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National Primary Drinking Water Regulations: Ground Water Rule; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141 and 142

[EPA–HQ–OW–2002–0061; FRL–8231–9]

RIN 2040–AA97

National Primary Drinking Water Regulations: Ground Water Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency is promulgating a National Primary Drinking Water Regulation, the Ground Water Rule, to provide for increased protection against microbial pathogens in public water systems that use ground water sources. This final rule is in accordance with the Safe Drinking Water Act as amended, which requires the Environmental Protection Agency to promulgate National Primary Drinking Water Regulations requiring disinfection as a treatment technique for all public water systems, including surface water systems and, as necessary, ground water systems.

The Ground Water Rule establishes a risk-targeted approach to target ground water systems that are susceptible to fecal contamination, instead of requiring disinfection for all ground water systems. The occurrence of fecal indicators in a drinking water supply is an indication of the potential presence of microbial pathogens that may pose a threat to public health. This rule requires ground water systems that are at risk of fecal contamination to take corrective action to reduce cases of illnesses and deaths due to exposure to microbial pathogens.

DATES: This final rule is effective on January 8, 2007. The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of January 8, 2007. For judicial review purposes, this final rule is promulgated as of 1 p.m. Eastern time on November 22, 2006, as provided in 40 Code of Federal Regulations (CFR) 23.7. The compliance date, unless otherwise noted, for the rule requirements is December 1, 2009.

ADDRESSES: The Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OW–2002–0061. 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.

Note: The EPA Docket Center suffered damage due to flooding during the last week of June 2006. The Docket Center is continuing to operate. However, during the cleanup, there will be temporary changes to Docket Center telephone numbers, addresses, and hours of operation for people who wish to visit the Public Reading Room to view documents. Consult EPA's **Federal Register** notice at 71 FR 54815 (September 19, 2006) or the EPA Web site at *http://www.epa.gov/epahome/dockets.htm* for current information on docket status, locations and telephone numbers.

FOR FURTHER INFORMATION CONTACT: Crystal Rodgers, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MC–4607M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–5275; e-mail address: *rodgers.crystal@epa.gov.* For general information, contact the Safe Drinking Water Hotline, telephone number: (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 10 a.m. to 4 p.m. Eastern time.

SUPPLEMENTARY INFORMATION:

I. General Information

Entities potentially regulated by the Ground Water Rule (GWR) are public water systems (PWSs) using ground water as a drinking water source. Regulated categories and entities include the following:

Category	Examples of regulated entities
Industry	Public ground water systems.
State, Local, Tribal or Federal Governments.	Public ground water systems.

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 applicability criteria found in § 141.400 of this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Abbreviations Used in This Document

AIDS Acquired Immune Deficiency Syndrome
AGI Acute Gastrointestinal Illness
AWWA American Water Works Association
ASDWA Association of State Drinking Water Administrators
AWWARF American Water Works Association Research Foundation
AWWSCo American Water Works Service Company
BGLB Brilliant green lactose bile broth
BGM Buffalo Green Monkey
BMPs Best Management Practices
CAFO Concentrated Animal Feeding Operation
CBI Confidential Business Information
CCR Consumer Confidence Report
CDBG Community Development Block Grant
CDC Centers for Disease Control and Prevention
CFR Code of Federal Regulation
COI Cost of Illness
CT The Residual Concentration of Disinfectant (mg/L) Multiplied by the Contact Time (in minutes)
CWS Community Water System
CWSS Community Water System Survey
DBPs Disinfection Byproducts
DWSRF Drinking Water State Revolving Fund
EA Economic Analysis
EPA United States Environmental Protection Agency
FR Federal Register
GAO United States Government Accountability Office
GI Gastrointestinal
GWUDI Ground Water Under the Direct Influence of Surface Water
GWR Ground Water Rule
GWS Ground Water System
HAV Hepatitis A Virus
HRRCA Health Risk Reduction and Cost Analysis
HSA Hydrogeologic Sensitivity Assessment
ICR Information Collection Request
IESWTR Interim Enhanced Surface Water Treatment Rule
IRFA Initial Regulatory Flexibility Analysis
LTB Lauryl tryptose broth
m Meters
mL Milliliters
MCL Maximum Contaminant Level
mg/L Milligrams per Liter
MPNIU Most Probable Number of Infectious Units
MRDL Maximum Residual Disinfectant Level
MWCO Molecular Weight Cut-Off
NCWS Non-Community Water System
NDWAC National Drinking Water Advisory Council
NF Nanofiltration
NODA Notice of Data Availability
NTNCWS Non-Transient Non-Community Water System
NTTAA National Technology Transfer and Advancement Act of 1995
NPDWR National Primary Drinking Water Regulation
O&M Operation and Maintenance

OMB Office of Management and Budget
P–A Presence-absence
PCR Polymerase Chain Reaction
PNR Public Notification Rule
PWS Public Water System
RFA Regulatory Flexibility Act
RIA Regulatory Impact Analysis
RO Reverse Osmosis
RT–PCR Reverse Transcriptase—Polymerase Chain Reaction
SAB Science Advisory Board
SBREFA Small Business Regulatory Enforcement Fairness Act
SD Standard Deviation
SDWA Safe Drinking Water Act
SDWIS Safe Drinking Water Information System
SEFA Small Entity Flexibility Analysis
Stage 2 DBPR Stage 2 Disinfectants and Disinfection Byproducts Rule
SWAP Source Water Assessment Program
SWTR Surface Water Treatment Rule
TCR Total Coliform Rule
TNCWS Transient Non-Community Water System
UIC Underground Injection Control
UMRA Unfunded Mandates Reform Act
US United States
USGS United States Geological Survey
UV Ultraviolet Radiation
VSL Value of Statistical Life
WHO World Health Organization
WTP Willingness To Pay

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II. Summary

This section includes a discussion of the purpose of the Ground Water Rule (GWR) and a summary of the GWR requirements.

A. Why Is EPA Promulgating the GWR?

EPA is promulgating the GWR to provide for increased protection against microbial pathogens, specifically viral and bacterial pathogens, in public water systems (PWSs) that use ground water sources. EPA is particularly concerned about ground water systems (GWSs) that are susceptible to fecal contamination because these systems may be at risk of supplying water that contains harmful microbial pathogens. Viral pathogens found in GWSs may include enteric viruses such as Echovirus, Coxsackie viruses, Hepatitis A and E, Rotavirus and Noroviruses (*i.e.*, Norwalk-like viruses) and enteric bacterial pathogens such as *Escherichia coli* (most *E. coli* is harmless but a few species are pathogenic, including *E. coli* O157:H7), *Salmonella* species, *Shigella* species, and *Vibrio cholerae*. Ingestion of these pathogens can cause gastroenteritis or, in certain cases, serious illnesses such as meningitis, hepatitis, or myocarditis. Health implications in sensitive subpopulations (*e.g.*, children, elderly, immuno-compromised) may be severe (*e.g.*, hemolytic uremic syndrome) and may cause death.

One goal of the GWR is to identify and target GWSs that are susceptible to fecal contamination because such contamination is the likely source of viral and bacterial pathogens in drinking water supplies. Ground water is fecally contaminated when fecal indicators (*e.g., E. coli*, enterococci, or coliphage) are present. While fecal indicators typically are not harmful when ingested, their presence demonstrates that there is a pathway for pathogenic viruses and bacteria to enter ground water sources. Another key objective of the rule is to protect public health by requiring these higher risk GWSs to monitor and, when necessary, take corrective action. Corrective action can include correcting all significant deficiencies; providing an alternate source of water; eliminating the source of contamination; or providing treatment that reliably achieves at least 99.99 percent (4-log) treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) for each contaminated ground water source. Each of these corrective actions is intended to remove all or nearly all fecal contamination, including both viral and bacterial pathogens. This rule implements section 1412(b)(8) of the 1996 Safe Drinking Water Act (SDWA) Amendments to promulgate a rule requiring GWSs to disinfect ''as necessary.'' The risk-targeted approach in this rule is a critical distinction from the approach outlined in the 1986 SDWA, which would have required all PWSs using surface water or ground water to disinfect. Because there are so many GWSs (approximately 147,000) in the United States, such a requirement would have been a great challenge for systems and States to implement.

This rule is necessary to protect public health because current regulatory provisions for GWSs (for example, sanitary survey requirements in the Total Coliform Rule (TCR) (54 FR 27544, June 29, 1989) (USEPA, 1989a)) do not adequately address fecal contamination at the ground water source. In fact, no Federal regulation exists that requires either monitoring of ground water sources or corrective action upon finding fecal contamination or identifying a significant deficiency during a sanitary survey. In addition, the U.S. Government Accountability Office (GAO) 1993 report (USGAO, 1993) found that many sanitary surveys did not evaluate one or more of the components that EPA recommended be evaluated, and that efforts to ensure correction were often limited. Also, GAO found that follow-up on major problems was often lacking. Moreover, the report found that problems associated with system infrastructure identified during sanitary surveys frequently remain uncorrected. The GWR provides much needed public health protection by requiring systems that do not treat their ground water sources to monitor their ground water source and to take corrective actions when fecal contamination or a significant deficiency is found.

In addition, EPA has evaluated data on outbreaks and the occurrence of waterborne viral and bacterial pathogens and indicators of fecal contamination in ground water supplying PWS wells. These data indicate that there is a subset of GWSs that are susceptible to fecal contamination; therefore, EPA believes that risk management strategies are needed to protect public health. Specifically, the Centers for Disease Control and Prevention (CDC) reports that between 1991 (the year in which the TCR became effective) and 2000, GWSs were associated with 68 waterborne disease outbreaks that caused 10,926 illnesses (Moore *et al.* (1993); Kramer *et al.* (1996); Levy *et al.* (1998); Barwick *et al.* (2000); and Lee *et al.* (2002)). These outbreaks accounted for 51 percent of all waterborne disease outbreaks in the United States during that time period. The major deficiencies identified by the CDC report as the likely cause of the outbreaks were source water contamination and inadequate treatment (or treatment failures); see Section III.C.2 for a summary of these outbreak data. Studies of viral and bacterial pathogens and/or fecal indicator occurrence in ground waters that supply PWSs show that dozens of the public ground water wells sampled had fecal indicator or viral presence in their wells. See Section III.C.3 of this preamble for a summary of occurrence studies. Based on these outbreak and occurrence data, along with concern about lack of monitoring and follow-up actions for GWSs, EPA has concluded that GWSs need to implement targeted, risk management strategies to protect public health from bacterial and viral pathogens in fecally contaminated ground water sources.

To provide a flexible, risk-targeted approach to achieve public health protection, this rule builds on existing State programs—some that emphasize the importance of disinfection and others that emphasize assessments and technical assistance—to identify and target susceptible GWSs. In addition, the GWR establishes treatment technique requirements, which provide public GWSs with multiple options to correct source water fecal contamination and significant deficiencies that present a public health risk. Furthermore, this rule establishes compliance monitoring requirements to ensure that treatment effectiveness is maintained.

B. What Does the GWR Require?

The GWR establishes a risk-targeted approach to identify GWSs susceptible to fecal contamination and requires corrective action to correct significant deficiencies and source water fecal contamination in public GWSs. A central objective of the GWR is to identify the subset of ground water sources that are at higher risk of fecal contamination among the large number

of existing GWSs (approximately 147,000), and then further target those systems that must take corrective action to protect public health. This risk-targeting strategy includes the following:

- Regular GWS sanitary surveys to check for significant deficiencies in eight key operational areas;
- A flexible program for identifying higher risk systems through existing TCR monitoring and State determinations; and
- Ground water source monitoring to detect fecal contamination at targeted GWSs that do not provide 4-log treatment of viruses.

Measures to protect public health include the following:

- Treatment technique requirements to address sanitary survey significant deficiencies and fecal contamination in ground water; and
- Compliance monitoring to ensure that 4-log treatment of viruses is maintained where it is used to comply with this rule.

To meet the treatment technique requirements of this rule, GWSs with a significant deficiency or evidence of source water fecal contamination, following consultation with their primacy agency (herein referred to as ''the State''), must implement one or more of the following corrective action options: Correct all significant deficiencies; provide an alternate source of water; eliminate the source of contamination; or provide treatment that reliably achieves at least 99.99 percent (4-log) treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) for each ground water source. Each of these corrective actions is intended to remove all or nearly all fecal contamination, including both viral and bacterial pathogens. In addition, the GWS must inform its customers of any uncorrected significant deficiencies or fecal indicator-positive ground water source samples.

The following sections provide more detailed information on the provisions of the GWR.

1. Sanitary Surveys

Sanitary surveys are an important tool for identifying potential vulnerabilities to fecal contamination at GWSs. The final GWR includes Federal sanitary survey requirements for all GWSs for the first time. This rule requires States, as a condition for primacy, to perform regular comprehensive sanitary surveys of the following eight critical components to the extent that they apply to the individual water system being surveyed: (1) Source; (2) treatment; (3) distribution system; (4) finished water storage; (5) pumps, pump facilities, and controls; (6) monitoring, reporting, and data verification; (7) system management and operation; and (8) operator compliance with State requirements. This rule includes conditions of primacy in 40 CFR part 142 under which States will have until December 31, 2012 to complete the initial sanitary survey cycle for community water systems (CWSs), except those that meet performance criteria, and until December 31, 2014 to complete the initial sanitary survey cycle for all non-community water system (NCWSs) and CWSs that meet performance criteria (refer to Section IV.A.1 for crtieria). Following the initial sanitary survey cycle, States must conduct these surveys every three years for CWSs (defined in § 141.2), and every five years for all NCWSs and CWSs that meet certain performance criteria as discussed in Section IV.A.1.

If a significant deficiency is identified as a result of a sanitary survey, the system must take corrective action. If the system does not complete corrective action within 120 days of receiving notification from the State, or is not in compliance with a State-approved corrective action plan and schedule, the system will be in violation of the treatment technique requirements of this rule.

The final GWR sanitary survey provision provides comprehensive and effective public health protection by specifying the scope and frequency of sanitary surveys and by requiring corrective action for systems with significant deficiencies.

2. Source Water Monitoring

This rule requires triggered source water monitoring and provides States with the option to require assessment source water monitoring. Source water monitoring is an effective tool to target at-risk systems that must take corrective action to protect public health. Indications of risk may come from total coliform monitoring, hydrogeologic sensitivity analyses, or other system-specific data and information.

In this rule, a GWS with a distribution system TCR sample that tests positive for total coliform is required to conduct triggered source water monitoring to evaluate whether the total coliform presence in the distribution system is due to fecal contamination in the ground water source. A GWS that does not provide at least 4-log treatment of viruses must conduct triggered source water monitoring upon being notified that a TCR sample is total coliform-positive. Within 24 hours of receiving the total coliform-positive notice, the system must collect at least one ground water sample from each ground water source (unless the GWS has an approved triggered source water monitoring plan that specifies the applicable source for collecting source samples). The GWS must test the ground water source sample(s) for the presence of one of three State-specified fecal indicators (*E. coli,* enterococci, or coliphage). If the source sample is fecal indicator-positive, this rule requires the GWS to notify the State and the public. Unless directed by the State to take immediate corrective action, the GWS must collect and test five additional source water samples for the presence of the same State-specified fecal indicator within 24 hours. If any one of the five additional source water samples tests positive for the State-specified fecal indicator (*E. coli,* enterococci, or coliphage), this rule requires the GWS to notify the State and the public and comply with the treatment technique requirements, which require the system to take one of four corrective actions discussed in the following section. The compliance date of the triggered source water monitoring requirement is December 1, 2009.

As a complement to the triggered source water monitoring provision, States have the option of requiring GWSs to conduct assessment source water monitoring. This flexible provision gives States the opportunity to target higher risk GWSs for additional source water monitoring and evaluation. The State may require a GWS to conduct assessment source water monitoring as needed. EPA recommends that States use Hydrogeologic Sensitivity Assessments (HSAs) and TCR/triggered source water monitoring results, along with other information to identify higher risk systems for assessment source water monitoring. For assessment source water monitoring, EPA recommends that GWSs take 12 monthly samples and test them for one of the GWR indicators (*E. coli*, enterococci, or coliphage). Corrective action for systems performing assessment source water monitoring is determined by the State.

3. Treatment Technique Requirements

This rule requires a GWS to comply with the treatment technique requirements if a significant deficiency is identified during a sanitary survey. Also, the rule requires a GWS to comply with the treatment technique requirements if one of the five additional ground water source samples (or at State discretion, the initial source

sample) has tested positive for fecal contamination (*i.e.*, the sample is positive for one of the three fecal indicators and is not invalidated by the State). The treatment technique requires that a GWS implement at least one of the following corrective actions: correct all significant deficiencies; provide an alternate source of water; eliminate the source of contamination; or provide treatment that reliably achieves at least 4-log treatment of viruses. Furthermore, the GWS must inform the public served by the water system of any uncorrected significant deficiencies and/or fecal contamination in the ground water source. The compliance date of the treatment technique requirements is December 1, 2009.

4. Compliance Monitoring

Compliance monitoring requirements are the final defense against viral and bacterial pathogens provided by this rule. All GWSs that provide at least 4-log treatment of viruses using chemical disinfection, membrane filtration, or a State-approved alternative treatment technology must conduct compliance monitoring to demonstrate treatment effectiveness. The compliance date of the compliance monitoring requirement is December 1, 2009.

C. How Has the Final Rule Changed From What EPA Proposed?

The primary elements of the proposed GWR were sanitary surveys, triggered monitoring, HSAs, routine monitoring, corrective action, and compliance monitoring. EPA received numerous comments on the proposed GWR and has carefully considered those comments in developing the final GWR. This consideration has led to a number of changes that the Agency believes will result in a more flexible, more targeted, more protective final GWR.

Most of the changes are minor and are discussed throughout this preamble in the pertinent sections. The most significant change from the proposed rule to the final rule is to the routine monitoring provision. The proposed routine monitoring provision would have required GWSs in sensitive aquifers, as defined by a State performed HSA, to collect monthly source water samples.

EPA received many negative comments on the HSA provision. Some States said that the proposed GWR did not allow sufficient time to conduct the HSA prior to the start of routine monitoring, which would result in GWSs in non-sensitive aquifers being required to monitor. Others stated that they would not do the HSA; rather, they would require all GWSs to conduct routine monitoring. In addition, EPA received comments that the routine monitoring provision was too burdensome.

If the HSA provision would not be implemented in many States to target the routine monitoring to systems in sensitive aquifers that are most at risk, then the Agency agrees with the commenters that the routine monitoring provision would be overly burdensome. This is because some systems, located in non-sensitive aquifers, would be conducting routine monitoring unnecessarily. Moreover, EPA now believes that it is more difficult to capture contamination than estimated in the proposal, which further highlights the importance of correctly identifying systems for which source water monitoring would be prudent. Furthermore, commenters strongly supported revision of the GWR proposal to maximize State flexibility and discretion in making system-specific decisions.

Given the importance of correctly targeting systems for source water monitoring, in conjunction with the State's desire for enough flexibility to ensure sensible decisions on a case-by-case basis, EPA decided to redesign the source water monitoring provision. Accordingly, the final rule does not include a national requirement for HSAs and routine monitoring for systems in sensitive aquifers. Rather, EPA concludes that the States are in the best position to assess which systems would most benefit from a source water monitoring program. The final provision is similar to routine monitoring but is now optional for States and has been renamed assessment source water monitoring. States argued in their comments that the information available to them from other programs such as source water assessments, wellhead protection plans, and historical data would be important factors to consider when determining the need for source water monitoring. Because States are best able to identify higher risk systems, the final GWR provides States with the option to require GWSs to perform assessment source water monitoring. The Agency finds the comments received on the proposal to be persuasive and to support the approach in the final GWR.

The purpose of the optional assessment source water monitoring requirement is to allow States to target such monitoring to GWSs that the State believes are at higher risk for fecal contamination. States specifically requested this flexibility and discretion in their comments to EPA. The flexibility of this provision provides many benefits. First, it gives States the ability to make case-by-case determinations of the need for source water monitoring. Given the variety of aquifer and well conditions across the United States and even within each State, State programs make more sense than a nationally-directed program. Second, the optional assessment source water monitoring requirement allows States to require assessment source water monitoring as needed. System conditions change over time and the ability of States to target this requirement to a specific system and time period will reduce burden and be critical to protecting public health by allowing States to focus attention on problem systems. The lack of time constraints will also allow States to prioritize susceptibility assessments and further target those systems most in need.

EPA recommends that States use HSAs as one tool to identify high risk systems for assessment source water monitoring. HSAs can be an effective screening tool to identify sensitive hydrogeologic settings that transmit water, and any pathogens in that water, quickly from the surface to the aquifer. States have other information available to them to target high risk systems, such as source water assessments, wellhead protection plans, and historical monitoring data. Data on past indications of source water fecal contamination, particularly from TCR monitoring, in combination with GWR triggered source water monitoring results, can be another important tool.

D. Does This Regulation Apply to My Water System?

The requirements in this final rule apply to all PWSs (CWSs and NCWSs) that use ground water sources, in whole or in part (including consecutive systems that receive finished ground water from another PWS), except that they do not apply to PWSs that combine all of their ground water with surface water or ground water under the direct influence of surface water (GWUDI) prior to treatment under the Surface Water Treatment Rule (SWTR) (54 FR 27486, June 29, 1989) (USEPA, 1989b). The GWR ensures that the same level of public health protection is provided to persons served solely by GWSs as to those served by mixed systems supplied by both ground water and surface water sources. See Section V.A of this preamble for more information on mixed systems.

III. Background

This section includes a discussion of the statutory requirements, regulatory

history, stakeholder involvement, and the public health concerns that this rule addresses.

A. What Is the Statutory Authority for the GWR?

Section 1412(b)(8) of the SDWA, as amended on August 6, 1996, requires EPA to promulgate National Primary Drinking Water Regulations (NPDWRs) requiring disinfection as a treatment technique for all PWSs, including surface water systems and, as necessary, GWSs. In addition, section 1412(b)(8) requires EPA to promulgate criteria as part of the regulations for determining whether disinfection should be required as a treatment technique for any PWS served by ground water. In contrast, the 1986 Amendments to the SDWA directed EPA to promulgate regulations requiring disinfection at all PWSs using either surface water or ground water. The SWTR implemented that requirement for surface water systems, but when Congress amended the SDWA again in 1996, EPA had not promulgated regulations requiring disinfection for PWSs that use ground water. In the legislative history of the 1996 Amendments to the SDWA, Congress identified several reasons for the delay, including the recognition that not all GWSs are at risk of contamination, as well as the high cost of across-the-board disinfection. This rule implements section 1412(b)(8) of the SDWA, as amended, by establishing a regulatory framework for determining which GWSs are susceptible to fecal contamination and requiring those systems to implement corrective action options, only one of which is to provide 4-log treatment of viruses (*e.g.*, disinfection).

Section 1413(a)(1) of the SDWA allows EPA to grant a State primary enforcement responsibility (''primacy'') for NPDWRs when EPA has determined that the State has adopted regulations that are no less stringent than EPA's. To obtain primacy for this rule, States must adopt comparable regulations within two years of EPA's promulgation of the final rule, unless EPA grants the State a two-year extension. State primacy requires, among other things, adequate enforcement (including monitoring and inspections) authority and reporting requirement. EPA must approve or deny State primacy applications within 90 days of submission to EPA (SDWA section 1413(b)(2)). In some cases, a State submitting revisions to adopt an NPDWR has primacy enforcement authority for the new regulation while EPA's decision on the revision is pending (SDWA section 1413(c)). Section 1445 of the SDWA authorizes the Administrator to establish monitoring, recordkeeping, and reporting regulations to assist the Administrator in determining compliance with the SDWA and in advising the public of the risks of unregulated contaminants. Section 1450 of the SDWA authorizes the Administrator to prescribe such regulations as are necessary or appropriate to carry out his or her functions under the Act.

B. What Is the Regulatory History of the GWR and How Were Stakeholders Involved?

EPA has devoted a tremendous effort to engage stakeholders in the development of the GWR. EPA began developing the GWR in 1987 to address potential fecal contamination of GWSs by requiring across-the-board disinfection, as directed by the 1986 Amendments to the SDWA. A preliminary public meeting on issues related to GWSs was held in 1990 (55 FR 21093, May 22, 1990) (USEPA, 1990). By 1992, EPA had developed a draft proposed rule that would have required disinfection for all GWSs (57 FR 33960, July 31, 1992) (USEPA, 1992). The draft proposed rule incorporated stakeholder input and was made available for stakeholder review. While some stakeholders supported the increased public health protection for people drinking ground water, most stakeholders were concerned that the rule was crafted such that all GWSs were assumed to be contaminated until monitoring proved otherwise and that disinfection waivers would be difficult to obtain.

Throughout the early and mid-1990s, EPA conducted technical discussions with *ad hoc* working groups during more than 50 conference calls, with participation of EPA Headquarters, EPA Regional offices, States, local governments, academicians, and trade associations. In 1996, Congress amended the SDWA and required EPA, under section 1412(b)(8), to develop regulations requiring disinfection as a treatment technique for GWSs ''as necessary.'' As discussed previously, this Amendment to the SDWA called for a different regulatory framework to address fecal contamination in GWSs. In light of this statutory change in direction, EPA determined that further stakeholder involvement would be crucial to establishing an effective approach for regulating fecal contamination in PWSs that use ground water sources.

Technical meetings were held in Irvine, California in July 1996 (USEPA, 1996), and in Austin, Texas in March 1997 (USEPA, 1997a). These technical discussions focused primarily on establishing a reasonable means for determining if a ground water source was vulnerable to fecal contamination. EPA evaluated the possibility of developing a vulnerability assessment tool that would consider hydrogeologic information and sources of fecal contamination.

In addition, EPA held a series of stakeholder meetings (in Portland, OR; Madison, WI; Dallas, TX; Lincoln, NE; and Washington, DC) designed to engage all stakeholders in developing a risk-based regulatory framework. The purpose of these meetings was to review available information on risk and to discuss methods to identify GWSs that are susceptible to fecal contamination, and therefore, should be required to take corrective actions. EPA also held three early involvement meetings with State representatives (in Portland, OR; Chicago, IL; and Washington, DC) and received valuable input from small system operators as part of an Agency outreach initiative under the Small Business Regulatory Enforcement Fairness Act. Over the course of these stakeholder meetings, the participants evaluated a continuum of regulatory approaches. The meetings fostered EPA's understanding of how State strategies fit together as a part of a national strategy. Taken together, the meetings were crucial in guiding the Agency's development of regulatory components for the GWR proposal.

On February 3, 1999, EPA distributed a preliminary draft preamble using the approach developed during the stakeholder meetings. Eighty individual comment letters were received from representatives of State and local governments, trade associations, academic institutions, individual PWSs, and other Federal agencies. EPA considered all of the comments received from this informal process as the Agency revised the draft proposal.

The proposed GWR was published in the **Federal Register** in 2000 (65 FR 30194, May 10, 2000) (USEPA, 2000a). The comment period closed on August 9, 2000, and EPA received comments from over 250 individuals, corporations, organizations, PWSs, States and Tribes, industry and trade associations, and environmental groups. EPA has carefully considered all of these comments in developing this final rule. Comments received on the proposed rule, along with EPA's responses, are compiled in the *Public Comment and Response Document for the Final Ground Water Rule* (USEPA, 2006c).

EPA published a Notice of Data Availability (NODA) in the **Federal Register** in 2006 (71 FR 15105, March

27, 2006) (USEPA, 2006e). The purpose of the NODA was to present additional studies that the Agency was considering in conducting its economic analysis for the final rule. The comment period closed on April 26, 2006. EPA received 14 sets of comments from individuals, trade associations, State and local governments, an organization, and a university. Comments received on the NODA, along with EPA's responses, are also compiled in the *Public Comment and Response Document for the Final Ground Water Rule* (USEPA, 2006c).

C. What Public Health Concerns Does the GWR Address?

This section explains the public health concerns associated with fecal contamination in GWSs by summarizing information on how ground water sources could become fecally contaminated, the causes of ground water outbreaks, and the health effects of consuming contaminated water.

1. Introduction

EPA estimates that approximately 114 million people consume drinking water from PWSs that use ground water sources (Table III–1). These PWSs (total of about 147,000) distribute disinfected or undisinfected ground water to their customers. Approximately 18 percent (20 million) of people served by PWSs that use ground water sources receive undisinfected water, while over 60 percent (70 million) receive either undisinfected water or water treated to less than 4-log inactivation or removal of viruses.

Over 100 million people receive ground water from community water systems (CWSs) (Table III–1), while about 14 million people receive ground water from non-community water systems (NCWSs); non-transient non-community water systems (NTNCWSs) serve ground water to about five million people and transient non-community water systems (TNCWSs) serve ground water to about nine million people. Table III–1 shows that, of the number of people receiving water from CWSs, NTNCWSs, and TNCWSs, approximately 9.3 million (9.2 percent), 3.6 million (71 percent), and 7.2 million, (83 percent), respectively, receive water that is not disinfected at all. The Table also shows that 56.8 million people served by CWSs, 4.7 million people served by NTNCWSs, and 8.6 million people served by TNCWSs receive water that is either undisinfected or treated to less than 4-log.

TABLE III–1.—POPULATION SERVED BY GROUND WATER SYSTEMS

[Millions]

	Total population served by ground water systems	Population served untreated ground water	Population served ground water that is either undisinfected or treated to less than 4-log
CWSs	100.4	9.3	56.8
NTNCWSs	5.1	3.6	4.7
TNCWSs	8.7	7.2	8.6

Source: Exhibit 4.4 of the GWR EA (USEPA, 2006d).

As discussed previously in Section II.A, the CDC identified source water contamination and inadequate treatment as the major causes for ground water-related outbreaks between 1991 and 2000. Untreated or inadequately treated ground water may contain viral and bacterial pathogens. Therefore, undisinfected ground water or water treated to less than 4-log may pose a public health risk to consumers.

Waterborne disease attributable to viral and bacterial pathogens is a significant public health problem. EPA's Science Advisory Board cited drinking water contamination, particularly contamination by pathogenic microorganisms, as one of the most important environmental risks (USEPA/SAB, 1990). The CDC reports significant numbers of recent waterborne disease outbreaks and cases of illness associated with ground waters (Moore *et al.* (1993); Kramer *et al.* (1996); Levy *et al.* (1998); Barwick *et al.* (2000); Lee *et al.* (2002)).

Most waterborne pathogens, including viral and bacterial pathogens, cause gastrointestinal (GI) illness with diarrhea, abdominal discomfort, nausea, vomiting, and other symptoms. The effects of a waterborne disease are usually acute, resulting from a single exposure. Most GI illnesses are generally of short duration and result in mild illness, but some can result in severe illness and even death. For example, during a recent ground water outbreak in New York, a healthy three-year old child died from hemolytic uremic syndrome (kidney failure) (New York State Department of Health, 2000). Waterborne pathogens also cause other serious disorders such as hepatitis, Legionnaires Disease, myocarditis, paralysis, acute hemorrhagic conjunctivitis, meningitis, and reactive arthritis. Waterborne pathogens have also been associated with diabetes, encephalitis, and other diseases (Lederberg, 1992).

Sensitive populations are at greater risk from waterborne disease from viral and bacterial pathogens than the general population. These sensitive subpopulations include children (especially the very young); the elderly; the malnourished; pregnant women; chronically ill patients (*e.g.*, those with diabetes or cystic fibrosis); and a broad category of those with compromised immune systems, such as AIDS patients, those with autoimmune disorders (*e.g.*, rheumatoid arthritis, lupus erythematosus, and multiple sclerosis), organ transplant recipients, and those receiving chemotherapy (Rose, 1997). Sensitive subpopulations (or those with compromised immune systems) represent almost 20 percent of the population in the United States (Gerba *et al.*, 1996). The severity and duration of illness is often greater in sensitive subpopulations than in healthy individuals, and may occasionally result in death.

