals due to independent rounding.

Source: Exhibit J.1a, USEPA 2005a.

c. Monitoring costs. Because systems already sample for the Stage 1 DBPR, costs for additional routine monitoring are determined by the change in the number of samples to be collected from the Stage 1 to the Stage 2 DBPR. The

Stage 2 DBPR monitoring requirements for systems are based only on population served and source water type, while the Stage 1 DBPR requirements are also based on the number of treatment plants. With this modification in monitoring scheme, the average system will have no change in monitoring costs. The number of samples required is estimated to increase for some systems but actually decrease from the Stage 1 to the Stage 2 DBPR for many systems. Table VI.D–8 summarizes the estimated additional routine monitoring costs for systems.

Table VI.D-8. Total Additional Routine Monitoring Costs for Systems.

Size Category	Total Additional Compliance Samples per Year	Total Labor Costs	Total Sampling Costs	Total Costs	Total Burden (Hours)	Total Burden (FTEs)
	A	B	C	D	E	F= E/2080
Surface Water and Mixed CWSs						
<500	(692)	$ 7,844	$ (166,169)	$ (158,325)	348	0.17
500-3,299	(3,571)	$ (58,617)	$ (857,050)	$ (915,667)	(2,369)	(1.14)
3,300-9,999	3,594	$ 91,070	$ 862,541	$ 953,611	3,594	1.73
10,000-49,999	(10,496)	$ (273,425)	$ (2,204,194)	$ (2,477,619)	(10,496)	(5.05)
50,000-249,999	1,452	$ 40,671	$ 305,021	$ 345,692	1,452	0.70
250,000-999,999	609	$ 19,041	$ 127,915	$ 146,956	609	0.29
1,000,000-4,999,999	128	$ 3,996	$ 26,846	$ 30,843	128	0.06
≥5 M	24	$ 735	$ 4,939	$ 5,674	24	0.01
National Totals	**(8,953)**	**$ (168,684)**	**$ (1,900,150)**	**$ (2,068,834)**	**(6,711)**	**(3.23)**
Disinfecting Ground Water Only CWSs						
<500	793	$ 26,209	$ 190,302	$ 216,511	1,173	0.56
500-9,999	5,777	$ 143,617	$ 1,386,523	$ 1,530,140	5,777	2.78
10,000-99,999	552	$ 14,385	$ 115,964	$ 130,349	552	0.27
100,000-499,999	(277)	$ (8,665)	$ (58,213)	$ (66,879)	(277)	(0.13)
> 500,000	(209)	$ (6,546)	$ (43,976)	$ (50,522)	(209)	(0.10)
National Totals	**6,636**	**$ 169,000**	**$ 1,590,600**	**$ 1,759,600**	**7,015**	**3.37**
Surface Water and Mixed NTNCWSs						
<500	0	$ 0	$ 0	$ 0	0	0.00
500-3,299	0	$ 0	$ 0	$ 0	0	0.00
3,300-9,999	96	$ 2,433	$ 23,040	$ 25,473	96	0.05
10,000-49,999	0	$ 0	$ 0	$ 0	0	0.00
50,000-249,999	16	$ 500	$ 3,360	$ 3,860	16	0.01
250,000-999,999	-	$ -	$ -	$ -	0	0.00
1,000,000-4,999,999	-	$ -	$ -	$ -	0	0.00
≥5 M	-	$ -	$ -	$ -	0	0.00
National Totals	**112**	**$ 2,933**	**$ 26,400**	**$ 29,333**	**112**	**0.05**
Disinfecting Ground Water Only NTNCWSs						
<500	1,241	$ 27,552	$ 297,860	$ 325,412	1,241	0.60
500-9,999	1,393	$ 34,481	$ 334,297	$ 368,779	1,393	0.67
10,000-99,999	63	$ 1,633	$ 13,163	$ 14,796	63	0.03
100,000-499,999	9	$ 270	$ 1,815	$ 2,085	9	0.00
> 500,000	-	$ -	$ -	$ -	0	0.00
National Totals	**2,705**	**$ 63,936**	**$ 647,135**	**$ 711,072**	**2,705**	**1.30**
Grand Totals	**500**	**$ 67,185**	**$ 363,986**	**$ 431,171**	**3,122**	**1.50**

Notes: (A) Shows the difference in total compliance monitoring samples from Stage 1 to Stage 2 for disinfecting systems and systems predicted to install disinfection for the GWR.

Source: Exhibits H.8a and H.8b, USEPA 2005a.

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3. State/Primacy Agency Costs

To estimate State/Primacy Agency costs, the estimated number of full-time equivalents (FTEs) required per activity is multiplied by the number of labor hours per FTE, the State/Primacy Agency hourly wage, and the number of States/Primacy Agencies. EPA estimated the number of FTEs required per activity based on experience implementing previous rules, such as the Stage 1 DBPR. State/Primacy Agency costs are summarized in Table VI.D–9.

Table VI.D-9. State/Primacy Agency Cost Summary.

	Total Hours	Average Hours per State	Cost/Labor Hour	Total Cost	Cost per State
	A	B = A/57	C	D	E = D/57
Implementation Activities					
Public Notification	11,856	208	$ 33.60	$ 398,362	$ 6,989
Regulation Adoption and Program Development	59,280	1,040	$ 33.60	$ 1,991,808	$ 34,944
Training State Staff	29,640	520	$ 33.60	$ 995,904	$ 17,472
Training PWS Staff and Technical Assistants	118,560	2,080	$ 33.60	$ 3,983,616	$ 69,888
Updating Data Management System	11,856	208	$ 33.60	$ 398,362	$ 6,989
Subtotal	**231,192**	**4,056**		**$ 7,768,051**	**$ 136,282**
Monitoring Plan Activities					
Monitoring Plans	27,464	482	$ 33.60	$ 926,016	$ 16,246
IDSE Activities					
IDSE Monitoring	66,312	1,163	$ 33.60	$ 2,228,095	$ 39,089
Additional Routine Monitoring Activities					
Recordkeeping and Compliance Tracking	47,424	832	$ 33.60	$ 1,593,446	$ 27,955
Operational Evaluation Costs	3,398	60	$ 33.60	$ 114,173	$ 2,003
Subtotal	**50,822**	**892**		**$ 1,707,619**	**$ 29,958**
Grand Total	**375,790**	**6,593**		**$ 12,629,781**	**$ 221,575**

Notes: All states/primacy agencies are assumed to incur some costs for each activity.
Source: Exhibits H.17 to H.20, USEPA 2005a.

4. Non-quantified Costs

All significant costs that EPA has identified have been quantified. In some instances, EPA did not include a potential cost element because its effects are relatively minor and difficult to estimate. For example, it may be less costly for a small system to merge with neighboring systems than to add advanced treatment. Such changes have both costs (legal fees and connecting infrastructure) and benefits (economies of scale). Likewise, procuring a new source of water would have costs for new infrastructure, but could result in lower treatment costs. Operational costs such as changing storage tank operation were also not considered as alternatives to treatment. These might be options for systems with a single problem area with a long residence time. In the absence of detailed information needed to evaluate situations such as these, EPA has included a discussion of possible effects where appropriate. In general, however, the expected net effect of such situations is lower costs to PWSs. Thus, the EA tends to present conservatively high estimates of costs in relation to non-quantified costs.

E. Household Costs of the Stage 2 DBPR

EPA estimates that, as a whole, households subject to the Stage 2 DBPR face minimal increases in their annual costs. Approximately 86 percent of the households potentially subject to the rule are served by systems serving at least 10,000 people; these systems experience the lowest increases in costs due to significant economies of scale. Households served by small systems that add treatment will face the greatest increases in annual costs. Table VI.E–1 summarizes annual household cost increases for all system sizes.

TABLE VI.E–1.—ANNUAL HOUSEHOLD COST INCREASES.

	Total number of households served	Mean annual household cost increase	Median annual household cost increase	90th percentile annual household cost increase	95th percentile annual household cost increase	Percentage of annual household cost increase < $12 (percent)	Percentage of annual household cost increase < $120 (percent)
Households Served by All Plants							
All Systems	101,553,868	$0.62	$0.03	$0.36	$0.98	99	100
All Small Systems	14,261,241	2.20	0.10	0.79	2.57	97	100
SW < 10,000	3,251,893	4.58	0.79	2.69	7.24	95	99
SW ≥ 10,000	62,137,350	0.46	0.02	0.35	1.81	99	100
GW < 10,000	11,009,348	1.49	0.02	0.39	0.99	98	100
GW ≥ 10,000	25,155,277	0.13	0.00	0.03	0.08	100	100
Households Served by Plants Adding Treatment							
All Systems	10,161,304	$5.53	$0.80	$10.04	$22.40	92	99
All Small Systems	591,623	46.48	18.47	168.85	197.62	38	89
SW < 10,000	285,911	43.05	13.79	173.53	177.93	47	85
SW ≥ 10,000	9,060,119	2.83	0.80	6.98	11.31	96	100
GW < 10,000	305,712	49.69	16.65	109.86	197.62	31	92
GW ≥ 10,000	509,562	5.97	1.37	26.82	33.84	79	100

Notes: Detail may not add to total due to independent rounding. Number of households served by systems adding treatment will be higher than households served by plants adding treatment because an entire system will incur costs even if only some of the plants for that system add treatment (this would result in lower household costs, however).

Source: Exhibit 7.15, USEPA 2005a.

F. Incremental Costs and Benefits of the Stage 2 DBPR

Incremental costs and benefits are those that are incurred or realized in reducing DBP exposures from one alternative to the next more stringent alternative. Estimates of incremental costs and benefits are useful in considering the economic efficiency of different regulatory options considered by the Agency. Generally, the goal of an incremental analysis is to identify the regulatory option where net social benefits are maximized. However, the usefulness of this analysis is constrained when major benefits and/or costs are not quantified or not monetized. Also, as pointed out by the Environmental Economics Advisory Committee of the Science Advisory Board, efficiency is not the only appropriate criterion for social decision making (USEPA 2000i).

For the proposed Stage 2 DBPR, presentation of incremental quantitative benefit and cost comparisons may be unrepresentative of the true net benefits of the rule because a significant portion of the rule's potential benefits are not quantified, particularly potential reproductive and developmental health effects (see Section VI.C). Table VI.F–1 shows the incremental monetized costs and benefits for each regulatory alternative. Evaluation of this table shows that incremental costs generally fall within the range of incremental benefits for each more stringent alternative. Equally important, the addition of any benefits attributable to the non-quantified categories would add to the benefits without any increase in costs.

Table VI.F–1 shows that the Preferred Alternative is the least-cost alternative. A comparison of Alternative 1 with the Preferred Alternative shows that Alternative 1 would have approximately the same benefits as the Preferred Alternative. The costs of Alternative 1 are greater due to the additional control of bromate. However, the benefits of Alternative 1 are less than the Preferred Alternative because the Agency is not able to estimate the additional benefits of reducing the bromate MCL. Alternative 1 was determined to be unacceptable due to the potential for increased risk of microbial exposure. Both benefits and costs are greater for Alternative 2 and Alternative 3 as compared to the Preferred Alternative. However, these regulatory alternatives do not have the risk-targeted design of the Preferred Alternative. Rather, implementation of these stringent standards would require a large number of systems to change treatment technology. The high costs of these regulatory alternatives and the drastic shift in the nation's drinking water practices were considered unwarranted at this time. (See Section VI.A of this preamble for a description of regulatory alternatives.)

TABLE VI.F–1.—INCREMENTAL COSTS AND BENEFITS OF THE STAGE 2 DBPR

WTP for non-fatal bladder cancer cases	Rule alternative	Annual costs	Annual benefits	Incremental costs	Incremental benefits	Incremental net benefits
		A	B	C	D	E=D – C
3 Percent Discount Rate						
Lymphoma	Preferred	$79	$1,531	$79	$1,531	$1,452
	Alternative 1 [1]	254	1,377	([1])	([1])	([1])
	Alternative 2	422	5,167	343	3,637	3,294
	Alternative 3	634	7,130	212	1,962	1,750
Bronchitis	Preferred	79	763	79	763	684

TABLE VI.F–1.—INCREMENTAL COSTS AND BENEFITS OF THE STAGE 2 DBPR—Continued

WTP for non-fatal bladder cancer cases	Rule alternative	Annual costs	Annual benefits	Incremental costs	Incremental benefits	Incremental net benefits
		A	B	C	D	E=D – C
	Alternative 1 [1]	254	686	([1])	([1])	([1])
	Alternative 2	422	2,575	343	1,812	1,469
	Alternative 3	634	3,552	212	978	765
7 Percent Discount Rate						
Lymphoma	Preferred	$77	$1,246	$77	$1,246	$1,170
	Alternative 1 [1]	242	1,126	([1])	([1])	([1])
	Alternative 2	406	4,227	330	2,981	2,651
	Alternative 3	613	5,832	207	1,605	1,399
Bronchitis	Preferred	77	621	77	621	544
	Alternative 1 [1]	242	561	([1])	([1])	([1])
	Alternative 2	406	2,105	330	1,484	1,154
	Alternative 3	613	2,904	207	799	593

Notes: Estimates are discounted to 2003 and given in 2003 dollars. Based on TTHM as an indicator, Villanueva et al. (2003) for baseline risk, and smoking/lung cancer cessation lag model. Assumes 26 percent of cases are fatal, 74 percent are non-fatal (USEPA 1999b). EPA recognizes that benefits may be as low as zero since causality has not yet been established between exposure to chlorinated water and bladder cancer.

[1] Alternative 1 appears to have fewer benefits than the Preferred Alternative because it does not incorporate the IDSE, as explained in Chapter 4. Furthermore, this EA does not quantify the benefits of reducing the MCL for bromate (and potentially associated cancer cases), a requirement that is included only in Alternative 1. This means that Alternative 1 is dominated by the Preferred Alternative in this analysis (having higher costs than the Preferred Alternative but lower benefits), and so it is not included in the incremental comparison of alternatives (Columns C–E). OMB states this in terms of comparing cost effectiveness ratios, but the same rule applies to an incremental cost, benefits, or net benefits comparison: ''When constructing and comparing incremental cost-effectiveness ratios, [analysts] * * * should make sure that inferior alternatives identified by the principles of strong and weak dominance are eliminated from consideration.'' (OMB Circular A–4, p. 10)

Source: Exhibit 9.13, USEPA 2005a.

G. Benefits From the Reduction of Co-occurring Contaminants

Installing certain advanced technologies to control DBPs has the added benefit of controlling other drinking water contaminants in addition to those specifically targeted by the Stage 2 DBPR. For example, membrane technology installed to reduce DBP precursors can also reduce or eliminate many other drinking water contaminants (depending on pore size), including those that EPA may regulate in the future. Removal of any contaminants that may face regulation could result in future cost savings to a water system. Because of the difficulties in establishing which systems would be affected by other current or future rules, no estimate was made of the potential cost savings from addressing more than one contaminant simultaneously.

H. Potential Risks From Other Contaminants

Along with the reduction in DBPs from chlorination such as TTHM and HAA5 as a resultof the Stage 2 DBPR, there may be increases in other DBPs as systems switch from chlorine to alternative disinfectants. For all disinfectants, many DBPs are not regulated and many others have not yet been identified. EPA will continue to review new studies on DBPs and their occurrence levels to determine if they pose possible health risks. EPA continues to support regulation of TTHM and HAA5 as indicators for chlorination DBP occurrence and believes that operational and treatment changes made because of the Stage 2 DBPR will result in an overall decrease in risk.

1. Emerging DBPs

Iodo-DBPs and nitrogenous DBPs including halonitromethanes are DBPs that have recently been reported (Richardson et al. 2002, Richardson 2003). One recent occurrence study sampled quarterly at twelve surface water plants using different disinfectants across the U.S. for several iodo-THMs and halonitromethane species (Weinberg et al. 2002). The concentrations of iodo-THMs and halonitromethane in the majority of samples in this study were less than the analytical minimum reporting levels; plant-average concentrations of iodo-THM and halonitromethane species were typically less than 0.002 mg/L, which is an order of magnitude lower than the corresponding average concentrations of TTHM and HAA5 at those same plants. Chloropicrin, a halonitromethane species, was also measured in the ICR with a median concentration of 0.00019 mg/L across all surface water samples. No occurrence data exist for the iodoacids due to the lack of a quantitative method and standards. Further work on chemical formation of iodo-DBPs and halonitromethanes is needed.

Iodoacetic acid was found to be cytotoxic and genotoxic in Salmonella and mammalian cells (Plewa et al. 2004a) as were some of the halonitromethanes (Kundu et al. 2004; Plewa et al. 2004b). Although potent in these in vitro screening studies, further research is needed to determine if these DBPs are active in living systems. No conclusions on human health risk can be drawn from such preliminary studies.

2. N-Nitrosamines

Another group of nitrogenous DBPs are the N-nitrosamines. A number of N-nitrosamines exist, and N-nitrosodimethylamine (NDMA), a probable human carcinogen (USEPA 1993), has been identified as a potential health risk in drinking water. NDMA is a contaminant from industrial sources and a potential disinfection byproduct from reactions of chlorine or chloramine with nitrogen containing organic matter and from some polymers used as coagulant aids. Studies have produced new information on the mechanism of formation of NDMA, but there is not enough information at this time to draw conclusions regarding a potential increase in NDMA occurrence as systems change treatment. Although there are studies that examined the occurrence of NDMA in some water systems, there are no systematic evaluations of the occurrence of NDMA and other nitrosamines in U.S. waters.

Recent studies have provided new occurrence information that shows NDMA forms in both chlorinated and chloraminated systems. Barrett et al. (2003) reported median concentrations of less than 2ng/L for the seven chlorine systems studied and less than 3 ng/L for 13 chloramine systems. Another study demonstrated that factors other than disinfectant type may play an important role in the formation of NDMA (Schreiber and Mitch 2005). More research is underway to determine the extent of NDMA occurrence in drinking water systems. EPA has proposed monitoring for NDMA under Unregulated Contaminant Monitoring Rule 2 (70 FR 49094, at 49103, August 22, 2005) (USEPA 2005m).

Risk assessments have estimated that the 10^{-6} lifetime cancer risk level is 7 ng/L based on induction of tumors at multiple sites. NDMA is also present in food, tobacco smoke, and industrial emissions, and additional research is underway to determine the relative exposure of NDMA in drinking water to these other sources.

3. Other DBPs

Some systems, depending on bromide and organic precursor levels in the source water and technology selection, may experience a shift to higher ratios, or concentrations, of brominated DBPs while the overall TTHM or HAA5 concentration may decrease. In some instances where alternative disinfectants are used, levels of chlorite and bromate may increase as a result of systems switching to chlorine dioxide or ozone, respectively. However, EPA anticipates that changes in chlorite and bromate concentration as a result of the Stage 2 DBPR will be minimal (USEPA 2005a). For most systems, overall levels of DBPs, as well as brominated DBP species, should decrease as a result of this rule. EPA continues to believe that precursor removal is a highly effective strategy to reduce levels of DBPs.

EPA also considered the impact this rule may have on microbial contamination that may result from altering disinfection practices. To address this concern, the Agency developed this rule jointly with the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR). EPA expects that the LT2ESWTR provisions will prevent increases in microbial risk resulting from the Stage 2 DBPR.

I. Effects of the Contaminant on the General Population and Groups Within the General Population That Are Identified As Likely To Be at Greater Risk of Adverse Health Effects

EPA's Office of Water has historically considered risks to sensitive subpopulations (including fetuses, infants, and children) when establishing drinking water assessments, advisories and other guidance, and standards (USEPA 1989) (56 FR 3526, January 30, 1991) (USEPA 1991). In the case of Stage 2 DBPR, maximizing health protection for sensitive subpopulations requires balancing risks to achieve the recognized benefits of controlling waterborne pathogens while minimizing risk of potential DBP toxicity. Experience shows that waterborne disease from pathogens in drinking water is a major concern for children and other subgroups (e.g., the elderly, immunocompromised, and pregnant women) because of their greater vulnerabilities (Gerba et al. 1996). EPA believes DBPs may also potentially pose risks to fetuses and pregnant women (USEPA 1998a). In addition, because the elderly population (age 65 and above) is naturally at a higher risk of developing bladder cancer, their health risks may further increase as a result of long-term DBP exposure (National Cancer Institute 2002).

In developing this rule, risks to sensitive subpopulations, including children, were taken into account in the assessments of disinfectants and DBPs. More details on sensitive subpopulations can be found in the Economic Analysis (USEPA 2005a). For each of the DBPs included in the Stage 2 DBPR, the maximum contaminant level goals (MCLG) are derived using the most sensitive endpoint among all available data and an intraspecies uncertainty factor of 10 which accounts for human variability including sensitive subpopulations, like children. The Agency has evaluated several alternative regulatory options and selected the one that balances cost with significant benefits, including those for sensitive subpopulations. The Stage 2 DBPR will result in a potential reduction in cancer risk and a potential reduction in reproductive and developmental risk to fetuses and pregnant women. It should be noted that the LT2ESWTR, which accompanies this rule, reduces pathogens in drinking water and further protects sensitive subpopulations. See Section VII.G for a discussion of EPA's requirements under Executive Order 13045.

J. Uncertainties in the Risk, Benefit, and Cost Estimates for the Stage 2 DBPR

For today's final rule, EPA has estimated the current baseline risk from exposure to DBPs in drinking water and projected the risk reduction and cost for various rule alternatives. There is uncertainty in the risk calculation, the benefit estimates, the cost estimates, and the interaction with other regulations. The EA has an extensive discussion of relevant uncertainties (USEPA 2005a). This section briefly summarizes the major uncertainties. Table VI.J–1 presents a summary of uncertainty in the cost and benefit estimates, refers to the section or appendix of the EA where the information is introduced, and estimates the potential effects that each may have on national cost and benefit estimates.

EPA believes that uncertainty in the compliance forecast has a potentially large influence on cost and benefit estimates for today's rule. Thus, the Agency has attempted to quantify the uncertainty by giving equal weight to two different compliance forecast approaches. One compliance forecast approach is based on the SWAT predictions, and the other is based on the ''ICR Matrix Method.'' The ICR Matrix Method uses the same basic approach as SWAT, but uses TTHM and HAA5 data from the ICR directly to estimate the percent of plants changing technology to comply with the Stage 2 DBPR and the resulting DBP reduction. To characterize the uncertainty of the compliance forecast results, EPA assumes a uniform distribution between SWAT and ICR Matrix Method results (USEPA 2005a). That is, the cost and benefit estimates presented in the preamble represent the midpoint between costs and benefits estimated using the SWAT model, and those estimated using the ICR Matrix Method. Cost estimates using the SWAT model are about 25% lower than the midpoint estimates, while those using the ICR Matrix Method are about 25% higher. Benefits estimated using the SWAT model are about 30% lower than the midpoint estimates, while those using the ICR Matrix Method are about 30% higher.

EPA believes the compliance forecast may be overstated because the technology decision tree does not consider low-cost, non-treatment system improvements that could be used to comply with the Stage 2 DBPR. These improvements, including things like flushing more frequently and managing storage facilities to reduce water age, could be used by systems to reduce TTHM and HAA5 levels for specific

locations in their distribution system to meet Stage 2 DBPR MCLs. Thus, the standard compliance forecast method as developed during the M/DBP FACA (with a 20 percent safety margin) is a reasonable estimation. However, SWAT does not explicitly consider the IDSE. To address uncertainty in the impact of the IDSE on the compliance forecast, EPA revised the compliance forecast methodology, assigning equal probability to 20 and 25 percent operational safety margins. EPA believes the 25 percent safety margin is a reasonable high-end estimate of system response to account for the influences of the IDSE. EPA used a spatial variability analysis to determine the appropriate safety margin to use to estimate the impact of the IDSE on the compliance forecast.

These alternative approaches for the compliance forecast estimate are used to represent a range of possible results and are incorporated into the cost and benefit models using Monte Carlo probability functions. EPA believes this approach helps inform the reader of the likely magnitude of the impact of the uncertainties.

In addition to quantifying some uncertainties in the compliance forecasts, EPA has explicitly accounted for uncertainty in estimated treatment technology costs. Treatment costs are modeled using a triangular distribution of ± 30 percent for Capital, and ± 15 percent for O&M costs to recognize that the assumptions for cost analysis to produce the national average are uncertain.

For the cost estimates, uncertainty also exists in baseline data inputs, such as the total number of disinfecting plants and their typical average and design flow rates. Other cost model inputs such as labor rates and laboratory fees also contain uncertainties. In these cases, EPA has evaluated available data and estimated a cost input value to represent the average of all water systems nationally. EPA recognizes that there is uncertainty in this average and variability in the characteristics of individual systems. The influence of these uncertainties on national cost estimates is expected to be fairly minor.

For the benefits estimates, uncertainty exists in model inputs such as the estimated PAR values and the cessation lag models. EPA considered three approaches to estimate attributable risk: (1) a range of risk derived from individual studies, (2) a risk estimate from a meta-analysis, and (3) a risk estimate from a pooled analysis. To quantify uncertainty in cessation lag, three independent cessation lag models derived from three different epidemiological studies are used. Also, two functional forms are used for each of these data sets and uncertainty in the parameters of those functions is included in the analysis. As noted previously, causality has not been established between DBP levels and cancer endpoints, so the lower bound of potential risk reductions may be as low as zero.

In a number of different contexts over the past few years, the Agency has considered the relative merits and assumptions encountered when employing meta-analyses. Cessation lag modeling is a relatively recent analysis that the Agency has incorporated into its risk analyses to more appropriately model the timing of health benefits. The specific papers upon which the Stage 2 analysis is based have been peer reviewed. However, the Agency believes that it is time to consider these Agency-wide science issues in a broader sense with outside experts to better inform the Agency's future analyses.

For monetization of benefits, EPA uses two alternatives for valuing non-fatal bladder cancer. Other uncertainties, such as the linear relationship between DBP reductions and reductions in bladder cancer cases avoided, are discussed qualitatively.

In addition to the uncertainties quantified as part of the benefits evaluation, other uncertainties that have not been quantified could result in either an over-or under-estimation of the benefits. Two of the greatest uncertainties affecting the benefits of the Stage 2 DBPR, benefits from potential reductions of cancers other than bladder and benefits from possible reductions in potential reproductive and developmental health effects, are unquantified. Both of these factors could result in an underestimation of quantified Stage 2 DBPR benefits.

TABLE VI.J–1.—EFFECTS OF UNCERTAINTIES ON NATIONAL ESTIMATES

Assumptions for which there is uncertainty	Section with full discussion of uncertainty	Potential effect on benefit estimate			Potential effect on cost estimates		
		Under-estimate	Over-estimate	Unknown impact	Under-estimate	Over-estimate	Unknown impact
Uncertainty in the industry baseline (SDWIS and 1995 CWSS data).	3.4			X			X
Uncertainty in observed data and predictive tools used to characterize DBP occurrence for the pre-Stage 1 baseline.	3.7			X			X
Uncertainty in predictive tools used to develop the compliance forecast for surface water systems (SWAT and ICR Matrix Method).	Chapter 5, Appendix A.	Quantified in primary analysis (addresses potential underestimate or overestimate)			Quantified in primary analysis (addresses potential underestimate or overestimate)		
Uncertainty in ground water compliance forecast methodologies.	Chapter 5, A and B.			X			X
Operational safety margin of 20%.	5.2			X			X
Impacts of the IDSE on the compliance forecast for the Preferred Regulatory Alternative.	5.3	Quantified in the primary analysis (addresses potential underestimate)			Quantified in the primary analysis (addresses potential underestimate)		

TABLE VI.J–1.—EFFECTS OF UNCERTAINTIES ON NATIONAL ESTIMATES—Continued

Assumptions for which there is uncertainty	Section with full discussion of uncertainty	Potential effect on benefit estimate			Potential effect on cost estimates		
		Under-estimate	Over-estimate	Unknown impact	Under-estimate	Over-estimate	Unknown impact
Uncertainty in the PAR value.	6.1.1 Appendix E.	Quantified in the primary analysis (addresses range of potential effects, but true values could lie outside range)					
Reduction in TTHM and HAA5 used as proxies for all chlorination DBPs.	6.3.3	.....	.....	X.			
DBPs have a linear no-threshold dose-response relationship for bladder cancer effects.	6.2.1	.....	X.				
Uncertainty in benefits valuation inputs.	6.5.2	Quantified in the primary analysis (addresses potential underestimate or overestimate)					
Benefits of reduced cancers other than bladder cancer are not included in the quantitative analysis.	6.7	Quantified in a sensitivity analysis (addresses potential underestimate)					
Value of potential reproductive and developmental health effects avoided is not quantified in the primary analysis.	6.8	X.					
Treatment costs do not include costs for minor operational changes predicted by SWAT.	7.4.1	.....	.....	.....	X.		
Median operational and water quality parameters considered for technology unit costs.	7.4.1	.....	.....	.....	.....	.....	X
Economies of scale for combination treatment technologies not considered.	7.4.1	.....	.....	.....	.....	X.	
Possible UV-chloramine synergy not taken into account.	7.4.1	.....	.....	.....	.....	X.	
Potential low-cost alternatives to treatment not considered.	7.4.2	.....	.....	.....	.....	X.	
Uncertainties in unit costs	7.4.3	.....	.....	.....	Quantified in primary analysis (addresses potential overestimate or underestimate)		

K. Benefit/Cost Determination for the Stage 2 DBPR

The Agency has determined that the benefits of the Stage 2 DBPR justify the costs. As discussed previously, the main concern for the Agency and the Advisory Committee involved in the Stage 2 rulemaking process was to provide more equitable protection from DBPs across the entire distribution system and reduce high DBP levels. The final rule achieves this objective using the least cost alternative by targeting sampling locations with high DBP levels and modifying how the annual average DBP level is calculated. This will reduce both average DBP levels associated with bladder cancer (and possibly other cancers) and peak DBP levels which are potentially associated with reproductive and developmental effects. In addition, this rule may reduce uncertainty about drinking water quality and may allow some systems to avoid installing additional technology to meet future drinking water regulations.

Table VI.K–1 presents net benefits for the four regulatory alternatives evaluated by EPA. This table shows that net benefits are positive for all four regulatory alternatives. Generally, analysis of net benefits is used to identify alternatives where benefits exceed costs, as well as the alternative that maximizes net benefits. However, analyses of net benefits should consider both quantified and non-quantified (where possible) benefits and costs. As discussed previously with incremental net benefits, the usefulness of this analysis in evaluating regulatory alternatives for the Stage 2 DBPR is somewhat limited because many benefits from this rule are non-quantified and non-monetized.

Table VI.K–1 shows that the Preferred Alternative is the least cost alternative. The Preferred Alternative has higher mean net benefits than Alternative 1. Alternatives 2 and 3 have higher benefits than the Preferred Alternative but also much greater costs. These regulatory alternatives do not have the risk-targeted design of the Preferred Alternative. Rather, a large number of systems would be required to make treatment technology changes to meet the stringent standards under these regulatory alternatives. Also, because causality has not been established between DBP exposure and bladder cancer, actual benefits may be as low as zero. EPA is promulgating the preferred regulatory alternative because the Agency believes that such a drastic shift in the nation's drinking water practices is not warranted at this time.

TABLE VI.K–1.—MEAN NET BENEFITS BY REGULATORY ALTERNATIVE ($MILLION)

Rule alternative	WTP for non-fatal bladder cancer cases	Mean annual costs	Mean annual benefits	Mean net benefits
3 Percent Discount Rate, 25 Years				
Preferred	Lymphoma	$78.8	$1,530.8	$1,452
A1		254.1	1,376.6	1,122
A2		421.7	5,167.4	4,746
A3		634.2	7,129.6	6,495
Preferred	Bronchitis	78.8	762.8	684
A1		254.1	685.9	432
A2		421.7	2,574.6	2,153
A3		634.2	3,552.2	2,918
7 Percent Discount Rate, 25 Years				
Preferred	Lymphoma	$76.8	$1,246.5	$1,170
A1		241.8	1,126.4	885
A2		406.4	4,227.2	3,821
A3		613.1	5,832.4	5,219
Preferred	Bronchitis	76.8	620.7	544
A1		241.8	560.8	319
A2		406.4	2,104.6	1,698
A3		613.1	2,903.8	2,291

Notes: Estimates are discounted to 2003 and given in 2003 dollars. Based on TTHM as an indicator, Villanueva et al. (2003) for baseline risk, and smoking/lung cancer cessation lag model. Assumes 26 percent of cases are fatal, 74 percent are non-fatal (USEPA 1999b). EPA recognizes that benefits may be as low as zero since causality has not yet been established exposure to chlorinated water and bladder cancer.

Source: Exhibits 9.10 and 9.11, USEPA 2005a.

The Agency also compared the costs and benefits for each regulatory alternative by calculating which option is the most cost-effective. The cost-effectiveness analysis compares the cost of the rule per bladder cancer case avoided. This cost-effectiveness measure is another way of examining the benefits and costs of the rule, but should not be used to compare alternatives because an alternative with the lowest cost per illness/death avoided may not result in the highest net benefits. Table VI.K–2 shows the cost of the rule per case avoided. This table shows that cost per case avoided for the preferred alternative seems favorable when compared to the willingness to pay estimates. Additional information about this analysis and other methods of comparing benefits and costs can be found in the EA (USEPA 2005a).

TABLE VI.K–2.—ESTIMATED COST PER DISCOUNTED CASED AVOIDED [1] FOR THE REGULATORY ALTERNATIVES, USING TTHM AS DBP INDICATOR AND SMOKING/LUNG CANCER CESSATION LAG MODEL ($MILLIONS, 2003)

Rule alternative	Cost per case avoided	
	3%	7%
Preferred	$.033	$.041
Alternative 1	1.18	1.42
Alternative 2	0.52	0.63
Alternative 3	0.57	0.69

[1] The cost effectiveness ratios are a potentially a high estimate because regulatory costs in the numerator are not adjusted by subtracting the avoided medical costs associated with cases avoided to produce a net cost numerator. Subtraction of theses costs would not be expected to alter the ranking of alternatives. In the case where thresholds of maximum public expenditure per case avoided are prescribed, defining the numerator more precisely by making such adjustments would be appropriate.

Notes: In reference to conducting incremental CEA, OMB states that analyst should make sure that "When constructing and comparing incremental cost-effectiveness ratios, [analysts] should make sure that inferior alternatives identified by the principles of strong and weak dominance are eliminated from consideration" (OMB Circular A–4, p. 10). Alternative 1 is dominated by the Preferred Alternative and is therefore not included in the incremental analysis. The reason for this domination is mainly that the Preferred Alternative includes IDSE and Alternative 1 does not; and to a lesser degree because the bromate control included in Alternative 1 increases the costs but the benefits of this control are not quantified at this time. Alternative 2 is compared directly to the Preferred Alternative (skipping Alternative 1) in this analysis. Cost per case avoided is in year 2003 dollars ($Millions), discounted for the 25 year analysis period to year 2005.

Source: Exhibit 9.14, USEPA, 2005a.

L. Summary of Major Comments

EPA received significant public comment on the analysis of benefits and costs of the proposed Stage 2 DBPR in the following areas: interpretation of health effects studies, derivation of benefits, use of SWAT, illustrative example, unanticipated risk issues, and valuation of cancer cases avoided. The following discussion summarizes public comment in these areas and EPA's responses.

1. Interpretation of Health Effects Studies

EPA requested comment on the conclusions of the cancer health effects section and the epidemiology and toxicology studies discussed. A number of comments questioned the overall

interpretation of the studies presented by EPA. A few comments pointed out missed studies. Commenters also asked about concordance between cancer epidemiology and toxicology. Some commenters also felt EPA did not discuss the broad range of risks from DBPs other than the ones regulated.

The Agency continues to believe that, although there is not a causal link, the cancer literature points to an association between bladder cancer and potentially rectal and colon cancer and exposure to chlorinated surface water. EPA has included in today's preamble the literature that commenters pointed out as missing and expands on its discussion of non-regulated DBPs.

EPA believes that a lack of bladder cancer effect in toxicological studies does not negate the findings in epidemiological studies at this time. Tumor site concordance between human and test animal is not necessary to determine carcinogenic potential. While there is evidence from human cancer epidemiology studies that lifetime consumption of the DBP mixture within chlorinated surface water poses a bladder cancer risk, the specific causative constituents have not been identified. EPA will continue to evaluate new mode-of-action data as it becomes available.