When humans are exposed to and infected by an enteric pathogen, such as a bacterium or virus, the pathogen becomes capable of reproducing in the gastrointestinal tract. As a result, healthy humans shed pathogens in their feces for a period ranging from days to weeks. This shedding of pathogens often occurs in the absence of any signs of clinical illness. Regardless of whether a pathogen causes clinical illness in the person who sheds it in his or her feces, the pathogen being shed may infect other people directly (by person-to-person spread, contact with contaminated surfaces, etc.), which is referred to as secondary spread.

Waterborne pathogens thus may infect people via a variety of routes.

Fecal contamination of drinking water is a primary cause of waterborne disease (Szewzyk *et al.*, 2000). Viral and bacterial pathogens associated with fecal contamination can reach ground water via pathways in the subsurface and near surface. First, fecal contamination from, for example, improper storage or management of manure, runoff from land-applied manure, leaking sewer lines, or failed septic systems can reach the ground water source by traveling—sometimes great distances—through the subsurface (especially through transmissive materials such as karst, gravel, or fractured bedrock). Twenty-five million households in the United States use conventional onsite wastewater treatment systems, according to the 1990 Census. These systems include septic systems and leach fields. A national estimate of failure rates of these systems is not available; however, a National Small Flows Clearinghouse survey reports that in 1993 alone, 90,632 failures were reported (USEPA, 1997b). The volume of septic tank waste alone that is released into the subsurface has been estimated at one trillion gallons per year (Canter and Knox, 1984). This contamination may eventually reach the intake zone of a drinking water well.

Second, fecal contamination from the surface may enter a drinking water well along the casing or through cracks in the sanitary seal if it is not properly constructed, protected, or maintained. In addition to source contamination, fecal contamination may also enter the distribution system when cross-connection controls fail or when negative pressure in a leaking pipe allows contaminant infiltration. A subset of GWSs is susceptible to contamination by one or more of these routes.

2. Waterborne Disease Outbreaks in Ground Water Systems

The Centers for Disease Control and Prevention (CDC) reports that between 1991 (the year in which implementation of the TCR began) and 2000, GWSs (both CWSs and NCWSs) were associated with 68 outbreaks that caused 10,926 illnesses (Table III–2). These account for 51 percent of all waterborne disease outbreaks in the United States during that period. The outbreak data illustrate that the major deficiency in GWSs was source water contamination. Contaminated source water was the cause of 79 percent of the outbreaks in GWSs (63 percent of CWS outbreaks and 86 percent of NCWS outbreaks), shown as untreated ground water and treatment deficiencies in Table III–2. Consumers of undisinfected water are especially vulnerable to source water contamination. Approximately 70 percent of GWSs provide either untreated ground water or provide treatment of less than 4-log virus inactivation or removal as discussed in the GWR EA (USEPA, 2006d).

Of the 68 outbreaks in GWSs, 14 (21 percent) were associated with specific bacterial pathogens (see Table III–3). The fecal bacterial pathogen *Shigella* caused more reported outbreaks (five, seven percent) than any other bacterial agent. Identified viral pathogens were associated with four (six percent) reported outbreaks. Etiologic agents were not identified in 39 (57 percent) outbreaks; however, EPA suspects that many of these outbreaks were caused by viruses given that it is generally more difficult to analyze for viral pathogens than bacterial pathogens. EPA regulates for protozoa, including *Giardia* and *Cryptosporidium,* under the SWTRs, which also cover GWUDI systems. For the most part, the outbreaks associated with protozoa that occurred in GWSs were later determined by the State to be GWUDI systems.

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Table III-2: Sources of Waterborne Disease Outbreaks in Ground Water Systems, 1991 – 2000

Cause of Contamination	Number of Outbreaks	Percent Outbreaks	Cases of Illness	Percent Illnesses	Cases per Outbreak
Community Water Systems					
Untreated Ground Water	5	26%	167	6%	33
Treatment Deficiency	7	37%	1,624	58%	232
Distribution System Deficiency	5	26%	803	29%	161
Miscellaneous/Unknown	2	11%	183	7%	92
Total	**19**	**100%**	**2,777**	**100%**	**146**
Noncommunity Water Systems					
Untreated Ground Water	23	47%	4,057	50%	176
Treatment Deficiency	19	39%	3,264	40%	172
Distribution System Deficiency	6	12%	442	5%	74
Miscellaneous/Unknown	1	2%	386	5%	386
Total	**49**	**100%**	**8,149**	**100%**	**166**
Combined					
Untreated Ground Water	28	41%	4,224	39%	151
Treatment Deficiency	26	38%	4,888	45%	188
Distribution System Deficiency	11	16%	1,245	11%	113
Miscellaneous/Unknown	3	4%	569	5%	190
Total	**68**	**100%**	**10,926**	**100%**	**161**

Sources: Moore *et al.* (1993); Kramer *et al.* (1996); Levy *et al.* (1998); Barwick *et al.* (2000); and Lee *et al.* (2002).

Table III-3: Etiology of Waterborne Outbreaks in Ground Water Systems, 1991-2000

	CWSs			NCWSs			TOTAL		
Causative Agent	Outbreaks	Cases of Illness	Percent of Total Outbreaks	Outbreaks	Cases of Illness	Percent of Total Outbreaks	Outbreaks	Cases of Illness	Percent of Total Outbreaks
Protozoa	**8**	**1,675**	**42.1%**	**3**	**576**	**6.1%**	**11**	**2,251**	**16.2%**
Giardia	5	136	26.3%	2	25	4.1%	7	161	10.3%
Cryptosporidium	3	1,539	15.8%	1	551	2.0%	4	2,090	5.9%
Virus	**-**	**-**	**0.0%**	**4**	**1,806**	**8.2%**	**4**	**1,806**	**5.9%**
Hepatitis A	-	-	0.0%	-	-	0.0%	-	-	0.0%
Norwalk Virus	-	-	0.0%	4	1,806	8.2%	4	1,806	5.9%
Bacteria	**6**	**1,037**	**31.6%**	**8**	**1,309**	**16.3%**	**14**	**2,346**	**20.6%**
Shigella	1	83	5.3%	4	473	8.2%	5	556	7.4%
Campylobacter	1	172	5.3%	2	51	4.1%	3	223	4.4%
Salmonella, non-typhoid	1	625	5.3%	-	-	0.0%	1	625	1.5%
S. typhimurium	1	124	5.3%	-	-	0.0%	1	124	1.5%
E. coli	1	22	5.3%	2	785	4.1%	3	807	4.4%
Vibrio	1	11	5.3%	-	-	0.0%	1	11	1.5%
Undetermined	**5**	**65**	**26.3%**	**34**	**4,458**	**69.4%**	**39**	**4,523**	**57.4%**
Total	**19**	**2,777**	**100.0%**	**49**	**8,149**	**100.0%**	**68**	**10,926**	**100.0%**

Note: Detail may not add to totals due to independent rounding.
Sources: Moore *et al.* (1993); Kramer *et al.* (1996); Levy *et al.* (1998); Barwick *et al.* (2000); and Lee *et al.* (2002).

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Large outbreaks are rarely associated with GWSs because most GWSs are small. In addition, the number of identified and reported outbreaks in the CDC database is believed to substantially understate the actual incidence of waterborne disease outbreaks and cases of illness (Craun and Calderon, 1996; National Research Council, 1997). This underestimation is due to a number of factors. Many people experiencing gastrointestinal illness do not seek medical attention. Where medical attention is provided, testing to identify the pathogenic agent is often not done and even if it is, the pathogenic agent may not be identified through correct testing (*e.g.,* when a sample is tested for a limited number of pathogens). Physicians often lack sufficient information to attribute gastrointestinal illness to any specific origin, such as drinking water, and few

States have an active outbreak surveillance program. Furthermore, the outbreak reporting system in the U.S. is paper-based and voluntary. Consequently, waterborne disease outbreaks are often not recognized in a community or, if recognized, are not traced to a drinking water source even though it may be the cause of the outbreak. Although it occurred in a community served by a surface water source, the 1993 *Cryptosporidium* outbreak in Milwaukee, Wisconsin is an example of how difficult it is to recognize a drinking waterborne disease outbreak. In one study of this large outbreak, only six percent sought health care and only six percent of those health care cases were tested for parasites (with only four percent of those cases specifically tested for *Cryptosporidium*) (Juranek, 1997). Thus, over 99 percent of estimated cases of illness went undiagnosed in this outbreak. In addition to epidemic illness, an unknown but probably significant portion of waterborne disease is endemic (*i.e.,* isolated cases not associated with an outbreak) and is even more difficult to recognize.

Collectively, the data indicate that outbreaks in GWSs are a problem and that source water contamination and inadequate treatment (or treatment failures) are responsible for the great majority of outbreaks.

3. Microbial Contamination in Public Ground Water Systems

The extent to which viral and bacterial pathogens occur in public ground water supplies influences the risk of exposure to populations consuming ground water from PWSs. Such risks of exposure pertain to populations using both undisinfected and disinfected water supplies. For undisinfected supplies, pathogens in the water are an immediate risk, since no treatment barrier exists prior to consumption. For disinfected supplies, if disinfection is inadequate or if treatment plant upsets occur, pathogens can reach consumers. These exposure risks were discussed in Section III.C.2 from an outbreak perspective. This section will discuss data on the occurrence of waterborne viral pathogens and indicators of fecal contamination in ground water supplying PWS wells.

a. *Occurrence studies and data.* For this rule, EPA examined the occurrence of viral pathogens and some fecal indicators. EPA reviewed data from 24 studies on pathogen and fecal indicator occurrence in ground water wells that supply PWSs. This total includes 16 studies described in the proposal, seven studies that became available since proposal as described in the NODA (USEPA, 2006e), and one study that was provided to EPA in comment as a result of the NODA. Each study was conducted independently and with a different objective and scope. The *Occurrence and Monitoring Document for the Final Ground Water Rule* (USEPA, 2006b) provides a detailed discussion of each examined occurrence study. The available data show a wide range of enterovirus and fecal indicator occurrence in water drawn from wells across the U.S. EPA selected 15 studies to estimate national viral and fecal indicator occurrence in ground water. To arrive at the conclusion that these 15 studies provide the best possible representation of ground water contamination at a national level, EPA evaluated all available studies (24 studies) that were applicable to the risk assessment analyses (USEPA, 2006d). See Section VII.B.1 of this preamble for a discussion of study selection.

Enterovirus cell culture data from the 15 studies were used to estimate the baseline risk related to virus occurrence in ground water. EPA believes that enterovirus cell culture measurements provide the best available basis for estimating pathogenic viral occurrence since they capture viruses that are infectious. However, because the cell culture procedure only captures a portion of all viruses that may actually occur in well water due to assay limitations, use of this method may underestimate viral occurrence.

EPA used data on the indicator *E. coli* from these same studies to inform estimates of fecal contamination occurrence. Indicator data are important because illness can result from consuming ground water with fecal contamination in the absence of identified viruses. For example, some viruses such as infectious norovirus are not recoverable, other viruses such as enteroviruses have variable and limited recovery, and a variety of bacteria of fecal origin can cause disease. EPA chose to use *E. coli* data instead of other fecal indicator data for this analysis. This choice was driven by EPA's assessment that *E. coli* will be the most likely fecal indicator used when PWSs implement the GWR, because *E. coli* is frequently used to fulfill follow-up monitoring requirements under the TCR. Therefore national estimates of *E. coli* occurrence can be used to inform potential cost implications for implementing the GWR. EPA recognizes that any indicator organism, including *E. coli,* may or may not co-occur with pathogens and that co-occurrence could be intermittent. *E. coli* is an imperfect indicator of viral occurrence. Some wells with *E. coli* have no viral occurrence. Some wells with viral occurrence have no *E. coli.*

b. *Estimates of national occurrence of viral and fecal indicator contamination.* This section discusses national occurrence of viral and fecal indicator (*E. coli*) contamination, which includes estimates of viral concentrations in contaminated wells and estimates of the probability that a well may have detectable viral and/or fecal indicator contamination. For purposes of this analysis, EPA uses the term ''sometime contamination'' as contamination that occurs at one or more points in time. Because fecal contamination is intermittent, viruses and *E. coli* will only be present at detectable levels some fraction of the time in a contaminated well. These fractions will vary from well to well. Some wells may be frequently contaminated but others may only be contaminated for a small fraction of time.

EPA analyzed the 15 studies for data to inform the concentration analysis. Among the 15 studies used for the national occurrence analysis, 12 provided data on occurrence of enterovirus cell culture and 11 provided data on occurrence of *E. coli.* Among the 12 data sets with enterovirus cell culture measurement, three included viral concentration data. Concentration measurements in the three surveys ranged from 0.09 to 212 enteric virus infectious units (plaque forming units) per 100 liters. Although the measurement methods were often not capable of detecting viruses at concentrations below 0.2 units per 100 liters, it is likely that viruses also occur at levels below the detection limit.

Data from each of the 15 studies were combined into one complete data set to determine the probabilities of sometime well contamination for viral (indicated by enterovirus cell culture) or fecal indicator (indicated by *E. coli*) contamination. The results of this effort led naturally to a combined analysis, which models occurrence and co-occurrence of viruses and *E. coli.* EPA's analysis also considers uncertainty and variability about these estimates. The model serves as the basis of EPA's national quantitative occurrence estimates. See the *Occurrence and Monitoring Document for the Final Ground Water Rule* for more information (USEPA, 2006b).

Overall, the analysis indicates a public health concern in that approximately 26 percent of the wells sometimes have fecal contamination (indicated by *E. coli*) and approximately 27 percent of the wells sometimes have

viral contamination. Due to the intermittent nature of fecal contamination, some of these wells are only contaminated for a small fraction of time. On average, wells with sometime virus occurrence have detectable concentrations about 11 percent of the time, and wells with sometime *E. coli* occurrence have detectable concentrations about 14 percent of the time. The remainder of the time, the well's water is essentially virus free (assuming that concentration is zero when not detected by measurement methods like those used in the occurrence studies). Compared to the analysis in the proposal, the number of wells with fecal contamination is greater but the frequency at which contamination occurs in each well is less.

In summary, EPA's occurrence analysis shows that fecal contamination is intermittent and that some individuals are at risk because pathogens and/or fecal indicators occur at PWSs that use ground water as a source of drinking water. The next section discusses this risk.

4. Potential Risk Implications From Occurrence Data

As discussed previously, to assess the public health risk associated with drinking ground water, EPA evaluated information and conducted analyses on (1) Health effects data from a range of pathogens, (2) waterborne disease outbreak data, and (3) occurrence data from ground water studies and surveys. As a result of this evaluation and analysis, EPA concludes that the potential risk to public health posed by a subset of PWSs with contaminated ground water sources is significant enough to warrant regulation.

When a PWS uses contaminated source water, its customers are at risk of infection and illness. Their risk depends on a number of factors including whether the system provides at least 4-log treatment of viruses, the frequency at which the well is contaminated, the level of contamination (*i.e.*, concentration), and the infectivity of the pathogens that are present.

To develop risk estimates from viral exposure, EPA considered two types of viruses, Type A (represented by data available on rotavirus) and Type B (represented by data available on enterovirus or echovirus), which are used to estimate risk from exposure to viral-contaminated wells. These two virus types have different infection morbidity and disease severity characteristics. Type A viruses are considered to be highly infectious but cause primarily mild illness, while Type B viruses are considered much less infectious but may cause more severe illnesses.

The infectivity of a virus relates the probability of infection to a given amount, or dose, of virus consumed. Together with infectivity, morbidity (risk of illness given infection) and mortality (risk of premature death given an illness) are used to predict the disease burden associated with a particular virus level in drinking water. As discussed in the previous section, a typical contaminated well may have detectable virus concentrations 11 percent of the time. The remainder of the time, the well's water is essentially virus free (assuming that concentration is zero when not detected by measurement methods like those used in the occurrence studies). EPA has viral concentration data from the three studies as discussed in Section III.C.3.b of this preamble. Virus concentration data combined with viral exposure data can be used to predict infection rates given viral dose-response information. Figure III–1 indicates the annual risk of infection from exposure to rotavirus, assuming one liter of water consumed per day, based on a range of possible mean annual source water concentrations and different levels of treatment. For example, if an untreated ground water source had a mean annual source water concentration of 0.1 viruses per 100 L (*e.g.*, a source water concentration of one virus per 100 L, 10 percent of the time), people consuming one liter of this water per day would have approximately a seven percent probability of being infected in the course of the year (90 percent confidence interval of three percent to 13 percent). The risk of infection implications from exposure to echovirus are 10 to 100 times less than those from rotavirus, assuming the same levels of exposure. However, illness resulting from infection of echovirus may be more severe than illness resulting from infection by rotavirus.

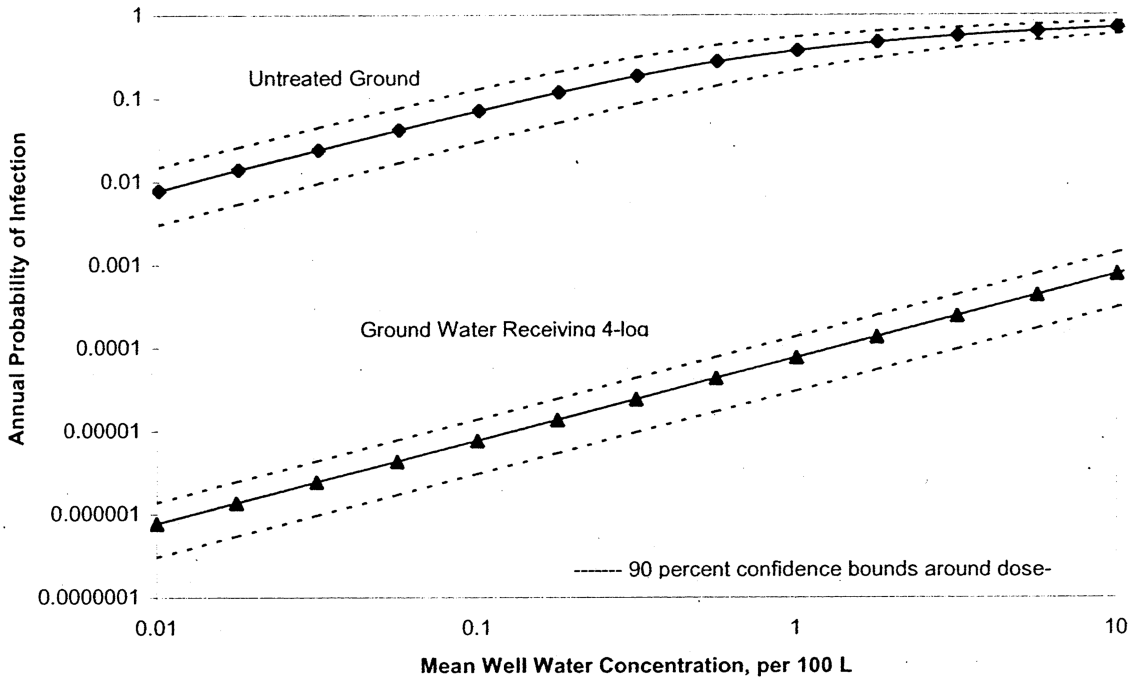
It is important to recognize that EPA's quantitative risk analysis is limited by the data available, specifically data on rotavirus and echovirus. Other pathogenic viruses also cause disease and may be more or less infectious than those modeled. Pathogens may cause chronic and acute illnesses in addition to those considered in the quantitative risk analysis. Furthermore, EPA's quantitative risk analysis does not consider bacterial illness and deaths resulting from contaminated drinking water due to limited data. Taken together, these limitations imply an underestimate of the actual illnesses and deaths that result from exposure to contaminated ground water when only these sources of uncertainty are considered. The GWR national risk implications from exposure to pathogenic viruses and bacteria are discussed in Section VII of this preamble and more fully discussed in the GWR EA (USEPA, 2006d).

Even at the levels EPA is able to quantify, the risk analysis supports the conclusion that a substantial number of people served by GWSs are at risk of exposure to waterborne pathogens. EPA's occurrence analysis (USEPA, 2006b) demonstrates that some wells have high viral occurrence while others have lower occurrence, and thus lower risk. For public health protection, it is most important to target those wells with higher occurrence. In addition, the occurrence analysis demonstrates that contamination is intermittent. Because of the intermittent nature of contamination, an ongoing monitoring program is critical to effectively target higher risk systems.

The intent of the GWR is to reduce risk by targeting susceptible systems for corrective action. The corrective action options are: Correct all significant deficiencies; provide an alternate source of water; eliminate the source of contamination; or provide treatment that reliably achieves at least 4-log treatment of viruses. As illustrated in Figure III–1, treatment will provide large improvements in public health. Thus, the final GWR components of sanitary surveys, source water monitoring, and corrective action are each critical steps to improving public health in communities served by undisinfected (or inadequately disinfected) GWSs.

Implementation of this rule is expected to result in approximately 42,000 avoided viral illnesses and one avoided death annually. The analysis is uncertain and these estimates could be an over-or under-estimate of actual illnesses and deaths. The nonquantified benefits are those that the Agency was unable to quantify due to data limitations, which include decreased incidence of other acute viral disease endpoints, decreased incidence of chronic viral illness sequelae, decreased incidence of bacterial illness and death, decreased incidence of waterborne disease outbreaks and epidemic illness, and decreased illness through minimizing treatment and distribution system failures. The nonquantified benefits associated with this rule are significant and are discussed in detail in Section 5.4 of the GWR EA (USEPA, 2006d).

Figure III-1: Estimated Annual Risks of Infection from Rotavirus for Different Exposure Conditions



IV. Discussion of GWR Requirements

This section describes the rule requirements and rationale for each component of the risk-targeted strategy of this rule. A summary of, and responses to, key comments on the proposed rule are also provided.

A. Sanitary Surveys

EPA believes that comprehensive, periodic sanitary surveys and the identification and correction of significant deficiencies are indispensable for ensuring the long-term safety of drinking water supplies. They are an important tool for identifying potential vulnerabilities to fecal contamination at GWSs. The final GWR includes Federal requirements for sanitary surveys of all GWSs for the first time.

This rule provides the States with flexibility to prioritize and carry out the sanitary survey process, while ensuring that the survey is an effective, preventive tool for GWSs. The sanitary survey provision in this rule builds on existing State sanitary survey programs established under the 1989 TCR and the Interim Enhanced Surface Water Treatment Rule (IESWTR) (63 FR 69477, December 16, 1998) (USEPA, 1998b) and gives States the authority to define both outstanding performance and significant deficiencies. At the same time, the GWR's sanitary survey requirements for minimum frequencies, scope, documentation, and mandatory corrective action strengthen existing sanitary survey programs and address many of the concerns associated with current sanitary survey programs as identified by the GAO (USGAO, 1993).

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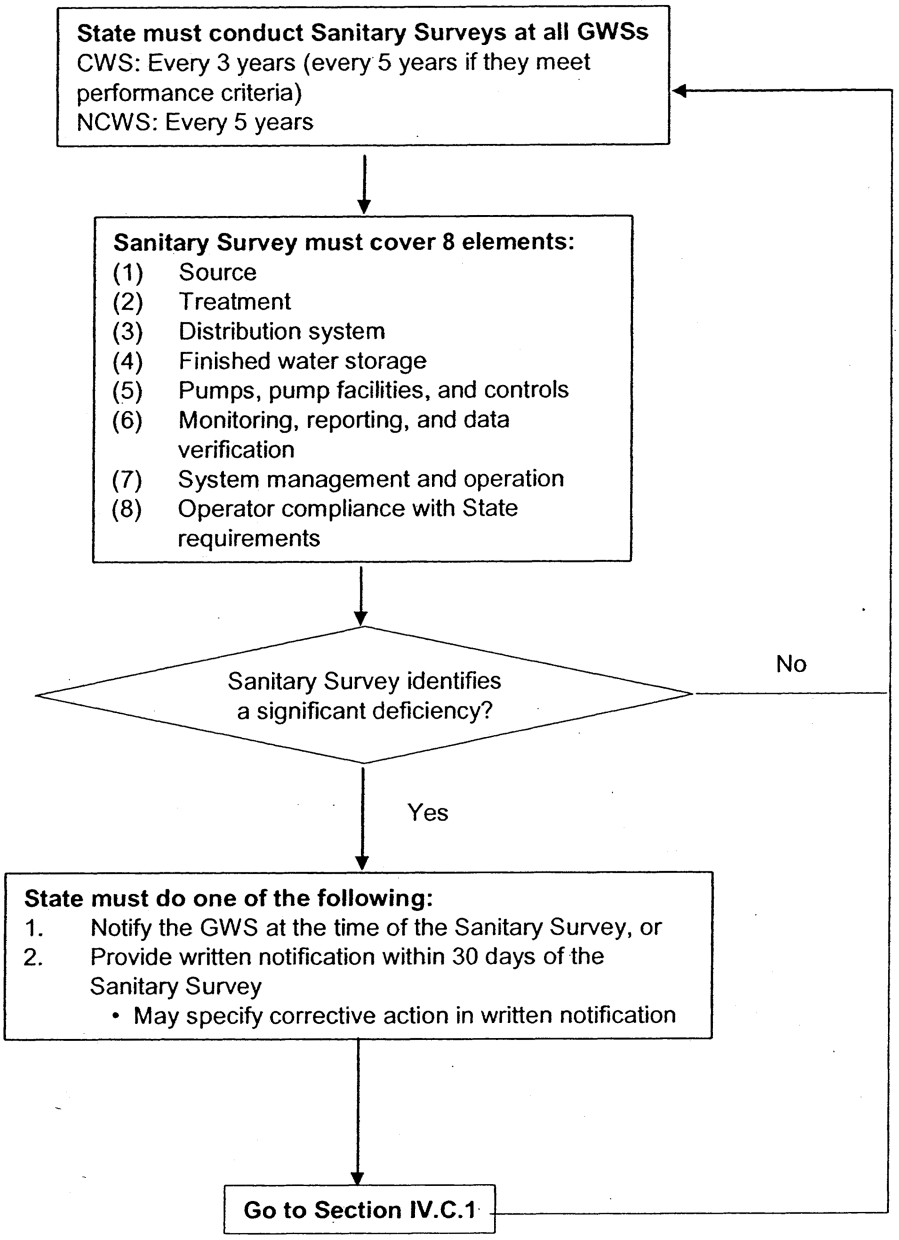
Figure IV-1: Sanitary Survey Requirements



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1. What Are the Requirements of This Rule?

This rule requires States to perform sanitary surveys for all GWSs. Ground water systems must provide the State with any pertinent, existing information that will enable the State to perform the sanitary survey. This rule goes beyond the existing definition of sanitary survey at § 141.2, explicitly references the use and relevance of source water assessments required under the 1996 SDWA Amendments, and specifies in more detail the scope of a sanitary survey. Specifically, this rule requires that States evaluate eight components as part of the sanitary survey to the extent that they apply to an individual system: (1) Source; (2) treatment; (3) distribution system; (4) finished water storage; (5) pumps, pump facilities, and controls; (6) monitoring, reporting, and data verification; (7) system management and operation; and (8) operator compliance with State requirements. This rule outlines the eight minimum elements using broad categories and recognizes that certain elements may not be present in a particular system depending on its size or complexity.

This rule requires States to conduct sanitary surveys of ground water CWSs every three years (every five years for CWSs that meet performance criteria as described in the following paragraph) and of ground water NCWSs every five years. States are required to complete the initial sanitary survey cycle by December 31, 2012 for CWSs, except those that meet performance criteria, and December 31, 2014 for all NCWSs and CWSs that meet performance criteria. States may conduct more frequent sanitary survey cycles for any GWS as appropriate.

This rule allows individual components of a sanitary survey to be conducted according to a phased review process (*e.g.*, as part of ongoing State assessment programs). While all

applicable components need not be evaluated at the same time, they must be evaluated within the required three-or five-year frequency interval. Also, this rule allows the three-year CWS schedule to be extended to a five-year frequency if the system meets certain criteria (referred to in this preamble as ''performance criteria''). These performance criteria are:

• Provides 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for all its ground water sources, or

• Has an outstanding performance record (as defined by the State) documented in previous sanitary surveys, and has no history of total coliform MCL or monitoring violations under the TCR since the last sanitary survey.

Finally, this rule requires that GWSs correct any significant deficiencies identified in sanitary surveys. Significant deficiencies, as determined by the State, include, but are not limited to, defects in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that the State determines to be causing, or have the potential for causing, the introduction of contamination into the water delivered to consumers.

Significant deficiencies may include, but are not limited to, the following:

Source

• Well near a source of fecal contamination (*e.g.*, failing septic systems or a leaking sewer line).

• Well in a flood zone.

• Improperly constructed well (*e.g.*, improper surface or subsurface seal).

• Spring boxes that are poorly constructed and/or subject to flooding.

Treatment

• Inadequate application of treatment chemicals (*e.g.*, disinfection contact time is inadequate).

• Lack of redundant mechanical components where disinfection is required.

• Unprotected cross-connections with treatment chemical systems.

• Inadequate treatment process monitoring.

Distribution System

• Negative pressures that could result in the entrance of contaminants.

• Inadequate disinfectant residual monitoring, when required.

• Unprotected cross-connections.

Finished Water Storage

• Inadequate internal cleaning and maintenance of storage tanks.

• Lack of proper screening of overflow pipes, drains, or vents.

• Storage tank roofs or covers need repair (*e.g.*, holes or hatch of improper construction).

Pumps, Pump Facilities, and Controls

• Inadequate pump capacity.

• Inadequate maintenance.

• Inadequate/inoperable control system.

Monitoring, Reporting, and Data Verification

• Failure to properly monitor water quality.

• Failure to meet reporting requirements.

• Inadequate recordkeeping.

System Management and Operation

• Failure to meet water supply demands/interruptions to service (*e.g.*, unreliable water source or lack of auxiliary power).

• Lack of approved emergency response plan.

• Inadequate follow-up to deficiencies noted in previous assessment/survey.

Operator Compliance with State Requirements

• Operator is not certified as required by the State.

• Lack of operator training.

The State must provide the GWS with written notification, which describes any significant deficiencies found, no later than 30 days after the State identifies the significant deficiency. The notice may be sent to the PWS, or it may be provided on-site either at the time the sanitary survey is conducted or the significant deficiency is identified. The State may specify appropriate follow-up corrective action steps in the notice or may notify the GWS of appropriate corrective actions during the consultation period. After receiving the written notification, the GWS has 30 days to consult with the State regarding corrective actions. However, the State may prescribe corrective actions and completion dates, including immediate and/or interim corrective actions, in lieu of the consultation process. Under this rule, a GWS must complete corrective action or be in compliance with a State-approved corrective action plan and schedule within 120 days of receiving written notice from the State, as described in Section IV.C of this preamble. Failure to do so will result in a treatment technique violation. This rule requires systems to notify customers of uncorrected significant deficiencies. When a significant deficiency is identified at a PWS that uses both ground water and surface water sources, the GWR treatment technique requirements apply except in cases where the State determines that the significant deficiency is in a portion of the distribution system that is served by surface water (or ground water under the direct influence of surface water).

2. What Is EPA's Rationale for the GWR Sanitary Survey Requirements?

As discussed in the proposed GWR, sanitary surveys enable States (and systems) to provide a comprehensive and accurate review of the components of water systems, to assess the operating conditions and adequacy of the water system, and to determine if past recommendations have been implemented effectively. A GWS has the responsibility of providing the information necessary to conduct a sanitary survey to the State upon request to enable a comprehensive assessment of the system. The purpose of the sanitary survey is to evaluate and document the capabilities of the water system's sources, treatment, storage, distribution network, operation and maintenance, and overall management to ensure the provision of safe water. In addition, sanitary surveys provide an opportunity for PWS inspectors to visit the water system and educate operators about proper monitoring and sampling procedures and to provide technical assistance.