Several comments were received on EPA's characterization of the literature on reproductive and developmental health risk. Some commenters wanted EPA to characterize reproductive and developmental health effects more strongly, stating that current research shows more evidence for these effects than described in the proposed preamble. Others thought that EPA's characterization in the proposal was too strong, and that EPA had overemphasized these health concerns. Some commenters noted that certain published studies were missing from EPA's risk discussion.

EPA believes that the characterization of reproductive and developmental risks in the final Stage 2 DBPR preamble is appropriate based on the weight of evidence evaluation of the reproductive and developmental epidemiology database described in Section III.C. EPA considered comments and incorporated additional and recent studies into its characterization of health risks in today's final preamble. While no causal link has been established, EPA's evaluation of the available studies continues to indicate a potential health hazard that warrants additional regulatory action beyond the Stage 1 DBPR. The inconsistencies and uncertainties remaining in the available science support the incremental nature of change in today's rule.

EPA did not include all findings from every study in the proposed DBPR preamble because the intent was to provide a summary overview and more importantly, the Agency's conclusions regarding the weight of evidence. The epidemiology literature has inconsistencies in its findings on the relationship between various reproductive and developmental health effects and DBPs. In this final preamble, EPA describes how recent studies since the proposal further inform the perspective of overall risk from exposure to DBPs. EPA continues to believe that studies indicate a potential hazard.

2. Derivation of Benefits

EPA received numerous comments on the derivation of benefits from occurrence estimates for the Stage 2 DBPR. The majority of the comments provided addressed EPA's use of a cessation lag model to estimate the timing of benefits and a PAR analysis to estimate reduced risks. Several commenters opposed the cessation lag model proposed by EPA, suggesting that EPA use a longer cessation lag period or conduct a sensitivity analysis on the cessation lag exponent.

In the effort to develop a cessation lag model specific to DBPs, EPA reviewed the available epidemiological literature for information relating to the timing of exposure and response, but could not identify any studies that could, alone or in combination, support a specific cessation lag model for DBPs in drinking water. Thus, in keeping with the SAB recommendation to consider other models in the absence of specific cessation lag information (USEPA 2001d), EPA explored the use of information on other carcinogens that could be used to characterize the influence of cessation lag in calculating benefits. The benefit analysis for today's rule uses three cessation lag models, which allows for a better characterization of uncertainty than did the approach used in the proposal. More details on this analysis are in the EA (USEPA 2005a).

Additional comments were received on the use of PAR values derived from epidemiology studies to determine the number of bladder cancer cases attributable to DBP exposure. Some commenters remarked that there was not sufficient evidence in the epidemiology studies used to develop a reliable PAR estimate. A key issue expressed in the comments was that studies that developed the PAR estimates did not adequately control for confounders. One commenter supported EPA review of the Villanueva (2003) meta-analysis, stating that this was the best available data on the issue.

EPA revised the methodology for calculating PAR values for bladder cancer associated with exposure to chlorinated drinking water by considering three different analytical approaches as described in Section V.B.2. EPA used the PAR values from all three approaches to estimate the number of bladder cancer cases ultimately avoided annually as a result of the Stage 2 DBPR. Taken together, the three approaches provide a reasonable estimate of the range of potential risk. For simplicity, EPA used the Villanueva *et al.* (2003) study to calculate the annual benefits of the rule. The benefit estimates derived from Villanueva *et al.* (2003) capture a substantial portion of the overall range of results, reflecting the uncertainty in both the underlying OR and PAR values, as well as the uncertainty in DBP reductions for Stage 2. More details on the PAR analysis can be found in the EA (USEPA 2005a).

3. Use of SWAT

Comments received on the use of SWAT for the compliance forecast claimed that the model probably underestimates DBP occurrence levels and hence underestimates compliance costs. Other commenters supported EPA's occurrence estimation methods and results. Some commenters added that monitoring under the IDSE will produce different results than monitoring for the ICR and that SWAT did not capture these changes.

EPA describes in detail the limitations of SWAT as well as all assumptions and uncertainties associated with the model in the EA published with today's rule. EPA believes that, for the reasons stated below, the standard compliance forecast method using SWAT, as developed during the M-DBP FACA, provides a reasonable prediction of national treatment changes and resulting DBP levels anticipated for the Stage 2 DBPR:

1. SWAT predictive equations for TTHM and HAA5 were calibrated to ICR-observed TTHM and HAA5 data.

2. SWAT estimates are based on 12 months of influent water quality data, treatment train information, and related characteristics for the 273 ICR surface water plants. EPA believes the ICR data provide a robust basis for the compliance forecast as it represents significant variability with respect to factors influencing DBP formation, including temperature, residence time, and geographical region.

3. EPA uses a ''delta'' approach to reduce the impact of uncertainty in

SWAT's predictive equations for TTHM and HAA5. Under this approach, EPA 1) estimates the difference in technology and TTHM and HAA5 concentration predictions between pre-Stage 1 and post-Stage 1; 2) estimates the difference in technology and TTHM and HAA5 concentration predictions between pre-Stage 1 and post-Stage 2; and 3) subtracts the result of the first estimate from the second estimate to predict the impacts between Stage 1 and Stage 2. Since each predictive estimate has bias in the same direction, EPA believes that this methodology minimized overall predictive error.

In response to commenters concerns about potential uncertainties in the SWAT predictions, EPA also developed the ''ICR Matrix Method.'' The ICR Matrix Method uses TTHM and HAA5 data from the ICR to estimate the percent of plants changing technology to comply with the Stage 2 DBPR and the resulting DBP reduction. The EA includes a detailed description of the ICR Matrix Method (USEPA 2005a). In the analysis for today's rule, EPA gives equal weight to SWAT and ICR Matrix Method predictions in estimating Stage 2 compliance forecasts and resultant reductions in DBP exposure. The ICR Matrix Method is also used to estimate reductions in the occurrence of peak TTHM and HAA5 concentrations because SWAT-predicted TTHM and HAA5 concentrations are valid only when considering national averages, not at the plant level.

EPA revised the Stage 2 DBPR compliance forecast methodology to quantify the potential impacts of the IDSE for large and medium surface water systems. For these systems, EPA predicted compliance implications using a safety margin of both 20 and 25 percent based on an analysis of spatial variability in TTHM and HAA5 occurrence. EPA assigned equal probability to the 20 and 25 percent safety margins because both alternatives are considered equally plausible. These changes result in a wider uncertainty range for the compliance cost estimates than under the EA of the proposed rule. EPA assumes the 20 percent operational safety margin accounts for variability in small surface water systems and all ground water systems. Small systems are not expected to find significantly higher levels that affect their compliance as a result of the IDSE because their distribution systems are not as complex as large systems. Additionally, the IDSE is not expected to significantly impact the compliance forecast for ground water systems because they have more consistent source water quality and do not experience significant year-to-year variability in TTHM and HAA5 occurrence.

As some commenters noted, any underestimation in costs as a result of the compliance forecast is associated with an underestimation in the benefits. Accordingly, EPA adjusted both cost and benefits estimates based on the ICR Matrix Method and the impact of the IDSE for the upper end of the compliance forecast range.

4. Illustrative Example

Many comments were received on the illustrative calculation of fetal loss benefits included in the proposed EA. Many commenters recommended that EPA remove this calculation because of uncertainties in the underlying data. Other commenters, however, expressed support for this calculation because of the magnitude of potential benefits, and suggested that EPA include these benefits in its primary analysis.

EPA believes that the reproductive and developmental epidemiologic data, although not conclusive, are suggestive of potential health effects in humans exposed to DBPs. EPA does not believe the available evidence provides an adequate basis for quantifying potential reproductive and developmental risks. Nevertheless, given the widespread nature of exposure to DBPs, the importance our society places on reproductive and developmental health, and the large number of fetal losses experienced each year in the U.S. (nearly 1 million), the Agency believes that it is appropriate to provide some quantitative indication of the potential risk suggested by some of the published results on reproductive and developmental endpoints, despite the absence of certainty regarding a causal link between disinfection byproducts and these risks and the inconsistencies between studies. However, the Agency is unable at this time to either develop a specific estimate of the value of avoiding fetal loss or to use a benefit transfer methodology to estimate the value from studies that address other endpoints.

5. Unanticipated Risk Issues

Comments were received that expressed concern about unanticipated risks that could result from the proposed Stage 2 DBPR. Several commenters remarked that regulation of TTHM and HAA5 would not control levels of other DBPs that may be more toxic than these indicator compounds, such as NDMA. Some commenters supported future research on the potential health effects of other DBPs. Other comments suggested that EPA further consider these risks when developing the final Stage 2 DBPR.

EPA has addressed the occurrence of other DBPs in Section VI.H of this document and in the EA (USEPA 2005a). Levels of some DBPs may increase because of treatment changes anticipated as a result of today's rule. However, these DBPs generally occur at much lower levels than TTHM and HAA5, often more than an order of magnitude less (USEPA 2005f, Weinberg et al. 2002). For NDMA, studies have shown formation in both chlorinated and chloraminated systems (Barrett et al. 2003). The uncertainties surrounding NDMA formation make determinations regarding the impact of the Stage 2 DBPR difficult. In addition, other routes of exposure appear to be more significant than drinking water. Dietary sources of NDMA include preserved meat and fish products, beer and tobacco. EPA is looking at calculating the relative source contribution of these routes of exposure compared to drinking water.

EPA continues to support the use of TTHM and HAA5 as indicators for DBP regulation. The presence of TTHM and HAA5 is representative of the occurrence of many other chlorination DBPs; thus, a reduction in the TTHM and HAA5 generally indicates an overall reduction of DBPs. EPA also supports additional research on unregulated and unknown DBPs to ensure continual public health protection.

6. Valuation of Cancer Cases Avoided

A number of commenters remarked on the valuation of cancer cases avoided. Some commenters supported the use of value of statistical life (VSL) analysis in monetizing the benefits of fatal bladder cancer cases avoided. Comments were also received in support of the addition of expected medical costs for treating fatal bladder cancer cases to the VSL estimates. Other commenters recommended that EPA further review the use of willingness-to-pay estimates used to value the non-fatal cancer cases avoided. These comments stated concern over the similarity of bronchitis and lymphoma to bladder cancer and the resulting limitation of benefits transfer.

EPA thanks commenters for expressing support of the use of VSL and valuation of fatal bladder cancer cases. EPA acknowledges that the willingness to pay (WTP) to avoid curable lymphoma or chronic bronchitis is not a perfect substitute for the WTP to avoid a case of non-fatal bladder cancer. However, non-fatal internal cancers, regardless of type, generally present patients with very similar

treatment, health, and long-term quality of life implications, including surgery, radiation or chemotherapy treatments (with attendant side effects), and generally diminished vitality over the duration of the illness. In the absence of more specific WTP studies, EPA believes the WTP values for avoiding a case of curable lymphoma or a case of chronic bronchitis provides a reasonable, though not definitive, substitute for the value of avoiding non-fatal bladder cancer.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, [58 FR 51735, (October 4, 1993)] the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

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

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

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

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

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action.'' As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2040–0265 (USEPA 2005n).

The information collected as a result of this rule will allow the States and EPA to determine appropriate requirements for specific systems, and to evaluate compliance with the rule. For the first three years after Stage 2 DBPR promulgation, the major information requirements involve monitoring activities, which include conducting the IDSE and submission of the IDSE report, and tracking compliance. The information collection requirements are mandatory (Part 141), and the information collected is not confidential.

The estimate of annual average burden hours for the Stage 2 DBPR for systems and States is 228,529 hours. This estimate covers the first three years of the Stage 2 DBPR and most of the IDSE (small system reports are not due until the fourth year). The annual average aggregate cost estimate is $9.8 million for operation and maintenance as a purchase of service for lab work and $6.6 million is associated with labor. The annual burden hour per response is 4.18 hours. The frequency of response (average responses per respondent) is 7.59 annually. The estimated number of likely respondents is 7,202 per year (the product of burden hours per response, frequency, and respondents does not total the annual average burden hours due to rounding). Because disinfecting systems have already purchased basic monitoring equipment to comply with the Stage 1 DBPR, EPA assumes no capital start-up costs are associated with the Stage 2 DBPR ICR.

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

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. In addition, EPA is amending the table in 40 CFR part 9 of currently approved OMB control numbers for various regulations to list the regulatory citations for the information requirements contained in this final rule.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. Small entities are defined as: (1) A small business as defined by the Small Business Administrations's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any ''not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' However, the RFA also authorizes an agency to use alternative definitions for each category of small entity, ''which are appropriate to the activities of the agency'' after proposing the alternative definition(s) in the **Federal Register** and taking comment. 5 U.S.C. 601(3)–(5). In addition, to establish an alternative small business definition, agencies must consult with SBA's Chief Council for Advocacy.

For purposes of assessing the impacts of today's rule on small entities, EPA considered small entities to be public water systems serving 10,000 or fewer persons. As required by the RFA, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7620, February 13, 1998), requested public comment, consulted with the Small Business Administration (SBA), and finalized the alternative definition in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that Final Rule, the alternative definition is applied to this regulation as well.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities regulated by this final rule are PWSs serving fewer than 10,000 people. We have determined that 92 small surface water and ground water under the direct influence of surface water (GWUDI) systems (or 2.16% of all

small surface water and GWUDI systems affected by the Stage 2 DBPR) will experience an impact of 1% or greater of average annual revenues. Of the 92, 40 small surface water and GWUDI systems (or 0.94% of all small surface water and GWUDI systems affected by the Stage 2 DBPR) will experience an impact of 3% or greater of average annual revenues. Further, 354 small ground water systems (or 1.02% of all small ground water systems affected by the Stage 2 DBPR) will experience an impact of 1% or greater of average annual revenues. Of the 354, 45 small ground water systems (or 0.13% of all small ground water systems affected by the Stage 2 DBPR) will experience an impact of 3% or greater of average annual revenues.

Although this final rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. The Stage 2 DBPR contains a number of provisions to minimize the impact of the rule on systems generally, and on small systems in particular. For example, small systems have a longer time frame to comply with requirements than large systems (see § 141.600(c) and § 141.620(c)). The final rule determines monitoring frequency based on population rather than plant-based monitoring requirements (see § 141.605 and § 141.621(a)) as proposed. Small systems will also have to take fewer samples than large systems due to the 40/30 waiver (see § 141.603(a)), for which small, ground water systems are expected to be able to qualify, and the very small system waiver (see § 141.604).

Funding may be available from programs administered by EPA and other Federal agencies to assist small PWSs in complying with the Stage 2 DBPR. The Drinking Water State Revolving Fund (DWSRF) assists PWSs with financing the costs of infrastructure needed to achieve or maintain compliance with SDWA requirements. Through the DWSRF, EPA awards capitalization grants to States, which in turn can provide low-cost loans and other types of assistance to eligible PWSs. Loans made under the program can have interest rates between 0 percent and market rate and repayment terms of up to 20 years. States prioritize funding based on projects that address the most serious risks to human health and assist PWSs most in need. Congress provided the DWSRF program $8 billion for fiscal years 1997 through 2004.

The DWSRF places an emphasis on small and disadvantaged communities. States must provide a minimum of 15% of the available funds for loans to small communities. A State has the option of providing up to 30% of the grant awarded to the State to furnish additional assistance to State-defined disadvantaged communities. This assistance can take the form of lower interest rates, principal forgiveness, or negative interest rate loans. The State may also extend repayment terms of loans for disadvantaged communities to up to 30 years. A State can set aside up to 2% of the grant to provide technical assistance to PWSs serving communities with populations fewer than 10,000.

In addition to the DWSRF, money is available from the Department of Agriculture's Rural Utility Service (RUS) and Housing and Urban Development's Community Development Block Grant (CDBG) program. RUS provides loans, guaranteed loans, and grants to improve, repair, or construct water supply and distribution systems in rural areas and towns of up to 10,000 people. In fiscal year 2003, RUS had over $1.5 billion of available funds for water and environmental programs. The CDBG program includes direct grants to States, which in turn are awarded to smaller communities, rural areas, and coloñas in Arizona, California, New Mexico, and Texas and direct grants to U.S. territories and trusts. The CDBG budget for fiscal year 2003 totaled over $4.4 billion.

Although not required by the RFA to convene a Small Business Advocacy Review (SBAR) Panel because EPA determined that the proposed rule would not have a significant economic impact on a substantial number of small entities, EPA did convene a panel to obtain advice and recommendations from representatives of the small entities potentially subject to this rule's requirements. For a description of the SBAR Panel and stakeholder recommendations, please see the proposed rule (USEPA 2003a).

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule may contain a Federal mandate that results in expenditures of $100 million or more for the State, Local, and Tribal governments, in the aggregate in the private sector in any one year. While the annualized costs fall below the $100 million threshold, the costs in some future years may be above the $100 million mark as public drinking water systems make capital investments and finance these through bonds, loans, and other means. EPA's year by year cost tables do not reflect that investments through bonds, loans, and other means spread out these costs over many years. The cost analysis in general does not consider that some systems may be eligible for financial assistance such as low-interest loans and grants through such programs as the Drinking Water State Revolving Fund.

As noted earlier, today's final rule is promulgated pursuant to section 1412 (b)(1)(A) of the Safe Drinking Water Act (SDWA), as amended in 1996, which directs EPA to promulgate a national primary drinking water regulation for a contaminant if EPA determines that the contaminant may have an adverse effect on the health of persons, occurs in PWSs with a frequency and at levels of public health concern, and regulation presents a meaningful opportunity for health risk reduction.

Section VI of this preamble discusses the cost and benefits associated with the Stage 2 DBPR. Details are presented in the Economic Analysis (USEPA 2005a).