Historically, sanitary surveys have been conducted by State drinking water programs as preventative tools for identifying water system deficiencies before contamination occurs. In 1976, EPA regulations required, as a condition of primacy, that States develop a systematic program for conducting sanitary surveys, but EPA did not define the scope of sanitary surveys or specify minimum criteria at that time. In 1989, the TCR included a provision requiring sanitary surveys for systems collecting fewer than five TCR samples per month (systems serving fewer than 4,100 people). For those systems, sanitary surveys are required under the TCR once every five years for CWSs and NCWSs (but once every 10 years for NCWSs that use protected or disinfected ground water). However, the TCR did not establish what must be evaluated in a sanitary survey or specifically address significant deficiencies.

Consequently, a number of concerns have been raised regarding post-TCR sanitary survey practices. For example, the GAO investigated sanitary survey practices in 1993 and found that many surveys did not evaluate one or more of the major components and operations that EPA requires be evaluated under the final GWR and that efforts to ensure that deficiencies were corrected were often limited (USGAO, 1993). A review of State regulations found that many States do not specifically require systems to correct deficiencies. These

factors, coupled with information on contaminant occurrence and analysis of microbial waterborne disease outbreak data, indicated that public health protection can be strengthened by requiring regular sanitary surveys, specifying the scope of surveys, and requiring corrective action of significant deficiencies.

In 1995, EPA and the States (through the Association of State Drinking Water Administrators) issued a joint guidance on sanitary surveys entitled *EPA/State Joint Guidance on Sanitary Surveys* (USEPA/ASDWA, 1995). Recognizing the essential role of sanitary surveys and the need to define the broad areas that all sanitary surveys should cover, the guidance recommended eight elements for a comprehensive sanitary survey. The guidance also recommended the development of assessment criteria, proper documentation of results, and thorough follow-up, tracking, and enforcement after the survey. The IESWTR, (USEPA, 1998b), requires States to address the same eight elements in sanitary surveys conducted at surface water systems and at GWUDI systems. The GWR incorporates the same eight elements into the sanitary survey requirements for GWSs to be consistent with, and as comprehensive as, the IESWTR. Based on consultation with the States and EPA regions, EPA believes that the majority of States today include the eight elements in their sanitary survey programs for both surface water and GWSs.

In addition to requiring these eight elements, the GWR requires the State to conduct sanitary surveys no less frequently than every three years for CWSs and every five years for NCWSs. This rule provides the State with the flexibility to reduce the frequency for CWSs to every five years for systems that meet performance criteria (refer to Section IV.A.1 for criteria). These frequencies are consistent with the recommendations for surface water systems made by the Microbial/Disinfection Byproducts Federal Advisory Committee, which included various stakeholders representing a wide range of sectors in the drinking water community. Given this, EPA believes that the same three- and five-year interval for conducting sanitary surveys is appropriate for GWSs. The GWR requires the first sanitary survey cycle to be completed by December 31, 2012 for CWSs, except those that meet performance criteria, and December 31, 2014 for all NCWSs and CWSs that meet performance criteria. See Section VI of this preamble for explanation of initial sanitary survey completion dates.

As noted earlier, this regulation attempts to build on existing State public health programs to the extent possible. Consequently, the GWR allows individual elements of a sanitary survey to be conducted on a phased review schedule as part of ongoing State assessment programs within the established three-or five-year frequency interval. This allows States to more efficiently use existing assessment schedules and maximize the effective allocation of staff resources and expertise across a State in conjunction with other priorities. EPA believes that the frequency of sanitary surveys and the required eight sanitary survey elements in this rule ensure greater public health protection while providing adequate flexibility for States and systems to effectively implement the requirements. The GWR requires the initial sanitary surveys to be completed six years after rule promulgation for CWSs and eight years after rule promulgation for NCWSs. The six to eight year time frame for initial sanitary surveys is based on several considerations. First, States need time to adopt the rule and obtain primacy (two to four years allowed by the SDWA at 1413(a)(1)). In addition, systems are given three years to comply with drinking water regulations by the SDWA at (1412(b)(10)). Finally, States need three to five years to complete the first cycle of sanitary surveys because there are many GWSs and States have limited resources.

A key finding of the GAO report was that deficiencies identified in one sanitary survey were often found still uncorrected at the next sanitary survey. For example, in a four-State sample of 200 sanitary surveys, GAO found approximately 60 percent of the surveys cited deficiencies that were also cited in previous surveys. While the report indicated that smaller systems (serving 3,300 or fewer people) were in the greatest need of improvement, GAO found that, regardless of system size, previously identified deficiencies frequently went uncorrected. GAO found that some States lacked the authority to ensure that water system owners and operators correct documented deficiencies. Additional causes for uncorrected deficiencies included a lack of documentation or ineffective tracking of survey results. The Agency believes that a sanitary survey is an effective tool for identifying significant deficiencies. Once identified, it is also essential that such deficiencies be corrected in a timely manner. A study of the effectiveness of a range of best management practices shows that follow-up and correction of sanitary survey deficiencies were correlated with lower levels of total coliform, fecal coliform, and *E. coli* (ASDWA, 1998). Thus, this rule requires that systems coordinate with the State within 30 days of being notified of the significant deficiency and that the systems correct the significant deficiency (or be on an enforceable State-prescribed schedule) within 120 days of being notified of the significant deficiency. See Section IV.C for details on corrective action time frames.

3. What Were the Key Issues Raised by Commenters on the Proposed GWR Sanitary Survey Requirements?

The majority of commenters on the GWR proposal were supportive of a sanitary survey requirement for all GWSs. Most commenters supported the proposed frequencies of three years for CWSs and five years for NCWSs. Several commenters noted that some States conduct surveys at more frequent intervals than required in this rule. However, a few commenters suggested extending the frequency interval for CWSs, because they believed that CWSs would be less likely to have significant deficiencies.

The Agency believes that frequent, comprehensive sanitary surveys are an important proactive public health measure and that the minimum frequencies of sanitary surveys under this rule balance public health protection with State implementation issues. This rule requirement is consistent with the frequency required for surface water systems under the IESWTR. The GWR provides flexibility in allowing States to perform more frequent sanitary surveys or to reduce the frequency for CWSs to five years if the CWS meets performance criteria (Section IV.A.1). States also have the flexibility to phase-in the evaluation of sanitary survey elements within the required frequency interval. The Agency believes that a frequency of three years for CWSs and five years for NCWSs, combined with flexibility on both timing and implementation, appropriately considers limited resource issues while advancing public health protection.

EPA specifically requested comments on ''grandfathering'' sanitary surveys conducted under the TCR to satisfy the initial sanitary survey requirements of the GWR. The majority of comments favored allowing the use of sanitary surveys conducted under the TCR or existing State programs to meet the initial sanitary survey requirements of the GWR. These comments were largely based on an interest in reducing State

implementation burden and allowing States to transition their existing sanitary survey programs into programs and schedules that meet the requirements of the GWR.

Because of the time frames laid out in the GWR for initial and repeat sanitary surveys, grandfathering sanitary surveys is not practicable. States must complete their initial CWS sanitary surveys six years after rule promulgation for CWSs and eight years for NCWSs. The deadline for completing the first round of sanitary surveys is longer than the minimum required sanitary survey frequency, so grandfathering would not result in a burden reduction for the State. For example, if a State were to grandfather a CWS sanitary survey from 2005, they would be required to complete a second sanitary survey by 2008 and a third by 2011, whereas a State that completed their first sanitary survey in 2009 would not be required to complete their second sanitary survey until 2012. As described in Section IV.A.2, the six to eight year time frame for initial sanitary surveys is based on several considerations. First, States need time to adopt the rule and obtain primacy (two to four years allowed under the SDWA at 1413(a)(1)). In addition, systems are given three years to comply with drinking water regulations by the SDWA at (1412(b)(10)). Finally, States need three to five years to complete the first cycle of sanitary surveys because there are many GWSs and States have limited resources.

EPA believes that it is important to reduce State implementation burden and that information from existing sanitary surveys and other sources is an important resource. Thus, this rule allows States to reduce the frequency of sanitary surveys for CWSs that meet performance criteria (Section IV.A.1) at any time subsequent to the effective date of this rule from every three to every five years. This allows States to reduce the implementation burden of sanitary surveys based on information collected under the TCR and existing sanitary survey programs while still ensuring a minimum sanitary survey frequency of five years for both CWSs and NCWSs. Since a significant proportion of GWSs are small NCWSs and the GAO report found the greatest need for improvement in smaller systems, EPA believes that a reduction in frequency for NCWSs would not advance public health protection. EPA notes that surveys or elements of sanitary surveys conducted under the TCR or as part of site assessment or other State programs may be used to meet the GWR requirements if they meet the criteria specified in the GWR (*i.e.*, if the minimum eight elements specified in the GWR are addressed at the specified GWR frequency).

EPA received a number of comments on the 30-day time frame that States have to notify a system when a significant deficiency is identified in the sanitary survey. Some commenters noted that this requirement is consistent with current procedures; notice of significant deficiencies is often provided to a system much sooner. However, other commenters were concerned that this requirement placed an unnecessary deadline on the State and that current State policies and practices adequately address timely notification of systems with significant deficiencies.

The Agency believes that timely notification of significant deficiencies is essential to the timely correction of those deficiencies and to the safety of drinking water. EPA believes requiring a 30-day maximum notification period in all States is reasonable, given the potential public health risk of significant deficiencies, and ensures equitable protection of public health across the nation.

EPA also received comments on what constitutes a significant deficiency under the GWR. EPA proposed defining significant deficiencies as a defect in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that the State determines to be causing, or has the potential for causing, the introduction of contamination into the water delivered to consumers. Several commenters urged EPA to go beyond that definition and require States to specify a minimum list of significant deficiencies under each of the applicable eight sanitary survey components set out in the EPA/State Joint Guidance on Sanitary Surveys. EPA also received comments regarding specific examples of significant deficiencies in each applicable component. Section IV.A.1 of this preamble includes specific examples of some significant deficiencies provided by commenters.

The Agency believes that to provide adequate public health protection, States must identify and require correction of all significant deficiencies. Also, EPA recognizes the importance for the State to include additional case-specific deficiencies. This rule states that significant deficiencies ''include, but are not limited to, defects in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that the State determines to be causing, or has the potential for causing, the introduction of contamination into the water delivered to consumers.'' The GWR requires each State, in its primacy application, to define and describe at least one specific significant deficiency in each of the eight sanitary survey elements. This enables States to work within their existing programs to define significant deficiencies as part of their primacy application and to define and describe significant deficiencies that may be unique to system size, type, location, or State requirements. EPA also recognizes that some systems may not have all eight components; for example, some TNCWSs may not have storage or require certified operators.

EPA requested comment on having public involvement and/or meetings for certain PWSs to discuss the results of sanitary surveys and specifically what approaches might be practical and not overly burdensome to involve the public in working with water systems to address the results of sanitary surveys. Some commenters suggested publishing the results in the system's Consumer Confidence Report (CCR) or reviewing the results at a public meeting. Others supported notifying the public that the results were available and how those results could be obtained. Some commenters noted that significant deficiencies would be corrected rapidly and that involving or informing the public after the correction might not be useful. One commenter suggested posting the results of surveys in a public place for non-community systems.

EPA believes that adequate opportunities exist for customers to obtain information on the complete sanitary survey of their water supplier. Results of sanitary surveys and notification from the State to the water supplier of significant deficiencies would be available to the public upon request from the State or the water supplier. However, EPA also believes that the public served by the water system should be made aware of significant deficiencies found in sanitary surveys that remain uncorrected and be fully informed as to how and when those deficiencies will be corrected. This rule requires systems to notify customers of such significant deficiencies including the date and nature of the significant deficiency, the schedule for correction, any interim measures taken, and the progress to date. The State may require the system to notify customers of corrected significant deficiencies. This requirement is described further in Section IV.D of this preamble.

EPA received comments suggesting that the sanitary survey provisions of

the TCR are sufficient to address viral and bacterial pathogens in GWSs and there is no need for sanitary surveys under the GWR. While EPA believes the TCR was a significant step forward for public health protection in 1989, the TCR does not require systems to correct significant deficiencies or require a minimum frequency of sanitary surveys for all systems. Thus, the GWR sanitary survey requirement better addresses the potential public health consequences of uncorrected significant deficiencies.

B. Source Water Monitoring

This rule requires ground water source monitoring as an essential element in its risk-targeted approach for identifying those GWSs with source water fecal contamination that need corrective action. Systems targeted for source water monitoring are those with an indication that they may be at risk for fecal contamination. Indicators of risk may come from total coliform monitoring, hydrogeologic sensitivity analyses, or other system-specific data and information. This rule requires triggered source water monitoring and provides States with the option to require assessment source water monitoring. Source water monitoring is not required for any GWS that is already providing at least 4-log treatment of viruses.

A GWS with a distribution system TCR sample that tests positive for total coliform is required to conduct triggered source water monitoring to evaluate whether the total coliform presence in the distribution system is due to fecal contamination in the ground water source. Triggered source water monitoring provides a critical ongoing evaluation of GWSs.

As a complement to the triggered source water monitoring provision, the GWR gives States the flexibility to require more comprehensive assessment source water monitoring on a case-by-case basis. The purpose of this optional assessment source water monitoring requirement is to target source water monitoring to systems that the State determines are at higher risk for fecal contamination. States are in the best position to assess which systems are at risk and would most benefit from source water monitoring.

EPA believes that source water monitoring targeted at higher risk systems, namely triggered source water monitoring, in conjunction with optional assessment source water monitoring, will be effective in identifying systems with source water fecal contamination. With implementation of the follow-up corrective action requirements outlined in Section IV.C, these requirements will provide meaningful opportunities to reduce public health risk for a substantial number of people served by GWSs.

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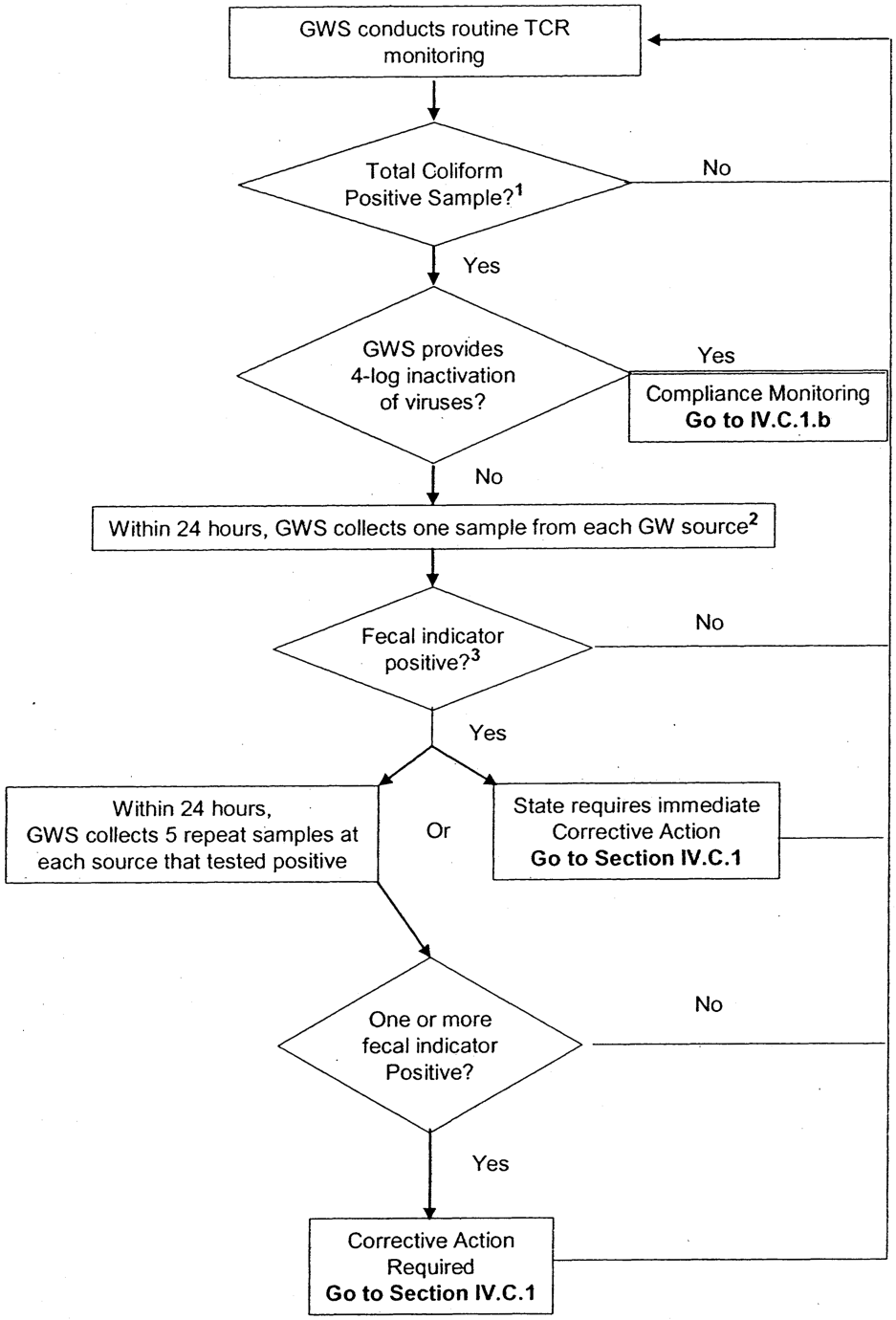
Figure IV-2: Triggered Source Water Monitoring Requirements



[1]Answer "no" if the sample is invalidated under 141.21(c) or the State determines that the cause of the total coliform-positive sample directly relates to the distribution system

[2]If approved by the State, systems with more than one ground water source may monitor at representative ground water source(s) according to a triggered source water monitoring plan

[3]*E. coli*, enterococci, or coliphage

BILLING CODE 6560–50–C

1. What Are the Requirements of This Rule?

a. *Triggered source water monitoring.* A GWS must conduct triggered source water monitoring within 24 hours of receiving notification that a routine sample collected in accordance with § 141.21(a) (TCR) is total coliform-positive. A GWS must collect at least one ground water source sample from each ground water source (*e.g.*, a well or spring) in use at the time the total coliform-positive sample was collected. Triggered source water monitoring is required unless: (1) The system provides at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for each ground water source; (2) the system is notified that a positive sample collected in accordance with § 141.21(a) (TCR) has been invalidated under § 141.21(c); or (3) the cause of the total coliform-positive collected under § 141.21(a) directly relates to the distribution system as determined by the system according to State criteria or as determined by the State. The State may extend the 24-hour limit on a case-by-case basis if the State determines that the system cannot collect the ground water source water sample within 24 hours due to circumstances beyond its control. In the case of an extension, the State must specify how much time the system has to collect the sample.

Systems are not required to conduct triggered source water monitoring if, according to State criteria or a State determination, the cause of the total coliform-positive sample collected under § 141.21(a) directly relates to the distribution system. If the GWS makes the decision according to State criteria, the GWS must document the decision in writing; if the decision is made by the State, the State must document the decision in writing. In the primacy application, the State must include criteria that will be used to determine that the cause of a total coliform-positive sample collected under § 141.21(a) is directly related to the distribution system.

If the State approves the use of *E. coli* as a fecal indicator for triggered source water monitoring, GWSs serving 1,000 people or fewer may use a TCR repeat sample collected from a ground water source to simultaneously meet the requirements of § 141.21(b) and satisfy the GWR's triggered source water monitoring requirements for that ground water source only.

If approved by the State, systems with more than one ground water source may conduct triggered source water monitoring at a representative ground water source or sources. The State may require systems with more than one ground water source to submit for approval a triggered source water monitoring plan that the system will use for representative sampling. A triggered source water monitoring plan must identify ground water sources that are representative of each monitoring site in the system's TCR sample siting plan.

If any initial triggered source water sample is fecal indicator-positive, the system must collect five additional source water samples within 24 hours at that site, unless the State requires immediate corrective action to address contamination at that site. The samples must be tested for the same fecal indicator for which the initial source water sample tested positive.

Ground water systems that purchase or sell finished drinking water (referred to as consecutive or wholesale systems, respectively) must comply with triggered source water monitoring provisions for their own sources.

Consecutive and wholesale systems must also comply with other triggered source water monitoring requirements. A consecutive GWS that has a total coliform-positive sample collected under § 141.21(a) (TCR) must notify the wholesale system(s) within 24 hours of being notified of the total coliform-positive sample. If a wholesale GWS receives notice from a consecutive system it serves that a sample collected under § 141.21(a) (TCR) is total coliform-positive, the wholesale GWS must conduct triggered source water monitoring. If the sample is fecal indicator-positive, in addition to notifying its own customers, the wholesale GWS must notify all consecutive systems served by that ground water source. The consecutive system is responsible for providing any required public notice to the persons it serves.

b. *Assessment source water monitoring.* The GWR provides States with the option to require systems to conduct assessment source water monitoring at any time and require systems to take corrective action. See Section IV.B.2.b for EPA's recommendations of when assessment source water monitoring may be appropriate and how to structure the monitoring program. If the State chooses to use HSAs to determine the appropriateness of assessment source water monitoring, then systems must comply with State requests for information.

c. *Source water microbial indicators and analytical methods.* A system that collects a source water sample to comply with this rule must analyze the sample for one of the three fecal indicators (*E. coli*, enterococci, or coliphage). Under this rule, GWSs must use one of seven specified analytical methods for *E. coli*, one of three methods specified for enterococci, or one of two methods specified for coliphage. The system is required to test at least a 100 mL sample volume for one of the three fecal indicators (*E. coli*, enterococci, or coliphage). All analyses must be conducted by a laboratory certified by the State or EPA.

d. *Invalidation of a fecal indicator-positive ground water source sample.* This rule allows systems to obtain written State invalidation of a fecal indicator-positive ground water source sample under either of the following conditions: (1) The system provides the State with written notice from the laboratory that improper sample analysis occurred; or (2) the State determines and documents in writing that there is substantial evidence that a fecal indicator-positive ground water source sample is due to a circumstance that does not reflect source water quality. If the State invalidates a fecal indicator-positive ground water source sample, the system must collect another ground water source sample within 24 hours of being notified of the invalidation by the State and have it analyzed for the same fecal indicator. The State may extend the 24-hour limit on a case-by-case basis if it determines that the system cannot collect the ground water source water sample within 24 hours due to circumstances beyond the system's control. In the case of an extension, the State must specify how much time the system has to collect the sample.

2. What Is EPA's Rationale for the GWR Source Water Monitoring Requirements?

a. *Triggered source water monitoring.*

i. Overall basis for provision. The GWR builds on the public health protection provided by the TCR by requiring systems to collect a ground water source sample when a TCR distribution system sample is total coliform-positive. Because a total coliform-positive sample in the distribution system may be caused by either a distribution system problem or source water contamination, the GWR triggered source water monitoring provision is necessary to distinguish between these two possible sources of fecal contamination. Thus, using the total coliform indicator is an efficient way to target higher risk systems where source water monitoring is warranted to investigate potential fecal

contamination. EPA believes that the GWR triggered source water monitoring provisions provide an effective means for improving public health protection.

Total coliform monitoring in the distribution system is already required under the TCR. Thus, total coliform monitoring provides a no-cost screening for potential fecal contamination and pathogen occurrence at the source. Total coliform is a sensitive indicator for the presence of potential fecal contamination. In the occurrence studies evaluated for the GWR, wells that were monitored with high frequency for enterovirus and total coliforms detected both enterovirus and total coliform in their source water (*i.e.*, Lieberman *et al.*, 2002; Karim *et al.*, 2004; Wisconsin Department of Health, 2000). Total coliform presence in source water can also be an indicator of recent surface and near surface water inflow to ground water, and pathogens originate at or near the surface.

Triggered source water monitoring provides an ongoing evaluation of fecal contamination in the source water of all GWSs. Because well conditions and sources of fecal contamination can change over time, EPA believes that the ongoing continuous assessment provided by triggered source water monitoring is important.

EPA believes that the triggered source water monitoring requirements of the GWR will effectively target higher risk GWSs. EPA's analysis indicates that the triggered source water monitoring provisions will identify nearly 40 percent of those wells with fecal contamination in their source water (See Chapter 6 of USEPA, 2006d). In addition, the wells with the highest frequencies of fecal contamination occurrence (which EPA believes are the highest risk wells from a public health perspective) will likely be captured first and wells with less frequent fecal contamination will be identified over time (USEPA, 2006d).

ii. Reduced burden for small systems. Under the final GWR, a GWS serving 1,000 people or fewer may use a TCR repeat sample to simultaneously meet requirements of the TCR and the GWR. Under the TCR, when a total coliform sample at a small system (serving 1,000 people or fewer) is positive, the TCR requires the system to collect four repeat samples (one upstream and proximate to the initial total coliform-positive, one at the same location, one downstream and proximate to the original total coliform-positive, and one at another unspecified location). If the State approves the use of *E. coli* as a fecal indicator for ground water source monitoring, the GWR allows these small systems to meet the repeat monitoring requirements of § 141.21(b) (TCR) by collecting their unspecified fourth repeat sample at the ground water source, thereby satisfying the GWR's triggered source water monitoring requirements for that ground water source at the same time. The purpose of this provision is to mitigate the triggered fecal indicator source water monitoring burden for small systems and to improve upon the diagnostic value of repeat sampling under the TCR.

The TCR repeat sample can be used for satisfying both the TCR repeat sample requirement and the initial source water fecal indicator under the GWR because the TCR methods and requirements provide the information necessary for complying with the GWR. If the repeat sample is negative for total coliform bacteria, then it is also negative for *E. coli* bacteria, and no further testing under the GWR is required. Under the TCR, if a repeat sample is positive for total coliform bacteria, the sample must then be further analyzed for the presence of either *E. coli* or fecal coliforms. If the sample is analyzed for *E. coli*, that will satisfy the GWR triggered monitoring requirements.

Total coliform bacteria are a group of bacteria that include *E. coli*. The methods approved for the analysis of the water samples taken under the TCR can be found at § 141.21. Most of these methods are also approved for *E. coli* monitoring under the GWR (see Table IV–1 and § 141.402(c)). The analytical methods approved for use under the TCR listed in Table IV–1 may all be used for both total coliform detection, and most can be used for subsequent *E. coli* detection under the GWR. Two of the methods approved under the TCR (and listed with an asterix in Table IV–1) can be used for total coliform detection only. In these two techniques (one of which is multiple tube fermentation and the other of which is membrane filtration using m-Endo medium), total coliforms are first cultured and confirmed. The laboratory analyst could then proceed to further analyze the total coliform-positive culture for either fecal coliforms or *E. coli* by simply choosing which subsequent medium to inoculate. Testing for fecal coliforms requires EC-Broth while testing for *E. coli* requires use of EC-MUG broth. These two broths are similar, and require the same incubation temperatures and conditions. The only difference between the two media is the addition of the substrate 4-methylumbelliferone-β-D-glucuronide (MUG) to EC Broth, which is added to detect *E. coli*. Thus, if the State has approved *E. coli* as the fecal indicator for the GWR, the *E. coli* sample analyzed under the TCR will meet the GWR source water sample requirements. For the TCR repeat sample, a PWS must collect a 100 mL water sample and analyze it for total coliform bacteria, and further analyze it for a fecal indicator if it is total coliform-positive. This means that small systems (serving 1,000 people or fewer) have no additional sampling burden or costs from the GWR triggered source water monitoring requirement for an initial source water sample.

TABLE IV–1.—METHODS APPROVED FOR DETECTION OF TOTAL COLIFORMS UNDER THE TCR AND FOR THE DETECTION OF *E. coli* UNDER THE GWR (SEE § 141.402(C) FOR DETAILS REGARDING THESE METHODS) **

Method technology type	Method	Total coliforms detected	E. coli detected	TCR/GWR approval
Multiple tube fermentation	(LTB/P–A → BGLB)*	X		X
	EC–MUG		X	X
	NA–MUG		X	X
Enzyme Substrate	Colilert/Colilert-18	X	X	X
	Colisure	X	X	X
	E* Colite Test	X	X	X
Membrane filtration	(m-Endo→LTB/BGLB)*	X		X
	EC–MUG		X	X
	MI Agar	X	X	X

TABLE IV–1.—METHODS APPROVED FOR DETECTION OF TOTAL COLIFORMS UNDER THE TCR AND FOR THE DETECTION OF *E. coli* UNDER THE GWR (SEE § 141.402(C) FOR DETAILS REGARDING THESE METHODS) **—Continued

Method technology type	Method	Total coliforms detected	E. coli detected	TCR/GWR approval
	m-ColiBlue 24 Test	X	X	X

* Methods in parentheses detect total coliforms but not *E. coli*; if a total coliform sample is determined by this method in the source water sample, the analyst can choose the appropriate inoculation medium to analyze for *E. coli*.

** If a total coliform sample is determined negative, no further testing under the GWR is required. If it is positive, the analyst can choose the appropriate *E. coli* method.

iii. Provision for total coliform-positive result directly related to the distribution system. EPA recognizes that some systems may have a known problem in their distribution system that causes total coliform-positive results. In cases when the cause of a total coliform-positive result collected under § 141.21(a) is directly related to the distribution system according to State criteria or a State determination, systems are not required to collect ground water source samples to investigate potential fecal contamination in the source water. A State must include in its primacy application the criteria it will use to determine whether the cause of a total coliform-positive sample collected under § 141.21(a) is directly related to the distribution system. Systems will use these criteria to determine if the cause of a total coliform-positive sample is directly related to the distribution system. If the sample meets the criteria, the system is not required to do triggered source water monitoring. The State needs to determine these criteria as part of their primacy package so that GWSs that collect a total coliform-positive sample can decide whether they need to collect a source water sample(s) within the required 24 hour timeframe. The system must document this determination to the State within 30 days so the State can ensure that the criteria are used correctly and that no potential public health risk from source water contamination has been overlooked. For issues not covered by the pre-determined criteria, the State can also make a determination that the cause of the total coliform-positive sample directly relates to the distribution system.

iv. Basis for additional fecal indicator sampling following triggered source water monitoring. Numerous public comments on the proposal expressed concern that a corrective action should not be required based on one source water indicator-positive sample, as EPA proposed for triggered source water monitoring. The rationale for the proposal was that the likelihood of a false positive result occurring in both the distribution system sample and the fecal indicator source water sample would be small, and therefore it would be likely that the source water positive result was caused by true contamination.

EPA has re-evaluated the use of repeat samples under the triggered source water monitoring provisions. Given that total coliform-positives in the distribution system can result from either distribution system or source water causes, a total coliform-positive in the distribution system does not necessarily predict fecal contamination of the source water. The possibility of false positives at the source and the associated potential for unnecessary follow-up corrective actions, even if relatively infrequent, prompted EPA to revise the final rule triggered source water monitoring provisions to require five additional samples following the initial positive sample before requiring corrective action (if one or more additional sample is positive), unless the State determines that immediate corrective action is necessary. In addition, the potential cost implications for a corrective action could be substantial, especially for small systems.

EPA believes that in most cases these five additional samples should capture the fecal contamination event since the samples are taken within 24 hours. Discrete contamination releases, such as fecal septage, together with discrete precipitation events, become dispersed by hydrogeological processes over time. As a result, shorter duration events at the original contamination source may become longer duration (*i.e.*, days or weeks) but more diluted events at the well. Thus, if an initial fecal indicator-positive is detected at the well, that occurrence should be detectable again with additional samples within 24 hours. Nevertheless, since the nature and source of contamination and the subsurface condition vary from site to site, prompt resampling within 24 hours is needed to capture events that may not be dispersed over time. Prompt resampling is particularly important in cases where the initial sampling event transpires at the tail-end of the well contamination event.

b. *Assessment source water monitoring.* As a complement to the triggered source water monitoring provision, States have the option of requiring systems to conduct assessment source water monitoring. This flexible provision gives States the opportunity to target higher risk systems for additional source water monitoring and require corrective action, if necessary. EPA decided not to include requirements for assessment source water monitoring in the GWR for the reasons given in Section II.C of the preamble. Rather, EPA decided to give States flexibility to require assessment source water monitoring on a case-by-case basis. The purpose for this optional source water monitoring provision is to target systems that the States believe are at high risk from fecal contamination for a thorough evaluation of source water quality. Also, this allows lower risk GWSs to avoid unnecessary sampling (as determined by States).