TABLE VII.D–1—PUBLIC AND PRIVATE COSTS FOR THE STAGE 2 DBPR (ANNUALIZED AT 3 AND 7 PERCENT, $MILLIONS)

	3% discount rate	7% discount rate	Percent of 3% grand total costs (percent)	Percent of 7% grand total costs (percent)
Surface Water Systems Costs	$41.4	$41.2	53	54
Ground Water Systems Costs	20.3	19.2	26	25
State Costs	1.7	1.7	2	2
Tribal Costs	0.4	0.4	1	0
Total Public	63.8	62.5	81	81
Surface Water Systems Costs	6.4	6.3	8	8
Ground Water Systems Costs	8.5	8.0	11	10
Total Private	15.0	14.3	19	19
Grand total	78.8	76.8	100	100

Note: Detail may not add due to independent rounding. Estimates are discounted to 2003 and given in 2003 dollars.
Source: Exhibits 3.2 and 7.5, USEPA 2005a.

To meet the UMRA requirement in section 202, EPA analyzed future compliance costs and possible disproportionate budgetary effects. The Agency believes that the cost estimates and regulatory alternatives indicated earlier and discussed in more detail in section VI of this preamble, accurately characterize future compliance costs of today's rule.

In analyzing disproportionate impacts, EPA considered the impact on (1) different regions of the United States, (2) State, local, and Tribal governments, (3) urban, rural and other types of communities, and (4) any segment of the private sector. This analysis is presented in Chapter 7of the Economic Analysis (USEPA 2005a). EPA analyzed four regulatory alternatives and selected the least costly of these in accordance with UMRA Section 205.

EPA has determined that the Stage 2 DBPR contains no regulatory requirements that might significantly or uniquely affect small governments. The Stage 2 DBPR affects all size systems. As described in section VII.C, EPA has certified that today's rule will not have a significant economic impact on a substantial number of small entities. Average annual expenditures for small CWSs to comply with the Stage 2 DBPR range from $27.7 to $26.1 million at a 3 and 7 percent discount rate, respectively.

Consistent with the intergovernmental consultation provisions of section 204 of the UMRA and Executive Order 12875, ''Enhancing the Intergovernmental Partnership,'' EPA has already initiated consultations with the governmental entities affected by this rule. The consultations are described in the proposed rule (68 FR 49654, August 18, 2003).

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between national government and the States, or on the distribution of power and responsibilities among various levels of government, as specified in Executive Order 13132. The final rule has one-time costs for implementation of approximately $7.8 million. Thus, Executive Order 13132 does not apply to this rule.

Although section 6 of Executive Order 13132 does not apply to this rule, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA nonetheless specifically solicited comment on the proposed rule from State and local officials and did consult with State and local officials in developing this rule. A description of that consultation can be found in the preamble to the proposed rule, 68 FR 49548, (August 18, 2003).

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop ''an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' Under Executive Order 13175, EPA may not issue a regulation that has Tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by Tribal governments, or EPA consults with Tribal officials early in the process of developing the proposed regulation and develops a Tribal summary impact statement.

EPA has concluded that this final rule may have Tribal implications, because it may impose substantial direct compliance costs on Tribal governments, and the Federal government will not provide the funds necessary to pay those costs.

Accordingly, EPA provides the following Tribal summary impact statement as required by section 5(b). EPA provides further detail on Tribal impact in the Economic Analysis (USEPA 2005a). Total Tribal costs are estimated to be approximately $391,773 per year (at a 3 percent discount rate) and this cost is distributed across 755 Tribal systems. The cost for individual systems depend on system size and source water type. Of the 755 Tribes that may be affected in some form by the Stage 2 DBPR, 654 use ground water as a source and 101 systems use surface water or GWUDI. Since the majority of Tribal systems are ground water systems

serving fewer than 500 people, approximately 15.6 percent of all Tribal systems will have to conduct an IDSE. As a result, the Stage 2 DBPR is most likely to have an impact on Tribes using surface water or GWUDI serving more than 500 people.

EPA consulted with Tribal officials early in the process of developing this regulation to permit them to have meaningful and timely input into its development. Moreover, in the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and Tribal governments, EPA specifically solicited comment on the proposed rule from Tribal officials.

As required by section 7(a), EPA's Tribal Consultation Official has certified that the requirements of the Executive Order has been met in a meaningful and timely manner. A copy of this certification has been included in the docket for this rule.

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

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under 12866, and; (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

While this final rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, EPA nonetheless has reason to believe that the environmental health or safety risk (i.e., the risk associated with DBPs) addressed by this action may have a disproportionate effect on children. EPA believes that the Stage 2 DBPR will result in greater risk reduction for children than for the general population. The results of the assessments are contained in Section VI.I of this preamble and in the Economic Analysis (USEPA 2005a). A copy of all documents has been placed in the public docket for this action.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This determination is based on the following analysis.

The first consideration is whether the Stage 2 DBPR would adversely affect the supply of energy. The Stage 2 DBPR does not regulate power generation, either directly or indirectly. The public and private utilities that the Stage 2 DBPR regulates do not, as a rule, generate power. Further, the cost increases borne by customers of water utilities as a result of the Stage 2 DBPR are a low percentage of the total cost of water, except for a very few small systems that might install advanced technologies that must spread that cost over a narrow customer base. Therefore, the customers that are power generation utilities are unlikely to face any significant effects as a result of the Stage 2 DBPR. In sum, the Stage 2 DBPR does not regulate the supply of energy, does not generally regulate the utilities that supply energy, and is unlikely significantly to affect the customer base of energy suppliers. Thus, the Stage 2 DBPR would not translate into adverse effects on the supply of energy.

The second consideration is whether the Stage 2 DBPR would adversely affect the distribution of energy. The Stage 2 DBPR does not regulate any aspect of energy distribution. The utilities that are regulated by the Stage 2 DBPR already have electrical service. As derived later in this section, the final rule is projected to increase peak electricity demand at water utilities by only 0.009 percent. Therefore, EPA estimates that the existing connections are adequate and that the Stage 2 DBPR has no discernable adverse effect on energy distribution.

The third consideration is whether the Stage 2 DBPR would adversely affect the use of energy. Because some drinking water utilities are expected to add treatment technologies that use electrical power, this potential impact is evaluated in more detail. The analyses that underlay the estimation of costs for the Stage 2 DBPR are national in scope and do not identify specific plants or utilities that may install treatment in response to the rule. As a result, no analysis of the effect on specific energy suppliers is possible with the available data. The approach used to estimate the impact of energy use, therefore, focuses on national-level impacts. The analysis estimates the additional energy use due to the Stage 2 DBPR and compares that analysis to the national levels of power generation in terms of average and peak loads.

The first step in the analysis is to estimate the energy used by the technologies expected to be installed as a result of the Stage 2 DBPR. Energy use is not directly stated in Technologies and Costs for the Final Long Term 2 Enhanced Surface Water Treatment Rule and Final Stage 2 Disinfectants and Disinfection Byproducts Rule (USEPA 2005g), but the annual cost of energy for each technology addition or upgrade necessitated by the Stage 2 DBPR is provided. An estimate of plant-level energy use is derived by dividing the total energy cost per plant for a range of flows by an average national cost of electricity of $0.076/ kilowatt hours per year (kWh/yr) (USDOE 2004a). These calculations are shown in detail in the Economic Analysis (USEPA 2005a). The energy use per plant for each flow range and technology is then multiplied by the number of plants predicted to install each technology in a given flow range. The energy requirements for each flow range are then added to produce a national total. No electricity use is subtracted to account for the technologies that may be replaced by new technologies, resulting in a conservative estimate of the increase in energy use. The incremental national annual energy usage is 0.12 million megawatt-hours (MWh).

According to the U.S. Department of Energy's Information Administration, electricity producers generated 3,848 million MWh of electricity in 2003 (USDOE 2004b). Therefore, even using the highest assumed energy use for the Stage 2 DBPR, the rule when fully implemented would result in only a 0.003 percent increase in annual average energy use.

In addition to average energy use, the impact at times of peak power demand is important. To examine whether increased energy usage might significantly affect the capacity margins of energy suppliers, their peak season generating capacity reserve was compared to an estimate of peak incremental power demand by water utilities.

Both energy use and water use peak in the summer months, so the most significant effects on supply would be seen then. In the summer of 2003, U.S. generation capacity exceeded consumption by 15 percent, or

approximately 160,000 MW (USDOE 2004b). Assuming around-the-clock operation of water treatment plants, the total energy requirement can be divided by 8,760 hours per year to obtain an average power demand of 13.28 MW. A more detailed derivation of this value is shown in the Economic Analysis (USEPA 2005a). Assuming that power demand is proportional to water flow through the plant and that peak flow can be as high as twice the average daily flow during the summer months, about 26.55 MW could be needed for treatment technologies installed to comply with the Stage 2 DBPR. This is only 0.017 percent of the capacity margin available at peak use.

Although EPA recognizes that not all areas have a 15 percent capacity margin and that this margin varies across regions and through time, this analysis reflects the effect of the rule on national energy supply, distribution, and use. While certain areas, notably California, have experienced shortfalls in generating capacity in the recent past, a peak incremental power requirement of 26.55 MW nationwide is not likely to significantly change the energy supply, distribution, or use in any given area. Considering this analysis, EPA has concluded that Stage 2 DBPR will not have any significant effect on the use of energy, based on annual average use and on conditions of peak power demand.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking involves technical standards. EPA has decided to use two voluntary consensus methods for HAA5 (Standard Method 6251 B, 1998 in the 20th Edition of Standard Methods for the Examination of Water and Wastewater and Standard Method 6251 B–94, 1994 available at *http://www.standardmethods.org*). In addition to these two consensus methods, EPA is also approving EPA Method 552.3 for HAA5, which also can be used to measure three unregulated HAAs that are not included in the consensus methods. The unregulated HAAs are included in the EPA method because some water systems monitor for them in order to better understand their treatment processes and provide greater public health protection. EPA is approving two voluntary consensus standards for daily monitoring for chlorite (Standard Method 4500–ClO_2 E, 1998, in the 20th Edition of Standard Methods for the Examination of Water and Wastewater and Standard Method 4500–ClO_2 E–00, 2000, available at *http://www.standardmethods.org*). EPA Method 327.0, Revision 1.1 is also being approved for daily monitoring for both chlorite and chlorine dioxide in order to provide an alternative to the titration procedure that is required in the Standard Methods. EPA is approving a method from American Society for Testing and Materials International for bromate, chlorite and bromide analyses (ASTM D 6581–00, 2000, ASTM International. Annual Book of ASTM Standards, Volume 11.01, American Society for Testing and Materials International, 2001 or any year containing the cited version of the method may be used). EPA is also approving three EPA methods (EPA Methods 317.0 Revision 2.0, 321.8, and 326.0) that provide greater sensitivity and selectivity for bromate than the ASTM consensus standard. These EPA methods are required in order to provide better process control for water systems using ozone in the treatment process and to allow for a reduced monitoring option. EPA Methods 317.0 Revision 2.0 and 326.0 can also be used to determine chlorite and bromide. Today's action approves eight voluntary consensus standards for determining free, combined, and total chlorine (SM 4500–Cl D, SM 4500–Cl F, and 4500–Cl G, 1998, in the 20th Edition of Standard Methods for the Examination of Water and Wastewater and SM 4500–Cl D–00, SM 4500–Cl F–00, and 4500–Cl G–00, 2000 available at *http://www.standardmethods.org* and ASTM D 1253–86(96), 1996, ASTM International, Annual Book of ASTM Standards, Volume 11.01, American Society for Testing and Materials International, 1996 or any year containing the cited version of the method may be used and ASTM D 1253–03, 2003, ASTM International, Annual Book of ASTM Standards, Volume 11.01, American Society for Testing and Materials International, 2004 or any year containing the cited version of the method may be used). EPA is approving four standards for determining total chlorine (SM 4500–Cl E and SM 4500–Cl I, 1998, in the 20th Edition of Standard Methods for the Examination of Water and Wastewater and SM 4500–Cl E–00 and SM 4500–Cl I–00, 2000 available at *http://www.standardmethods.org*). Two standards for determining free chlorine are approved in today's rule (SM 4500–Cl H, 1998, in the 20th Edition of Standard Methods for the Examination of Water and Wastewater and SM 4500–Cl H–00, 2000 available at *http://www.standardmethods.org*). Today's action approves three voluntary consensus standards for measuring chlorine dioxide (4500–ClO_2 D and 4500–ClO_2 E, 1998, in the 20th Edition of Standard Methods for the Examination of Water and Wastewater and 4500–ClO_2 E–00, 2000 available at *http://www.standardmethods.org*). EPA is approving six standards for determining TOC and DOC (SM 5310 B, SM 5310 C, and SM 5310 D, 1998, in the 20th Edition of Standard Methods for the Examination of Water and Wastewater and SM 5310 B–00, SM 5310 C–00, and SM 5310 D–00, 2000 available at *http://www.standardmethods.org*). Two standards for determining UV_{254} are approved in today's rule (SM 5910 B, 1998, in the 20th Edition of Standard Methods for the Examination of Water and Wastewater and SM 5910 B–00, 2000 available at *http://www.standardmethods.org*). EPA is also approving EPA Method 415.3 Revision 1.1 for the determination of TOC and SUVA (DOC and UV_{254}). This EPA method contains method performance data that are not available in the consensus standards.

Copies of the ASTM standards may be obtained from the American Society for Testing and Materials International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. The Standard Methods may be obtained from the American Public Health Association, 1015 Fifteenth Street, NW., Washington, DC 20005.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations or Low-Income Populations

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agency missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. EPA has

considered environmental justice related issues concerning the potential impacts of this action and consulted with minority and low-income stakeholders. A description of this consultation can be found in the proposed rule (USEPA 2003a).

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

In accordance with Section 1412(d) and (e) of the SDWA, the Agency consulted with the Science Advisory Board, the National Drinking Water Advisory Council (NDWAC), and the Secretary of Health and Human Services on today's rule.

EPA met with the SAB to discuss the Stage 2 DBPR on June 13, 2001 (Washington, DC), September 25–26, 2001 (teleconference), and December 10–12, 2001 (Los Angeles, CA). Written comments from the December 2001 meeting of the SAB addressing the occurrence analysis and risk assessment were generally supportive. SAB comments are discussed in greater detail within the proposal.

EPA met with the NDWAC on November 8, 2001, in Washington, DC to discuss the Stage 2 DBPR proposal. The Advisory Committee generally supported the need for the Stage 2 DBPR based on health and occurrence data, but also stressed the importance of providing flexibility to the systems implementing the rule. The results of these discussions are included in the docket for the proposed rule.

L. Plain Language

Executive Order 12866 requires each agency to write its rules in plain language. Readable regulations help the public find requirements quickly and understand them easily. They increase compliance, strengthen enforcement, and decrease mistakes, frustration, phone calls, appeals, and distrust of government. EPA made every effort to write this preamble to the final rule in as clear, concise, and unambiguous manner as possible.

M. Analysis of the Likely Effect of Compliance With the Stage 2 DBPR on the Technical, Managerial, and Financial Capacity of Public Water Systems

Section 1420(d)(3) of SDWA, as amended, requires that, in promulgating a National Primary Drinking Water Regulation (NPDWR), the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, managerial, and financial (TMF) capacity of PWSs. This analysis is described in more detail and can be found in the Economic Analysis (USEPA 2005a). Analyses reflect only the impact of new or revised requirements, as established by the LT2ESWTR; the impacts of previously established requirements on system capacity are not considered.

EPA has defined overall water system capacity as the ability to plan for, achieve, and maintain compliance with applicable drinking water standards. Capacity encompasses three components: technical, managerial, and financial. Technical capacity is the physical and operational ability of a water system to meet SDWA requirements. This refers to the physical infrastructure of the water system, including the adequacy of source water and the adequacy of treatment, storage, and distribution infrastructure. It also refers to the ability of system personnel to adequately operate and maintain the system and to otherwise implement requisite technical knowledge. Managerial capacity is the ability of a water system to conduct its affairs to achieve and maintain compliance with SDWA requirements. Managerial capacity refers to the system's institutional and administrative capabilities. Financial capacity is a water system's ability to acquire and manage sufficient financial resources to allow the system to achieve and maintain compliance with SDWA requirements.

EPA estimated the impact of the Stage 2 DBPR on small and large system capacity as a result of the measures that systems are expected to adopt to meet the requirements of the rule (e.g., selecting monitoring sites for the IDSE, installing/upgrading treatment, operator training, communication with regulators and the service community, etc.). The Stage 2 DBPR may have a substantial impact on the capacity of the 1,743 plants in small systems and 518 plants in large systems that must make changes to their treatment process to meet the Stage 2 DBPR requirements. However, while the impact to these systems is potentially significant, only 3.8 percent of all plants regulated under the Stage 2 DBPR (2,261 of 60,220) will be affected by this requirement. Since individual systems may employ more than one plant, it is likely that fewer than 1,620 systems (3.4 percent of 48,293 systems) will be affected by this requirement. The new IDSE and monitoring requirements are expected to have a small impact on the technical and managerial capacity of small systems, a moderate impact on the financial capacity of some small systems, and a much smaller impact on large systems. The capacity of systems that must conduct an operational evaluation will only be impacted in a minor way, while those systems that must only familiarize themselves with the rule (the large majority of systems) will not face any capacity impact as a result of the Stage 2 DBPR.

N. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective March 6, 2006.

VIII. References

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List of Subjects

40 CFR Part 9

Reporting and recordkeeping requirements.

40 CFR Part 141

Environmental protection, Chemicals, Indians-lands, Incorporation by reference, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Environmental protection, Administrative practice and procedure, Chemicals, Indians-lands, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: December 15, 2005.

Stephen L. Johnson,

Administrator.

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

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

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

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

■ 2. In § 9.1 the table is amended as follows:

■ a. Under the heading ''National Primary Drinking Water Regulations Implementation'' by adding entries in numerical order for ''§ 141.600–141.605, 141.620–141.626, 141.629''.

■ b. Under the heading ''National Primary Drinking Water Regulations Implementation'' by removing entries ''§ 142.14(a),142.14(a)–(d)(3)'' and adding entries in numerical order for ''142.14(a) (1)–(7), 142.14(a)(8), 142.14(b)–(d) and 142.16(m)'' as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
National Primary Drinking Water Regulations	
* * * * *	
141.600–141.605	2040–0265
141.620–141.626	2040–0265
141.629	2040–0265
National Primary Drinking Water Regulations Implementation	
* * * * *	
142.14(a)(1)–(7)	2040–0265
142.14(a)(8)	2040–0265
142.14(b)–(d)	2040–0090
* * * * *	
142.16(m)	2040–0265

* * * * *

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

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

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

■ 4. Section 141.2 is amended by adding, in alphabetical order, definitions for ''Combined distribution system'', ''Consecutive system'', ''Dual sample sets'', ''Finished water'', ''GAC20'', ''Locational running annual average'', and ''Wholesale system'' and revising the definition of ''GAC10'' to read as follows:

§ 141.2 Definitions.

* * * * *

Combined distribution system is the interconnected distribution system consisting of the distribution systems of wholesale systems and of the consecutive systems that receive finished water.

* * * * *

Consecutive system is a public water system that receives some or all of its finished water from one or more wholesale systems. Delivery may be through a direct connection or through the distribution system of one or more consecutive systems.

* * * * *

Dual sample set is a set of two samples collected at the same time and same location, with one sample analyzed for TTHM and the other

sample analyzed for HAA5. Dual sample sets are collected for the purposes of conducting an IDSE under subpart U of this part and determining compliance with the TTHM and HAA5 MCLs under subpart V of this part.

* * * * *

Finished water is water that is introduced into the distribution system of a public water system and is intended for distribution and consumption without further treatment, except as treatment necessary to maintain water quality in the distribution system (*e.g.*, booster disinfection, addition of corrosion control chemicals).

* * * * *

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, except that the reactivation frequency for GAC10 used as a best available technology for compliance with subpart V MCLs under § 141.64(b)(2) shall be 120 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 240 days.

* * * * *

Locational running annual average (LRAA) is the average of sample analytical results for samples taken at a particular monitoring location during the previous four calendar quarters.

* * * * *

Wholesale system is a public water system that treats source water as necessary to produce finished water and then delivers some or all of that finished water to another public water system. Delivery may be through a direct connection or through the distribution system of one or more consecutive systems.

§ 141.12 [Removed]

■ 5. Section 141.12 is removed and reserved.

§ 141.30 [Removed]

■ 6. Section 141.30 is removed.

§ 141.32 [Removed]

■ 7. Section 141.32 is removed and reserved.

■ 8. Section 141.33 is amended by revising the first sentence of paragraph (a) introductory text and adding paragraph (f) to read as follows:

§ 141.33 Record maintenance.

* * * * *

(a) Records of microbiological analyses and turbidity analyses made pursuant to this part shall be kept for not less than 5 years. * * *

* * * * *

(f) Copies of monitoring plans developed pursuant to this part shall be kept for the same period of time as the records of analyses taken under the plan are required to be kept under paragraph (a) of this section, except as specified elsewhere in this part.

■ 9. Section 141.53 is amended by revising the table to read as follows:

§ 141.53 Maximum contaminant level goals for disinfection byproducts.

* * * * *

Disinfection byproduct	MCLG (mg/L)
Bromodichloromethane	zero
Bromoform	zero
Bromate	zero
Chlorite	0.8
Chloroform	0.07
Dibromochloromethane	0.06
Dichloroacetic acid	zero
Monochloroacetic acid	0.07
Trichloroacetic acid	0.02

■ 10. Section 141.64 is revised to read as follows:

§ 141.64 Maximum contaminant levels for disinfection byproducts.

(a) *Bromate and chlorite.* The maximum contaminant levels (MCLs) for bromate and chlorite are as follows:

Disinfection byproduct	MCL (mg/L)
Bromate	0.010
Chlorite	1.0

(1) *Compliance dates for CWSs and NTNCWSs.* Subpart H systems serving 10,000 or more persons must comply with this paragraph (a) beginning January 1, 2002. Subpart H systems serving fewer than 10,000 persons and systems using only ground water not under the direct influence of surface water must comply with this paragraph (a) beginning January 1, 2004.

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

Disinfection by-product	Best available technology
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

(b) TTHM and HAA5. (1) Subpart L—RAA compliance. (i) Compliance dates. Subpart H systems serving 10,000 or more persons must comply with this paragraph (b)(1) beginning January 1, 2002. Subpart H systems serving fewer than 10,000 persons and systems using only ground water not under the direct influence of surface water must comply with this paragraph (b)(1) beginning January 1, 2004. All systems must comply with these MCLs until the date specified for subpart V compliance in § 141.620(c).

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

(ii) The Administrator, pursuant to section 1412 of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for TTHM and HAA5 identified in this paragraph (b)(1):

Disinfection byproduct	Best available technology
Total trihalomethanes (TTHM) and Haloacetic acids (five) (HAA5).	Enhanced coagulation or enhanced softening or GAC10, with chlorine as the primary and residual disinfectant

(2) Subpart V—LRAA compliance. (i) Compliance dates. The subpart V MCLs for TTHM and HAA5 must be complied with as a locational running annual average at each monitoring location beginning the date specified for subpart V compliance in § 141.620(c).

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

(ii) The Administrator, pursuant to section 1412 of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for TTHM and HAA5 identified in this paragraph (b)(2)

for all systems that disinfect their source water:

Disinfection by-product	Best available technology
Total trihalomethanes (TTHM) and Haloacetic acids (five) (HAA5).	Enhanced coagulation or enhanced softening, plus GAC10; or nanofiltration with a molecular weight cutoff ≤1000 Daltons; or GAC20

(iii) The Administrator, pursuant to section 1412 of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for TTHM and HAA5 identified in this paragraph (b)(2) for consecutive systems and applies only to the disinfected water that consecutive systems buy or otherwise receive:

Disinfection by-product	Best available technology
Total trihalomethanes (TTHM) and Haloacetic acids (five) (HAA5).	Systems serving ≥10,000: Improved distribution system and storage tank management to reduce residence time, plus the use of chloramines for disinfectant residual maintenance Systems serving <10,000: Improved distribution system and storage tank management to reduce residence time

■ 11. Section 141.131 is amended as follows:
■ a. By revising paragraph (a),
■ b. By revising paragraphs (b)(1) and (b)(2),
■ c. By revising the table in paragraph (c)(1),
■ d. By revising paragraphs (d)(2), (d)(3), (d)(4)(i), and (d)(4)(ii),
■ e. By adding paragraph (d)(6).

§ 141.131 Analytical requirements.

(a) *General.* (1) Systems must use only the analytical methods specified in this section, or their equivalent as approved by EPA, to demonstrate compliance with the requirements of this subpart and with the requirements of subparts U and V of this part. These methods are effective for compliance monitoring February 16, 1999, unless a different effective date is specified in this section or by the State.

(2) The following documents are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at EPA's Drinking Water Docket, 1301 Constitution Avenue, NW., EPA West, Room B102, Washington, DC 20460, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* EPA Method 552.1 is in Methods for the Determination of Organic Compounds in Drinking Water-Supplement II, USEPA, August 1992, EPA/600/R–92/129 (available through National Information Technical Service (NTIS), PB92–207703). EPA Methods 502.2, 524.2, 551.1, and 552.2 are in Methods for the Determination of Organic Compounds in Drinking Water-Supplement III, USEPA, August 1995, EPA/600/R–95/131 (available through NTIS, PB95–261616). EPA Method 300.0 is in Methods for the Determination of Inorganic Substances in Environmental Samples, USEPA, August 1993, EPA/600/R–93/100 (available through NTIS, PB94–121811). EPA Methods 300.1 and 321.8 are in Methods for the Determination of Organic and Inorganic Compounds in Drinking Water, Volume 1, USEPA, August 2000, EPA 815–R–00–014 (available through NTIS, PB2000–106981). EPA Method 317.0, Revision 2.0, ''Determination of Inorganic Oxyhalide Disinfection By-Products in Drinking Water Using Ion Chromatography with the Addition of a Postcolumn Reagent for Trace Bromate Analysis,'' USEPA, July 2001, EPA 815–B–01–001, EPA Method 326.0, Revision 1.0, ''Determination of Inorganic Oxyhalide Disinfection By-Products in Drinking Water Using Ion Chromatography Incorporating the Addition of a Suppressor Acidified Postcolumn Reagent for Trace Bromate Analysis,'' USEPA, June 2002, EPA 815–R–03–007, EPA Method 327.0, Revision 1.1, ''Determination of Chlorine Dioxide and Chlorite Ion in Drinking Water Using Lissamine Green B and Horseradish Peroxidase with Detection by Visible Spectrophotometry,'' USEPA, May 2005, EPA 815–R–05–008 and EPA Method 552.3, Revision 1.0, ''Determination of Haloacetic Acids and Dalapon in Drinking Water by Liquid-liquid Microextraction, Derivatization, and Gas Chromatography with Electron Capture Detection,'' USEPA, July 2003, EPA–815–B–03–002 can be accessed and downloaded directly on-line at *http://www.epa.gov/safewater/methods/sourcalt.html.* EPA Method 415.3, Revision 1.1, ''Determination of Total Organic Carbon and Specific UV Absorbance at 254 nm in Source Water and Drinking Water,'' USEPA, February 2005, EPA/600/R–05/055 can be accessed and downloaded directly on-line at *www.epa.gov/nerlcwww/ordmeth.htm.* Standard Methods 4500–Cl D, 4500–Cl E, 4500–Cl F, 4500–Cl G, 4500–Cl H, 4500–Cl I, 4500–ClO_2 D, 4500–ClO_2 E, 6251 B, and 5910 B shall be followed in accordance with Standard Methods for the Examination of Water and Wastewater, 19th or 20th Editions, American Public Health Association, 1995 and 1998, respectively. The cited methods published in either edition may be used. Standard Methods 5310 B, 5310 C, and 5310 D shall be followed in accordance with the Supplement to the 19th Edition of Standard Methods for the Examination of Water and Wastewater, or the Standard Methods for the Examination of Water and Wastewater, 20th Edition, American Public Health Association, 1996 and 1998, respectively. The cited methods published in either edition may be used. Copies may be obtained from the American Public Health Association, 1015 Fifteenth Street, NW., Washington, DC 20005. Standard Methods 4500–Cl D–00, 4500–Cl E–00, 4500–Cl F–00, 4500–Cl G–00, 4500–Cl H–00, 4500–Cl I–00, 4500–ClO_2 E–00, 6251 B–94, 5310 B–00, 5310 C–00, 5310 D–00 and 5910 B–00 are available at *http://www.standardmethods.org* or at EPA's Water Docket. The year in which each method was approved by the Standard Methods Committee is designated by the last two digits in the method number. The methods listed are the only Online versions that are IBR-approved. ASTM Methods D 1253–86 and D 1253–86 (Reapproved 1996) shall be followed in accordance with the Annual Book of ASTM Standards, Volume 11.01, American Society for Testing and Materials International, 1996 or any ASTM edition containing the IBR-approved version of the method may be used. ASTM Method D1253–03 shall be followed in accordance with the Annual Book of ASTM Standards, Volume 11.01, American Society for Testing and Materials International, 2004 or any ASTM edition containing the IBR-approved version of the method may be used. ASTM Method D 6581–00 shall be followed in accordance with the Annual Book of ASTM Standards, Volume 11.01, American Society for Testing and Materials International, 2001 or any ASTM edition containing the IBR-approved version of the method may be used; copies may be obtained from the American Society for Testing and

Materials International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959.

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

APPROVED METHODS FOR DISINFECTION BYPRODUCT COMPLIANCE MONITORING

Contaminant and methodology [1]	EPA method	Standard method [2]	SM online [9]	ASTM method [3]
TTHM				
P&T/GC/ElCD & PID	502.2 [4]			
P&T/GC/MS	524.2			
LLE/GC/ECD	551.1			
HAA5				
LLE (diazomethane)/GC/ECD		6251 B [5]	6251 B–94	
SPE (acidic methanol)/GC/ECD	552.1 [5]			
LLE (acidic methanol)/GC/ECD	552.2, 552.3			
Bromate				
Ion chromatography	300.1			D 6581–00
Ion chromatography & post column reaction.	317.0 Rev 2.0 [6], 326.0 [6]			
IC/ICP–MS	321.8 [6 7]			
Chlorite				
Amperometric titration		4500–ClO_2 E [8]	4500–ClO_2 E–00 [8]	
Spectrophotometry	327.0 Rev 1.1 [8]			
Ion chromatography	300.0, 300.1, 317.0 Rev 2.0, 326.0.			D 6581–00

[1] P&T = purge and trap; GC = gas chromatography; ElCD = electrolytic conductivity detector; PID = photoionization detector; MS = mass spectrometer; LLE = liquid/liquid extraction; ECD = electron capture detector; SPE = solid phase extraction; IC = ion chromatography; ICP–MS = inductively coupled plasma/mass spectrometer.
[2] 19th and 20th editions of Standard Methods for the Examination of Water and Wastewater, 1995 and 1998, respectively, American Public Health Association; either of these editions may be used.
[3] Annual Book of ASTM Standards, 2001 or any year containing the cited version of the method, Vol 11.01.
[4] If TTHMs are the only analytes being measured in the sample, then a PID is not required.
[5] The samples must be extracted within 14 days of sample collection.
[6] Ion chromatography & post column reaction or IC/ICP-MS must be used for monitoring of bromate for purposes of demonstrating eligibility of reduced monitoring, as prescribed in § 141.132(b)(3)(ii).
[7] Samples must be preserved at the time of sampling with 50 mg ethylenediamine (EDA)/L of sample and must be analyzed within 28 days.
[8] Amperometric titration or spectrophotometry may be used for routine daily monitoring of chlorite at the entrance to the distribution system, as prescribed in § 141.132(b)(2)(i)(A). Ion chromatography must be used for routine monthly monitoring of chlorite and additional monitoring of chlorite in the distribution system, as prescribed in § 141.132(b)(2)(i)(B) and (b)(2)(ii).
[9] The Standard Methods Online version that is approved is indicated by the last two digits in the method number which is the year of approval by the Standard Method Committee. Standard Methods Online are available at *http://www.standardmethods.org.*

(2) Analyses under this section for disinfection byproducts must be conducted by laboratories that have received certification by EPA or the State, except as specified under paragraph (b)(3) of this section. To receive certification to conduct analyses for the DBP contaminants in §§ 141.64, 141.135, and subparts U and V of this part, the laboratory must:

(i) Analyze Performance Evaluation (PE) samples that are acceptable to EPA or the State at least once during each consecutive 12 month period by each method for which the laboratory desires certification.

(ii) Until March 31, 2007, in these analyses of PE samples, the laboratory must achieve quantitative results within the acceptance limit on a minimum of 80% of the analytes included in each PE sample. The acceptance limit is defined as the 95% confidence interval calculated around the mean of the PE study between a maximum and minimum acceptance limit of +/−50% and +/−15% of the study mean.

(iii) Beginning April 1, 2007, the laboratory must achieve quantitative results on the PE sample analyses that are within the following acceptance limits:

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

DBP	Acceptance limits (percent of true value)	Comments
Bromate	±30	

(iv) Beginning April 1, 2007, report quantitative data for concentrations at least as low as the ones listed in the following table for all DBP samples analyzed for compliance with §§ 141.64, 141.135, and subparts U and V of this part:

DBP	Minimum reporting level (mg/L) [1]	Comments
TTHM [2]		
Chloroform	0.0010	
Bromodichloromethane	0.0010	
Dibromochloromethane	0.0010	
Bromoform	0.0010	
HAA5 [2]		
Monochloroacetic Acid	0.0020	
Dichloroacetic Acid	0.0010	
Trichloroacetic Acid	0.0010	
Monobromoacetic Acid	0.0010	
Dibromoacetic Acid	0.0010	
Chlorite	0.020	Applicable to monitoring as prescribed in § 141.132(b)(2)(1)(B) and (b)(2)(ii).
Bromate	0.0050 or 0.0010	Laboratories that use EPA Methods 317.0 Revision 2.0, 326.0 or 321.8 must meet a 0.0010 mg/L MRL for bromate.

[1] The calibration curve must encompass the regulatory minimum reporting level (MRL) concentration. Data may be reported for concentrations lower than the regulatory MRL as long as the precision and accuracy criteria are met by analyzing an MRL check standard at the lowest reporting limit chosen by the laboratory. The laboratory must verify the accuracy of the calibration curve at the MRL concentration by analyzing an MRL check standard with a concentration less than or equal to 110% of the MRL with each batch of samples. The measured concentration for the MRL check standard must be ±50% of the expected value, if any field sample in the batch has a concentration less than 5 times the regulatory MRL. Method requirements to analyze higher concentration check standards and meet tighter acceptance criteria for them must be met in addition to the MRL check standard requirement.

[2] When adding the individual trihalomethane or haloacetic acid concentrations to calculate the TTHM or HAA5 concentrations, respectively, a zero is used for any analytical result that is less than the MRL concentration for that DBP, unless otherwise specified by the State.

* * * * *

(c) * * *

(1) * * *

Methodology	SM (19th or 20th ed)	SM Online [2]	ASTM method	EPA method	Residual measured [1]			
					Free Cl_2	Combined Cl_2	Total Cl_2	ClO_2
Amperometric Titration	4500–C D	4500–C D–00	D 1253–86 (96), 03		X	X	X	
Low Level Amperometric Titration.	4500–C E	4500–C E–00					X	
DPD Ferrous Titrimetric	4500–C F	4500–C F–00			X	X	X	
DPD Colorimetric	4500–C G	4500–C G–00			X	X	X	
Syringaldazine (FACTS)	4500–C H	4500–C H–00			X			
Iodometric Electrode	4500–C I	4500–C I–00					X	
DPD	4500–C O_2 D							X
Amperometric Method II	4500–C O_2 E	4500–C O_2 E–00						X
Lissamine Green Spectrophotometric.				327.0 Rev 1.1				X

[1] X indicates method is approved for measuring specified disinfectant residual. Free chlorine or total chlorine may be measured for demonstrating compliance with the chlorine MRDL and combined chlorine, or total chlorine may be measured for demonstrating compliance with the chloramine MRDL.

[2] The Standard Methods Online version that is approved is indicated by the last two digits in the method number which is the year of approval by the Standard Method Committee. Standard Methods Online are available at *http://www.standardmethods.org.*

* * * * *

(d) * * *

(2) *Bromide.* EPA Methods 300.0, 300.1, 317.0 Revision 2.0, 326.0, or ASTM D 6581–00.