While EPA believes that triggered source water monitoring will capture many high risk systems, EPA also recognizes that the triggered source water monitoring provisions have limitations. Triggered source water monitoring under the TCR may not be timely (soon enough) or frequent enough to identify systems with intermittent fecal contamination. Also, coliforms are not a good indicator in certain aquifers in which viruses travel faster and further than bacteria. EPA believes that assessment source water monitoring can be an important complement to triggered source water monitoring because assessment source water monitoring provides a thorough examination of the source water at those systems that States deem to be at potentially high risk from fecal contamination. The flexibility of this requirement allows States to require assessment source water monitoring when and where it is needed most. Source water quality can change over time, so it is important for States to be

able to use assessment source water monitoring at any point in time. State programs work closely with PWSs on a daily basis and are thus knowledgeable about system specific conditions and issues. Therefore, EPA believes that the States are in the best position to assess for which systems the thorough evaluation of source water quality provided by assessment source water monitoring is most appropriate. EPA believes that assessment source water monitoring programs within the States' discretion will be important to identify fecally contaminated systems for which corrective action is necessary to protect public health. EPA expects that States may use assessment source water monitoring for high-risk systems that are potentially susceptible to fecal contamination, especially where contamination is often present but intermittent enough to be missed by triggered source water monitoring.

i. EPA's recommendations for targeting systems for assessment source water monitoring. Information on a system's potential susceptibility to fecal contamination is available to the States from many sources. For example, HSAs, source water assessments, wellhead protection plans, past microbial monitoring data particularly triggered source water monitoring results and frequency, and sanitary survey findings are available to States. In addition to these sources of information, EPA recommends that States consider the following risk factors in targeting susceptible systems for assessment source water monitoring: (1) High population density combined with on-site wastewater treatment systems, particularly those in aquifers with restricted geographic extent, such as barrier island sand aquifers; (2) aquifers in which viruses may travel faster and further than bacteria (*e.g.* alluvial or coastal plain sand aquifers); (3) shallow unconfined aquifers; (4) aquifers with thin or absent soil cover; (5) wells previously identified as having been fecally contaminated; and (6) sensitive aquifers. These factors are described in more detail below.

Some localities may be at high risk because they serve large, sometimes seasonal, populations in areas without centralized sewage treatment and their aquifers are of restricted geographic extent, such as barrier island sand aquifers and Great Lakes island karst limestone aquifers. In these locations, the large population using septic tanks can overload the subsurface attenuation capability. Outbreaks have occurred in such resort communities (*e.g.*, South Bass Island, OH, Ohio EPA, 2005, CDC, 2005; Drummond Island, MI, Ground Water Education in Michigan, 1992; Chippewa County Health Department, unpublished report, 1992) due to overloaded septic tanks.

Viruses travel faster and further than bacteria in some aquifers. In barrier island sand aquifers, traditional bacterial fecal indicator organisms such as total coliform and *E. coli* may not be mobile or sufficiently long-lived in the subsurface so as to adequately indicate the hazard from longer-lived and more mobile viral pathogens. Thus, a system could have fecal contamination and yet not be triggered for source water monitoring by TCR monitoring results. In such cases, assessment source water monitoring using coliphage would be the best means for identifying fecal contaminants because coliphage is a viral fecal indicator and thus is more likely to reach the well than bacterial indicators such as *E. coli* and enterococci.

Shallow, unconfined aquifers are high risk because the vertical flow path to the aquifer is short and unrestricted by barriers. Pathogens originate at or near the surface and may be more likely to contaminate well water when the travel time for infiltrating precipitation is short and unhindered.

Wells previously identified as having been fecally contaminated should be considered high risk because such fecal contamination can reoccur. For example, wells in this category may include wells associated with a previous acute TCR violation related to the source or those wells that had an initial fecal indicator-positive triggered source water sample but had five negative additional samples (especially wells with highly variable source water such as those in sensitive aquifers). Wells with highly variable source water may be subject to occasional short-lived contamination events. Thus it is possible to have a true fecal indicator-positive sample followed by true fecal indicator-negative samples. Exposures during intermittent contamination events can be significant, so it is important to identify such high-risk systems. This is best accomplished through a thorough source water evaluation program such as assessment source water monitoring.

Sensitive aquifers (*e.g.*, karst, fractured bedrock, or gravel) can have fast (kilometers per day) and direct ground water flow through large interconnected openings (void spaces) during which very little pathogen attenuation may occur (either by natural inactivation or attachment) between a fecal source of contamination and the well. Consequently, sensitive aquifers are efficient at transmitting pathogens, if present, from surface and near-surface sources to PWS wells. Ground water flow in non-sensitive aquifers (such as a sand aquifer) tends to be very slow (feet per day), takes a very indirect path around a very large number of sand grains, and provides more opportunities for pathogen die-off and attachment. The faster flow travel time within a sensitive, as opposed to a non-sensitive, aquifer enables a much larger contaminant plume from potential fecal contamination events (*e.g.*, failing septic systems or a leaking sewer line).

When ground water flow is fast and direct as in sensitive aquifers, contamination can be short and intermittent and difficult to capture. The frequency by which triggered source water monitoring is prompted via detection of a total coliform-positive sample under the TCR may not be timely enough to recognize that a well is at risk from fecal contamination. First, TCR monitoring at some systems is infrequent. Small systems conduct limited total coliform monitoring in the distribution system under the TCR and thus intermittent fecal contamination of the source could be missed (*i.e.*, these systems may conduct triggered source water monitoring infrequently under the GWR). Second, the lag time between an initial fecal contamination event and total coliform presence in the distribution system may be several days. Thus, if the fecal contamination event is of short duration, triggered source water monitoring may not capture the initial event.

Some of the largest reported waterborne disease outbreaks in GWSs have occurred among systems drawing water from sensitive aquifers. Table IV–2 provides a summary of recent outbreaks reported in sensitive aquifers. The number and nature of recent waterborne outbreaks shown in the table suggest that additional measures are necessary to protect those consuming water from PWS wells in sensitive aquifers. Noteworthy among these outbreaks is the South Bass Island, Ohio outbreak. After that outbreak in 2004, 16 of the 18 TNCWSs on South Bass Island tested positive for fecal indicator organisms (Ohio EPA, 2005; CDC, 2005). Thus, the monitoring protections offered by the TCR were inadequate to protect the community from experiencing a waterborne disease outbreak in this karst limestone aquifer.

TABLE IV–2.—RECENT WATERBORNE DISEASE OUTBREAKS (PWSS) REPORTED IN KARST LIMESTONE AND FRACTURED BEDROCK (SENSITIVE) AQUIFERS

Location	Reference	Number of illnesses/agent
Outbreaks in Karst Limestone Aquifers		
South Bass Island, OH	Ohio EPA, 2005; CDC, 2005	1,450/Norovirus, *Campylobacter, Salmonella.*
Walkerton, Ontario, Canada	Health Canada, 2000; Bopp *et al.*, 2003; Worthington *et al.*, 2002.	1,346 cases/*E. coli* O157:H7 (+ *Campylobacter*); 7 deaths.
Brushy Creek, TX	Bergmire-Sweat *et al.*, 1999; Lee *et al.*, 2001	1,300–1,500 cases/*Cryptosporidium* (not recognized as GWUDI until after the outbreak).
Reading, PA	Moore *et al.*, 1993	551 cases/*Cryptosporidium* (not recognized as GWUDI until after the outbreak).
Racine, MO	MO Department of Health, unpublished report, 1992.	28 cases/HAV.
Drummond Island, MI	Ground Water Education in Michigan, 1992; Chippewa County Health Department, unpublished report, 1992.	39 cases/Unknown.
Cabool, MO	Swerdlow *et al.*, 1992	243 cases/E. coli O157:H7; 4 deaths.
Outbreaks in Fractured Bedrock Aquifers		
Big Horn Lodge, WY	Anderson *et al.*, 2003	35/Norovirus.
Atlantic City, WY	Parshionikar *et al.*, 2003	84/Norovirus.
Couer d'Alene, ID	Rice *et al.*, 1999	117/Arcobacter butzleri.
Island Park, ID	CDC, 1996	82 cases/Shigella.
Northern AZ	Lawson *et al.*, 1991	900 cases/Norwalk virus.

Where the type of aquifer is unknown, EPA recommends that the State conduct an HSA to identify sensitive aquifers and to determine if assessment source water monitoring is appropriate. In sensitive aquifers, more frequent monitoring could more quickly identify wells with fecal contamination. EPA recommends that States use HSAs as a tool to determine at-risk GWSs, and EPA intends to provide guidance on how to conduct HSAs.

Several means can be used to evaluate wells without site-specific inspections to determine if they are located in sensitive hydrogeologic settings. For example, hydrogeologic data are available from published and unpublished materials such as maps, reports, and well logs. As discussed in more detail in the GWR proposal (USEPA, 2000a), the United States Geologic Survey (USGS), U.S. Department of Agriculture's Natural Resource Conservation Service, USGS Earth Resources Observation System Data Center, the EPA Source Water Assessment Program and Wellhead Protection Program, State geological surveys, and universities have substantial amounts of regional site-specific information. States can also base assessments on available information about the character of the regional geology, regional maps, and rock outcrop studies.

In summary, HSAs can be an effective screening tool for identifying GWSs susceptible to fecal contamination for which assessment source water monitoring would be appropriate and beneficial.

ii. EPA's recommendations for assessment source water monitoring program. EPA recommends that States require systems that are conducting assessment source water monitoring to collect a total of 12 ground water source samples that represent each month the system provides ground water to the public. The 12 sample minimum is based on several considerations:

- The sampling frequency should consider diminishing returns on the effectiveness of identifying fecally contaminated wells;
- The sampling should be frequent enough to capture a range of conditions that can vary over the course of a year; and
- The sampling frequency should consider ground water source monitoring costs incurred by GWSs.

EPA estimates that about 26 percent of all wells have *E. coli* occurrence at some time, but the periods of such contamination may be very short and thus difficult to detect by the triggered source water monitoring requirements for some systems. With 12 assessment ground water source samples alone (*i.e.*, absent any triggered source water monitoring), at least half of the wells with sometime *E. coli* contamination would be expected to test positive at least once. Table IV–3 shows that as sampling frequency increases above 12 samples, the ability to identify additional wells that have *E. coli* presence rises more slowly and that relatively smaller percentages of additional wells with *E. coli* are identified per additional sample assay. This table shows that the sampling with 12 assays (*i.e.*, tests) captures 52 percent of the wells with sometime *E. coli* contamination, but sampling with 24 assays only captures an additional nine percent.

TABLE IV–3.—NUMBER OF *E. coli* ASSAYS AND PERCENT CONTAMINATED WELLS IDENTIFIED

Number of assays (N)	Fraction identified (Mean in percent)
3	28
6	40
12	52
24	61
36	65
48	68
60	70

The wells that the assessment source water monitoring identifies as contaminated tend to be those that have frequent occurrence of *E. coli*. Those wells with highly infrequent *E. coli* occurrence would be difficult to capture even with a significant increase in number of samples because the overall period of time of indicator occurrence is small relative to when the sampling occurs.

Considering the costs of additional assays (beyond 12 assessment ground water source samples) and the reduced efficiency at identifying additional

contaminated wells, EPA believes that 12 assays are appropriate.

EPA recommends that the assessment source water monitoring program be representative of the system's typical operation. Using a minimum of 12 samples for assessment source water monitoring would also ensure sampling for each month that most systems are in operation, which is important because of the impact that seasonal events can have on contamination (*e.g.*, heavy rain events). For seasonal systems, EPA recommends equally distributing 12 samples or sampling during consecutive years.

The option under the GWR for States to specify assessment source water monitoring requirements allows States to initiate a more thorough source water monitoring program than that resulting from the triggered source water monitoring provisions alone on a case-by-case basis, as deemed appropriate. For example, a sanitary survey may indicate that there has been a recent development of added source water vulnerability that would warrant additional source water sampling to discern whether there is potential fecal contamination beyond that which would be triggered through the TCR. Additionally, belated recognition of the significance of karst limestone after an outbreak (*e.g.*, Walkerton, Ontario; South Bass Island, Ohio) suggests that States may choose to specify identification of sensitive aquifers combined with assessment source water monitoring to enhance multi-barrier protection.

c. *Source Water Samples*

i. Source water microbial indicators. The final GWR requires GWSs that are performing triggered source water monitoring to monitor their ground water source(s) for one of three fecal indicators (*E. coli*, enterococci, or coliphage). The State must specify which fecal indicator the GWSs must test for in their ground water source(s). EPA recommends that States use these same requirements for GWSs performing assessment source water monitoring.

In this rule, EPA is authorizing the use of *E. coli* and enterococci as bacterial indicators of fecal contamination. Both of these indicators are closely associated with fresh fecal contamination and are found in high concentrations in sewage and septage. Approved analytical methods for these indicators are commercially available, simple, reliable, and inexpensive. *E. coli* is monitored under the TCR and therefore GWSs are familiar with its measurement and interpretation. Enterococci are recommended as one of the indicators for fecally contaminated recreational waters and therefore have widespread use. Enterococci may be a more sensitive fecal indicator than *E. coli* in certain aquifer settings and therefore may be the preferred indicator in such locations.

EPA is also authorizing the use of coliphage as a viral indicator of fecal contamination. Coliphage are viruses that infect the bacterium *E. coli*. They are closely associated with fecal contamination because they do not tend to infect other non-fecal bacteria. Because they are viruses, their stability and transport through soil and certain aquifer types are similar to the fate and transport of pathogenic viruses. There are two categories of coliphage—somatic coliphage and male-specific coliphage. Local knowledge of hydrogeological conditions may inform which of the indicators may be most effective for identifying fecal contamination (USEPA, 2006b). EPA plans to publish a guidance manual to help to inform such decisions. This rule gives States the discretion to specify use of *E. coli*, enterococci, or one of the coliphage types to monitor for potential presence of fecal contamination in ground water sources.

ii. Basis for requiring one versus more than one fecal indicator. EPA's Science Advisory Board (SAB) and the National Drinking Water Advisory Council (NDWAC) recommended that EPA require monitoring for coliphage *and* either *E. coli* or enterococci for source water monitoring. The reasons stated by SAB and NDWAC were that (1) Ground water occurrence data show that no single indicator can fully capture all fecal contamination, (2) coliphage is an important indicator of enteric virus contamination in terms of transport and survival characteristics, and (3) a significant portion of waterborne disease risk is associated with exposure to pathogenic viruses in ground water sources utilized by a subset of PWSs (USEPA, 2000h and 2000i).

EPA had insufficient data to evaluate the effectiveness, on a national level, of using both coliphage and either *E. coli* or enterococci as source water indicators of fecal contamination. While coliphage data is available for many of the occurrence studies used to estimate national occurrence for *E. coli*, the methods used to measure coliphage are often based on high volume analysis and a variety of methods different than those specified under the final GWR. Thus, EPA could not determine whether SAB's proposal would provide additional effectiveness.

EPA is concerned with the potential increase in sampling burden relative to the additional number of fecally contaminated wells that would be identified using two indicators compared to the use of one indicator. The analytical cost for coliphage (viral fecal indicator) monitoring is estimated to be about two to three times the cost for bacterial fecal indicator monitoring. Therefore, requiring a GWS to monitor for both bacterial and viral fecal indicators would more than double the analytical costs for GWSs. Based on the limited data available, EPA believes that it is not reasonable to require all GWSs to monitor for both a bacterial and a coliphage indicator in their source water.

EPA believes that the most appropriate indicator may vary from State to State or site to site. This may be due to regional or site-specific differences or other reasons that may be identified by the State. EPA intends to provide guidance on how to determine which indicator may be most appropriate to use.

For the reasons discussed above, EPA believes that the use of a single fecal indicator (*E. coli*, enterococci, or coliphage) provides a cost-effective means for identifying fecally contaminated wells and protecting public health.

iii. Sample volume and analytical methods. This rule requires GWSs performing triggered source water monitoring to collect and test at least a 100 mL sample volume. EPA recommends that States use this requirement for assessment source water monitoring. The final GWR requires a minimum sample volume of 100 mL because most utilities are familiar with this sample volume for bacterial indicator analysis, and the two EPA approved coliphage methods include at least this volume in their procedures. EPA believes that specifying a higher minimum sample volume would unduly increase the cost per sample (especially due to shipping). Furthermore, if a higher minimum sample volume were specified in the GWR, small systems would not be able to realize the considerable monitoring cost savings from use of TCR repeat sampling previously discussed in Section IV.B.2.a.ii.

With regard to analytical methods used for ground water source monitoring under this rule, four of the seven methods for the analysis of *E. coli* in source waters allowed under this rule are consensus methods described in *Standard Methods for the Examination of Water and Wastewater* (20th editions) (APHA, 1998). The three *E. coli* methods that are not consensus methods are as follows: MI agar (a membrane filter method), the ColiBlue 24 test (a

membrane filter method), and the E*Colite test (a defined dehydrated medium to which water is added). EPA has already evaluated and approved these three methods for use under the TCR. In the proposed rule § 141.403(d), footnotes 4 and 5, the use of MI agar with Membrane Filtration Method was allowed. Membrane Filtration Method is an EPA-approved drinking water method, as indicated in footnote 4, while footnote 5 cites a manuscript describing MI agar. Subsequent to the proposal of the GWR, EPA developed EPA method 1604 ''Total Coliforms and *Escherichia coli* in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium)'' (USEPA, 2002c). This method was created to ensure consistency with other EPA microbiological methods and was promulgated under the Clean Water Act for use in ambient water monitoring July 21, 2003 (68 FR 43272–43283) at 40 CFR 136.3, Table 1A, footnote 22. Method 1604 is equivalent to both the manuscript and the EPA-approved Membrane Filtration Method, and EPA has indicated in Section 5.4.2.1.3 of the *Manual for the Certification of Laboratories Analyzing Drinking Water* (USEPA, 2005b) that Method 1604 is identical. EPA Method 1604 is available on the EPA Web site at *http://www.epa.gov/microbes*. This rule allows EPA Method 1604 because the Agency believes it will be easily available to the public.

Three enterococci methods for the analysis of source water are allowed under this rule; two of these are consensus methods in *Standard Methods* (APHA, 1998), and the third (Enterolert) was published in a peer-reviewed journal article (Budnick *et al.*, 1996). The description for each of the *E. coli* and enterococci methods explicitly states that the method is appropriate for fresh waters or drinking waters. The proposed rule, § 141.403(d), footnote 8 of the table, also proposed to allow EPA Method 1600 (USEPA, 1997d) as an approved variation of one of the two consensus methods, *Standard Method* 9230C, for enterococci. However, subsequent to the proposal of the GWR, EPA slightly modified EPA Method 1600 (USEPA, 2002a) and promulgated the new version under the Clean Water Act on July 21, 2003 (68 FR 43272–43283), at § 136.3, Table 1A, Footnote 25. The revised method replaced the 1997 version on the EPA Web site (*http://www.epa.gov/microbes*). EPA does not regard the changes in the newer version of Method 1600 as substantive and, aside from changes in format, contact, and grammar, has indicated the differences between the two versions in a memo dated March 12, 2004 that is included in the Water Docket for the GWR. This rule allows the more recent version of EPA Method 1600 because, and in addition to a few updates and more clarifications, the Agency believes that it will be much more easily available to the public.

EPA proposed to allow, and continues to allow under this rule, the use of the two coliphage methods, U.S. EPA Methods 1601 and 1602 (USEPA, 2001a, 2001b), for source water testing—a new two-step enrichment method (Method 1601) and a single-agar layer method (Method 1602) recently optimized for ground water samples. These methods have been round-robin tested (USEPA, 2003a and b) and the Agency has also conducted performance studies, using 10 laboratories, on the two proposed methods. A full report of each of the two performance studies is available in the Water Docket. They are entitled (1) *Results of the Interlaboratory Validation of EPA Method 1601 for Presence/Absence of Male-specific (F+) and Somatic Coliphage in Water by Two-Step Enrichment* (USEPA, 2003a), and (2) *Results of the Interlaboratory Validation of EPA Method 1602 for Enumeration of Male-specific (F+) and Somatic Coliphage in Water by Single Agar Layer* (SAL) (USEPA, 2003b).

With regard to method cost, EPA queried seven laboratories that participated in the round-robin performance testing of the proposed coliphage tests. Based upon this survey, EPA estimates that the coliphage tests (not including sampling or shipping costs) will cost about $59–$65 per test (DynCorp, 2000). This compares to about $20–25 for bacterial indicators.

iv. Invalidation of a fecal indicator-positive ground water source sample. This rule allows the State to invalidate a fecal indicator-positive triggered source water monitoring sample if the system provides the State with written notice from the laboratory that improper sample analysis occurred, or if the State determines and documents in writing that there is substantial evidence that a fecal indicator-positive ground water source sample is not related to source water quality. These provisions are consistent with the sample invalidation criteria under the TCR and provide a necessary flexibility to States.

3. What Were the Key Issues Raised by Commenters on the Proposed GWR Source Water Monitoring Requirements?

a. *Triggered source water monitoring.*

i. Use of total coliform-positive result as a trigger for source water fecal indicator monitoring. Many commenters maintained that a single total coliform-positive sample was too sensitive of a trigger to prompt a requirement to collect a ground water source sample. Among their reasons were that a single total coliform-positive sample in the distribution system is not necessarily linked to any source water problem or even a public health risk. Some argued that other triggers were more suitable, such as an acute MCL violation or a non-acute MCL violation under the TCR. A number of commenters were opposed to triggered source water monitoring altogether.

As discussed in Section IV.B.2, EPA believes that triggered source water monitoring is an important requirement to protect public health. In response to commenters' concerns that a single total coliform-positive sample in the distribution system is not necessarily linked to any source water problem, EPA has added language in the final GWR that allows States to determine that the cause of a total coliform-positive collected under § 141.21(a) is directly related to the distribution system and will thus not be a trigger for fecal indicator source water monitoring. Because the time available to make the determination is short, the State may develop criteria for systems to use to make the determination, which would be followed by a report to the State.

Unless clearly indicated otherwise, EPA believes that a total coliform-positive sample in the distribution system is an indication of potential microbial contamination of the GWS that may have originated from the ground water source. This is a potentially serious public health risk that warrants follow-up action.

EPA believes that basing triggered source water monitoring on TCR MCL violations would not be sensitive enough to identify the majority of fecal contamination events at the source. EPA estimated that the percentage of fecally contaminated wells that would be identified under such a provision would be an order of magnitude less than under the requirements of the final rule. Consequently, EPA believes that such a requirement would not be adequately protective.

ii. Consecutive system and wholesale system requirements. EPA requested comment on which GWR requirements should apply to consecutive systems and specifically who should be responsible for triggered source water monitoring after a total coliform-positive sample is found in the consecutive system's distribution system. Many commenters recommended that the seller (or wholesale) system be responsible for

ground water source monitoring, not the consecutive system. Others suggested the State should decide which system should take the ground water source sample. In addition, some commenters maintained that the buyer (or consecutive) system should not be responsible for meeting the treatment technique requirements (*e.g.*, 4-log treatment) for sources.

EPA infers that some commenters based their comments on an understanding that consecutive systems were only systems that received all their finished water from a wholesale system, although that is not always correct. Since the GWR proposal, EPA defined ''consecutive system'' and ''wholesale system'' in § 141.2 in the Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR) (71 FR 388, January 4, 2006) (USEPA, 2006g). In those definitions, which apply to all requirements in 40 CFR Part 141 (including the GWR), EPA specified and clarified that consecutive systems include both systems that receive all of their finished water from one or more wholesale systems and systems that receive some of their finished water from one or more wholesale systems (with the balance coming from a source or sources operated and treated, as necessary, by the consecutive system).

The Agency has added requirements to clarify the responsibilities of consecutive and wholesale systems in response to comments received, and to facilitate implementation and compliance. EPA believes that public health and risk concerns underlying the requirement for triggered ground water source monitoring after a total coliform-positive sample are equally applicable to consecutive systems and wholesale systems. EPA also believes that the system that operates the ground water source should be responsible for any required triggered or assessment source water monitoring and any required corrective actions, including 4-log treatment installation, operation, and compliance monitoring.

Without treatment, water quality problems in the wholesale system will remain in the water delivered to the consecutive system and thus water quality problems in the consecutive system may be related to problems in the wholesale system (even if the wholesale system has not identified the problems). Therefore, in the GWR, specific triggered source water monitoring requirements apply to consecutive systems and wholesale systems (as explained in the following paragraphs) unless the cause of the total coliform-positive collected under § 141.21(a) directly relates to the distribution system as determined by the system according to State criteria, or as determined by the State.

Consecutive systems that have a total coliform-positive sample must notify the wholesale system(s) within 24 hours of being notified of the total coliform-positive sample so that the wholesale system(s) can conduct triggered source water monitoring, since the wholesale system's source water may be the cause. Also, a consecutive system with its own ground water source(s) that has a total coliform-positive sample under the TCR must conduct triggered source water monitoring of its own sources, just like any other GWS that must conduct triggered source water monitoring. A consecutive system that has no source of its own (*i.e.*, it receives all of its finished water from one or more wholesale systems) is not required to conduct triggered source water monitoring, since it has no source water. Only systems that produce finished ground water (*i.e.*, have their own sources) are required to conduct triggered source water monitoring.

Consecutive systems are required to comply with the GWR treatment technique requirements only in cases of contamination in the consecutive system's own ground water source. Consecutive systems are not required to comply with GWR treatment technique requirements if a fecal indicator-positive is detected only in the wholesale system's ground water source; only the system with the source contamination must comply with the GWR treatment technique requirements (in this case, the wholesale system). Similarly, wholesale systems are not required to comply with GWR treatment technique requirements if a fecal indicator-positive is detected only in the consecutive system's ground water source and not in the wholesale system's source; again, only the system with the source contamination must comply with the GWR treatment technique requirements (in this case, the consecutive system).

iii. Repeat samples to confirm initial fecal indicator-positive. Several commenters raised concerns that a single positive fecal indicator source water sample should not result in a corrective action because the indicator sample result may be a false positive. The same commenters recommended that repeat samples be taken to confirm the initial result before requiring corrective action. In response to commenters and based on the discussion in Section IV.B.2, unless the State determines that corrective action should be taken following an initial fecal indicator-positive source water sample, the final GWR requires that the GWS take five additional samples, and that only if one of those samples is fecal indicator-positive is corrective action required. This prevents systems from incurring costs from the application of unnecessary corrective actions. The State may require the system to take corrective action after the first fecal indicator-positive source water sample.

EPA believes that five additional samples following a positive triggered source water monitoring sample provides a reasonable balance between ensuring that corrective actions are warranted, avoiding excessive re-sampling costs, and avoiding an incorrect conclusion that the initial positive was false (*i.e.*, avoiding a situation in which corrective action is needed but not taken because of false re-sample results). EPA believes that multiple samples, rather than one, are needed to ensure that corrective action is taken when necessary. EPA proposed using five repeat samples under the routine monitoring provisions (65 FR 30230) (USEPA, 2000a). Commenters wanted EPA to use repeat samples for the triggered monitoring provisions also because they were concerned about false positives and systems taking unnecessary corrective actions. They recommended four or five repeat samples for triggered monitoring. In response to comments, the final GWR requires five repeat samples under the triggered source water monitoring provisions.

iv. Source water monitoring burden. In the final GWR, EPA has reduced the sampling burden for small systems serving 1,000 people or fewer. Under the TCR, a system that collects one or fewer routine samples per month (systems that serve 1,000 people or fewer) with a total coliform-positive sample (that has not been invalidated) is already required to collect a set of four repeat samples in the distribution system within 24 hours of the total coliform-positive sample. Under this rule, one of the four repeat samples required under the TCR may be used to satisfy the GWR source water monitoring requirements if the sample is taken at a ground water source and only if the State approves the use of *E. coli* as a fecal indicator.

In addition, the final rule reduces sampling burden for systems with more than one well (*e.g.*, many large systems). Based on comments received, the GWR provides flexibility for systems with more than one well. The triggered source water monitoring provision allows systems with more than one ground water source, upon State approval, to sample a representative ground water source (or sources)

following any total coliform-positive sample. The State may require systems with more than one ground water source to submit for approval a triggered source water monitoring plan that the system will use for representative sampling. EPA believes that this alternative can be as protective of public health as monitoring all wellheads, provided that the chosen wells are truly representative of all wellheads. In addition, for situations where a particular sample site is inaccessible, the State may identify an alternate sampling site that is representative of the water quality of the ground water at the inaccessible sample site.

b. *Routine Monitoring.* Many comments regarding routine source water monitoring were related to HSAs. Many commenters suggested State discretion on which systems should be considered sensitive and thus be required to do routine monitoring.

EPA has taken public comments on routine monitoring and HSAs into consideration, as discussed in Section II.C. The final GWR provides State the option to require assessment source water monitoring at GWSs that the State determines to be most susceptible to fecal contamination. EPA believes that this optional provision is an important tool that should be used by States to protect public health.

EPA recommends HSAs as one way to identify higher risk systems for which assessment source water monitoring would be beneficial and appropriate. Based on comments received, the final GWR does not require HSAs or assessment source water monitoring, except as provided by the State (see Section II.C).

c. *Source water microbial indicators and analytical methods.* This rule allows a State to direct a system to use *E. coli*, enterococci, or coliphage for ground water source monitoring. Regarding coliphage testing, one major issue raised by commenters pertained to the performance of the two proposed coliphage methods. Many commenters questioned method reliability, specificity, sensitivity, false-positive rates, and lack of comprehensive field testing. They were also concerned about analytical costs and the availability of laboratory capacity. As explained earlier, the Agency believes that the results of performance studies indicate that both methods have been validated for reliable use in drinking water contexts. As discussed in Section IV.B.2, EPA recognizes that the analytical costs for coliphage testing are more than double the cost for bacterial (*E. coli* and enterococci) analyses. Therefore, EPA believes that many States will specify a bacterial fecal indicator for GWR source water monitoring based on cost. However, the Agency allows coliphage testing in this rule due to awareness that some laboratories are proficient in coliphage analysis and that this indicator may be preferred over others, depending on site-specific knowledge. While EPA recognizes that limited laboratory capacity for coliphage testing may be an issue, this rule provides States with discretion in determining which fecal indicators (*E. coli*, enterococci, or coliphage) will be used. EPA expects that one of the factors that States may use to decide which fecal indicator to specify is laboratory capacity.

C. Corrective Action Treatment Techniques for Systems With Significant Deficiencies or Source Water Fecal Contamination

The final GWR provides for regular, comprehensive sanitary surveys of all GWSs and triggered source water and optional assessment source water monitoring to determine at-risk GWSs. This rule requires the subset of systems with sanitary survey significant deficiencies or source water fecal contamination to complete corrective actions in a timely manner to ensure public health protection. Failure to complete corrective actions within 120 days, including meeting deadlines for interim actions and measures, or comply with a State-approved corrective action plan and schedule, constitutes a treatment technique violation under this rule.