(3) *Total Organic Carbon (TOC).* Standard Method 5310 B or 5310 B–00 (High-Temperature Combustion

Method) or Standard Method 5310 C or 5310 C–00 (Persulfate-Ultraviolet or Heated-Persulfate Oxidation Method) or Standard Method 5310 D or 5310 D–00 (Wet-Oxidation Method) or EPA Method 415.3 Revision 1.1. Inorganic carbon must be removed from the samples prior to analysis. TOC samples may not be filtered prior to analysis. TOC samples must be acidified at the time of sample collection to achieve pH less than or equal to 2 with minimal addition of the acid specified in the method or by the instrument manufacturer. Acidified TOC samples must be analyzed within 28 days.

(4) * * *

(i) Dissolved Organic Carbon (DOC). Standard Method 5310 B or 5310 B–00 (High-Temperature Combustion Method) or Standard Method 5310 C or 5310 C–00 (Persulfate-Ultraviolet or Heated-Persulfate Oxidation Method) or Standard Method 5310 D or 5310 D–00 (Wet-Oxidation Method) or EPA Method 415.3 Revision 1.1. DOC samples must be filtered through the 0.45 μm pore-diameter filter as soon as practical after sampling, not to exceed 48 hours. After filtration, DOC samples must be acidified to achieve pH less than or equal to 2 with minimal addition of the acid specified in the method or by the instrument manufacturer. Acidified DOC samples must be analyzed within 28 days of sample collection. Inorganic carbon must be removed from the samples prior to analysis. Water passed through the filter prior to filtration of the sample must serve as the filtered blank. This filtered blank must be analyzed using procedures identical to those used for analysis of the samples and must meet the following criteria: DOC < 0.5 mg/L.

(ii) Ultraviolet Absorption at 254 nm (UV_{254}). Standard Method 5910 B or 5910 B–00 (Ultraviolet Absorption Method) or EPA Method 415.3 Revision 1.1. UV absorption must be measured at 253.7 nm (may be rounded off to 254 nm). Prior to analysis, UV_{254} samples must be filtered through a 0.45 μm pore-diameter filter. The pH of UV_{254} samples may not be adjusted. Samples must be analyzed as soon as practical after sampling, not to exceed 48 hours.

* * * * *

(6) *Magnesium.* All methods allowed in § 141.23(k)(1) for measuring magnesium.

■ 12. Section 141.132 is amended by:

■ a. Redesignating paragraphs (b)(1)(iii) through (b)(1)(v) as paragraphs (b)(1)(iv) through (b)(1)(vi);

■ b. Adding a new paragraph (b)(1)(iii);

■ c. Revising newly redesignated paragraph (b)(1)(iv); and

■ d. Revising paragraph (b)(3)(ii).

The addition and revisions read as follows:

§ 141.132 Monitoring requirements.

* * * * *

(b) * * *

(1) * * *

(iii) *Monitoring requirements for source water TOC.* In order to qualify for reduced monitoring for TTHM and HAA5 under paragraph (b)(1)(ii) of this section, subpart H systems not monitoring under the provisions of paragraph (d) of this section must take monthly TOC samples every 30 days at a location prior to any treatment, beginning April 1, 2008 or earlier, if specified by the State. In addition to meeting other criteria for reduced monitoring in paragraph (b)(1)(ii) of this section, the source water TOC running annual average must be ≤4.0 mg/L (based on the most recent four quarters of monitoring) on a continuing basis at each treatment plant to reduce or remain on reduced monitoring for TTHM and HAA5. Once qualified for reduced monitoring for TTHM and HAA5 under paragraph (b)(1)(ii) of this section, a system may reduce source water TOC monitoring to quarterly TOC samples taken every 90 days at a location prior to any treatment.

(iv) Systems on a reduced monitoring schedule may remain on that reduced schedule as long as the average of all samples taken in the year (for systems which must monitor quarterly) or the result of the sample (for systems which must monitor no more frequently than annually) is no more than 0.060 mg/L and 0.045 mg/L for TTHMs and HAA5, respectively. Systems that do not meet these levels must resume monitoring at the frequency identified in paragraph (b)(1)(i) of this section (minimum monitoring frequency column) in the quarter immediately following the monitoring period in which the system exceeds 0.060 mg/L or 0.045 mg/L for TTHMs and HAA5, respectively. For systems using only ground water not under the direct influence of surface water and serving fewer than 10,000 persons, if either the TTHM annual average is >0.080 mg/L or the HAA5 annual average is >0.060 mg/L, the system must go to the increased monitoring identified in paragraph (b)(1)(i) of this section (sample location column) in the quarter immediately following the monitoring period in which the system exceeds 0.080 mg/L or 0.060 mg/L for TTHMs or HAA5 respectively.

* * * * *

(3) ***

(i) ***

(ii) Reduced monitoring.

(A) Until March 31, 2009, systems required to analyze for bromate may reduce monitoring from monthly to quarterly, if the system's average source water bromide concentration is less than 0.05 mg/L based on representative monthly bromide measurements for one year. The system may remain on reduced bromate monitoring until the running annual average source water bromide concentration, computed quarterly, is equal to or greater than 0.05 mg/L based on representative monthly measurements. If the running annual average source water bromide concentration is ≥0.05 mg/L, the system must resume routine monitoring required by paragraph (b)(3)(i) of this section in the following month.

(B) Beginning April 1, 2009, systems may no longer use the provisions of paragraph (b)(3)(ii)(A) of this section to qualify for reduced monitoring. A system required to analyze for bromate may reduce monitoring from monthly to quarterly, if the system's running annual average bromate concentration is ≤0.0025 mg/L based on monthly bromate measurements under paragraph (b)(3)(i) of this section for the most recent four quarters, with samples analyzed using Method 317.0 Revision 2.0, 326.0 or 321.8. If a system has qualified for reduced bromate monitoring under paragraph (b)(3)(ii)(A) of this section, that system may remain on reduced monitoring as long as the running annual average of quarterly bromate samples ≤0.0025 mg/L based on samples analyzed using Method 317.0 Revision 2.0, 326.0, or 321.8. If the running annual average bromate concentration is >0.0025 mg/L, the system must resume routine monitoring required by paragraph (b)(3)(i) of this section.

* * * * *

§ 141.133 [Amended]

■ 13. Section 141.133 is amended in the last sentence of paragraph (d) by revising the reference ''§ 141.32'' to read ''subpart Q of this part''.

■ 14. Section 141.135 is amended by revising paragraph (a)(3)(ii) to read as follows:

§ 141.135 Treatment technique for control of disinfection byproduct (DBP) precursors.

(a) * * *

(3) * * *

(ii) Softening that results in removing at least 10 mg/L of magnesium hardness (as $CaCO_3$), measured monthly according to § 141.131(d)(6) and calculated quarterly as a running annual average.

* * * * *

■ 15. Section 141.151 is amended by revising paragraph (d) to read as follows:

§ 141.151 Purpose and applicability of this subpart.

* * * * *

(d) For the purpose of this subpart, detected means: at or above the levels prescribed by § 141.23(a)(4) for inorganic contaminants, at or above the levels prescribed by § 141.24(f)(7) for the contaminants listed in § 141.61(a), at or above the levels prescribed by § 141.24(h)(18) for the contaminants listed in § 141.61(c), at or above the levels prescribed by § 141.131(b)(2)(iv) for the contaminants or contaminant groups listed in § 141.64, and at or above the levels prescribed by § 141.25(c) for radioactive contaminants.

* * * * *

■ 16. Section 141.153 is amended by revising paragraphs (d)(4)(iv)(B) and (d)(4)(iv)(C) to read as follows:

§ 141.153 Content of the reports.

* * * * *

(d) * * *

(4) * * *

(iv) * * *

(B) When compliance with the MCL is determined by calculating a running annual average of all samples taken at a monitoring location: the highest average of any of the monitoring locations and the range of all monitoring locations expressed in the same units as the MCL. For the MCLs for TTHM and HAA5 in § 141.64(b)(2), systems must include the highest locational running annual average for TTHM and HAA5 and the range of individual sample results for all monitoring locations expressed in the same units as the MCL. If more than one location exceeds the TTHM or HAA5 MCL, the system must include the locational running annual averages for all locations that exceed the MCL.

(C) When compliance with the MCL is determined on a system-wide basis by calculating a running annual average of all samples at all monitoring locations: the average and range of detection expressed in the same units as the MCL. The system is required to include individual sample results for the IDSE conducted under subpart U of this part when determining the range of TTHM and HAA5 results to be reported in the annual consumer confidence report for the calendar year that the IDSE samples were taken.

* * * * *

Appendix A to Subpart Q [Amended]

■ 17. In Subpart Q, Appendix A is amended as follows:

■ a. In entry I.B.2. in the fifth column, remove the endnote citation ''9'' and add in its place ''11'';

■ b. In entry I.B.11. in the fourth column, remove the endnote citation ''10'' and add in its place ''12'';

■ c. In entry I.B.12. in the fourth column, remove the endnote citation ''10'' and add in its place ''12'';

■ d. In entry I.G. in the first column, remove the endnote citation ''11'' and add in its place ''13'';

■ e. In entry I.G.1. in the third column, remove the endnote citation ''12'' and add in its place ''14'' and remove the citation in the third column ''141.12, 141.64(a)'' and in its place add ''141.64(b)'' (keeping the endnote citation to endnote 14) and in the fifth column remove the citation ''141.30'' and add in numerical order the citations ''141.600–141.605, 141.620–141.629'';

■ f. In entry I.G.2. revise the entry ''141.64(a)'' to read ''141.64(b)'' and in the fifth column add in numerical order the citations ''141.600–141.605, 141.620–141.629''.

■ g. In entry I.G.7. in the fourth column, remove the endnote citation ''13'' and add in its place ''15'';

■ h. In entry I.G.8. in the second column, remove the endnote citation ''14'' and add in its place ''16'';

■ i. In entry II. in the first column, remove the endnote citation ''15'' and add in its place ''17'';

■ j. In entry III.A. in the third column, remove the endnote citation ''16'' and add in its place ''18'';

■ k. In entry III.B in the third column, remove the endnote citation ''17'' and add in its place ''19'';

■ l. In entry IV.E. in the first column, remove the endnote citation ''18'' and add in its place 20''; and

■ m. In entry III.F in the second column, remove the endnote citation ''19'' and add in its place ''21''.

■ 18. In Subpart Q, Appendix A, remove endnote 14 and add in its place, to read as follows: ''14.§§ 141.64(b)(1) 141.132(a)–(b) apply until §§ 141.620–141.630 take effect under the schedule in § 141.620(c).

■ 19–20. In Subpart Q, Appendix B is amended as follows:

■ a. In entry G.77. in the third column, remove the endnote citation ''16'' and add in its place ''17'';

■ b. In entry H. (the title) in the first column, remove the endnote citation ''17'' and add in its place ''18'';

■ c. In entry H.80. in the third column, remove the endnote citations ''17, 18'' and add in its place ''19, 20'' and remove the number ''0.10/'';

■ d. In entry H.81. in the third column, remove the endnote citation ''20'' and add in its place ''21''; and

■ e. In entry H.84. in the second column, remove the endnote citation ''21'' and add in its place ''22'' and in the third column remove the endnote citation ''22'' and add in its place ''23''.

■ f. Revise endnotes 18 and 19.

The revisions read as follows:

Appendix B to Subpart Q

* * * * *

■ 18. Surface water systems and ground water systems under the direct influence of surface water are regulated under subpart H of 40 CFR 141. Subpart H community and non-transient non-community systems serving ≥10,000 must comply with subpart L DBP MCLs and disinfectant maximum residual disinfectant levels (MRDLs) beginning January 1, 2002. All other community and non-transient non-community systems must comply with subpart L DBP MCLs and disinfectant MRDLs beginning January 1, 2004. Subpart H transient non-community systems serving ≥10,000 that use chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning January 1, 2002. All other transient non-community systems that use chlorine dioxide as a disinfectant or oxidant must comply with the chlorine dioxide MRDL beginning January 1, 2004.

■ 19. Community and non-transient non-community systems must comply with subpart V TTHM and HAA5 MCLs of 0.080 mg/L and 0.060 mg/L, respectively (with compliance calculated as a locational running annual average) on the schedule in § 141.620.

* * * * *

■ 21. Part 141 is amended by adding new subpart U to read as follows:

Subpart U—Initial Distribution System Evaluations

141.600 General requirements.
141.601 Standard monitoring.
141.602 System specific studies.
141.603 40/30 certification.
141.604 Very small system waivers.
141.605 Subpart V compliance monitoring location recommendations.

Subpart U—Initial Distribution System Evaluations

§ 141.600 General requirements.

(a) The requirements of subpart U of this part constitute national primary drinking water regulations. The regulations in this subpart establish monitoring and other requirements for identifying subpart V compliance monitoring locations for determining compliance with maximum contaminant levels for total

trihalomethanes (TTHM) and haloacetic acids (five)(HAA5). You must use an Initial Distribution System Evaluation (IDSE) to determine locations with representative high TTHM and HAA5 concentrations throughout your distribution system. IDSEs are used in conjunction with, but separate from, subpart L compliance monitoring, to identify and select subpart V compliance monitoring locations.

(b) *Applicability.* You are subject to these requirements if your system is a community water system that uses a primary or residual disinfectant other than ultraviolet light or delivers water that has been treated with a primary or residual disinfectant other than ultraviolet light; or if your system is a nontransient noncommunity water system that serves at least 10,000 people and uses a primary or residual disinfectant other than ultraviolet light or delivers water that has been treated with a primary or residual disinfectant other than ultraviolet light.

(c) *Schedule.* (1) You must comply with the requirements of this subpart on the schedule in the table in this paragraph (c)(1).

If you serve this population	You must submit your standard monitoring plan or system specific study plan [1] or 40/30 certification [2] to the State by or receive very small system waiver from State	You must complete your standard monitoring or system specific study by	You must submit your IDSE report to the State by [3]
Systems that are not part of a combined distribution system and systems that serve the largest population in the combined distribution system			
(i) ≥100,000	October 1, 2006	September 30, 2008	January 1, 2009.
(ii) 50,000–99,999	April 1, 2007	March 31, 2009	July 1, 2009.
(iii) 10,000–49,999	October 1, 2007	September 30, 2009	January 1, 2010.
(iv) <10,000 (CWS Only).	April 1, 2008	March 31, 2010	July 1, 2010.
Other systems that are part of a combined distribution system			
(v) Wholesale system or consecutive system.	—at the same time as the system with the earliest compliance date in the combined distribution system.	—at the same time as the system with the earliest compliance date in the combined distribution system.	—at the same time as the system with the earliest compliance date in the combined distribution system.

[1] If, within 12 months after the date identified in this column, the State does not approve your plan or notify you that it has not yet completed its review, you may consider the plan that you submitted as approved. You must implement that plan and you must complete standard monitoring or a system specific study no later than the date identified in the third column.

[2] You must submit your 40/30 certification under § 141.603 by the date indicated.

[3] If, within three months after the date identified in this column (nine months after the date identified in this column if you must comply on the schedule in paragraph (c)(1)(iii) of this section), the State does not approve your IDSE report or notify you that it has not yet completed its review, you may consider the report that you submitted as approved and you must implement the recommended subpart V monitoring as required.

(2) For the purpose of the schedule in paragraph (c)(1) of this section, the State may determine that the combined distribution system does not include certain consecutive systems based on factors such as receiving water from a wholesale system only on an emergency basis or receiving only a small percentage and small volume of water from a wholesale system. The State may also determine that the combined distribution system does not include certain wholesale systems based on factors such as delivering water to a consecutive system only on an emergency basis or delivering only a small percentage and small volume of water to a consecutive system.

(d) You must conduct standard monitoring that meets the requirements in § 141.601, or a system specific study that meets the requirements in § 141.602, or certify to the State that you meet 40/30 certification criteria under § 141.603, or qualify for a very small system waiver under § 141.604.

(1) You must have taken the full complement of routine TTHM and HAA5 compliance samples required of a system with your population and source water under subpart L of this part (or you must have taken the full complement of reduced TTHM and HAA5 compliance samples required of a system with your population and source water under subpart L if you meet reduced monitoring criteria under subpart L of this part) during the period specified in § 141.603(a) to meet the 40/30 certification criteria in § 141.603. You must have taken TTHM and HAA5 samples under §§ 141.131 and 141.132 to be eligible for the very small system waiver in § 141.604.

(2) If you have not taken the required samples, you must conduct standard monitoring that meets the requirements in § 141.601, or a system specific study that meets the requirements in § 141.602.

(e) You must use only the analytical methods specified in § 141.131, or otherwise approved by EPA for monitoring under this subpart, to demonstrate compliance with the requirements of this subpart.

(f) IDSE results will not be used for the purpose of determining compliance with MCLs in § 141.64.

§ 141.601 Standard monitoring.

(a) *Standard monitoring plan.* Your standard monitoring plan must comply with paragraphs (a)(1) through (a)(4) of this section. You must prepare and submit your standard monitoring plan to the State according to the schedule in § 141.600(c).

(1) Your standard monitoring plan must include a schematic of your distribution system (including distribution system entry points and their sources, and storage facilities), with notes indicating locations and dates of all projected standard monitoring, and all projected subpart L compliance monitoring.

(2) Your standard monitoring plan must include justification of standard monitoring location selection and a summary of data you relied on to justify standard monitoring location selection.

(3) Your standard monitoring plan must specify the population served and system type (subpart H or ground water).

(4) You must retain a complete copy of your standard monitoring plan submitted under this paragraph (a), including any State modification of your standard monitoring plan, for as long as

you are required to retain your IDSE report under paragraph (c)(4) of this section.

(b) *Standard monitoring.* (1) You must monitor as indicated in the table in this paragraph (b)(1). You must collect dual sample sets at each monitoring location. One sample in the dual sample set must be analyzed for TTHM. The other sample in the dual sample set must be analyzed for HAA5. You must conduct one monitoring period during the peak historical month for TTHM levels or HAA5 levels or the month of warmest water temperature. You must review available compliance, study, or operational data to determine the peak historical month for TTHM or HAA5 levels or warmest water temperature.

Source water type	Population size category	Monitoring periods and frequency of sampling	Distribution system monitoring locations [1]				
			Total per monitoring period	Near entry points	Average residence time	High TTHM locations	High HAA5 locations
Subpart H							
	<500 consecutive systems	one (during peak historical month) [2].	2	1	.....	1	
	<500 non-consecutive systems	.....	2	.....	.....	1	1
	500–3,300 consecutive systems.	four (every 90 days)	2	1	.....	1	
	500–3,300 non-consecutive systems.	.....	2	.....	.....	1	1
	3,301–9,999	.....	4	.....	1	2	1
	10,000–49,999	six (every 60 days)	8	1	2	3	2
	50,000–249,999	.....	16	3	4	5	4
	250,000–999,999	.....	24	4	6	8	6
	1,000,000–4,999,999	.....	32	6	8	10	8
	≥5,000,000	.....	40	8	10	12	10
Ground Water							
	<500 consecutive systems	one (during peak historical month) [2].	2	1	.....	1	
	<500 non-consecutive systems	.....	2	.....	.....	1	1
	500–9,999	four (every 90 days)	2	.....	.....	1	1
	10,000–99,999	.....	6	1	1	2	2
	100,000–499,999	.....	8	1	1	3	3
	≥500,000	.....	12	2	2	4	4

[1] A dual sample set (i.e., a TTHM and an HAA5 sample) must be taken at each monitoring location during each monitoring period.
[2] The peak historical month is the month with the highest TTHM or HAA5 levels or the warmest water temperature.

(2) You must take samples at locations other than the existing subpart L monitoring locations. Monitoring locations must be distributed throughout the distribution system.

(3) If the number of entry points to the distribution system is fewer than the specified number of entry point monitoring locations, excess entry point samples must be replaced equally at high TTHM and HAA5 locations. If there is an odd extra location number, you must take a sample at a high TTHM location. If the number of entry points to the distribution system is more than the specified number of entry point monitoring locations, you must take samples at entry points to the distribution system having the highest annual water flows.

(4) Your monitoring under this paragraph (b) may not be reduced under the provisions of § 141.29 and the State may not reduce your monitoring using the provisions of § 142.16(m).

(c) *IDSE report.* Your IDSE report must include the elements required in paragraphs (c)(1) through (c)(4) of this section. You must submit your IDSE report to the State according to the schedule in § 141.600(c).

(1) Your IDSE report must include all TTHM and HAA5 analytical results from subpart L compliance monitoring and all standard monitoring conducted during the period of the IDSE as individual analytical results and LRAAs presented in a tabular or spreadsheet format acceptable to the State. If changed from your standard monitoring plan submitted under paragraph (a) of this section, your report must also include a schematic of your distribution system, the population served, and system type (subpart H or ground water).

(2) Your IDSE report must include an explanation of any deviations from your approved standard monitoring plan.

(3) You must recommend and justify subpart V compliance monitoring locations and timing based on the protocol in § 141.605.

(4) You must retain a complete copy of your IDSE report submitted under this section for 10 years after the date that you submitted your report. If the State modifies the subpart V monitoring requirements that you recommended in your IDSE report or if the State approves alternative monitoring locations, you must keep a copy of the State's notification on file for 10 years after the date of the State's notification. You must make the IDSE report and any State notification available for review by the State or the public.

§ 141.602 System specific studies.

(a) *System specific study plan.* Your system specific study plan must be based on either existing monitoring results as required under paragraph (a)(1) of this section or modeling as required under paragraph (a)(2) of this section. You must prepare and submit your system specific study plan to the State according to the schedule in § 141.600(c).

(1) *Existing monitoring results.* You may comply by submitting monitoring results collected before you are required to begin monitoring under § 141.600(c). The monitoring results and analysis must meet the criteria in paragraphs (a)(1)(i) and (a)(1)(ii) of this section.

(i) *Minimum requirements.* (A) TTHM and HAA5 results must be based on samples collected and analyzed in accordance with § 141.131. Samples must be collected no earlier than five years prior to the study plan submission date.

(B) The monitoring locations and frequency must meet the conditions identified in this paragraph (a)(1)(i)(B). Each location must be sampled once during the peak historical month for TTHM levels or HAA5 levels or the month of warmest water temperature for every 12 months of data submitted for that location. Monitoring results must include all subpart L compliance monitoring results plus additional monitoring results as necessary to meet minimum sample requirements.

System Type	Population size category	Number of monitoring locations	Number of samples	
			TTHM	HAA5
Subpart H:				
	<500	3	3	3
	500–3,300	3	9	9
	3,301–9,999	6	36	36
	10,000–49,999	12	72	72
	50,000–249,999	24	144	144
	250,000–999,999	36	216	216
	1,000,000–4,999,999	48	288	288
	≥ 5,000,000	60	360	360
Ground Water:				
	<500	3	3	3
	500–9,999	3	9	9
	10,000–99,999	12	48	48
	100,000–499,999	18	72	72
	≥ 500,000	24	96	96

(ii) *Reporting monitoring results.* You must report the information in this paragraph (a)(1)(ii).

(A) You must report previously collected monitoring results and certify that the reported monitoring results include all compliance and non-compliance results generated during the time period beginning with the first reported result and ending with the most recent subpart L results.

(B) You must certify that the samples were representative of the entire distribution system and that treatment, and distribution system have not changed significantly since the samples were collected.

(C) Your study monitoring plan must include a schematic of your distribution system (including distribution system entry points and their sources, and storage facilities), with notes indicating the locations and dates of all completed or planned system specific study monitoring.

(D) Your system specific study plan must specify the population served and system type (subpart H or ground water).

(E) You must retain a complete copy of your system specific study plan submitted under this paragraph (a)(1), including any State modification of your system specific study plan, for as long as you are required to retain your IDSE report under paragraph (b)(5) of this section.

(F) If you submit previously collected data that fully meet the number of samples required under paragraph (a)(1)(i)(B) of this section and the State rejects some of the data, you must either conduct additional monitoring to replace rejected data on a schedule the State approves or conduct standard monitoring under § 141.601.

(2) *Modeling.* You may comply through analysis of an extended period simulation hydraulic model. The extended period simulation hydraulic model and analysis must meet the criteria in this paragraph (a)(2).

(i) *Minimum requirements.* (A) The model must simulate 24 hour variation in demand and show a consistently repeating 24 hour pattern of residence time.

(B) The model must represent the criteria listed in paragraphs (a)(2)(i)(B)(1) through (9) of this section.

(1) 75% of pipe volume;

(2) 50% of pipe length;

(3) All pressure zones;

(4) All 12-inch diameter and larger pipes;

(5) All 8-inch and larger pipes that connect pressure zones, influence zones from different sources, storage facilities, major demand areas, pumps, and control valves, or are known or expected to be significant conveyors of water;

(6) All 6-inch and larger pipes that connect remote areas of a distribution system to the main portion of the system;

(7) All storage facilities with standard operations represented in the model; and

(8) All active pump stations with controls represented in the model; and

(9) All active control valves.

(C) The model must be calibrated, or have calibration plans, for the current configuration of the distribution system during the period of high TTHM formation potential. All storage facilities must be evaluated as part of the calibration process. All required calibration must be completed no later than 12 months after plan submission.

(ii) *Reporting modeling.* Your system specific study plan must include the information in this paragraph (a)(2)(ii).

(A) Tabular or spreadsheet data demonstrating that the model meets requirements in paragraph (a)(2)(i)(B) of this section.

(B) A description of all calibration activities undertaken, and if calibration is complete, a graph of predicted tank levels versus measured tank levels for the storage facility with the highest residence time in each pressure zone, and a time series graph of the residence time at the longest residence time storage facility in the distribution system showing the predictions for the entire simulation period (*i.e.*, from time zero until the time it takes to for the model to reach a consistently repeating pattern of residence time).

(C) Model output showing preliminary 24 hour average residence time predictions throughout the distribution system.

(D) Timing and number of samples representative of the distribution system planned for at least one monitoring period of TTHM and HAA5 dual sample monitoring at a number of locations no

less than would be required for the system under standard monitoring in § 141.601 during the historical month of high TTHM. These samples must be taken at locations other than existing subpart L compliance monitoring locations.

(E) Description of how all requirements will be completed no later than 12 months after you submit your system specific study plan.

(F) Schematic of your distribution system (including distribution system entry points and their sources, and storage facilities), with notes indicating the locations and dates of all completed system specific study monitoring (if calibration is complete) and all subpart L compliance monitoring.

(G) Population served and system type (subpart H or ground water).

(H) You must retain a complete copy of your system specific study plan submitted under this paragraph (a)(2), including any State modification of your system specific study plan, for as long as you are required to retain your IDSE report under paragraph (b)(7) of this section.

(iii) If you submit a model that does not fully meet the requirements under paragraph (a)(2) of this section, you must correct the deficiencies and respond to State inquiries concerning the model. If you fail to correct deficiencies or respond to inquiries to the State's satisfaction, you must conduct standard monitoring under § 141.601.

(b) *IDSE report.* Your IDSE report must include the elements required in paragraphs (b)(1) through (b)(6) of this section. You must submit your IDSE report according to the schedule in § 141.600(c).

(1) Your IDSE report must include all TTHM and HAA5 analytical results from subpart L compliance monitoring and all system specific study monitoring conducted during the period of the system specific study presented in a tabular or spreadsheet format acceptable to the State. If changed from your system specific study plan submitted under paragraph (a) of this section, your IDSE report must also include a schematic of your distribution system, the population served, and system type (subpart H or ground water).

(2) If you used the modeling provision under paragraph (a)(2) of this section, you must include final information for the elements described in paragraph (a)(2)(ii) of this section, and a 24-hour time series graph of residence time for each subpart V compliance monitoring location selected.

(3) You must recommend and justify subpart V compliance monitoring locations and timing based on the protocol in § 141.605.

(4) Your IDSE report must include an explanation of any deviations from your approved system specific study plan.

(5) Your IDSE report must include the basis (analytical and modeling results) and justification you used to select the recommended subpart V monitoring locations.

(6) You may submit your IDSE report in lieu of your system specific study plan on the schedule identified in § 141.600(c) for submission of the system specific study plan if you believe that you have the necessary information by the time that the system specific study plan is due. If you elect this approach, your IDSE report must also include all information required under paragraph (a) of this section.

(7) You must retain a complete copy of your IDSE report submitted under this section for 10 years after the date that you submitted your IDSE report. If the State modifies the subpart V monitoring requirements that you recommended in your IDSE report or if the State approves alternative monitoring locations, you must keep a copy of the State's notification on file for 10 years after the date of the State's notification. You must make the IDSE report and any State notification available for review by the State or the public.

§ 141.603 40/30 certification.

(a) *Eligibility.* You are eligible for 40/30 certification if you had no TTHM or HAA5 monitoring violations under subpart L of this part and no individual sample exceeded 0.040 mg/L for TTHM or 0.030 mg/L for HAA5 during an eight consecutive calendar quarter period beginning no earlier than the date specified in this paragraph (a).

If your 40/30 certification is due	Then your eligibility for 40/30 certification is based on eight consecutive calendar quarters of subpart L compliance monitoring results beginning no earlier than [1]
(1) October 1, 2006.	January 2004.
(2) April 1, 2007.	January 2004.
(3) October 1, 2007.	January 2005.
(4) April 1, 2008.	January 2005.

[1] Unless you are on reduced monitoring under subpart L of this part and were not required to monitor during the specified period. If you did not monitor during the specified period, you must base your eligibility on compliance samples taken during the 12 months preceding the specified period.

(b) *40/30 certification.* (1) You must certify to your State that every individual compliance sample taken under subpart L of this part during the periods specified in paragraph (a) of this section were ≤0.040 mg/L for TTHM and ≤0.030 mg/L for HAA5, and that you have not had any TTHM or HAA5 monitoring violations during the period specified in paragraph (a) of this section.

(2) The State may require you to submit compliance monitoring results, distribution system schematics, and/or recommended subpart V compliance monitoring locations in addition to your certification. If you fail to submit the requested information, the State may require standard monitoring under § 141.601 or a system specific study under § 141.602.

(3) The State may still require standard monitoring under § 141.601 or a system specific study under § 141.602 even if you meet the criteria in paragraph (a) of this section.

(4) You must retain a complete copy of your certification submitted under this section for 10 years after the date that you submitted your certification. You must make the certification, all data upon which the certification is based, and any State notification available for review by the State or the public.

§ 141.604 Very small system waivers.

(a) If you serve fewer than 500 people and you have taken TTHM and HAA5 samples under subpart L of this part, you are not required to comply with this subpart unless the State notifies you that you must conduct standard monitoring under § 141.601 or a system specific study under § 141.602.

(b) If you have not taken TTHM and HAA5 samples under subpart L of this part or if the State notifies you that you must comply with this subpart, you must conduct standard monitoring under § 141.601 or a system specific study under § 141.602.

§ 141.605 Subpart V compliance monitoring location recommendations.

(a) Your IDSE report must include your recommendations and justification for where and during what month(s) TTHM and HAA5 monitoring for subpart V of this part should be conducted. You must base your recommendations on the criteria in paragraphs (b) through (e) of this section.

(b) You must select the number of monitoring locations specified in the table in this paragraph (b). You will use these recommended locations as subpart V routine compliance monitoring locations, unless State requires different

or additional locations. You should distribute locations throughout the distribution system to the extent possible.

Source water type	Population size category	Monitoring frequency [1]	Distribution system monitoring location			
			Total per monitoring period [2]	Highest TTHM locations	Highest HAA5 locations	Existing subpart L compliance locations
Subpart H:						
	<500	per year	2	1	1	.....
	500–3,300	per quarter	2	1	1	
	3,301–9,999	per quarter	2	1	1	.....
	10,000–49,999	per quarter	4	2	1	1
	50,000–249,999	per quarter	8	3	3	2
	250,000–999,999	per quarter	12	5	4	3
	1,000,000–4,999,999	per quarter	16	6	6	4
	≥5,000,000	per quarter	20	8	7	5
Ground water:						
	<500	per year	2	1	1	
	500–9,999	per year	2	1	1	
	10,000–99,999	per quarter	4	2	1	1
	100,000–499,999	per quarter	6	3	2	1
	≥500,000	per quarter	8	3	3	2

[1] All systems must monitor during month of highest DBP concentrations.
[2] Systems on quarterly monitoring must take dual sample sets every 90 days at each monitoring location, except for subpart H systems serving 500–3,300. Systems on annual monitoring and subpart H systems serving 500–3,300 are required to take individual TTHM and HAA5 samples (instead of a dual sample set) at the locations with the highest TTHM and HAA5 concentrations, respectively. Only one location with a dual sample set per monitoring period is needed if highest TTHM and HAA5 concentrations occur at the same location, and month, if monitored annually).

(c) You must recommend subpart V compliance monitoring locations based on standard monitoring results, system specific study results, and subpart L compliance monitoring results. You must follow the protocol in paragraphs (c)(1) through (c)(8) of this section. If required to monitor at more than eight locations, you must repeat the protocol as necessary. If you do not have existing subpart L compliance monitoring results or if you do not have enough existing subpart L compliance monitoring results, you must repeat the protocol, skipping the provisions of paragraphs (c)(3) and (c)(7) of this section as necessary, until you have identified the required total number of monitoring locations.

(1) Location with the highest TTHM LRAA not previously selected as a subpart V monitoring location.

(2) Location with the highest HAA5 LRAA not previously selected as a subpart V monitoring location.

(3) Existing subpart L average residence time compliance monitoring location (maximum residence time compliance monitoring location for ground water systems) with the highest HAA5 LRAA not previously selected as a subpart V monitoring location.

(4) Location with the highest TTHM LRAA not previously selected as a subpart V monitoring location.

(5) Location with the highest TTHM LRAA not previously selected as a subpart V monitoring location.

(6) Location with the highest HAA5 LRAA not previously selected as a subpart V monitoring location.

(7) Existing subpart L average residence time compliance monitoring location (maximum residence time compliance monitoring location for ground water systems) with the highest TTHM LRAA not previously selected as a subpart V monitoring location.

(8) Location with the highest HAA5 LRAA not previously selected as a subpart V monitoring location.

(d) You may recommend locations other than those specified in paragraph (c) of this section if you include a rationale for selecting other locations. If the State approves the alternate locations, you must monitor at these locations to determine compliance under subpart V of this part.

(e) Your recommended schedule must include subpart V monitoring during the peak historical month for TTHM and HAA5 concentration, unless the State approves another month. Once you have identified the peak historical month, and if you are required to conduct routine monitoring at least quarterly, you must schedule subpart V compliance monitoring at a regular frequency of every 90 days or fewer.

■ 20. Part 141 is amended by adding new subpart V to read as follows:

Subpart V—Stage 2 Disinfection Byproducts Requirements

141.620 General requirements.
141.621 Routine monitoring.
141.622 Subpart V monitoring plan.
141.623 Reduced monitoring.
141.624 Additional requirements for consecutive systems.
141.625 Conditions requiring increased monitoring.
141.626 Operational evaluation levels.
141.627 Requirements for remaining on reduced TTHM and HAA5 monitoring based on subpart L results.
141.628 Requirements for remaining on increased TTHM and HAA5 monitoring based on subpart L results.
141.629 Reporting and recordkeeping requirements.

Subpart V—Stage 2 Disinfection Byproducts Requirements

§ 141.620 General requirements.

(a) *General.* The requirements of subpart V of this part constitute national primary drinking water regulations. The regulations in this subpart establish monitoring and other requirements for

achieving compliance with maximum contaminant levels based on locational running annual averages (LRAA) for total trihalomethanes (TTHM) and haloacetic acids (five)(HAA5), and for achieving compliance with maximum residual disinfectant residuals for chlorine and chloramine for certain consecutive systems.

(b) *Applicability.* You are subject to these requirements if your system is a community water system or a nontransient noncommunity water system that uses a primary or residual disinfectant other than ultraviolet light or delivers water that has been treated with a primary or residual disinfectant other than ultraviolet light.

(c) *Schedule.* You must comply with the requirements in this subpart on the schedule in the following table based on your system type.