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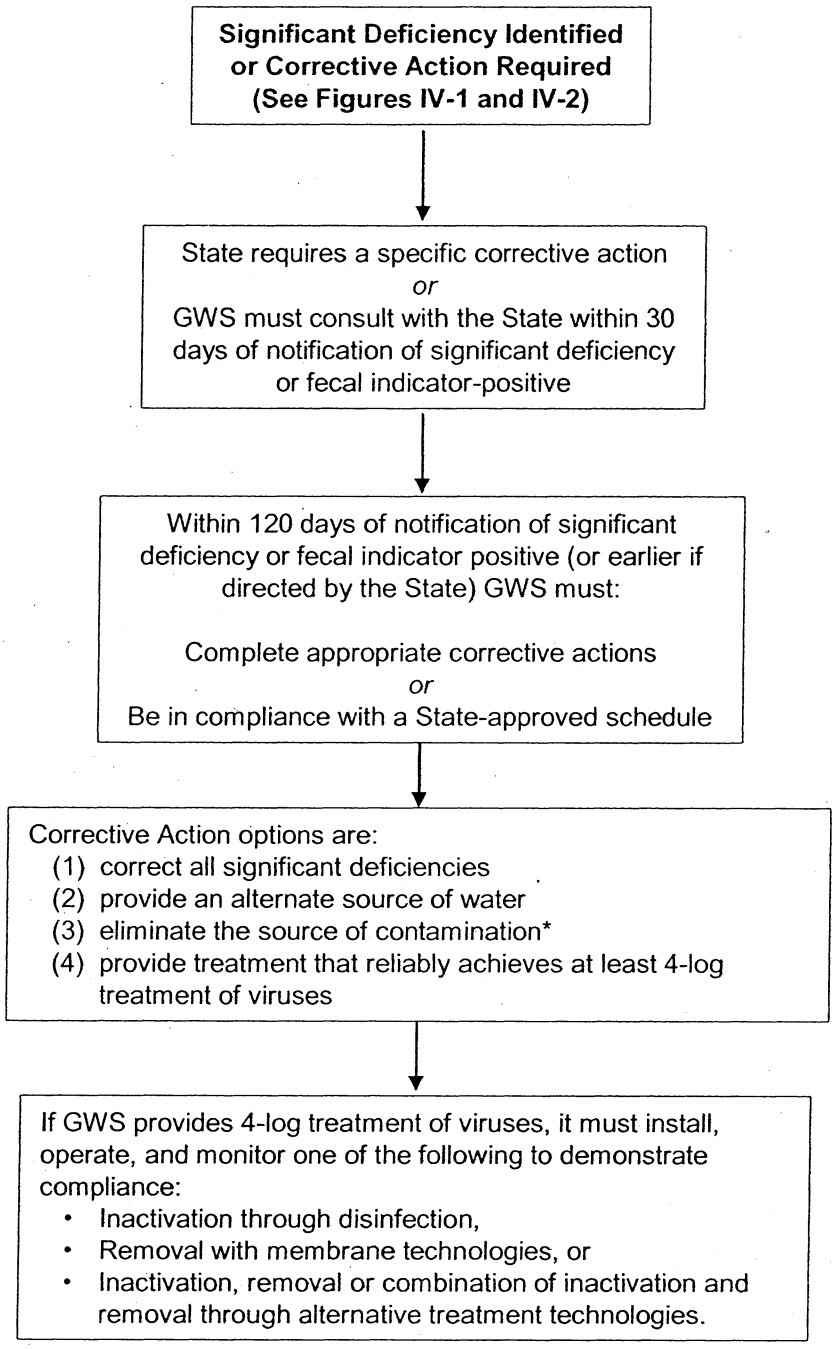
Figure IV-3: Corrective Action Treatment Technique Requirements



* If the State and GWS cannot determine the cause of the source water contamination, and the State determines based on follow-up monitoring or other evidence that the contamination is unlikely to occur again, the State may determine that the source of contamination has been eliminated.

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1. What Are the Requirements of This Rule?

When a system has a significant deficiency, it must consult with the State regarding appropriate corrective action within 30 days of receiving a written notice of the significant deficiency. When a system receives a written notice from a laboratory indicating a fecal indicator positive result in one of the five additional triggered source water monitoring samples, the system must consult with the State regarding appropriate corrective action. When a system receives a written notice from a laboratory indicating a fecal indicator

positive result and the State has determined that corrective action is necessary, the system must consult with the State regarding appropriate corrective action. Consultation must take place within 30 days. In any event, the State may specify corrective action without consultation. In the consultation process, the State may approve and/or modify corrective actions and completion schedules proposed by the system, or the State may specify alternatives. The State may also specify interim corrective action measures.

The GWR rule requires that within 120 days (or earlier if directed by the State) of receiving the notification from the State or laboratory described in the preceding paragraph, the GWS must either (i) Complete appropriate corrective actions in accordance with applicable State plan review processes or other State guidance or direction, or (ii) be in compliance with a State-approved corrective action plan and schedule. If a system is unable to complete corrective action within 120 days or on the schedule specified by the State, then the system is in violation of the treatment technique requirement.

Systems must notify the State within 30 days of completing any State approved or specified corrective action. As a condition of primacy, States must verify that the corrective action has been completed within the next 30 days. States may verify that the corrective action has been completed and has successfully addressed the significant deficiency and/or fecal contamination in the ground water source either by a site visit or by written documentation from the system, which could consist of the system's notification to the State.

a. *What corrective action alternatives are provided for in this rule?* When a system has a significant deficiency or a fecal indicator-positive ground water source sample (either by the initial triggered sample, or positive additional sample, as determined by the State), the GWS must implement one or more of the following corrective action options: (1) Correct all significant deficiencies (*e.g.*, repairs to well pads and sanitary seals, repairs to piping tanks and treatment equipment, control of cross-connections); (2) provide an alternate source of water (*e.g.*, new well, connection to another PWS); (3) eliminate the source of contamination (*e.g.*, remove point sources, relocate pipelines and waste disposal, redirect drainage or run-off, provide or fix existing fencing or housing of the wellhead); or (4) provide treatment that reliably achieves at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for each ground water source requiring corrective action.

b. *Compliance monitoring for systems providing at least 4-log treatment of viruses.* This rule also establishes compliance monitoring requirements for GWSs that provide at least 4-log treatment of viruses as a corrective action. This rule also establishes compliance monitoring requirements for those systems that have notified the State that they provide at least 4-log treatment of viruses for their ground water sources before the first customer and are therefore not required to meet the triggered source water monitoring requirement of this rule.

Treatment technologies capable of providing at least a 4-log treatment of viruses include the following:

- Inactivation, with a sufficient disinfection concentration and contact time, through disinfection with chlorine, chlorine dioxide, ozone, or through anodic oxidation. Disinfectant concentration and contact time (CT) can be based on existing CT tables (USEPA, 1991) or State-approved alternatives.
- Removal with membrane technologies with an absolute molecular weight cut-off (MWCO), or an alternate parameter that describes the exclusion characteristics of the membrane, that can reliably achieve at least a 4-log removal of viruses.
- Inactivation, removal or combination of inactivation and removal through alternative treatment technologies (*e.g.*, ultraviolet radiation (UV)) approved by the State, if the alternative treatment technology, alone or in combination (*e.g.*, UV with filtration, chlorination with filtration), can reliably provide at least 4-log treatment of viruses.

Under this rule, systems providing 4-log treatment of viruses using chemical disinfection must monitor for and must meet and maintain a State-determined residual disinfectant concentration (*e.g.*, 4-log inactivation of viruses based on CT tables) or State-approved alternatives every day the GWS serves from the ground water source to the public.

Systems serving greater than 3,300 people and using chemical disinfection (*e.g.*, chlorine) to provide 4-log inactivation must continuously monitor the residual disinfectant concentration using analytical methods specified in § 141.74(a)(2) (Analytical and monitoring requirements) at a location approved by the State, and record the lowest residual disinfectant level each day that the GWS serves water from the ground water source to the public. The system must maintain the State-determined residual disinfectant concentration every day the GWS serves from the ground water source.

Systems serving 3,300 people or fewer that use chemical disinfection must monitor the residual disinfectant concentration using analytical methods specified in § 141.74(a)(2) (Analytical and monitoring requirements) at a location approved by the State either by taking at least one grab sample every day the GWS serves water to the public or by continuously monitoring the disinfectant residual. Systems collecting grab samples must record the disinfectant residual level each day that the GWS serves water from the ground water source to the public. The system must take a grab sample during the hour of peak flow or at another time specified by the State. Systems serving 3,300 people or fewer that use continuous residual monitoring equipment must record the lowest residual disinfectant level each day that the GWS serves water from the ground water source to the public.

If a GWS taking grab samples has a sample measurement that falls below the State-specified residual disinfectant concentration, then the system must take follow-up samples at least every four hours until the State-specified residual disinfectant level is restored. If a system using continuous monitoring equipment fails to maintain the State-specified disinfectant residual level necessary to achieve 4-log inactivation of viruses, the system must restore the disinfectant residual level to the State-specified level within four hours. If continuous disinfectant monitoring equipment fails, the GWS must take a grab sample at least every four hours until the equipment is back on-line. The system has 14 days to resume continuous monitoring. Failure to restore the residual disinfectant level to that required for 4-log inactivation of viruses within four hours, using either continuous monitoring or grab sampling, is a treatment technique violation.

Ground water systems that use a membrane filtration treatment technology must maintain the integrity of the membrane and monitor and operate the membrane filtration system in accordance with State-specified monitoring and compliance requirements (*e.g.*, membrane performance parameters and integrity testing). If a system fails to meet these requirements or maintain the integrity of the membrane, it must correct the problem within four hours or be in violation of the treatment technique requirement.

Systems that use a State-approved alternative treatment technology must monitor and operate the alternative treatment in accordance with all compliance requirements that the State determines to be necessary to demonstrate that at least 4-log treatment of viruses is achieved. If the system does not comply with these requirements, fails to maintain at least 4-log treatment of viruses, and does not restore proper operation within four hours, the system is in violation of the treatment technique requirement.

GWSs providing at least 4-log treatment of viruses may discontinue treatment if the State determines (*e.g.*, based on source water monitoring or replacement of the source) and documents in writing that the need for 4-log treatment of viruses no longer exists for that ground water source. GWSs that discontinue treatment with State approval must comply with the triggered source water requirements of this rule. GWSs that provide 4-log treatment of viruses and notify the State that they are not subject to the source water monitoring requirements of this rule but subsequently discontinue 4-log treatment of viruses must have State approval and must comply with the triggered source water requirements of this rule.

2. What Is EPA's Rationale for the GWR Treatment Technique Requirements?

EPA believes that fecal contamination in ground water sources of undisinfected or minimally disinfected GWSs and significant deficiencies demonstrate public health risks that require prompt corrective action. Application of corrective actions in cases of source water fecal contamination or significant deficiencies provides benefits of eliminating existing problems and can also preempt future public health risks, such as an outbreak. EPA believes that requiring treatment technique provisions to respond to fecally contaminated ground water sources and/or significant deficiencies identified by sanitary surveys will provide enforcement authority to EPA and States to ensure that appropriate corrective actions will be implemented.

The GAO reported that failure to correct deficiencies identified in sanitary surveys is a significant concern (USGAO, 1993). An analysis of Best Management Practices (BMPs) (ASDWA, 1998) showed that correction of deficiencies was correlated with lower levels of total coliform, fecal coliform, and *E. coli*. Therefore, EPA believes that the treatment technique requirements in this rule will result in reduced exposures to fecal contamination and associated health risks.

Findings from a review of the Environmental Law Reporter contained in the *Baseline Profile Document for the Ground Water Rule* (USEPA, 2000g) indicate that (1) Not all States specifically require systems to correct deficiencies, and (2) a number of States may not have the legal authority to require systems to correct deficiencies. The treatment technique requirements of this rule provide for timely correction, as well as public notification, of fecal contamination and significant deficiencies. Treatment corrective actions provide for inactivation or removal of microbes of public health concern in some ground waters and results in reduced exposures and associated health risks. The rule also allows non-treatment alternatives such as removing the source of contamination or providing an alternate source water, both of which also result in reduced exposures and associated health risks.

To avoid unwarranted action, EPA has added a provision under the final rule that allows additional sampling of the source water with the initial fecal indicator-positive sample before requiring corrective action. If the State determines that corrective action is appropriate from the initial fecal indicator-positive finding, then no additional sampling would be required. This provision is discussed in Section IV.B.2.a.

a. *Corrective Actions and Treatment Technique Requirements.* To develop the treatment technique requirements, EPA evaluated existing State requirements and the measures available to systems to address fecal contamination. EPA believes that effective corrective actions include correcting significant deficiencies, eliminating the source of contamination, providing an alternate source of safe drinking water, or providing 4-log treatment of viruses. States and systems have the flexibility to take site-specific factors into consideration when implementing these corrective actions.

i. Corrective action technologies. Chemical disinfection technologies are commonly used by both ground water and surface water systems to provide disinfection prior to distribution of drinking water. EPA believes that 4-log inactivation is protective in disinfecting GWSs (see Figure III–1). Under the SWTR, EPA requires at least 4-log removal and/or inactivation of viruses. Since the frequency of viral occurrence and virus concentrations are generally lower in ground water supplies than in surface water supplies, EPA believes the 4-log requirement for GWSs is as protective as the current treatment requirements for surface water supplies. Figure III–1 indicates the range of protection anticipated from the 4-log requirement for GWSs having viral contamination in their source water.

Numerous studies have investigated the efficacy of chemical disinfectants to inactivate viruses. Free chlorine was shown to be able to achieve 4-log inactivation of hepatitis A virus (HAV) at a temperature of 15 degrees Celsius, a pH of 6–9, and a CT of four mg-min/L (USEPA, 1991). Chlorine dioxide achieves 4-log inactivation of HAV at a temperature of 15 degrees Celsius, a pH of 6–9, and a CT of 16.7 mg-min/L (USEPA, 1991). Ozone achieves a 4-log inactivation of poliovirus at a temperature of 15 degrees Celsius, a pH of 6–9, and a CT of 0.6 mg-min/L (USEPA, 1991). Chemical disinfection is a demonstrated technology that can achieve 4-log inactivation of viruses. The CT value needed to provide 4-log inactivation of viruses is dependent on site-specific conditions, including the disinfectant demand, water temperature and pH. States and systems may use existing inactivation (CT) tables (USEPA, 1991) or State-approved alternatives to determine the chemical disinfectant doses required to achieve a 4-log inactivation of viruses.

Membrane filtration technologies can achieve 4-log or greater removal of viruses, as long as the absolute MWCO of the membrane, or alternate parameter that describes the exclusion characteristics of the membrane, is smaller than the diameter of viruses. For instance, reverse osmosis (RO) can achieve greater than 4-log removal of particles (including viruses) larger than 0.5 nm in diameter when the absolute MWCO of the RO membrane is less than 0.5 nm (Jacangelo *et al.*, 1995). In addition, nanofiltration (NF) can achieve greater than 4-log removal of particles with a diameter of 0.5 nm or larger when the absolute MWCO of the NF membrane is 200–400 Daltons. Viruses range in diameter from 20–900 nm. The absolute MWCOs of specific membranes must be determined for the specific membranes to meet these conditions. This rule also allows for other filtration treatment technologies to be used to meet the 4-log treatment requirement.

The GWR proposal explicitly included UV light in the regulatory text as a stand-alone treatment technology that could provide a 4-log virus inactivation. However, data published subsequent to the GWR proposal indicated that some viruses, particularly adenoviruses, are very resistant to UV

light. The GWR proposal was based on information available at the time of the proposal regarding UV doses required to provide a 4-log inactivation of HAV and the design doses achieved by available UV reactors, which are lower than the UV doses needed to achieve 4-log inactivation of adenovirus.

Further, EPA believes that UV reactors must undergo challenge testing to validate the dose level delivered so that effective public health protection is provided in systems using UV disinfection. At present, EPA is unaware of available challenge testing procedures that can be used to validate the performance of UV reactors at dose levels needed for a 4-log inactivation of adenovirus.

The final GWR modifies the proposal by removing the explicit reference to UV as a stand-alone technology to achieve 4-log virus inactivation. EPA is concerned that fecally-contaminated ground water may contain adenoviruses, or other viruses, that are more resistant to UV inactivation than HAV, and currently available testing procedures cannot validate UV reactor performance at the UV dose levels needed for inactivation.

EPA believes that UV technology can be used in a series configuration or in combination with other inactivation or removal technologies to provide a total 4-log treatment of viruses to meet this rule's requirements. EPA also believes that a UV reactor dose verification procedure for 4-log inactivation of a range of viruses may be developed in the future. With the future development of UV validation procedures, it may become feasible for systems to demonstrate that they can achieve 4-log inactivation of viruses with a single UV light reactor. Therefore, this rule allows States to approve and set compliance monitoring and performance parameters for any alternative treatment, including UV light or UV light in combination with another treatment technology, that will ensure that systems continuously meet the 4-log virus treatment requirements. This requirement is both protective of public health and provides systems and States with needed flexibility for site-specific decisions. It ensures protection against known heath risks associated with waterborne viruses; allows systems to make use of technologies that are already in place or are more appropriate for the system's size, location, or configuration; and provides the opportunity for systems to take advantage of future technology developments.

ii. Corrective action time frame. EPA believes that timely correction of source water fecal contamination and significant deficiencies in GWSs is an essential component of the public health measures presented in this rule.

EPA has extended the proposed 90-day deadline for completing corrective actions to 120 days, which includes additional time for a 30-day GWS/State consultation period. In the case of source water fecal contamination, an investigation into the cause of contamination should be conducted during this 30 day period. This consultation allows the State, in discussion with the system, to determine the most appropriate corrective action for the problem identified to ensure public health protection. To reduce burden, the State may specify the corrective action in its significant deficiency notice to the system.

EPA believes that in many situations, a system can complete corrective actions within 120 days because many corrective actions are easy to implement, such as repairing a well seal. Where this is not the case, for example if a system needs to make capital improvements, the GWR allows States to determine an alternate schedule. The State is in the best position to make these case-by-case determinations of the most appropriate schedule to protect public health. The GWR also allows the State to require immediate interim corrective action to protect consumers while longer-term actions are implemented.

There may be cases in which systems and States have thoroughly investigated and cannot determine the cause of fecal contamination of the source water and believe that the source is no longer vulnerable to such contamination. If the State determines based on follow-up monitoring or other evidence that the contamination is unlikely to occur again, the State may consider the source of contamination to be eliminated. EPA considers such a system to be high risk and recommends that States follow up such a determination with assessment source water monitoring as described in Section IV.B.2.b. Commenters supported State discretion in making system-specific decisions. EPA is providing this interpretation in support of this goal.

iii. Discontinuing treatment. If the State determines that the need for 4-log treatment no longer exists, the State may allow a system to discontinue treatment. EPA believes that in certain situations (*i.e.*, consolidation, replacement or rehabilitation of ground water sources, mitigation of source of contamination), where both corrective action has addressed the public health risks and the system has demonstrated to the State that corrective action has been successful (*e.g.*, through source water monitoring or sanitary surveys), it may be appropriate to allow systems to discontinue 4-log treatment of ground water sources. If the State allows a system to discontinue 4-log treatment, the system is then subject to the source water monitoring requirements of this rule.

b. *Monitoring for the Effectiveness and Reliability of Treatment.* All GWSs that provide treatment must routinely monitor the treatment effectiveness to ensure that public health is protected. Because of considerations regarding resources and the technical capacities of small water systems, this rule includes different monitoring requirements for systems of different sizes while still effectively ensuring public health protection. The 1996 Amendments to the SDWA recognized the importance of considering both the special needs of small systems that serve 3,300 people or fewer and the need to ensure equal public health protection to consumers served by small and large PWSs.

EPA believes that it is appropriate for disinfecting systems serving greater than 3,300 people to install and operate continuous disinfection monitoring equipment. These systems will generally have the expertise to operate and maintain the necessary equipment, and continuous monitoring and recording will alleviate some of the monitoring burden for larger systems. Systems serving 3,300 people or fewer are provided the flexibility to use either grab sampling or continuous monitoring. This option is important because some small systems may not have the capacity to purchase, operate, and maintain continuous disinfection monitoring equipment. For all systems, the monitoring must take place at or prior to the first customer to ensure that the required level of treatment has been achieved prior to serving water to the public.

For GWSs that use membrane filtration systems to achieve at least 4-log removal of viruses, the system must monitor the membrane filtration process in accordance with all State-specified monitoring requirements. In addition, the system must operate the membrane filtration in accordance with all State-specified compliance requirements. A GWS that uses membrane filtration is in compliance with the 4-log removal requirement for viruses when:

- The membrane has an absolute MWCO, or alternate parameter that describes the exclusion characteristics of the membrane, that can reliably achieve 4-log removal of viruses;

• The membrane process is operated in accordance with State-specified compliance requirements; and

• The integrity of the membrane is intact.

To ensure compliance with the virus removal requirements of the GWR in systems that practice membrane filtration, systems must monitor to verify that the membrane filtration is operating as specified and that the membrane is intact. Without these compliance monitoring requirements, failure of membrane filtration may not be detected by the system and consumers may be exposed to potentially fecally contaminated water. This could result in a failure to maintain at least 4-log treatment of viruses.

In cases where 4-log treatment of viruses is interrupted, the requirement that systems must restore 4-log treatment of viruses is consistent with requirements for surface water systems under the SWTR (USEPA, 1989b) and protects public health while providing flexibility for GWSs to address operational issues.

If the State has not approved compliance criteria for the system to use to demonstrate 4-log treatment by the time that the system is required to conduct compliance monitoring, the system should comply with ground water source monitoring in § 141.402 until the State approves compliance criteria for the system to use to demonstrate 4-log treatment. EPA is concerned that systems may inadvertently provide inadequately treated water (*i.e.*, < 4-log treatment) if they are not using State approved compliance criteria.

3. What Were the Key Issues Raised by Commenters on the Proposed GWR Treatment Technique Requirements?

a. *State Consultation Versus Approval.* EPA received many comments related to the State's ability to require the system to implement a specific treatment technique in response to significant deficiencies or source water fecal contamination. The proposed GWR required the system only to consult with the State on the appropriate corrective action option for the system. Several commenters expressed concern that with only a consultation requirement, a system could implement a treatment technique that the State would consider inappropriate or unreliable, such as disinfection by a system that is incapable of reliably operating a disinfection treatment system. To address these concerns, the final GWR requires systems to implement corrective actions in accordance with applicable State plan review processes, or other State guidance or direction, including interim measures, or be in compliance with a State-approved corrective action plan and schedule. EPA believes that existing State plan review and permitting activities, such as those established in accordance with the primacy requirements at § 142.10(b)(5), will ensure that systems implement the most appropriate corrective action.

b. *UV Disinfection.* EPA received comments on the use of UV technology to meet the treatment technique requirements of the GWR. The GWR proposal included UV as a stand-alone treatment to meet the GWR treatment requirements and provided monitoring requirements for systems using UV technology, as well as State-determined performance requirements for UV technology.

Commenters requested more information on the use of UV for virus inactivation, including UV dose tables and criteria to assist States in evaluating UV reactors. Commenters also noted that data published subsequent to the GWR proposal indicated that some viruses, in particular adenoviruses, are very resistant to UV light. Data show that a dose of 186 mJ/cm^2 is required to achieve 4-log inactivation of adenovirus (68 FR 47713, August 11, 2003) (USEPA, 2003c). This information suggests that HAV, the virus considered in the GWR proposal discussion of UV, may not be an appropriate indicator of the virus inactivation performance of UV reactors. EPA agrees that UV reactors may need to provide higher doses than those contemplated in the GWR proposal to achieve 4-log inactivation of viruses. Moreover, there is currently limited information available for States to make determinations regarding performance requirements for UV reactors to ensure that adequate virus inactivation is being achieved.

Further, EPA believes that testing of full-scale UV reactors is necessary to ensure disinfection performance and a consistent level of public health protection. Full-scale testing avoids the significant difficulties encountered in predicting UV reactor disinfection performance based solely on modeled results or the results of testing at a reduced scale. All flow-through UV reactors deliver a distribution of doses due to variations in light intensity within the UV reactor and the different flow paths of particles passing through the reactor. The reactor-delivered dose also varies temporally due to processes such as UV lamp aging and fouling, changes in UV absorbance of the water being treated, and fluctuations in reactor flow rates.

A full-scale test typically involves using a surrogate microorganism. However, EPA is not aware of an available challenge microorganism that allows for full-scale testing of UV reactors to demonstrate a 4-log inactivation of adenovirus. EPA believes that methodologies for challenge testing at doses necessary to inactivate UV-resistant viruses may be developed in the future.

The final GWR does not include specific performance, monitoring, or design requirements related to the use of UV technology. This is based on the comments received regarding the use of UV technology to meet the GWR requirements, new data regarding UV dosages necessary for virus inactivation, and the difficulties in performing full-scale demonstrations of 4-log virus inactivation at those doses.

However, EPA does believe that UV technology may be used in a series configuration or in combination with other inactivation or removal technologies to provide a total 4-log treatment of viruses to meet this rule's requirements. The State has the flexibility to approve treatment alternatives not specified in the rule, which could include UV disinfection. When using an alternative treatment technology, the State must specify monitoring and compliance requirements necessary to ensure that the virus treatment requirements of this rule are being met. The alternative treatment option in this rule could be applied to stand-alone UV disinfection if challenge testing protocols for 4-log virus inactivation are developed in the future.

c. *Corrective Action Time Frame.* EPA requested comment on the appropriateness of the time frame for providing corrective actions. Several commenters suggested that the proposed 90-day corrective action time frame was too short and that systems would not be able to meet this deadline. Some commenters also stated that 90 days would not be sufficient for systems seeking an extension of the 90-day deadline for completing the corrective action to obtain State approval of a plan and schedule within 90 days due to factors outside of the system's control, such as the need to obtain competitive bids or to gain the approval of the local government. On the other hand, several commenters stated that a 90-day corrective action time frame for systems with fecally contaminated source water was too long and would place consumers at an increased risk.

EPA received additional comments opposing the requirement on the State to approve corrective action plans

within the same 90 days required for the system to submit the plans (for systems seeking an extension of the 90-day deadline for completing the corrective action). The commenters pointed out that under the proposed rule, systems could potentially submit plans on the 90th day, leaving insufficient time for the State to review the plans.

The final GWR extends the proposed 90-day deadline for completing corrective actions from 90 to 120 days, which includes additional time for an initial 30-day GWS/State consultation period. This 30-day consultation serves a number of purposes. First, GWSs and States can investigate the cause of contamination. Second, the GWS and State may consult on the most appropriate corrective action. Third, the GWS and State may develop a corrective action plan and schedule that could extend beyond the 120-day period if necessary. This addresses the concerns that GWSs would not be able to complete their corrective action or receive an extension. This consultation period provides the GWS and State the assurance requested by commenters that they not be subject to factors outside of their control. Concerns about corrective action taking too long have been addressed by the provision to require GWSs to do interim corrective action measures at the State's request. In addition, this rule requires States to identify in their primacy application their rules or other authorities to demonstrate that they can ensure that GWSs take the appropriate corrective action, including interim measures, if necessary, pending completion of corrective actions.

EPA believes that the revised process for corrective actions under this rule will (1) Allow the State to ensure that the system is held accountable in a reasonable time frame for implementing corrective actions, and (2) utilize the strengths of existing State plan review processes or other State guidance, requirements, or direction. Systems and States continue to have the flexibility to complete corrective action on a more rapid schedule than 120 days.

D. Providing Notification and Information to the Public

Section 1414(c)(1) of the 1996 SDWA amendments requires that PWSs notify persons served when violations of drinking water standards occur. EPA published a revised Public Notification Rule (PNR) in 2000 (65 FR 25981, May 4, 2000) (USEPA, 2000j). Subsequent EPA drinking water regulations that affect public notification requirements typically include amendments to the PNR as a part of the individual rulemaking. This rule amends the PNR at § 141.202(a) and § 141.203(a) and requires Tier 1 notice for detection of a fecal indicator in a ground water source sample (see § 141.403) and Tier 2 notice for treatment technique violations (see § 141.404). Also, this rule requires Tier 3 notice for monitoring violations (see § 141.403 or § 141.404(b)). In addition, this rule amends the Consumer Confidence Report (CCR) (§ 141.153(b) Appendix A to subpart O) requirements and includes language to be used when informing the public of significant deficiencies and fecal indicator-positive results in ground water source samples. Since the CCR only applies to CWSs, a special notice requirement for uncorrected significant deficiencies is included in the treatment technique section of this rule for NCWSs. The language included in this section parallels language included in the CCR. Table IV–4 summarizes the GWR notification requirements.

The purpose of public notification is to alert customers of potential risks from violations of drinking water standards and to inform them of any steps they should take to avoid or minimize such risks. A PWS is required to give public notice when it fails to comply with existing drinking water regulations, has been granted a variance or exemption from the regulations, or is facing other situations posing a potential risk to public health. Public water systems are required to provide such notices to all persons served by the water system. The PNR divides the public notice requirements into three tiers, based on the seriousness of the violation or situation.

Tier 1 is for violations and situations with significant potential to have serious adverse effects on human health as a result of short-term exposure. Notice is required within 24 hours of the violation. Drinking water regulation Tier 1 notice violation categories and other situations include, but are not limited to, the following:

- An acute violation of the MCL for total coliforms when fecal coliform or *E. coli* are present in the water distribution system, or when the water system fails to analyze the sample for fecal coliforms or *E. coli* when any repeat sample tests positive for coliform (as specified in § 141.21(e));
- Occurrence of waterborne disease outbreaks, or other waterborne emergencies; and
- Other violations or situations with significant potential to have serious adverse effects on human health as a result of short-term exposure, as determined by the State either in its regulations or on a case-by-case basis. The State is explicitly authorized to add other violations and situations to the Tier 1 list when necessary to protect public health where short-termexposure is a concern.

Tier 2 is for other violations and situations with the potential to have serious adverse effects on human health. Notice is required within 30 days, with an extension of up to three months permitted at the discretion of the State. Violations requiring a Tier 2 notice include all MCL and treatment technique violations, except where Tier 1 notice is required, and specific monitoring violations when determined by the State.

Tier 3 is for all other violations and situations requiring a public notice not included in Tier 1 and Tier 2. Notice is required within 12 months of the violation and may be included in the Consumer Confidence Report at the option of the water system. Violations requiring a Tier 3 notice are principally monitoring and reporting violations.

1. What Are the Requirements of This Rule?

a. *GWR violations requiring a Tier 1 notice.* A Tier 1 notice is required if a GWS has a ground water source sample collected under § 141.402(a) or § 141.402(b) that is positive for one of the three fecal indicators that are discussed in Section IV.B and is not invalidated by the State.

b. *GWR violations requiring a Tier 2 notice.* A Tier 2 notice is required if:

- A GWS with a significant deficiency or with fecal contamination in the ground water source fails to take corrective action in accordance with the treatment technique requirements in § 141.403(a);
- A GWS fails to comply with a State-approved schedule and plan, including State-specified interim measures, to correct a significant deficiency and/or eliminate fecal contamination in a ground water source at any time after State approval or State direction pursuant to § 141.403(a)(2); or
- A GWS provides 4-log treatment of viruses but fails to maintain 4-log treatment, and the GWS does not restore 4-log treatment within four hours.

c. *GWR violations requiring a Tier 3 notice.* A Tier 3 public notice is required for failure to conduct required ground water source monitoring, including source water monitoring when a system has a total coliform-positive sample in the distribution system (§ 141.402(a)(2)), source water monitoring following a fecal indicator source water positive (§ 141.402(a)(3)), and, if required by the State, assessment source water monitoring (§ 141.402(b)). Additionally,

failure to conduct required compliance monitoring (§ 141.403(b)) requires a Tier 3 public notice.

d. *Special notice informing the public of significant deficiencies and fecal indicator-positives in ground water source samples.* In addition to the public notice requirements of § 141.202, § 141.203, and § 141.204, this rule requires PWSs that use ground water sources to inform customers of an uncorrected significant deficiency and CWSs to inform customers of a fecal indicator-positive ground water source sample that is not invalidated by the State. Under this rule, the GWS must continue to inform the public annually until the significant deficiency is corrected and, in the case of CWSs, the fecal contamination in the ground water source is addressed under § 141.403(a). The State may also direct GWSs to inform the public of corrected significant deficiencies.