If you are this type of system	You must comply with subpart V monitoring by: [1]
Systems that are not part of a combined distribution system and systems that serve the largest population in the combined distribution system	
(1) System serving ≥ 100,000	April 1, 2012.
(2) System serving 50,000–99,999	October 1, 2012.
(3) System serving 10,000–49,999	October 1, 2013.
(4) System serving > 10,000	October 1, 2013 if no Cryptosporidium monitoring is required under § 141.701(a)(4) or October 1, 2014 if Cryptosporidium monitoring is required under § 141.701(a)(4) or (a)(6)
Other systems that are part of a combined distribution system	
(5) Consecutive system or wholesale system	—at the same time as the system with the earliest compliance date in the combined distribution system.

[1] The State may grant up to an additional 24 months for compliance with MCLs and operational evaluaton levels if you require capital improvements to comply with an MCL.

(6) Your monitoring frequency is specified in § 141.621(a)(2).

(i) If you are required to conduct quarterly monitoring, you must begin monitoring in the first full calendar quarter that includes the compliance date in the table in this paragraph (c).

(ii) If you are required to conduct monitoring at a frequency that is less than quarterly, you must begin monitoring in the calendar month recommended in the IDSE report prepared under § 141.601 or § 141.602 or the calendar month identified in the subpart V monitoring plan developed under § 141.622 no later than 12 months after the compliance date in this table.

(7) If you are required to conduct quarterly monitoring, you must make compliance calculations at the end of the fourth calendar quarter that follows the compliance date and at the end of each subsequent quarter (or earlier if the LRAA calculated based on fewer than four quarters of data would cause the MCL to be exceeded regardless of the monitoring results of subsequent quarters). If you are required to conduct monitoring at a frequency that is less than quarterly, you must make compliance calculations beginning with the first compliance sample taken after the compliance date.

(8) For the purpose of the schedule in this paragraph (c), the State may determine that the combined distribution system does not include certain consecutive systems based on factors such as receiving water from a wholesale system only on an emergency basis or receiving only a small percentage and small volume of water from a wholesale system. The State may also determine that the combined distribution system does not include certain wholesale systems based on factors such as delivering water to a consecutive system only on an emergency basis or delivering only a small percentage and small volume of water to a consecutive system.

(d) Monitoring and compliance. (1) Systems required to monitor quarterly. To comply with subpart V MCLs in § 141.64(b)(2), you must calculate LRAAs for TTHM and HAA5 using monitoring results collected under this subpart and determine that each LRAA does not exceed the MCL. If you fail to complete four consecutive quarters of monitoring, you must calculate compliance with the MCL based on the average of the available data from the most recent four quarters. If you take more than one sample per quarter at a monitoring location, you must average all samples taken in the quarter at that location to determine a quarterly average to be used in the LRAA calculation.

(2) Systems required to monitor yearly or less frequently. To determine compliance with subpart V MCLs in § 141.64(b)(2), you must determine that each sample taken is less than the MCL. If any sample exceeds the MCL, you must comply with the requirements of § 141.625. If no sample exceeds the MCL, the sample result for each monitoring location is considered the LRAA for that monitoring location.

(e) *Violation.* You are in violation of the monitoring requirements for each quarter that a monitoring result would be used in calculating an LRAA if you fail to monitor.

§ 141.621 Routine monitoring.

(a) *Monitoring.* (1) If you submitted an IDSE report, you must begin monitoring at the locations and months you have recommended in your IDSE report submitted under § 141.605 following the schedule in § 141.620(c), unless the State requires other locations or additional locations after its review. If you submitted a 40/30 certification under § 141.603 or you qualified for a very small system waiver under § 141.604 or you are a nontransient noncommunity water system serving <10,000, you must monitor at the location(s) and dates identified in your monitoring plan in § 141.132(f), updated as required by § 141.622.

(2) You must monitor at no fewer than the number of locations identified in this paragraph (a)(2).

Source water type	Population size category	Monitoring Frequency [1]	Distribution system monitoring location total per monitoring period [2]
Subpart H:			
	<500	per year	2
	500–3,300	per quarter	2
	3,301–9,999	per quarter	2
	10,000–49,999	per quarter	4
	50,000–249,999	per quarter	8
	250,000–999,999	per quarter	12
	1,000,000–4,999,999	per quarter	16
	≥ 5,000,000	per quarter	20
Ground Water:			
	<500	per year	2
	500–9,999	per year	2
	10,000–99,999	per quarter	4
	100,000–499,999	per quarter	6
	≥ 500,000	per quarter	8

[1] All systems must monitor during month of highest DBP concentrations.
[2] Systems on quarterly monitoring must take dual sample sets every 90 days at each monitoring location, except for subpart H systems serving 500–3,300. Systems on annual monitoring and subpart H systems serving 500–3,300 are required to take individual TTHM and HAA5 samples (instead of a dual sample set) at the locations with the highest TTHM and HAA5 concentrations, respectively. Only one location with a dual sample set per monitoring period is needed if highest TTHM and HAA5 concentrations occur at the same location (and month, if monitored annually).

(3) If you are an undisinfected system that begins using a disinfectant other than UV light after the dates in subpart U of this part for complying with the Initial Distribution System Evaluation requirements, you must consult with the State to identify compliance monitoring locations for this subpart. You must then develop a monitoring plan under § 141.622 that includes those monitoring locations.

(b) Analytical methods. You must use an approved method listed in § 141.131 for TTHM and HAA5 analyses in this subpart. Analyses must be conducted by laboratories that have received certification by EPA or the State as specified in § 141.131.

§ 141.622 Subpart V monitoring plan.

(a)(1) You must develop and implement a monitoring plan to be kept on file for State and public review. The monitoring plan must contain the elements in paragraphs (a)(1)(i) through (a)(1)(iv) of this section and be complete no later than the date you conduct your initial monitoring under this subpart.

(i) Monitoring locations;

(ii) Monitoring dates;

(iii) Compliance calculation procedures; and

(iv) Monitoring plans for any other systems in the combined distribution system if the State has reduced monitoring requirements under the State authority in § 142.16(m).

(2) If you were not required to submit an IDSE report under either § 141.601 or § 141.602, and you do not have sufficient subpart L monitoring locations to identify the required number of subpart V compliance monitoring locations indicated in § 141.605(b), you must identify additional locations by alternating selection of locations representing high TTHM levels and high HAA5 levels until the required number of compliance monitoring locations have been identified. You must also provide the rationale for identifying the locations as having high levels of TTHM or HAA5. If you have more subpart L monitoring locations than required for subpart V compliance monitoring in § 141.605(b), you must identify which locations you will use for subpart V compliance monitoring by alternating selection of locations representing high TTHM levels and high HAA5 levels until the required number of subpart V compliance monitoring locations have been identified.

(b) If you are a subpart H system serving > 3,300 people, you must submit a copy of your monitoring plan to the State prior to the date you conduct your initial monitoring under this subpart, unless your IDSE report submitted under subpart U of this part contains all the information required by this section.

(c) You may revise your monitoring plan to reflect changes in treatment, distribution system operations and layout (including new service areas), or other factors that may affect TTHM or HAA5 formation, or for State-approved reasons, after consultation with the State regarding the need for changes and the appropriateness of changes. If you change monitoring locations, you must replace existing compliance monitoring locations with the lowest LRAA with new locations that reflect the current distribution system locations with expected high TTHM or HAA5 levels. The State may also require modifications in your monitoring plan. If you are a subpart H system serving > 3,300 people, you must submit a copy of your modified monitoring plan to the State prior to the date you are required to comply with the revised monitoring plan.

§ 141.623 Reduced monitoring.

(a) You may reduce monitoring to the level specified in the table in this paragraph (a) any time the LRAA is ≤0.040 mg/L for TTHM and ≤0.030 mg/L for HAA5 at all monitoring locations. You may only use data collected under the provisions of this subpart or subpart L of this part to qualify for reduced monitoring. In addition, the source water annual average TOC level, before any treatment, must be ≤4.0 mg/L at each treatment plant treating surface water or ground water under the direct influence of surface water, based on monitoring conducted under either § 141.132(b)(1)(iii) or § 141.132(d).

Source water type	Population size category	Monitoring frequency [1]	Distribution system monitoring location per monitoring period
Subpart H:			
	<500	.....	monitoring may not be reduced.
	500–3,300	per year	1 TTHM and 1 HAA5 sample: one at the location and during the quarter with the highest TTHM single measurement, one at the location and during the quarter with the highest HAA5 single measurement; 1 dual sample set per year if the highest TTHM and HAA5 measurements occurred at the same location and quarter.
	3,301–9,999	per year	2 dual sample sets: one at the location and during the quarter with the highest TTHM single measurement, one at the location and during the quarter with the highest HAA5 single measurement.
	10,000–49,999	per quarter	2 dual sample sets at the locations with the highest TTHM and highest HAA5 LRAAs.
	50,000–249,999	per quarter	4 dual sample sets—at the locations with the two highest TTHM and two highest HAA5 LRAAs.
	250,000–999,999	per quarter	6 dual sample sets—at the locations with the three highest TTHM and three highest HAA5 LRAAs.
	1,000,000–4,999,999	per quarter	8 dual sample sets—at the locations with the four highest TTHM and four highest HAA5 LRAAs.
	≥ 5,000,000	per quarter	10 dual sample sets—at the locations with the five highest TTHM and five highest HAA5 LRAAs.
Ground Water:			
	<500	every third year	1 TTHM and 1 HAA5 sample: one at the location and during the quarter with the highest TTHM single measurement, one at the location and during the quarter with the highest HAA5 single measurement; 1 dual sample set per year if the highest TTHM and HAA5 measurements occurred at the same location and quarter.
	500–9,999	per year	1 TTHM and 1 HAA5 sample: one at the location and during the quarter with the highest TTHM single measurement, one at the location and during the quarter with the highest HAA5 single measurement; 1 dual sample set per year if the highest TTHM and HAA5 measurements occurred at the same location and quarter.
	10,000–99,999	per year	2 dual sample sets: one at the location and during the quarter with the highest TTHM single measurement, one at the location and during the quarter with the highest HAA5 single measurement.
	100,000–499,999	per quarter	2 dual sample sets; at the locations with the highest TTHM and highest HAA5 LRAAs.
	≥ 500,000	per quarter	4 dual sample sets at the locations with the two highest TTHM and two highest HAA5 LRAAs.

[1] Systems on quarterly monitoring must take dual sample sets every 90 days.

(b) You may remain on reduced monitoring as long as the TTHM LRAA ≤0.040 mg/L and the HAA5 LRAA ≤0.030 mg/L at each monitoring location (for systems with quarterly reduced monitoring) or each TTHM sample ≤0.060 mg/L and each HAA5 sample ≤0.045 mg/L (for systems with annual or less frequent monitoring). In addition, the source water annual average TOC level, before any treatment, must be ≤4.0 mg/L at each treatment plant treating surface water or ground water under the direct influence of surface water, based on monitoring conducted under either § 141.132(b)(1)(iii) or § 141.132(d).

(c) If the LRAA based on quarterly monitoring at any monitoring location exceeds either 0.040 mg/L for TTHM or 0.030 mg/L for HAA5 or if the annual (or less frequent) sample at any location exceeds either 0.060 mg/L for TTHM or 0.045 mg/L for HAA5, or if the source water annual average TOC level, before any treatment, >4.0 mg/L at any treatment plant treating surface water or ground water under the direct influence of surface water, you must resume routine monitoring under § 141.621 or begin increased monitoring if § 141.625 applies.

(d) The State may return your system to routine monitoring at the State's discretion.

§ 141.624 Additional requirements for consecutive systems.

If you are a consecutive system that does not add a disinfectant but delivers water that has been treated with a primary or residual disinfectant other than ultraviolet light, you must comply with analytical and monitoring requirements for chlorine and chloramines in § 141.131 (c) and § 141.132(c)(1) and the compliance requirements in § 141.133(c)(1) beginning April 1, 2009, unless required earlier by the State, and report monitoring results under § 141.134(c).

§ 141.625 Conditions requiring increased monitoring.

(a) If you are required to monitor at a particular location annually or less frequently than annually under § 141.621 or § 141.623, you must increase monitoring to dual sample sets once per quarter (taken every 90 days) at all locations if a TTHM sample is >0.080 mg/L or a HAA5 sample is >0.060 mg/L at any location.

(b) You are in violation of the MCL when the LRAA exceeds the subpart V MCLs in § 141.64(b)(2), calculated based on four consecutive quarters of monitoring (or the LRAA calculated based on fewer than four quarters of data if the MCL would be exceeded regardless of the monitoring results of subsequent quarters). You are in violation of the monitoring requirements for each quarter that a monitoring result would be used in calculating an LRAA if you fail to monitor.

(c) You may return to routine monitoring once you have conducted increased monitoring for at least four consecutive quarters and the LRAA for every monitoring location is ≤0.060 mg/L for TTHM and ≤0.045 mg/L for HAA5.

§ 141.626 Operational evaluation levels.

(a) You have exceeded the operational evaluation level at any monitoring location where the sum of the two previous quarters' TTHM results plus twice the current quarter's TTHM result, divided by 4 to determine an average, exceeds 0.080 mg/L, or where the sum of the two previous quarters' HAA5 results plus twice the current quarter's HAA5 result, divided by 4 to determine an average, exceeds 0.060 mg/L.

(b)(1) If you exceed the operational evaluation level, you must conduct an operational evaluation and submit a written report of the evaluation to the State no later than 90 days after being notified of the analytical result that causes you to exceed the operational evaluation level. The written report must be made available to the public upon request.

(2) Your operational evaluation must include an examination of system treatment and distribution operational practices, including storage tank operations, excess storage capacity, distribution system flushing, changes in sources or source water quality, and treatment changes or problems that may contribute to TTHM and HAA5 formation and what steps could be considered to minimize future exceedences.

(i) You may request and the State may allow you to limit the scope of your evaluation if you are able to identify the cause of the operational evaluation level exceedance.

(ii) Your request to limit the scope of the evaluation does not extend the schedule in paragraph (b)(1) of this section for submitting the written report. The State must approve this limited scope of evaluation in writing and you must keep that approval with the completed report.

§ 141.627 Requirements for remaining on reduced TTHM and HAA5 monitoring based on subpart L results.

You may remain on reduced monitoring after the dates identified in § 141.620(c) for compliance with this subpart only if you qualify for a 40/30 certification under § 141.603 or have received a very small system waiver under § 141.604, plus you meet the reduced monitoring criteria in § 141.623(a), and you do not change or add monitoring locations from those used for compliance monitoring under subpart L of this part. If your monitoring locations under this subpart differ from your monitoring locations under subpart L of this part, you may not remain on reduced monitoring after the dates identified in § 141.620(c) for compliance with this subpart.

§ 141.628 Requirements for remaining on increased TTHM and HAA5 monitoring based on subpart L results.

If you were on increased monitoring under § 141.132(b)(1), you must remain on increased monitoring until you qualify for a return to routine monitoring under § 141.625(c). You must conduct increased monitoring under § 141.625 at the monitoring locations in the monitoring plan developed under § 141.622 beginning at the date identified in § 141.620(c) for compliance with this subpart and remain on increased monitoring until you qualify for a return to routine monitoring under § 141.625(c).

§ 141.629 Reporting and recordkeeping requirements.

(a) *Reporting.* (1) You must report the following information for each monitoring location to the State within 10 days of the end of any quarter in which monitoring is required:

(i) Number of samples taken during the last quarter.

(ii) Date and results of each sample taken during the last quarter.

(iii) Arithmetic average of quarterly results for the last four quarters for each monitoring location (LRAA), beginning at the end of the fourth calendar quarter that follows the compliance date and at the end of each subsequent quarter. If the LRAA calculated based on fewer than four quarters of data would cause the MCL to be exceeded regardless of the monitoring results of subsequent quarters, you must report this information to the State as part of the first report due following the compliance date or anytime thereafter that this determination is made. If you are required to conduct monitoring at a frequency that is less than quarterly, you must make compliance calculations beginning with the first compliance sample taken after the compliance date, unless you are required to conduct increased monitoring under § 141.625.

(iv) Whether, based on § 141.64(b)(2) and this subpart, the MCL was violated at any monitoring location.

(v) Any operational evaluation levels that were exceeded during the quarter and, if so, the location and date, and the calculated TTHM and HAA5 levels.

(2) If you are a subpart H system seeking to qualify for or remain on reduced TTHM/HAA5 monitoring, you must report the following source water TOC information for each treatment plant that treats surface water or ground water under the direct influence of surface water to the State within 10 days of the end of any quarter in which monitoring is required:

(i) The number of source water TOC samples taken each month during last quarter.

(ii) The date and result of each sample taken during last quarter.

(iii) The quarterly average of monthly samples taken during last quarter or the result of the quarterly sample.

(iv) The running annual average (RAA) of quarterly averages from the past four quarters.

(v) Whether the RAA exceeded 4.0 mg/L.

(3) The State may choose to perform calculations and determine whether the MCL was exceeded or the system is eligible for reduced monitoring in lieu of having the system report that information

(b) *Recordkeeping.* You must retain any subpart V monitoring plans and your subpart V monitoring results as required by § 141.33.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

■ 21. The authority citation for part 142 continues to read as follows:

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

■ 22. Section 142.14 is amended by adding paragraph (a)(8) to read as follows:

§ 142.14 Records kept by States.

(a) * * *

(8) Any decisions made pursuant to the provisions of 40 CFR part 141, subparts U and V of this part.

(i) IDSE monitoring plans, plus any modifications required by the State, must be kept until replaced by approved IDSE reports.

(ii) IDSE reports and 40/30 certifications, plus any modifications

required by the State, must be kept until replaced or revised in their entirety.

(iii) Operational evaluations submitted by a system must be kept for 10 years following submission.

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■ 23. Section 142.16 is amended by adding paragraph (m) to read as follows:

§ 142.16 Special primacy requirements.

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(m) *Requirements for States to adopt 40 CFR part 141, subparts U and V.* In addition to the general primacy requirements elsewhere in this part, including the requirements that State regulations be at least as stringent as federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subparts U and V, must contain a description of how the State will implement a procedure for addressing modification of wholesale system and consecutive system monitoring on a case-by-case basis for part 141 subpart V outside the provisions of § 141.29 of this chapter, if the State elects to use such an authority. The procedure must ensure that all systems have at least one compliance monitoring location.

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[FR Doc. 06–3 Filed 1–3–06; 8:45 am]

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