The information provided to the public must include the following (as applicable to CWSs and NCWSs as described above): (1) The nature of the uncorrected significant deficiency or fecal contamination (for CWSs), if the source is known, and the date the significant deficiency was identified by the State or the date of the fecal indicator-positive ground water source sample (for CWSs); (2) for CWSs, if the fecal contamination in the ground water source has been addressed under § 141.403(a) and the date of elimination; (3) the State-approved plan and schedule for correction including interim measures, progress to date, and any interim measures completed, for any significant deficiency and for CWSs, fecal contamination in the ground water source that has not been addressed under § 141.403(a); (4) for CWSs, a description of the potential health effects using the health effects language of § 141.153, Appendix A to subpart O, if the system receives notice of a fecal indicator-positive ground water source sample that is not invalidated by the State; and (5) if directed by the State, notification of corrected deficiencies and how and when they were corrected.

To satisfy these special notification requirements, the GWR requires a CWS to inform the public served by the water system in the CCR. A NCWS must inform the public served by the water system in a manner approved by the State (*e.g.*, posting in conspicuous places in the area served by the water system for a period of time or distributing information directly to the public served by the water system) within 12 months of being notified of a significant deficiency. Systems must continue to inform the public annually until the significant deficiency is corrected and, in the case of CWSs, fecal contamination in the ground water source is addressed in accordance with § 141.403(a). If a significant deficiency is corrected before the next CCR is issued (for CWSs) or within 12 months (for non-CWSs), public notification is not required unless directed by the State.

TABLE IV–4.—SUMMARY OF GWR PUBLIC NOTIFICATION REQUIREMENTS

Systems must comply with the following notification requirements when . . .	Reference
Tier 1 Public Notification	
Triggered source water monitoring sample or assessment source water monitoring sample is positive for *E. coli*, enterococci, or coliphage (and is not invalidated).	§ 141.402(g).
Tier 2 Public Notification	
A system fails to take corrective action following: ■ State direction to take corrective action for a fecal indicator-positive sample, ■ Receipt of laboratory notice of fecal indicator-positive ground water source sample as a result of triggered source water monitoring under § 141.402(a)(3), or ■ Receipt of State written notice of significant deficiency.	§ 141.404(d).
A system fails to comply with a State-approved schedule and plan (including interim measures) related to correcting a significant deficiency and/or eliminating fecal contamination in a ground water source.	§ 141.404(d).
A system that elects to provide such treatment in lieu of triggered source water monitoring fails to maintain 4-log treatment of viruses [NOTE: There is no violation and public notification required if the system restores 4-log treatment within four hours.].	§ 141.404(d).
Tier 3 Public Notification	
A system fails to conduct triggered source water monitoring or assessment source water monitoring.	§ 141.403(d).
A system fails to conduct monitoring to demonstrate compliance with 4-log treatment requirement.	§ 141.403(d).

TABLE IV–4.—SUMMARY OF GWR PUBLIC NOTIFICATION REQUIREMENTS—Continued

Systems must comply with the following notification requirements when . . .	Reference
Special Notification Requirements	
CWSs: System has an uncorrected significant deficiency (or corrected significant deficiency if directed by the State) or a source water fecal indicator-positive sample. System must repeat notice annually until significant deficiency corrected or fecal contamination addressed in accordance with § 141.403(1). ■ Provide notice as part of CCR. ■ If significant deficiency is corrected before the next CCR, notification is not required unless directed by the State.	Notice must include: —nature of significant deficiency or ground water fecal contamination, and date. —if the fecal contamination has been addressed under § 141.403(a), and date. —State-approved plan and schedule, including interim measures completed (if process ongoing). —required fecal indicator-positive language at: —§ 141.403(a)(7)(i).
NCWSs: System has an uncorrected significant deficiency (or corrected significant deficiency if directed by the State). System must repeat notice annually until significant deficiency corrected. ■ Provide notice in manner approved by the State for significant deficiencies (*e.g.*, posting in conspicuous places in service area or direct distribution of information to public served). ■ If significant deficiency is corrected within 12 months, notification is not required unless directed by the State.	Notice must include: —nature of significant deficiency and date. —State-approved plan and schedule, including interim measures completed (if process ongoing). —§ 141.403(a)(7)(ii).

2. What Is EPA's Rationale for the Public Notice Requirements?

EPA believes that to provide adequate public health protection from fecally contaminated ground water, the public must be informed of both existing and potential significant problems. EPA recognizes that immediate public notification is key to providing effective communication when there is an imminent public health risk. In the proposed rule, EPA considered requiring Tier 1 notice for all violations. The final GWR, however, requires Tier 1 notice only when a ground water source sample tests positive for one of the three fecal indicators that are discussed in Section IV.B. The presence of a fecal indicator in a ground water source sample means that fecal contamination is likely to reach consumers and may have significant potential for serious adverse health effects from a short-term exposure. Other violations of this rule require Tier 2 or Tier 3 notice, depending on the nature of the violation and potential for adverse health effects.

The Agency believes that it is important for the public to be informed when systems are unable to comply with the GWR requirements that are established to protect public health. EPA's intent is for the public to be informed within an appropriate time frame without unnecessary alarm. Under the final GWR, the following treatment technique violations have been changed from Tier 1 to Tier 2 notice:

• Failure to correct a significant deficiency and/or eliminate fecal contamination in a ground water source;

• Failure to be in compliance with a corrective action schedule and plan within 120 days or to comply with the plan and schedule after State approval; and

• Failure to restore 4-log treatment of viruses within four hours.

EPA believes that these violations require Tier 2 notice because of the potential for serious adverse health effects from fecal contamination if treatment technique requirements are not met. Failure to conduct ground water source monitoring or compliance monitoring under this rule requires a Tier 3 notice public notice. EPA believes that the public notification requirements of this rule are protective of public health by providing timely and appropriate public notification of violations and situations that may affect public health.

Public right-to-know was a key tenet of the 1996 Amendments to the SDWA. The final GWR requirements allow the public to become involved in any decision-making process for corrective actions taken by the GWS and provide information for individual health decisions.

Consistent with the requirements for the Consumer Confidence Report (CCR) to include all detected regulated contaminants, the special public information requirements of the GWR require CWSs to include information on any fecal contamination of its ground water sources. In addition to addressing the requirements for CCRs, EPA believes this notice is important in informing individual health decisions. Use of the existing CCR public information process for CWSs minimizes the burden on CWSs. EPA believes that the Tier 1 notice requirements for NCWSs are adequate and appropriate for informing the public of fecal contamination of ground water sources and providing information for individual health decisions so no additional notice is required for fecal contamination at NCWSs.

EPA also believes that the public must be fully informed of uncorrected significant deficiencies because such deficiencies may affect their water supply and pose a health risk. In addition, EPA believes that this notification of uncorrected significant deficiencies will provide an additional incentive to water systems for rapid correction of significant deficiencies. To minimize the burden on CWS the final GWR requires them to use the CCR to report uncorrected significant deficiencies. Because the public served by NCWSs do not receive CCRs, this rule requires States to determine the appropriate method(s) (*e.g.*, posting in conspicuous places, hand delivery) for NCWSs to inform the public of uncorrected significant deficiencies. In order to provide the public with complete information on their water system, GWSs are required to continue informing the public of uncorrected significant deficiencies until corrective actions are completed.

Under the Tier 1 public notice requirements, NCWSs must provide public notice of a fecal indicator-positive source water in a form and

manner designed to reach transient and non-transient users of the PWS. This could include conspicuous posting, hand delivery or other methods approved by the State. This notice would continue until fecal contamination is corrected.

EPA believes that there may be circumstances when the public should be informed of significant deficiencies that have been corrected and that States are in the best position to make a decision to require notification of the public. These circumstances include significant deficiencies that, although corrected, presented a public health risk prior to correction; significant deficiencies that were uncorrected for long periods of time; and significant deficiencies at systems with persistent significant deficiency issues. Notification in these circumstances allows the public served by a PWS to become involved in any decision-making processes for management, operation, and maintenance of the water system and it also provides information for individual health decisions. Notification of corrected significant deficiencies that had been uncorrected for long periods provides closure for the public that has been notified previously of the uncorrected significant deficiency. In addition, notification of corrected significant deficiencies allows a community to better evaluate the management of their system because they will have complete information on significant deficiencies at their system.

3. What Were the Key Issues Raised by Commenters on the Proposed GWR Public Notification Requirements?

a. *Treatment technique violations.* In the proposed GWR, EPA considered Tier 1 notice for the following: (1) Detection of a fecal indicator-positive in a ground water source sample that is not invalidated by the State; (2) failure to correct a State-identified significant deficiency or source water fecal contamination within 90 days or failure to obtain, within the same 90 days, State approval of a plan and schedule for meeting the treatment technique requirement; and (3) failure to perform source water monitoring. In general, commenters responded that Tier 1 notice for failure to correct a significant deficiency within 90 days or in accordance with the State-approved time frame is not warranted. Other commenters stated that only a confirmed fecal indicator-positive sample in the source water of a system that does not provide 4-log treatment of viruses should require Tier 1 notice. A few commenters supported EPA's proposed treatment technique violation Tier 1 notice. However, most commenters suggested that Tier 2 notice, rather than Tier 1 notice, is appropriate for treatment technique violations.

EPA agrees that the public health risk associated with documented fecal contamination warrants a Tier 1 notice. EPA agrees that not all failures to correct a significant deficiency warrant a Tier 1 notice, since not all significant deficiencies will result in an imminent danger to public health. For the specific case of a failure to correct source water fecal contamination, the existing Tier 1 notification requirements allow States to continue to require public notification for as long as fecal contamination is present. The final GWR also requires that CWSs and NCWSs include notice of uncorrected significant deficiencies and that CWSs provide notice of source water fecal contamination for as long as significant deficiencies or fecal contamination remain uncorrected. CWSs must include this in the CCR, and NCWSs will use a form of notification approved by the State.

b. *Monitoring violations.* Some commenters responded that failure to perform any source water monitoring should not require Tier 1 notice but rather Tier 2 notice. Other commenters stated that failure to conduct triggered source water monitoring should require a Tier 1 notice, while failure to conduct assessment source water monitoring should require a Tier 2 notice. In general, commenters believed that requiring a Tier 1 notice for failure to collect a source water sample would unnecessarily alarm the public. Other commenters supported a Tier 3 notice for failure to conduct source water monitoring so that the GWR would be consistent with other monitoring violation notification requirements of § 141.204.

EPA agrees that failure to collect source water samples or conduct compliance monitoring may not warrant a Tier 1 notification since lack of monitoring data does not indicate there is an imminent danger to public health and such notification could unnecessarily alarm the public. Consistent with § 141.204, the final GWR requires a Tier 3 notice for violations of the monitoring requirements, failure to collect ground water source samples, or failure to conduct compliance monitoring. EPA notes that States continue to have the authority to require a Tier 2 notice for monitoring violations if the State determines that this level of notification is warranted.

Some commenters stated that since the TCR governs the quality of water provided to a system's customers, it is inappropriate to require public notice for failure to conduct source water sampling under the GWR. EPA disagrees with the comment and believes that it is appropriate to establish public notification requirements for GWSs that fail to monitor for fecal contamination in their source water because fecal contamination can be a significant health risk. EPA recognizes that the TCR protects against distribution system contamination; however, as part of the GWR risk-targeting strategy, the Agency believes that source water monitoring is an integral component in both assessing potential fecal contamination in the source water and eliminating this contamination before it reaches the distribution systems.

c. *Special notice informing the public of significant deficiencies or a fecal indicator-positive ground water sample.* EPA requested comment on practicable approaches to involve the public in working with their systems to address the results of sanitary surveys or detection of source water fecal contamination. Some commenters suggested publishing the results in a system's CCR, reviewing the results at a public meeting, or posting the results of surveys in a public place for NCWSs. Others supported notifying the public that the results were available and how those results could be obtained. Some commenters noted that significant deficiencies or source water fecal contamination would be corrected rapidly and that involving or informing the public after the correction might not be useful.

EPA believes that adequate opportunities exist for customers to obtain general information on the sanitary survey of their water supplier since the complete sanitary survey report is available from both the State and the PWS upon request. EPA believes that the public served by a GWS should be made aware of uncorrected significant deficiencies and source water fecal contamination. The final GWR uses an existing public information process, the CCR, to inform consumers of water from CWSs of uncorrected significant deficiencies found during sanitary surveys or of source water fecal contamination. NCWSs will use a State approved process such as continuous posting in conspicuous places and hand-delivered notices to inform consumers of uncorrected significant deficiencies. NCWSs will use the State-approved Tier 1 notification process to notify the public of fecal source water contamination. No additional notice of fecal contamination is required for

NCWSs. If directed by the State, GWSs must also provide notification of corrected significant deficiencies.

E. What Are the Reporting and Recordkeeping Requirements for Systems?

The GWR establishes new reporting and recordkeeping requirements for GWSs that are necessary to ensure that systems continue to meet the requirements of the rule and that States have the information needed to perform their oversight responsibilities.

Specifically, the GWR reporting requirements ensure that States are aware of any failure to provide an adequate level of treatment, completed corrective actions, and system decisions that triggered source water monitoring is not necessary based on State criteria.

The recordkeeping requirements of this rule ensure that information is available to States during sanitary surveys or other instances to verify that systems are complying with the requirements of this rule for corrective actions, notice to the public, decisions not to conduct triggered source water monitoring, and invalidation of fecal indicator-positive ground water source samples.

This section discusses the new requirements and the key issues raised by commenters.

1. Reporting Requirements

In addition to the reporting requirements of § 141.31, a GWS must provide the following information to the State (see § 141.405(a)): (1) A GWS conducting compliance monitoring must notify the State as soon as possible, but in no case later than the end of the next business day, any time the system fails to meet any State-specified compliance requirements including, but not limited to, minimum residual disinfectant concentration, membrane operating criteria or membrane integrity, and alternative treatment operating criteria, if operation in accordance with the criteria or requirements is not restored within four hours; (2) a GWS must notify the State within 30 days after completing any corrective action for GWSs with significant deficiencies or source water fecal contamination; and (3) if a GWS is subject to source water monitoring requirements but is not required to monitor its source because it determines using State criteria that a total coliform-positive samples is related to distribution systems conditions pursuant to § 141.402(a)(5)(ii), then the GWS must provide documentation that it met the State criteria to the State within 30 days of the total coliform-positive sample.

2. Recordkeeping Requirements

In addition to the reporting requirements of § 141.31, a GWS must maintain the following information in its records (see § 141.405(b)): (1) Documentation of corrective actions; (2) documentation of notice to the public of (a) An uncorrected significant deficiency, or (b) a fecal indicator-positive ground water source sample that is not invalidated; (3) records of decisions where either (a) The State determines, and documents in writing, that the cause of a total coliform-positive sample collected under routine coliform sampling is directly related to the distribution system, or (b) the GWS determines, according to State criteria, that the cause of a total coliform-positive sample collected under routine coliform sampling directly relates to the distribution system; (4) for consecutive systems, documentation of notification to the wholesale system(s) of total coliform-positive samples that are not invalidated; and (5) for systems required to perform compliance monitoring (a) Records of the lowest daily residual disinfectant value and records of the date and duration of any failure to maintain the State-prescribed minimum residual for a period of more than four hours, and (b) records of State-specified compliance requirements for membrane filtration and of parameters specified by the State for State-approved alternative treatment and records of the date and duration of any failure to meet the membrane operating, membrane integrity, or alternative treatment operating requirements for more than four hours.

3. What Were the Key Issues Raised by Commenters on the Proposed GWR Reporting and Recordkeeping Requirements for Systems?

Most commenters agreed with the system recordkeeping and reporting requirements in the proposed rule and that recordkeeping and submittals are appropriate for systems that disinfect. Commenters mentioned that these requirements should be consistent with those required under other regulations, such as the TCR or the Stage 1 DBPR.

EPA agrees that the recordkeeping and reporting for systems under this rule are appropriate and ensure that information is available to the State in performing their oversight responsibilities. The records must be available for review during sanitary surveys and investigations of treatment technique failures. EPA believes that the recordkeeping and reporting requirements for systems under this rule are consistent with those required under other regulations.

Commenters also mentioned that systems should keep documentation of how the system operators determined the proper disinfectant concentration. EPA notes that this is a recordkeeping requirement for the State and is required under this rule.

Others commenters stated that recordkeeping requirements in the proposed rule were unrealistic and excessive for extremely small systems (such as many NCWSs). EPA notes that many of the recordkeeping requirements for systems under this rule are associated with corrective actions and compliance monitoring, and that only systems with significant deficiencies, source water contamination, or source water treatment would be required to keep these records. The records must be available for review during sanitary surveys and investigations of treatment technique failures.

F. What Are the Special Primacy, Reporting, and Recordkeeping Requirements for States?

The GWR establishes new special primacy, reporting, and recordkeeping requirements for States.

With regards to special primacy requirements, 40 CFR part 142, National Primary Drinking Water Regulations Implementation, 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, 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 special primacy conditions of this rule (§ 142.16(o)) ensure (1) That States have the legal authority to require correction of significant deficiencies and/or source water fecal contamination, as well as the authority to require source water monitoring, (2) that States adopt and implement adequate procedures for sanitary surveys, and that (3) States develop criteria for source water monitoring and treatment technique requirements.

With regards to reporting and recordkeeping, the SDWA establishes requirements that a State or eligible Indian Tribe must meet to assume and maintain primacy for its PWSs. Among others, these requirements include

keeping records and making reports available on activities that EPA requires by regulation.

The reporting requirements of this rule ensure that EPA is notified when the most recent sanitary survey was completed, the date a system completed corrective action, and of systems providing at least 4-log treatment of viruses.

The recordkeeping requirements of this rule ensure that States maintain various records to determine compliance with this rule.

This section discusses these new requirements and the key issues raised by commenters on these requirements.

1. Primacy Requirements

The SDWA established requirements that a State or eligible Indian Tribe must meet to assume and maintain primary enforcement responsibility (*i.e.*, primacy). These requirements include the following:

- Adopting drinking water regulations that are no less stringent than Federal drinking water regulations;
- Adopting and implementing adequate procedures for enforcement;
- Keeping records on EPA-regulated activities and making records available;
- Issuing variances and exemptions (if allowed by the State) under conditions no less stringent than allowed under the SDWA; and
- Adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations.

To implement this rule, the State is required to adopt the following revisions to 40 CFR part 141:

- § 141.21—Coliform sampling.
- § 141.28—Certified laboratories.
- § 141.153—Content of the reports.
- § 141.202—Tier 1 Public Notice—Form, manner, and frequency of notice.
- § 141.203—Tier 2 Public Notice—Form, manner, and frequency of notice.
- § 141.204—Tier 3 Public Notice—Form, manner, and frequency of notice.
- Subpart O—Regulated contaminants.
- Subpart Q—Public Notification of Drinking Water Violations, Appendix A, NPDWR Violations and Other Situations Requiring Public Notice.
- Subpart Q—Public Notification of Drinking Water Violations, Appendix B, Standard Health Effects Language for Public Notification.
- Subpart Q—Public Notification of Drinking Water Violations, Appendix C, List of Acronyms Used in Public Notification Regulation.
- Subpart S—Ground Water Rule.

In addition to adopting the basic primacy requirements specified in 40 CFR part 142, States are required to address special primacy conditions pertaining to specific requirements where implementation of the rule involves activities beyond general primacy provisions. The State must include these regulation-specific provisions in an application for approval of their program revision. Under this rule, the special primacy conditions are in the following four categories: Legal Authority, Sanitary Surveys, Source Water Microbial Monitoring, and Treatment Technique Requirements.

The application for approval of a State program revision that will adopt 40 CFR part 141, subpart S, must contain a description of how the State will accomplish these four program requirements.

a. *Legal authority.* The application for primacy must demonstrate that the State has: (i) The authority contained in statute or regulation to ensure that GWSs take the appropriate corrective actions, including interim measures, if necessary, needed to address significant deficiencies; (ii) the authority contained in statute or regulation to ensure that GWSs conduct source water monitoring; (iii) the authority contained in statute or regulation to ensure that GWSs take the appropriate corrective actions, including interim measures, if necessary, to address any source water fecal contamination identified during source water monitoring; and (iv) the authority contained in statute or regulation to ensure that GWSs consult with the State regarding corrective action(s).

b. *State practices or procedures for sanitary surveys.* In addition to the general requirements for sanitary surveys, a primacy application must describe how the State will implement a sanitary survey program and include an evaluation of the following eight sanitary survey components: source; treatment; distribution system; finished water storage; pumps, pump facilities, and controls; monitoring, reporting, and data verification; system management and operation; and operator compliance with State requirements.

The State must conduct sanitary surveys that address the eight sanitary survey components no less frequently than every three years for CWSs and every five years for NCWS.

The State may conduct sanitary surveys once every five years for CWSs if the system meets performance criteria (see Section IV.A.1). In its primacy application, the State must describe how it will determine whether a CWS has an outstanding performance record.

The State must define and describe in its primacy application at least one specific significant deficiency in each of the eight sanitary survey elements.

As a condition of primacy, the State must provide GWSs with written notice describing any significant deficiencies no later than 30 days after the State identifies the significant deficiency. The notice may specify corrective actions and deadlines for completion of corrective actions.

c. *State practices or procedures for source water microbial monitoring.* The State's primacy application must include a description of the following: (i) The criteria the State will use for extending the 24-hour time limit for a system to collect a ground water source sample to comply with the source water monitoring requirements; (ii) the criteria the State or GWS will use to determine that the cause of a total coliform-positive sample is directly related to the distribution system; (iii) the criteria the State will use for determining whether to invalidate a fecal indicator-positive ground water source sample; and (iv) the criteria the State will use to allow systems to conduct source water microbial monitoring at a location after treatment.

d. *State practices or procedures for treatment technique requirements.* As a condition of primacy, the State must verify within 30 days after the GWS has reported to the State that it has completed corrective action that significant deficiencies or source water fecal contamination have been addressed either through written confirmation from GWSs or a site visit by the State. A GWS's written notice may serve as this verification. The State's primacy application must include the following: (i) Notification methods that the States will require NCWSs to use to inform the public of uncorrected significant deficiencies; (ii) the process the State will use to confirm that a GWS achieves at least a 4-log treatment of viruses; (iii) the process the State will use to determine the minimum residual disinfectant concentration; (iv) the State-approved alternative technologies to achieve at least 4-log treatment of viruses; (v) the monitoring and compliance requirements the State will require for GWSs treating to at least 4-log treatment of viruses; (vi) the monitoring, compliance and membrane integrity testing requirements the State will require to demonstrate virus removal for GWSs using membrane filtration technologies; and (vii) the criteria, including public health-based considerations and incorporating on-site investigations and source water

monitoring results, the State will use to determine if a GWS may discontinue 4-log treatment of viruses.

2. Reporting Requirements

States are required to report violations, variance and exemption status, and enforcement actions to EPA according to the provisions of § 142.15. The final GWR adds the following three reporting requirements to these provisions (§ 142.15(c)(7)): (i) The month and year in which the most recent sanitary survey was completed, or for a State that uses a phased review process, the date that the last element of the applicable eight elements was evaluated for each GWS, (ii) the date the GWS completed corrective action, and (iii) all GWSs providing at least 4-log treatment of viruses for a ground water source.

3. Recordkeeping Requirements

The regulation at § 142.14 requires States with primacy to keep various records. This rule requires States to keep the following additional records: (i) Records of written notices of significant deficiencies; (ii) Records of corrective action plans, schedule approvals, and State-specified interim measures; (iii) Records of confirmations that a significant deficiency has been corrected and/or the fecal contamination in the ground water source has been addressed; (iv) Records of State determinations and records of ground water system's documentation for not conducting triggered source water monitoring; (v) Records of invalidations of fecal indicator-positive ground water source samples; (vi) Records of State approvals of source water monitoring plans; (vii) Records of notices of the minimum residual disinfection concentrations (when using chemical disinfection) needed to achieve at least 4-log virus inactivation before or at the first customer; (viii) Records of notices of the State-specified monitoring and compliance requirements (when using membrane filtration or alternative treatment) needed to achieve at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log inactivation and removal) before or at the first customer; (ix) Records of written notices from the GWS that it provides at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for each ground water source; and (x) Records of written determinations that the GWS may discontinue 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log inactivation and removal).

4. What Were the Key Issues Raised by Commenters on the Proposed GWR Special Primacy, Reporting, and Recordkeeping Requirements for States?

Many commenters responded to this request for comment and generally indicated that the requirements should be simplified and that a greater level of flexibility be afforded to the States.

Commenters questioned why the States need to identify their approach and rationale for determining the fecal indicators to be used and commented that States, at their discretion, should be able to use any EPA-approved method. Commenters also felt that States should have the latitude to allow different indicators if changes in technologies or laboratory resources prompt an amendment. EPA agrees with these comments, and this rule does not include a requirement regarding selection of a fecal indicator.

Some commenters believe that the GWR should provide specific information on how GWSs can achieve 4-log removal of viruses and how States should evaluate treatment techniques to assure compliance with the rule. In particular, the commenters wanted more information and guidance on how States and GWSs would determine what disinfectant residual level or operational parameters (in the case of membrane filtration or alternative treatment technologies, such as UV) GWSs would have to maintain to ensure that the GWS is achieving 4-log treatment of viruses. The commenters indicated that describing in their primacy package the approach they will use in determining which specific treatment option is appropriate in a given circumstance will be an arduous task.

EPA recognizes that selection and approval of a treatment technique option is system-specific. This rule does not require States to describe in their primacy package the approach they will use in determining which specific treatment option is appropriate in a given circumstance. This rule does require the States to describe any State-approved alternative technologies that GWSs may use to meet the treatment technique requirements. With regard to specific treatment techniques, EPA has recently issued the *Membrane Filtration Guidance Manual* (USEPA, 2005a) and is developing an ultraviolet disinfection guidance manual. EPA intends to develop a GWR Corrective Action guidance for further information regarding corrective actions and treatment techniques for GWSs.

Commenters indicated that a State should not have to describe ''how it will consult'' with water suppliers regarding treatment requirements. EPA believes that the process requiring PWS consultation with the State prior to implementing corrective action is important in ensuring that appropriate corrections occur. EPA recognizes that States have a long history of consulting with water systems, so the Agency removed this provision from the special primacy requirements in this rule. Instead, the GWR requires that States identify the authority that they have to ensure consultation, which ensures that corrective actions occur, as necessary.

G. Variances and Exemptions

Section 1415 of the SDWA allows States to grant variances from NPDWRs under certain conditions; section 1416 establishes the conditions under which States may grant exemptions to MCL or treatment technique requirements. These conditions and EPA's view on their applicability to the GWR are summarized as follows:

1. Variances

Section 1415 of the SDWA specifies two provisions under which general variances to treatment technique requirements may be granted:

(1) A State that has primacy may grant a variance to a PWS from any requirement to use a specified treatment technique for a contaminant if the PWS demonstrates to the satisfaction of the State that the treatment technique is not necessary to protect public health because of the nature of the PWS's raw water source. EPA may prescribe monitoring and other requirements as conditions of the variance (section 1415(a)(1)(B)).

(2) EPA may grant a variance from any treatment technique requirement upon a showing by any person that an alternative treatment technique not included in such requirement is at least as efficient in lowering the level of the contaminant (section 1415(a)(3)).

EPA does not believe that the variance provision under the SDWA at 1415(a)(1)(B) is applicable to GWSs under this rule. As discussed above, the regulation employs a targeted approach whereby corrective action is required only for those systems that have the most risk '' those systems that have found fecal contamination in their source water as indicated by source water monitoring, or have been found to be susceptible to contamination as indicated by a significant deficiency from a sanitary survey. Thus, the treatment technique requirements account for the nature of the PWS raw

water source. The GWR does not require the use of disinfection, nor does it compel the system to address the raw water source if, for example, an alternate source of drinking water is available.

With respect to the variances authorized under 1415(a)(3), EPA notes that this provision is unlikely to be used because the four treatment techniques provided in the GWR cover a broad range of options and States can approve any alternative treatment technologies. Given this broad range of treatment technique options, it is unlikely that a system could demonstrate to EPA that an alternative treatment technique not included in the regulation is at least as efficient in lowering the level of the contaminant of concern.

Section 1415(e) of the SDWA describes small PWS variances, but these cannot be granted for a treatment technique for a microbial contaminant. Hence, small PWS variances are not allowed for the GWR.

2. Exemptions

Under SDWA section 1416(a), a State may exempt any PWS from a treatment technique requirement upon a finding 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 PWS was in operation on the effective date of the treatment technique requirement, or for a PWS that was not in operation by that date, no reasonable alternative source of drinking water is available to the new PWS; (3) the exemption will not result in an unreasonable risk to health; and (4) management or restructuring changes (or both) cannot reasonably result in compliance with the Act or improve the quality of drinking water.

EPA believes that granting an exemption to the treatment requirements of the GWR would result in an unreasonable risk to health. As described in section III.C, microbial contamination causes acute health effects, which may be severe in sensitive subpopulations. Moreover, the additional treatment requirements of the GWR are targeted to PWSs with the highest degree of risk. Due to these factors, EPA does not support the granting exemptions from the GWR.

V. Explanation of Extent of GWR

A. Mixed Systems

This rule applies to PWSs (CWSs and NCWSs) that use ground water in whole or in part (except GWUDI systems), unless all ground water is commingled with surface water before treatment at the surface water treatment plant is applied, in which case surface water treatment regulations apply. This means that the treatment technique requirements of the GWR for significant deficiencies apply to any system using both ground water and surface water that has a significant deficiency identified past the point of surface water treatment, unless the State determines that the significant deficiency is in a portion of the system served solely by surface water. EPA believes that the same level of public health protection provided by this rule to persons served solely by ground water must be provided to persons served by ground water supplies in mixed systems.

EPA received comments regarding the applicability of the proposed GWR to systems that serve both ground water and surface water. Commenters noted that the requirements for these ''mixed systems'' were not explicit for the individual rule components such as sanitary surveys and triggered source water monitoring. For example, commenters specifically noted that the proposed GWR did not address how to conduct the triggered source water monitoring requirement after a total coliform-positive under the TCR was detected in systems where ground water and surface water are blended in the distribution system.

EPA has included more explicit regulatory language that describes how ''mixed systems'' must comply with individual components of this rule to assist PWSs in understanding and implementing the GWR provisions. There are approximately 3,700 mixed systems in the U.S. This rule explicitly addresses general applicability and the applicability of specific GWR components to mixed systems. The complexity and variety of configurations and operations in these mixed systems do not allow for all the possible scenarios to be addressed within a regulatory framework, so States will have the discretion to make a site-specific determination whether a significant deficiency is in a portion of the system served solely by surface water.

EPA will provide further information through implementation guidance and other non-regulatory approaches to assist States and water systems in meeting the intent of this rule, to target GWSs that are at risk of fecal contamination and to require these systems to take corrective action to protect public health. In some cases, it may be possible to identify customers or portions of the distribution system in mixed systems served solely by surface water or ground water. In other cases, it may not be possible or may be transitory due to complex and/or variable system hydraulic conditions.

B. Cross-Connection Control

EPA is concerned about fecal contamination entering distribution systems; however, cross-connection control requirements are not a part of this rule, though the proposal contained cross-connection consideration. The *Stage 2 Microbial and Disinfection Byproducts Federal Advisory Committee's Agreement in Principle* (65 FR 83015, December 2000) (USEPA, 2000b) states that cross-connections and backflow in distribution systems represent a significant public health risk and that EPA should initiate a process to address cross-connection control and backflow prevention requirements as part of the six-year review of the TCR. EPA has published its intent to consider such requirements as part of the revisions to the TCR (67 FR 19030, April 17, 2002) (USEPA, 2002b).

VI. Implementation

This section describes the regulations and other procedures and policies that States must adopt, as well as the requirements that public GWSs would have to meet to implement this rule. Also discussed are the compliance deadlines for these requirements.

States must continue to meet all other conditions of primacy at 40 CFR part 142. Section 1413(a)(1) of the 1996 SDWA Amendments provides two years (plus more time if the Region approves) after promulgation of the final GWR for the State to adopt drinking water regulations that are no less stringent than the final GWR in order to obtain primacy for the GWR.

GWSs must continue to meet all other applicable requirements of 40 CFR part 141. The SDWA as amended in 1996 (see section 1412(b)(10)) provides three years after promulgation for compliance with new regulatory requirements. Accordingly, the GWR requirements that apply to the PWS directly, specifically the requirements found under subpart S of 40 CFR part 141 (source water monitoring, corrective actions and treatment technique requirements, compliance monitoring, recordkeeping and reporting, and public notice and public information), take effect three years after promulgation. The State may, in the case of an individual system, provide additional time of up to two years for capital improvements, if necessary, in accordance with the statute.

This rule includes conditions of primacy at 40 CFR part 142 under which States will have until December 31, 2012 to complete the initial sanitary survey cycle for CWSs, except those meet performance criteria, and until December 31, 2014 to complete the initial sanitary survey cycle for all NCWSs and CWSs that meet performance criteria (refer to Section IV.A.1 for criteria). These sanitary survey implementation deadlines provide time for States to adopt the rule and obtain primacy (two to four years allowed by the SDWA at 1413(a)(1)). In addition, systems are given three years to comply with drinking water regulations by the SDWA at (1412(b)(10)). Finally, States need three to five years to complete the first cycle of sanitary surveys because there are many GWSs and States have limited resources.

The GWR places the same sanitary survey frequency requirements on GWSs as is currently required of surface water systems under 40 CFR part 141 subpart H.

GWSs must comply with all applicable requirements beginning December 1, 2009 unless otherwise noted.

VII. Economic Analysis (Health Risk Reduction and Cost Analysis)

This section summarizes the Health Risk Reduction and Cost Analysis (HRRCA) in support of the final GWR. This analysis has been revised and updated from the HRRCA prepared for the proposal as required by section 1412(b)(3)(C) of the SDWA. In addition, under Executive Order 12866, Regulatory Planning and Review, EPA must estimate the costs and benefits of this rule in an Economic Analysis (EA). EPA has prepared an EA (USEPA, 2006d) to comply with the requirements of this order and to update the SDWA HRRCA. The EA document for the GWR is available in the docket and is also published on the government's Web site *http://www.regulations.gov*.

The HRRCA consists of seven elements as follows: (1) Quantifiable and nonquantifiable health risk reduction benefits; (2) quantifiable and nonquantifiable health risk reduction benefits from reductions in co-occurring contaminants; (3) quantifiable and nonquantifiable costs that are likely to occur solely as a result of compliance; (4) incremental costs and benefits of rule alternatives; (5) effects of the contaminant on the general population and sensitive subpopulations including infants, children, pregnant women, elderly, and immunocompromised; (6) increased health risks that may occur as a result of compliance; and (7) other relevant factors such as uncertainties in the analysis. A summary of these elements is provided in this section of the preamble, and a complete discussion can be found in the GWR EA (USEPA, 2006d).

Both the benefits and the costs discussed in this section are presented as annualized present values in 2003 dollars. This process allows comparison of cost and benefit streams that are variable over a given time period and differs from the GWR proposal (USEPA, 2000a), which only used an annual estimate. The time frame used for both benefit and cost comparisons in this rule is 25 years. This time interval accounts for early rule implementation activities (*e.g.*, States adopting the criteria of the regulation) and the time for different types of compliance actions to be realized up through year 25 following rule promulgation (*e.g.*, identification and correction of sanitary survey deficiencies, identification of wells that are fecally contaminated and subsequent corrective action). The Agency uses social discount rates of both three percent and seven percent to calculate present values from the stream of benefits and costs and also to annualize the present value estimates. The GWR EA (USEPA, 2006d) also shows the undiscounted stream of both benefits and costs over the 25 year time frame.

The quantified benefits are calculated based only on endemic, acute disease illness, and death from some viral, but not bacterial, contamination of PWS wells. EPA was able to monetize only this subset of total benefits which were compared to the total costs of this rule. The total benefits, both quantified and nonquantified, are estimated using illness and death data as well as non-health benefits such as avoided costs (*e.g.*, restaurant closures) due to outbreaks. Furthermore, the total health benefits are estimated based on a full range of health effects, including acute and chronic illness and endemic and epidemic disease from both bacteria and virus contamination. EPA believes that the quantified benefits for this rule underestimate reduction in risk because the Agency was only able to calculate a subset of the total benefits; peer reviewers of the GWR benefit analysis agree that the quantified benefits are biased low. The costs of the rule stem mostly from the sanitary survey and the correction of significant deficiencies as well as the triggered source water monitoring and corrective action provisions described earlier in this preamble.

This section of the preamble includes 12 elements as follows: (A) Rationale for choosing a different alternative from the proposed alternative, (B) occurrence and risk analyses that support this rule, (C) both quantified and nonquantified benefits, (D) both quantified and nonquantified costs, (E) potential impact on households, (F) incremental costs and benefits, (G) benefits from simultaneous reduction of co-occurring contaminants, (H) increases in risk due to other contaminants, (I) effects on the general population and special subgroups, (J) uncertainties in risk, benefit, and cost estimates, (K) benefit/cost determination, and (L) major comments and responses. Section VII.F presents the benefits and costs for the four regulatory alternatives that were considered in this rule. Table VII–1 provides a summary of monetized benefits and costs for each GWR regulatory alternative.

TABLE VII–1.—MONETIZED BENEFITS AND COSTS FOR GWR REGULATORY ALTERNATIVES

[Millions, 2003$]

Rule alternative	3% Discount rate		7% Discount rate	
	Mean	5th–95th Percentiles	Mean	5th–95th Percentiles
National GWR Benefits				
Enhanced COI:				
Risk-Targeted Approach	$19.7	$6.5–$45.4	$16.8	$5.5–$38.6
Sanitary Survey	3.6	0.9–9.3	2.9	0.7–7.5
Multi-barrier Approach	21.3	7.1–48.7	18.2	6.0–41.6

TABLE VII–1.—MONETIZED BENEFITS AND COSTS FOR GWR REGULATORY ALTERNATIVES—Continued

[Millions, 2003$]

Rule alternative	3% Discount rate		7% Discount rate	
	Mean	5th–95th Percentiles	Mean	5th–95th Percentiles
Across the Board Disinfection	70.2	18.3–177.0	61.9	16.1–156.3
Traditional COI:				
Risk-Targeted Approach	10.0	2.2–27.0	8.6	1.9–22.9
Sanitary Survey	1.9	0.3–5.5	1.5	0.2–4.5
Multi-barrier Approach	10.8	2.5–28.9	9.3	2.1–24.8
Across the Board Disinfection	35.5	6.5–102.4	31.5	5.7–90.8
National GWR Costs				
Risk-Targeted Approach	61.8	45.2–81.4	62.3	46.1–81.6
Sanitary Survey	15.3	11.8–19.2	15.3	11.9–19.0
Multi-barrier Approach	67.9	49.4–89.5	69.4	51.0–90.6
Across the Board Disinfection	686.4	636.8–735.4	665.3	612.3–717.0

A. How Has the Final Rule Alternative Changed From the Proposed Rule Alternative?

The primary elements of the GWR alternative that EPA proposed were sanitary surveys, triggered source water monitoring, hydrogeologic sensitivity analyses (HSAs), routine monitoring, corrective action, and compliance monitoring. This alternative was termed ''multi-barrier approach.'' After the proposal, EPA considered comments received as discussed in section II.C of this preamble. This review resulted in the Agency choosing a different final rule alternative, Alternative 2, or the ''risk-targeted approach.'' EPA believes that the final rule is a logical outgrowth of the proposed rule, that it is supported by comments, and that it provides public health benefits while apportioning costs in a more flexible targeted manner.

EPA continues to believe that the elements of the multi-barrier approach are important. At first, EPA attempted to redesign the multi-barrier approach to resolve the issues raised by commenters. In this redesigned structure, HSAs were optional and routine monitoring (renamed assessment source water monitoring) was a required up-front monitoring program limited to 1 year of monthly samples. EPA has estimated the costs and benefits for this variation of the multi-barrier approach in the final EA (Alternative 3). However, EPA ultimately determined that the structure of this variation of the multi-barrier approach was too restrictive to achieve the full potential benefits of an assessment source water monitoring program. In addition, it did not provide sufficient flexibility to States, which was a major theme of the comments EPA received. Therefore, EPA decided to redesign the source water monitoring provision by making assessment source water monitoring an option that States can require as they see fit. The purpose of this optional requirement is to target source water monitoring to systems that the States believe are at a higher risk for microbial contamination. EPA believes that States are in the best position to assess which systems would most benefit from a comprehensive source water monitoring program. EPA recommends that States use HSAs as one tool to identify high risk systems for assessment source water monitoring. The risk-targeted approach of the final rule contains sanitary surveys, triggered source water monitoring, optional assessment source water monitoring, corrective action, and compliance monitoring.

For the Economic Analysis of the final rule alternative, EPA did not include potential costs and benefits of assessment source water monitoring. This is because assessment source water monitoring is an optional requirement under the final GWR. Thus, the EA considers quantified costs and benefits only of sanitary surveys, triggered source water monitoring, corrective action, and compliance monitoring. Throughout the EA, the final rule alternative is listed as Alternative 2—the risk-targeted approach. A discussion of the costs and benefits for the regulatory alternatives considered may be found in Chapter 8 of the EA (USEPA, 2006d).

B. Analyses That Support This Rule

EPA estimates national viral and fecal indicator occurrence based on data from several studies. The following discussion summarizes EPA's occurrence and risk analyses that support this rule.

1. Occurrence Analysis

a. *Study selection.* As discussed in Section III.C.3 of this preamble and in the NODA, EPA examined data from 24 studies of pathogen and fecal indicator occurrence in ground water wells that supply PWSs (USEPA, 2006e). EPA selected 15 of these studies to use in the risk assessment analysis to estimate national viral and fecal indicator occurrence in ground water. The *Occurrence and Monitoring Document for the Final Ground Water Rule* (USEPA, 2006b) provides a detailed discussion of each occurrence study evaluated.

To assist study selection and occurrence modeling, EPA convened a two-day statistical workshop in May 2005. The core workgroup included expert participants from several government agencies and private consulting firms working as U.S. government advisors. A summary of the workgroup proceedings, including a list of all participants, is included in the final docket for this rulemaking. The charge to the workgroup was to consider how to improve modeling of viral and indicator occurrence. The statisticians strongly recommended that EPA make use of all the available data unless there were known quality assurance problems with a data set or the well contamination scenario was outside the normal operating range of U.S. PWS wells.

After the workshop, EPA followed through on the workgroup's recommendations and used all available data sets having enterovirus and fecal indicator occurrence in ground water source(s) from PWS wells in the United States with some exceptions. Of the 16 studies described in the proposed GWR, EPA did not use data from five studies to inform the national occurrence

estimates for this rule. EPA did not use the data set of alluvial wells from Missouri that were substantially affected by severe Mississippi River flooding (Vaughn, 1996). Data from a California study (Yates *et al.*, 1999) were deleted from further consideration because data were available only by well and not by sample, so the probability of viruses detected by individual assays could not be assessed. Data from the Whittier, California study (Yanko *et al.*, 1999) were not used because the study author, in comment on the proposal, suggested that the observed somatic coliphage occurrence was not due to fecal contamination. EPA did not use data from Honolulu, Hawaii (Fujioka and Yoneyama, 2001) because the wells were not sampled for pathogenic viruses and because *E. coli* are endemic in tropical ecosystems and not simply indicators of fecal origin. EPA did not use data from the U.S.-Mexico Border study because the human virus data were never reported in written form.

Of the seven studies that became available since proposal and described in the NODA, EPA did not use four studies to inform national occurrence estimates. EPA did not use the data from the set of wells developed by Karim *et al.* (2003; 2004), because these 20 wells are also included in Abbaszadegan *et al.* (2003). EPA did not have sufficient information to distinguish which of the 20 wells from Karim (2003; 2004) were the same wells from Abbaszadegan *et al.* (2003) and, therefore, only used the larger data set. EPA did not use the National Field Study data (USEPA, 2006f) because the data set includes both PWS and domestic wells, and insufficient information is available to identify which wells are PWS wells. Also, the National Field Study data set (USEPA, 2006f) included virus cell culture measurements using smaller sample volumes than all of the other data sets. EPA did not use data from La Crosse, Wisconsin (Borchardt *et al.*, 2004) because this was a small study of four wells (and two other wells sampled once only) in one locality which, although not regulated as GWUDI, were under investigation to determine if that regulatory determination was correct. EPA did not use data from another small study of two wells in Missoula, Montana because of the size of the data set. In addition, EPA added one study of 38 wells from Helena, Montana that was submitted to EPA in response to the NODA.

b. *Description of occurrence data used to characterize national viral and indicator occurrence.* Table VII–2 shows the 15 studies used to inform national occurrence estimates for viruses and indicators. One data set (Lieberman *et al.*, 2002), targeted wells based on presence of total coliforms and other indicators of vulnerability to fecal contamination. Another data set (Abbaszadegan *et al.*, 2003), targeted a representation of wells throughout the United States based on hydrogeological conditions, but excluded any wells that were poorly constructed, ground water under the direct influence of surface water (GWUDI), or without well logs. Other studies sampled a subset of wells in a particular State, region, or hydrogeological setting. Most of the studies were designed to capture subsets of the total PWS well population. EPA excluded data from wells that States had identified as being GWUDI. Only a couple of the studies included such wells in their sample set (Lieberman *et al.*, 2002, Atherholt *et al.*, 2003). PWS using wells with GWUDI are required to meet the same treatment technique requirements for pathogens that pertain surface water supplies and are not subject to the requirements of this rule. EPA's analysis to develop national estimates for virus and indicator frequency of occurrence in wells made no attempt to weight any of the studies to compensate for any perceived over- or under-representation of the subset as compared with the total population.

TABLE VII–2.—LIST OF STUDIES USED IN NATIONAL OCCURRENCE ANALYSIS

Lieberman *et al.*, 2002 (multiple States).
Abbaszadegan, *et al.*, 2003 (multiple States).
Lindsey *et al.*, 2002 (Pennsylvania Non-community Wells).
Francy *et al.*, 2004 (Southeast Michigan).
Atherholt *et al.*, 2003 (New Jersey).
Davis and Witt, 2000 (Missouri Ozark Plateau #1).
Femmer, 2000 (Missouri Ozark Plateau #2).
USEPA *et al.*, 1998d (Wisconsin Migrant Worker Camp).
Doherty, 1998 (New England).
Battigelli, 1999 (Three-State Study: Wisconsin).
Banks *et al.*, 2001 (Three-State Study: Maryland).
Banks and Battigelli, 2002 (Three-State Study: Maryland).
Minnesota DOH, 2000 (Three-State Study: Minnesota).
USEPA, 1998a (EPA Vulnerability Study).
Miller and Meek, 2006 (Montana).

Using enterovirus cell culture and *E. coli* data from the 15 studies, EPA modeled virus and fecal indicator (*E. coli*) occurrence in ground water. EPA believes that enterovirus cell culture measurements provide the best available basis for estimating pathogenic viral occurrence since it captures viruses that are alive and infectious. However, because the cell culture procedure only captures a portion of the types of pathogenic viruses that may actually occur in well water, use of this metric underestimates total viral occurrence. EPA did not use PWS samples assayed using PCR methods to estimate national viral occurrence for this rule because PCR methods cannot discriminate between infectious and non-infectious viruses. Three of the 15 studies included viral concentration data (Lieberman *et al.*, 2002, Abbaszadegan, *et al.*, 2003 and Lindsey *et al.*, 2002). EPA used data from these studies to inform national estimates for viral concentrations among wells modeled to have viral occurrence. However, since the sampling sites from Lieberman *et al.*, 2002 were selected because they had a history of total coliform contamination or other evidence of vulnerability (whereas the sample sites from the other two studies had no such site selection bias), EPA only used viral concentration data from Lieberman *et al.*, 2002 for a small portion of wells in the U.S.

EPA used data on the indicator *E. coli* to inform estimates of fecal contamination occurrence. Indicator data is important because illness can result from consuming ground water with fecal contamination in the absence of identified viruses. EPA chose to use *E. coli* as the indicator organism to inform national fecal contamination occurrence for several reasons. First, analysis using two or more indicator organisms becomes increasingly complex. Second, substantial variability among studies in choice of indicators, indicator assay method, sample volumes and, in the case of coliphage, bacterial host and host range, adds uncertainty when data sets are combined. Third, for any one indicator other than *E. coli,* the number of assays with consistency of measurement is small. Fourth and most important, EPA believes that *E. coli* will be the most likely fecal indicator used when PWS implement the GWR and therefore national estimates of *E. coli* occurrence can be used to inform potential cost implications for implementing the GWR.

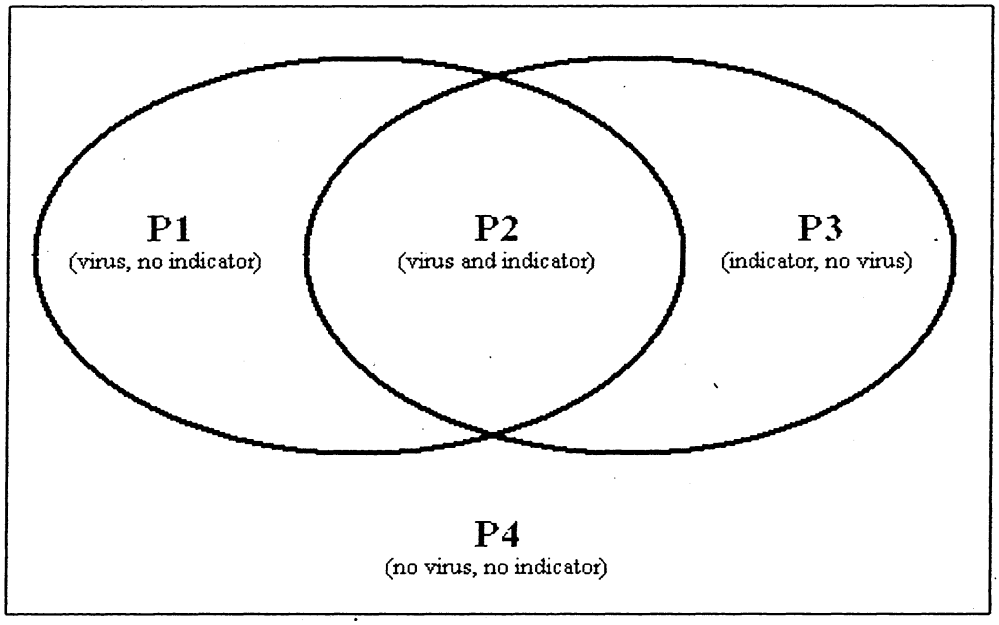
c. *How data were used to estimate national occurrence of viral and fecal contamination.* Data from each of 15 studies were combined into one single data set used to determine the probabilities of wells having anytime viral (indicated by enterovirus cell culture) or fecal indicator (indicated by *E. coli*) contamination. The results of this effort led naturally to a combined analysis, which also modeled co-occurrence of viruses and *E. coli.* This combined model serves as the basis of EPA's national quantitative occurrence estimates.

EPA's occurrence model includes four categories of wells:

- Wells with no *E. coli* occurrence, but some virus occurrence,
- Wells with both *E. coli* and virus occurrence,
- Wells with no virus, but some *E. coli* occurrence, and
- Wells with neither *E. coli* nor virus occurrence.

The fractions of wells falling into these four categories are named P1, P2, P3, and P4, respectively. The categories and parameters P1 through P4 are illustrated in the Venn diagram of Figure VII–1.

Figure VII-1: Categories of Indicator and Viral Classification Among PWS Wells in U.S.



Because fecal contamination is intermittent, viruses and *E. coli* will only be present some fraction of time in a contaminated well. These fractions will vary from well to well and EPA has modeled these different fractions as distributions. One parameter pair describes the distribution for viruses and another parameter pair describes the distribution for *E. coli*. These four parameters, together with the fractions of wells falling into the four categories, are the parameters estimated in the national occurrence model.

The *Economic Analysis for the Final Ground Water Rule* describes the statistical methods used to estimate model parameters (USEPA, 2006d). That document details the statistical model, estimation methods, and summary results. The GWR EA also includes a number of Exhibits that describe the central estimates (means) and their uncertainties.

Central estimates for key parameters are as follows:

- P1 = percentage of wells having virus, but no *E. coli* = 10 percent
- P2 = percentage of wells having both virus and *E. coli* = 16 percent
- P3 = percentage of wells having *E. coli*, but no virus = 10 percent
- P4 = percentage of wells having no virus and no *E. coli* = 64 percent
- On average, wells with some virus occurrence have detectable concentrations 11 percent of the time.
- On average, wells with some *E. coli* occurrence have detectable concentrations 14 percent of the time.

EPA attempted to evaluate occurrence based on the hydrogeologic characteristics of the aquifer. However, because very few data sets allowed for differentiation of viral or indicator presence among sensitive versus non-sensitive wells, no significant difference in viral or indicator presence could be discerned from the limited data. Therefore, the same P1, P2, P3, and P4 estimates were assumed for all wells, without regard to aquifer sensitivity.

Although EPA could not stratify the available viral occurrence data between wells drawn from sensitive or non-sensitive aquifers, EPA was able to discern two classifications of well type according to overall vulnerability characteristics (more and less vulnerable wells). The data from Lieberman *et al.*, 2002 were used to represent virus concentrations in more vulnerable wells and the combined data from Abbaszadegan *et al.*, 2003 and Lindsey *et al.*, 2002 were used to represent concentrations in less vulnerable wells.

EPA used acute and non-acute TCR maximum contaminant level (MCL) violation data to estimate the percent of wells considered more vulnerable. Based on this data, EPA estimated that about 2.5 percent of wells in the U.S., which have modeled viral presence, would have viral concentrations like the non-GWUDI wells in Lieberman *et al.*, 2002 (more vulnerable). Similarly, EPA estimated that about 97.5 percent of the wells in the U.S. (100—2.5 percent) which have modeled viral presence would have concentrations like those of Abbaszadegan *et al.* (2003) and Lindsey *et al.* (2002) (less vulnerable).

2. Risk Analyses

a. *Baseline risk estimates.* The framework for developing the estimates of baseline risk from consumption of contaminated ground water is in accordance with the standard framework detailed in the *EPA Policy for Risk Characterization* (USEPA, 1995a), EPA's *Guidance for Risk Characterization* (USEPA, 1995b), and EPA's *Policy for Use of Probabilistic Analysis in Risk Assessment* (USEPA,

1997c). A complete discussion of EPA's risk analyses in support of this rule can be found in the GWR EA (USEPA, 2006d). The discussion below is an overview of the analyses, focusing on how information on occurrence, exposure, and dose-response is combined to produce estimates of health risk.

EPA's occurrence model predicts the fraction of wells that have some degree of viral contamination. The model also predicts degree of contamination, in terms of the varying fractions of time that viruses can be detected. In the probabilistic risk analysis, Monte Carlo techniques are used to simulate large numbers of wells with differing fractions of time that virus is present.

In addition to assigning different fractions of time, the risk model also assigns different concentration levels to the simulated contaminated wells. Each well is assigned one concentration value and this is treated as the well's concentration whenever the well has virus present. EPA does this by sampling from the actual virus concentrations that were observed in the occurrence studies. Viral concentrations among more vulnerable wells are sampled from the measured values of non-GWUDI wells in the Lieberman *et al.*, 2002, study. Concentrations in less vulnerable wells are sampled from those measured in the Abbaszadegan, *et al.*, 2003 and Lindsey *et al.*, 2002 studies.

EPA's risk model then estimates exposure levels, or doses, for consumers of the contaminated well water. A consumer's dose on a day when virus is present depends on the virus concentration, the level of disinfection employed by the water system, and the volume of tap water that the consumer ingests. For systems that do not disinfect, the tap water is assumed to have the same virus concentration as the source water. In contrast, properly operating systems that disinfect are assumed to inactivate 99 percent (2-log) to more than 99.99 percent (4-log) of viral pathogens, depending on the disinfection practices employed. A consumer's daily dose is computed as the product of the tap water concentration, the fraction of viral pathogens NOT inactivated and the volume of water ingested.

Next, the consumer's daily dose is translated to risk of infection via EPA's dose-response modeling. EPA's risk model applies the calculated dose, based on viral cell culture measurement, for both Type A and Type B viruses. Daily probabilities of infection are then derived on the basis of the daily dose, according to dose-response models. Annual probabilities of infection are then derived from the daily estimates, based on the number of days per year in which a virus is expected to be present.

Next, morbidity factors (risk of illness given infection), secondary spread of illness to other individuals, and mortality factors (risk of premature death given an illness), derived from the literature, are used to estimate the annual probability for illness and premature death. EPA's risk assessment model includes variability and uncertainty ranges for morbidity and mortality to account for different effects in different subpopulations.

b. *Risk reduction estimates.* The methodology for estimating the reduction in risk for the regulatory alternatives builds upon the approach and assumptions used to establish the baseline risk. The primary difference between the modeling for estimating the baseline risk model and the modeling for estimating the risk reduction from a given regulatory alternative is that the latter incorporates a change in the concentration of viral pathogens reaching the finished drinking water of the exposed population. These changes reflect either a reduction in pathogen concentration between source water and finished water due to disinfection or the elimination of the pathogen from other non-treatment corrective actions addressing the source water contamination. In addition to accounting for the magnitude of pathogen exposure reduction, an important component of the risk reduction modeling is to account for the timing of when those reductions occur over a 25 year analysis timeframe following promulgation of the rule.

For the baseline risk analysis, each well in the simulation process is designated as either having a virus present at some time or never having a virus present. For those wells having some viral occurrence, values are assigned for the virus concentration and the fraction of time that virus occurs. The risk reduction part of the model uses the exact same simulated wells as those generated in the baseline risk part of the model.

For the sake of efficiency in implementing the simulation modeling process, those wells designated as never having a virus present are recognized as having zero risk reduction potential and are counted as such in the model outputs, but are not run through the detailed steps of the risk reduction model.

For those wells that do have a virus present, the risk reduction model answers the following three questions:

(1) Is a corrective action performed on this well as a result of the regulatory alternative being considered?

(2) What is the finished water virus concentration following corrective action?

(3) In what year following rule implementation is the corrective action performed?

The risk reduction model then processes the reduced virus concentrations through the dose-response functions for infectivity and the morbidity and mortality factors as in the baseline risk assessment.

Estimates of cases avoided, calculated for all of the individual wells, are then aggregated across all wells to arrive at the total national estimates of risk reduction. In addition, some of the assumptions and data used in the risk reduction model are uncertain and are therefore input as uncertainty distributions. As a result of the uncertainty reflected in those inputs, together with the uncertainty reflected in other inputs to the baseline risk model that are also carried into the risk reduction model, the output of the model is a range of values of cases avoided. The range is used by EPA to determine the expected value and the 90 percent confidence bounds on that expected value.

The GWR EA (USEPA, 2006d) describes in more detail the specific assumptions and inputs—including considerations of uncertainty—that are used to model risk reduction for each of the four rule options at the individual well level and the aggregation of those well level estimates to obtain the overall national estimates of risk reduction.

C. What Are the Benefits of the GWR?

The quantified benefits of this rule result from reductions in endemic acute viral illness and death from two groups of viruses (called Type A and Type B). Type A virus is represented by rotavirus and is highly infectious but has essentially only mild health effects. Type B virus is represented by enterovirus or echovirus (a member of the enterovirus group) and is moderately infectious, but can have severe health consequences though the majority of illnesses from Type B viruses are also mild. Additionally, the quantified benefits are based only on endemic, acute illness that occurs as a result of virus in PWS wells under normal operating conditions. Illnesses due to treatment interruptions or failures or to distribution system deficiencies are not quantified. Bacterial illnesses and deaths avoided are also not quantified.

As shown in Table VII–3 below, the annualized present value of the quantified benefits of this rule are $19.7 million (using a three percent discount rate and an enhanced cost-of-illness value that includes lost unpaid labor (*e.g.*, household production) and leisure time for people within and outside the paid labor force), with a 90 percent confidence interval of $6.5 to $45.4 million. Using traditional cost-of-illness values at the same discount rate, the annualized present value of the quantified benefits of the rule are $10.0 million, with a 90 percent confidence interval of $2.2 to $27.0 million. At a seven percent discount rate and the enhanced cost-of-illness value, the annualized present value of the quantified benefits are $16.8 million, with a 90 percent confidence interval of $5.5 to $38.6 million. Using the traditional cost-of-illness values, the annualized present value of the quantified benefits are $8.6 million, with a 90 percent confidence interval of $1.9 to $22.9 million at a seven percent discount rate.

TABLE VII–3.—SUMMARY OF ANNUALIZED PRESENT VALUE QUANTIFIED BENEFITS

[$Millions, 2003$]

System type	Annualized benefits at three percent discount rate			Annualized benefits at seven percent discount rate		
	Mean	90 Percent confidence bound		Mean	90 Percent confidence bound	
		Lower (5th %ile)	Upper (95th %ile)		Lower (5th %ile)	Upper (95th %ile)
Enhanced COI:						
CWSs	$16.0	$5.4	$37.0	$13.7	$4.6	$31.6
NTNCWSs	0.9	0.3	2.2	0.8	0.2	1.8
TNCWSs	2.7	0.8	6.2	2.3	0.7	5.1
Total	19.7	6.5	45.4	16.8	5.5	38.6
Traditional COI:						
CWSs	8.2	1.9	22.3	7.1	1.6	19.1
NTNCWSs	0.5	0.1	1.3	0.4	0.1	1.0
TNCWSs	1.3	0.3	3.4	1.1	0.2	2.8
Total	10.0	2.2	27.0	8.6	1.9	22.9

Note: Estimates are derived from independent model runs and, therefore, detail may not add to total. Values are for endemic viral illnesses and deaths avoided over the 25-year period, expressed in annualized dollars. See VII.C.4 for additional rule benefits.

1. Calculation of Baseline Health Risk

As part of the quantitative analysis to determine the GWR benefits, EPA estimated the ''baseline risk'' (pre-GWR)—the number of people becoming ill and/or dying each year from Type A (represented by rotavirus) and Type B (represented by enterovirus or echovirus) viral infection due to consumption of ground water from public water supplies (see Table VII–4). The risk analysis uses these two viruses as surrogates for waterborne viruses. The annual estimated number of viral illnesses from exposure to Type A and Type B viruses ranges from about 33,000 to 476,000 cases, with a mean of approximately 185,000 cases. EPA estimates that about 0.3 to 11 deaths per year (mean of three deaths) prior to this rule as a result of exposure to viruses. These numbers are the ''baseline'' used to estimate the health risk reduction and their associated monetized value of risk reduction due to implementation of this rule. As discussed earlier, bacterial illnesses and deaths are not considered in the baseline, and only endemic, acute viral illnesses from the two surrogate viruses are considered.

TABLE VII–4.—ESTIMATES OF BASELINE VIRAL ILLNESSES AND DEATHS DUE TO CONTAMINATION OF GROUND WATER SYSTEMS

Virus type	Illnesses per year		Deaths per year	
	Mean	5th–95th Percentiles	Mean	5th–95th Percentiles
Type A (rotavirus)	175,168	32,652–435,381	1.2	0.2–2.9
Type B (enterovirus or echovirus)	10,018	501–40,718	2.0	0.0–8.1
Total	185,186	33,153–476,099	3.2	0.3–11.0

2. Calculation of Avoided Illnesses and Deaths

The GWR requirements are projected to result in a significant reduction in exposure to fecal contamination. EPA used a risk assessment model to estimate the avoided viral illnesses and deaths. The risk assessment model estimates reductions in baseline incidence considering the effects of the sanitary survey and triggered source water monitoring. Assessment source water monitoring is optional and is not included in this analysis (see Section VII J.10). Table VII–5a shows the calculated viral illnesses and deaths avoided due to the GWR. The rule is expected to avoid (mean value) approximately 42,000 viral illnesses and one viral death annually (averaged over 25 years). Details of the assumptions and methodology used in the model are described in the GWR EA (USEPA, 2006d). Table VII–5b shows the

calculated viral illnesses and deaths avoided due to the GWR by system type. More detailed information about the GWR benefits assessment and all data and analyses used in predicting those benefits can be found in the GWR EA (USEPA, 2006d).

TABLE VII–5A.—SUMMARY OF ANNUAL VIRAL ILLNESSES AND DEATHS AVOIDED FOR THE GWR

Virus type	Illnesses avoided per year		Deaths avoided per year	
	Mean	5th–95th Percentiles	Mean	5th–95th Percentiles
Type A (rotavirus)	39,442	10,093–79,925	0.3	0.1–0.5
Type B (enterovirus or echovirus)	2,426	181–8,114	0.5	0.0–1.6
Total	41,868	10,274–88,039	0.7	0.1–2.1

Note: Details may not add to totals due to independent rounding and independent statistical analyses.
Source: GWR Illness Model.

TABLE VII–5B.—SUMMARY OF ANNUAL AVOIDED VIRAL ILLNESSES AND DEATHS BY SYSTEM TYPE

System type	Illnesses avoided per year		Deaths avoided per year	
	Mean	5th–95th Percentiles	Mean	5th–95th Percentiles
CWSs	32,031	8,704–68,994	0.6	0.1–1.8
NTNCWSs	2,094	533–4,308	0.03	0.0–0.1
TNCWSs	7,743	1,037–14,738	0.1	0.01–0.2
Total	41,868	10,274–88,039	0.7	0.1–2.1

Note: Estimates are derived from independent model runs, and, therefore, detail may not add to total. Values are endemic, acute viral illnesses and deaths avoided following full implementation of the GWR and only accounts for rotavirus and echovirus.
Source: Derived from GWR model output.

3. Derivation of Quantified Benefits

EPA quantified the benefits for the GWR based on reductions in the risk of endemic, acute viral illness as explained in Section VII.B.2. Next, EPA monetized benefits for nonfatal viral illnesses and mortalities avoided by the GWR. Table VII–3 shows the estimated monetized value for viral illnesses and deaths avoided by the GWR.

Benefits for nonfatal cases of endemic, acute viral illness were calculated using a cost-of-illness (COI) approach. Traditional COI valuations focus on medical costs and lost work time and leave out significant categories of benefits, specifically, the reduced utility from being sick (*i.e.*, lost personal or nonwork time, including activities such as child care, homemaking, community service, time spent with family, and recreation), although some COI studies also include an estimate for unpaid labor (household production) valued at an estimated wage rate designed to reflect the market value of such labor (*e.g.*, median wage for household domestic labor).

Ideally, a comprehensive willingness to pay (WTP) estimate would be used that includes all categories of loss in a single number. However, a review of the literature indicated that the available studies were not suitable for valuing acute viral illness; hence, estimates from this literature are inappropriate for use in this analysis. Instead, EPA presents two COI estimates: a traditional approach that only includes valuation for medical costs and lost work time (including some portion of unpaid household production) and an enhanced approach that also factors in valuations for lost unpaid work time for employed people, reduced utility (or sense of well-being) associated with decreased enjoyment of time spent in non-work activities, and lost productivity at work on days when workers are ill but go to work anyway. The first two categories of loss are estimated by multiplying the average wage rate by the number of non-work waking hours. The third category is estimated by multiplying all waking hours (work and non-work) by 30 percent of the wage rate for days when subjects are ill but report for work anyway.

The computation of COI involves two broad categories of costs—direct and indirect medical costs. All costs are updated to a common year (2003) used as the starting point for projecting benefits into future time periods. For Type A viruses, each cost component has a separate estimate made based on age and the health state of the individual (healthy or immunocompromised). For Type B viruses, cost components have separate estimates based both on age and on the type of care required (*i.e.*, no medical care, outpatient care, or inpatient care). Chapter 5 of the GWR EA (USEPA, 2006d) has a detailed breakout of both Type A and Type B COI estimates.

For both the Enhanced COI and Traditional COI, the direct cost for a case of Type A or Type B viral illness is derived by summing the costs of outpatient and inpatient care (in 2003$). Outpatient care consists of an initial physician visit ($114.55) and the product of the cost of each follow-up visit ($66.18) and the number of follow-up visits. Multiplying this sum by the percentage of patients that utilize outpatient services yields the weighted unit cost of outpatient care. The cost of inpatient care consists of the costs of the initial doctor visit in the hospital ($152.87), any follow-up visits ($52.25), and the hospital charges (calculated on a per day basis, with costs ranging from $1,007 per day for Type A illnesses to $4,870 per day for a severe case of Type B illness). As with outpatient costs, multiplying the sum of doctor visits and hospital charges by the percentage of patients who require inpatient care yields the weighted unit cost of inpatient care.

The sum of the weighted unit costs of outpatient and inpatient care equals the weighted direct costs. The weighted direct medical costs per case of Type A viral illness ranges from an average cost of $0 (for healthy patients, five years old

and up requiring no medical care) to $4,486 (for immunocompromised patients younger than five years old). The weighted direct medical costs per case of Type B viral illness range from an average of $0 (for patients requiring no medical care) to $23,431 (for patients less than one month old requiring inpatient care).

Total indirect cost is the sum of the value of patient days lost, the value of productivity lost, and the value of care giver days lost. For the Enhanced COI, the total indirect cost associated with a case of Type A viral illness ranges from an average of $103 (for healthy patients 16 years old and older) to $2,136 (for immunocompromised patients under two years of age). Indirect costs associated with cases of Type B viral illness range from $336 (for patients 16 years old and older requiring no medical care) to $2,990 (for patients under 16 years of age requiring inpatient care).

For the Traditional COI, the total indirect cost associated with a case of Type A viral illness ranges from an average of $39 (for healthy patients 16 years old and older) to $426 (for immunocompromised patients two years of age and younger). Indirect costs associated with cases of Type B viral illness range from $126 (for patients 16 years old and older requiring no medical care) to $596 (for patients requiring inpatient care).

The valuation of children's time presents unique problems. The best approach when valuing children's health effects is the use of child-specific valuations of these effects. For direct costs, EPA has used such valuations. Indirect costs, however, prove more challenging. As noted in the *Children's Health Valuation Handbook* (USEPA, 2003c), ''[children's] time lost to sickness also has value, although no direct measure exists for this loss.'' In this instance, the Handbook states that, ''as a second-best option, * * * transfer benefit values estimated for adults to children.'' The Enhanced COI uses this guideline, in conjuncture with Executive Order 13045 (''Protection of Children from Environmental Health Risks and Safety Risks''), and assumes a day lost due to illness (lost patient day) for the duration of illness for patients younger than 16 years to be valued at $199.36 (based on the median post-tax wage). In contrast, the Traditional COI assigns no lost patient day value for children under 16 years of age because this approach assigns a monetary value only to lost wages (or lost unpaid work time for adults not in the paid labor market). Both the Traditional and Enhanced COI approaches assume that a caregiver stays home with these children, introducing additional lost caregiver days for each lost patient day. The number of days lost entirely to illness, either by the adult patient or caregiver, is multiplied by $227.79 (for the Enhanced COI) or $85.12 (for the Traditional COI), the average value of a lost day.

In addition, for days when an individual is well enough to work but still experiencing symptoms, such as diarrhea, the Enhanced COI estimate also includes a 30 percent loss of work and leisure productivity (*i.e.* 30 percent of the wage rate times 16 hours) based on a study of giardiasis illness (Harrington *et al.*, 1985). In the Traditional COI analysis, productivity losses are not included for either work or nonwork time. No productivity losses are assigned to children under 16 years of age under either the Traditional or Enhanced COI approaches.

The Agency believes that losses in productivity and lost leisure time are unquestionably present and that these categories have positive value; consequently, the Traditional COI estimate understates the true value of these loss categories. However, using the wage rate to estimate the loss of utility during non-work hours may understate or overstate the value of this loss, depending on severity of illness and other factors. Similarly, using 30 percent of the wage rate to estimate the value of lost productivity in work and leisure when a person is still experiencing symptoms but is well enough to go to work may understate or overstate benefits. EPA notes that these estimates should not be regarded as upper and lower bounds. In particular, the Enhanced COI estimate may not be an upper bound, because it may not fully incorporate the value of pain and suffering.

As with the avoided mortality valuation, the real wages used in the COI estimates were increased by a real income growth factor that varies by year, but is the equivalent of about 1.8 percent per year over the 25-year period. This approach of adjusting for real income growth was recommended by the SAB (USEPA, 2000d) because the median real wage is expected to grow each year (by approximately 1.8 percent). Correspondingly, the real income growth factor of the COI estimates increases by the equivalent of 1.8 percent per year (except for medical costs, which are not directly tied to wages).

Reductions in mortalities were monetized using EPA's standard methodology for monetizing mortality risk reduction. This methodology is based on a distribution of value of statistical life (VSL) estimates from 26 labor market and stated preference studies. For this analysis, EPA incorporated the Weibell Distribution into the benefit model Monte-Carlo simulation and updated the VSLs to 2003 dollars. The updated mean VSL in 2003 dollars is $7.4 million. A real income growth factor was applied to these estimates of approximately 1.8 percent per year for the 25-year time span following implementation. Income elasticity for VSL was estimated as a triangular distribution that ranged from 0.08 to 1.00, with a mode of 0.40. VSL values for the 25-year time span are shown in the GWR EA in Exhibit B.6 (USEPA, 2006d). A more detailed discussion of these studies and the VSL estimate can be found in EPA's *Guidelines for Preparing Economic Analyses* (USEPA, 2000c).

4. Nonquantifiable Benefits

There are substantial benefits attributable to the GWR that are not quantified as part of this rulemaking because of data limitations. The GWR quantifies only the endemic, acute illnesses and deaths due to rotavirus and enterovirus. By reducing bacterial and other viral illnesses and deaths, this rule provides significant health benefits beyond the monetized benefit estimates. Chronic illnesses (such as diabetes, dilated cardiomyopathy, and reduced kidney function), kidney failure, and hypertension (*e.g.*, Garg *et al.*, 2005) resulting from waterborne viral and bacterial pathogens are also not quantified but provide additional benefits, although such cases are likely to be relatively rare. Additional health benefits will accrue from preventing outbreaks, reducing periods with insufficient disinfection, and minimizing contaminant infiltration into distribution systems.

This rule will also result in non-health benefits such as avoided outbreak response costs, increased information gained through source water monitoring that will in turn provide benefits to the systems and their customers, and reduced uncertainty regarding drinking water safety, which may lead to reduced costs for averting behaviors.

In addition, the optional assessment source water monitoring provision will provide additional benefits similar to those already described (*i.e.* reduction in viral and bacterial illness). However, EPA was not able to quantify either the benefits or costs of this program because EPA does not know the extent to which States will use the option or the manner in which they will implement it. Because this provision could potentially

increase both benefits and cost, a more complete discussion can be found in the Section VII.J.10 of this preamble.

EPA believes that, collectively, these benefits, both health and non-health, significantly exceed those which EPA was able to quantify and are a major basis for supporting the preferred regulatory alternative. A qualitative discussion of these nonquantified benefits is included in Section 5.4 of the GWR EA (USEPA, 2006d); a summary of this discussion appears below.

a. *Decreased incidence of illness from bacteria.* In addition to reducing the number of illnesses and deaths due to drinking water related to some viral illnesses, the ground water source monitoring and corrective actions taken under the GWR will also reduce the number of illness and deaths due to bacteria in drinking water. EPA was unable to quantify the benefits from preventing bacterial illness; however, EPA provides a rough estimate of illnesses and deaths prevented through:

- Estimating potential bacterial illnesses avoided;
- Estimating a mortality rate for waterborne bacterial illness; and
- Estimating potential annual deaths avoided by the GWR.

The first of the analytical steps applies the ratio of waterborne disease outbreak incidence rates between bacteria and viruses to the quantified viral cases avoided to estimate bacterial cases avoided. The second analytical step derives mortality rates for types of bacterial illness associated with waterborne disease outbreaks. The third analytical step combines the first two steps to devise a rough estimate of annual bacterial deaths avoided. EPA estimates that total quantified benefits could increase by a factor of five if EPA was able to account for additional deaths and hospitalizations caused by bacterial illness being avoided (*i.e.*, not even considering the value of reduced non-fatal non-hospitalization caused bacterial illnesses). More information on this calculation can be found in Chapter 5 of the GWR EA (USEPA, 2006d).

b. *Decreased illness from other viruses.* Quantified benefits accrue from endemic, acute illnesses associated with rotavirus (a Type A virus) and enterovirus or echovirus (a Type B virus) as discussed previously. Nonquantified health benefits attributable to viruses include decreased incidence of gastroenteritis caused by other Type A viruses such as norovirus, astrovirus, and adenovirus; decreased incidence of other acute disease endpoints (*e.g.*, hepatitis and conjunctivitis) caused by types of viruses not modeled in the quantified benefits analysis; and decreased incidence of chronic illness associated with Type B virus (*e.g.*, diabetes and dilated cardiomyopathy).

The health effects of norovirus (the most common Type A virus) illness include acute onset of nausea, vomiting, abdominal cramps, and diarrhea (USEPA, 2006d). EPA believes that nausea and vomiting associated with norovirus, typically absent in rotavirus illness, suggest that the norovirus disease burden (*e.g.*, number of productive days lost) associated with PWS wells is important, especially for adults with whom norovirus disease is quite prevalent. EPA believes that if norovirus were included in the quantified benefits, there would be significantly greater monetized benefits for Type A viruses, because monetized rotavirus disease burden (the only Type A virus modeled) provides only a small benefit for adults since most adults are immune to rotavirus.

Other acute and chronic viral illnesses can be acquired from consuming ground water contaminated with other Type A or Type B viruses, but the Agency was unable to quantify or monetize them. These include severe, acute illnesses such as hepatitis A; milder, acute illnesses such as conjunctivitis; and severe chronic illnesses such as diabetes and dilated cardiomyopathy. Most chronic illnesses are costly to treat. Lifetime costs associated with a new case of diabetes, for example, assuming an average illness duration of 30 years, are estimated at $227,032 using a three percent discount rate and $143,733 using a seven percent discount rate (year 2003 dollars). For dilated cardiomyopathy, the lifetime (21 year average) cost is $61,117 (seven percent discount rate, year 2003 dollars). These illnesses are discussed in further detail in the GWR EA (USEPA, 2006d).

c. *Other nonquantifiable benefits.* Other nonquantified health benefits include decreased incidence of waterborne disease outbreaks and epidemic illness and decreased illness through minimizing treatment failures or fewer episodes with inadequate treatment. The nonquantified non-health benefits include improved perception of ground water quality and perception about reduced risk associated with PWS wells, potential reduced use of bottle water and point-of-use devices, reduced time spent on averting behavior such as obtaining alternative water supplies, and avoided costs associated with outbreak response.

Pathogenic protozoa can occur in PWS wells, typically when such systems are misclassified and are not recognized as GWUDI systems. In PWSs with elevated ground water temperatures, *Naegleria fowleri* can colonize the distribution system, well, well gravel-pack, or aquifer. *N. fowleri* is fatal when inhaled (and treatment is not timely) and two five-year old boys died in the same week from exposure via a GWS in Arizona (Marciano-Cabral *et al.*, 2003). *N. fowleri* is inactivated by disinfection, so corrective action implemented as the result of this rule that includes disinfection may prevent death from this organism. However, the benefits from avoiding these deaths are nonquantified. Cryptosporidiosis and giardiasis outbreaks in sensitive PWS wells have also occurred (see Section III.C.2). Sanitary surveys and additional monitoring under the GWR combined with existing source water assessments and Long Term 2 Surface Water Treatment Rule (LT2ESWTR) (71 FR 654, January 5, 2006) (USEPA, 2006i) implementation can, in combination, minimize the likelihood of misclassification of PWS wells (as non-GWUDI) and reduce the likelihood of outbreaks associated with such misclassification. This rule only qualitatively considers the benefits of identifying misclassified PWS wells.

Several nonhealth benefits from this rule were also recognized by EPA but were not monetized. The nonhealth benefits of this rule include avoided outbreak response costs (such as the costs of providing public health warnings, boiling drinking water and providing alternative supplies, remediation and repair, and testing and laboratory costs). Expenses associated with outbreaks can be significant. For example, an analysis of the economic impacts of a waterborne disease outbreak in Walkerton, Ontario (population 5,000) estimated the economic impact excluding medically related costs to be over $43 million in Canadian dollars (approximately $32 million in U.S. dollars) (Livernois, 2002). The author believed that this was a conservative estimate.

5. How Have the Benefits Changed Since the Proposal?

The estimated annual quantified benefits for the GWR have changed from $205 million (year 2000 dollars, both at 3 percent and 7 percent discount rates) to $19.7 million (year 2003 dollars, at 3 percent) using enhanced cost-of-illness estimates and $10.0 million (year 2003 dollars, at 3 percent) using traditional cost-of-illness estimates (these are $16.8 and $8.6 using a 7 percent discount rate). The proposal only included the enhanced cost-of-illness measure. The change in quantified benefits is due to

changes in both the economic analysis estimates (*e.g.*, interpretation of occurrence and other data) and GWR provisions. However, changes in the economic analysis estimates are the dominant factor in explaining the large change in benefits from the proposal.

Estimates in the GWR EA that were changed and that most influenced the change in the quantified benefit estimate include:

- Frequency and duration of viral occurrence in wells;
- Percentage of wells associated with high versus low viral concentrations;
- Efficiency by which virally contaminated wells are identified and prescribed corrective action;
- Severity of symptoms associated with predicted illnesses
- Monetized value of illnesses avoided; and
- Using net present values and then annualizing benefits.

EPA believes that the changes made in the GWR EA since proposal substantially improve upon the scientific basis for the quantified benefits, a major issue raised by public comments (see Section VII.J of this preamble for further discussion of public comments). Chapter 5 of the GWR EA describes the basis for the analysis (USEPA, 2006d).

Changes in the rule provisions also impacted the final benefit estimate but these changes are not as significant as the changes made in the economic analysis. In addition, the benefits (as well as costs) for the optional assessment source water monitoring and additional fecal indicator sampling following triggered source water monitoring are not included in the final rule analysis. These potential impacts are discussed in Section VII.J.10.

Another major change in the GWR EA since proposal is a more thorough analysis of the nonquantified benefits. EPA's analysis of the potential benefits from avoided bacterial illness suggests that the nonquantified benefits may exceed the quantified benefits by a factor of five (see Chapter 5.4 of the GWR EA for a full description of nonquantified benefits, USEPA, 2006d).

D. What Are the Costs of the GWR?

1. Summary of Quantified Costs

In estimating the costs of this rule, the Agency considered impacts on public water systems and on States. Table VII–6 summarizes these costs in terms of annualized present value: $61.8 million (using a three percent discount rate) and $62.3 million (using a seven percent discount rate). Most costs occur early in the implementation schedule, therefore the values do not differ much using different discount rates.

To calculate the national costs of compliance, the Agency used a Monte-Carlo simulation model specifically developed for the GWR. The main advantage of this modeling approach is that in addition to providing average compliance costs, it also estimates the range of costs within each PWS size and category. It also allows the Agency to capture the variability and uncertainty in areas such as PWS configuration, current treatment in-place, source water quality, existing State requirements, unit costs of treatment technologies, and compliance forecasts. The 90 percent confidence bounds shown in Table VII–6 reflect the quantified uncertainties.

Table VII-6: Total Annualized Present Value Costs ($Millions, 2003$)

Discount Rate	Systems			States			Total		
	Mean Value	90 Percent Confidence Bound		Mean Value	90 Percent Confidence Bound		Mean Value	90 Percent Confidence Bound	
		Lower (5th %ile)	Upper (95th %ile)		Lower (5th %ile)	Upper (95th %ile)		Lower (5th %ile)	Upper (95th %ile)
3 percent	$ 50.0	$ 34.3	$ 68.8	$ 11.8	$ 10.9	$ 12.6	$ 61.8	$ 45.2	$ 81.4
7 percent	$ 50.6	$ 35.2	$ 69.0	$ 11.7	$ 10.9	$ 12.6	$ 62.3	$ 46.1	$ 81.6

Notes: Detail may not add to totals due to independent rounding.

Table VII–6 shows the estimated annualized present value costs of this rule. Drinking water utilities will incur approximately 81 percent of the rule's costs. States will incur the remaining costs of the rule. In addition to the mean estimates of costs, the Agency calculated 90 percent confidence intervals by considering, for example, the uncertainty in the mean unit technology costs. Table VII–7 shows the undiscounted capital costs and all one-time costs for both water systems and States. The derivation of these cost numbers can be found in Chapter 6 of the GWR EA (USEPA, 2006d). The itemized costs of this rule are presented below for systems and States, respectively.

Table VII-7: Total Initial Capital and One-Time Costs ($Millions, 2003$)

	PWSs Serving ≤10,000			PWSs Serving > 10,000			Total		
		90 Percent Confidence Bound			90 Percent Confidence Bound			90 Percent Confidence Bound	
	Mean Value	Lower (5th %ile)	Upper (95th %ile)	Mean Value	Lower (5th %ile)	Upper (95th %ile)	Mean Value	Lower (5th %ile)	Upper (95th %ile)
CWS Total Initial Capital	$ 79	$ 29	$ 158	$ 62	$ 24	$ 117	$ 141	$ 53	$ 275
NTNCWS Total Initial Capital	$ 31	$ 12	$ 60	$ 0	$ 0	$ 1	$ 31	$ 12	$ 61
TNCWS Total Initial Capital	$ 173	$ 64	$ 339	$ 1	$ 0	$ 2	$ 174	$ 64	$ 341
Total Initial PWS Capital Costs	$ 283	$ 105	$ 556	$ 64	$ 24	$ 120	$ 346	$ 129	$ 676
CWS Implementation Costs	$ 5	$ 5	$ 5	$ 0	$ 0	$ 0	$ 5	$ 5	$ 5
NTNCWS Implementation Costs	$ 2	$ 2	$ 2	$ 0	$ 0	$ 0	$ 2	$ 2	$ 2
TNCWS Implementation Costs	$ 9	$ 9	$ 9	$ 0	$ 0	$ 0	$ 9	$ 9	$ 9
Total One-Time PWS Costs	$ 16	$ 16	$ 16	$ 0	$ 0	$ 0	$ 17	$ 17	$ 17
State Start-Up Cost							$ 13	$ 13	$ 13
Total State One-Time Costs							$ 13	$ 13	$ 13

Notes: Detail may not add to totals due to independent rounding.
The mean and confidence bounds are equal for both systems and state implementation costs because EPA derived these costs from point estimates.

2. Derivation of Quantified Costs

a. *Summary of Baseline Estimate.* To quantify the effects of the rule, it is necessary to have a baseline against which to compare the set of regulatory requirements. The baseline is a characterization of the industry and its operations under the conditions expected to exist before systems make changes to meet requirements of this rule. As discussed in Section IV of this preamble, the regulatory requirements can be system, entry point, or well level requirements. These requirements, to a large extent, depend upon the levels of existing protection from microbial risks, e.g., disinfection levels. Table VII–8a presents the major baseline information for this rule. The number of entry points or wells varies by system size, with larger systems generally having more entry points. Chapter 4 of the GWR EA for this rule provides a detailed description of the GWR baselines (USEPA, 2006d).

b. *Rule Implications.* To calculate the cost impact of each rule alternative on GWSs, the Agency estimated how many systems and their associated entry points to distribution systems and wells would be affected by the various rule requirements based on national fecal indicator occurrence information, as discussed in Section VII.B.1. The Agency developed compliance forecast estimates that predict the number of systems, entry points, or wells that incur costs to comply with each regulatory requirement. Table VII–8b shows these numbers broken down by system type and size category. Chapter 6 of the GWR EA for this rule provides further description of the estimates of rule implications (USEPA, 2006d).

c. *System Costs.* This rule is estimated to cost public GWSs $50.0 million annually using a three percent discount rate ($50.6 million annually using a seven percent discount rate). The cost impacts to systems complying with the GWR stem from implementing the rule, assisting with sanitary surveys, performing source water and compliance monitoring, and performing corrective actions. Not every system is expected to incur all of these costs because the compliance activities for systems depend on the results from sanitary surveys, analysis of total coliform samples under the TCR, and source water monitoring.

The estimated costs for each of the rule requirements are summarized in Table VII–8c with a mean, upper bound, and lower bound. The mean and confidence bounds are equal for some of the costs because EPA derived these costs from point estimates. The total annualized costs to systems are presented in Table VII–9 by system size and type. The detailed calculation of these cost numbers are presented in Chapter 6 of the GWR EA (USEPA, 2006d).

To analyze the different rule components, the Agency had to distinguish between correction of significant deficiencies identified during sanitary surveys and the corrective actions that result from fecal indicator-positive ground water source samples. It was not possible to estimate costs for all conceivable corrective actions that a system may potentially encounter on a national level due to system-to-system variability. As a result, the Agency estimated costs for representative corrective actions that may be implemented to address significant deficiencies identified by sanitary surveys and source water fecal contamination, respectively. Table VII–10 shows the representative corrective actions.

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Table VII-8a: GWR Baselines: Number of Systems, Entry Points, and Wells

System Size	Total Number of Systems	Number of Entry Points per System	Number of Wells per System	Number of Wells per Entry Point	Entry Points with at least 4 logs of Viral Disinfection	Entry Points with less than 4 logs of Viral Disinfection	Entry Points without Disinfection
	A	B	C	D = C/B	E	F	G
Community Water Systems (CWSs)							
<100	12,843	1.3	1.5	1.1	3,996	3,689	9,168
101-500	14,358	1.6	2.0	1.2	8,873	8,191	6,343
501-1,000	4,649	2.0	2.3	1.2	3,547	3,274	2,262
1,001-3,300	5,910	2.4	3.1	1.3	5,378	4,964	4,002
3,301-10K	2,884	3.2	4.6	1.4	3,547	3,274	2,459
10,001-50K	1,444	5.6	9.8	1.7	3,856	3,559	698
50,001-100K	167	11.3	16.1	1.4	583	538	770
100,001-1 Million	103	12.4	49.9	4.0	545	503	227
> 1 Million	3	11.4	49.9	4.4	34	-	-
Nontransient Noncommunity Water Systems (NTNCWSs)							
<100	9,456	1.0	1.5	1.5	850	1,892	6,714
101-500	6,758	1.0	2.0	2.0	608	1,352	4,798
501-1,000	1,894	1.0	2.3	2.3	170	379	1,345
1,001-3,300	715	1.0	3.1	3.1	64	143	508
3,301-10K	73	1.0	4.6	4.6	7	15	52
10,001-50K	10	1.0	9.8	9.8	1	2	7
50,001-100K	1	1.0	16.1	16.1	0	0	1
100,001-1 Million	1	1.0	49.9	49.9	0	0	1
> 1 Million	-	1.0	49.9	49.9	-	-	-
Transient Noncommunity Water Systems (TNCWSs)							
<100	64,448	1.0	1.5	1.5	1,160	10,441	52,847
101-500	18,993	1.0	2.0	2.0	342	3,077	15,574
501-1,000	1,940	1.0	2.3	2.3	35	314	1,591
1,001-3,300	585	1.0	3.1	3.1	11	95	480
3,301-10K	74	1.0	4.6	4.6	1	12	61
10,001-50K	19	1.0	9.8	9.8	0	3	16
50,001-100K	1	1.0	16.1	16.1	0	0	1
100,001-1 Million	1	1.0	49.9	49.9	0	0	1
> 1 Million	-	1.0	49.9	49.9	-	-	-

Table VII-8b: Summary of Rule Implications

System Size	Systems Receiving Sanitary Survey	Systems with Corrective Actions for Significant Deficiencies	Entry Points with Triggered Monitoring	Entry Points with Corrective Actions for Triggered Monitoring	Entry Points with Viral Disinfection Increased from less than 4 logs to 4 logs	Previously Non-disinfecting Entry Points Taking Corrective Action	Entry Points with Incremental Compliance Monitoring
	A	B	C	D	E	F	G*
Community Water Systems (CWSs)							
<100	12,843	2,181	12,797	1,249	358	891	248
101-500	14,358	2,444	14,819	1,625	917	709	292
501-1,000	4,649	789	5,578	608	360	248	105
1,001-3,300	5,910	1,001	8,910	712	396	317	130
3,301-10K	2,884	492	5,638	617	353	264	111
10,001-50K	1,444	245	4,357	655	548	107	54
50,001-100K	167	28	1,295	226	93	133	46
100,001-1 Million	103	18	749	136	94	42	20
> 1 Million	3	-	-	-	-	-	-
Nontransient Noncommunity Water Systems (NTNCWSs)							
<100	9,456	1,608	8,609	687	150	537	149
101-500	6,758	1,148	6,149	533	119	415	170
501-1,000	1,894	322	1,724	149	33	117	50
1,001-3,300	715	121	651	86	19	67	27
3,301-10K	73	12	66	10	2	8	3
10,001-50K	10	2	9	2	0	1	1
50,001-100K	1	0	1	0	0	0	0
100,001-1 Million	1	0	1	0	0	0	0
> 1 Million	-	-	-	-	-	-	-
Transient Noncommunity Water Systems (TNCWSs)							
<100	64,448	10,990	63,295	6,915	1,143	5,772	1,602
101-500	18,993	3,234	18,648	2,026	337	1,689	696
501-1,000	1,940	329	1,905	208	35	174	73
1,001-3,300	585	99	574	76	12	63	26
3,301-10K	74	13	73	12	2	10	4
10,001-50K	19	3	19	3	1	3	1
50,001-100K	1	0	1	0	0	0	0
100,001-1 Million	1	0	1	0	0	0	0
> 1 Million	-	-	-	-	-	-	-

*G indicates number of entry points with treatment corrective actions. F-G indicates non treatment corrective actions

Table VII-8c: Annualized Costs for Meeting Each of the GWR Provisions to Systems and States ($Millions, 2003$)

		Rule Implementation & Annual Administration	Sanitary Surveys	Corrective Actions for Significant Deficiencies	Triggered Monitoring	Corrective Actions for Triggered Monitoring	Compliance Monitoring	Total Costs
		A	B	C	D	E	F	G
				3%				
Systems	Mean	$0.93	$0.21	$8.46	$5.44	$25.64	$9.35	$50.02
	Lower Bound (5th %ile)	$0.93	$0.11	$5.74	$5.32	$14.90	$3.02	$34.28
	Upper Bound (95th %ile)	$0.93	$0.31	$11.60	$5.56	$38.39	$16.97	$68.76
States	Mean	$9.20	$1.45	$0.56	$0.09	$0.46	$0.00	$11.77
	Lower Bound (5th %ile)	$9.20	$0.66	$0.52	$0.06	$0.32	$0.00	$10.87
	Upper Bound (95th %ile)	$9.20	$2.23	$0.61	$0.12	$0.61	$0.01	$12.64
Total	Mean	$10.13	$1.66	$9.02	$5.52	$26.10	$9.36	$61.79
	Lower Bound (5th %ile)	$10.13	$0.77	$6.25	$5.38	$15.22	$3.02	$45.15
	Upper Bound (95th %ile)	$10.13	$2.54	$12.21	$5.67	$39.00	$16.98	$81.41
				7%				
Systems	Mean	$1.33	$0.20	$8.13	$5.39	$27.20	$8.32	$50.57
	Lower Bound (5th %ile)	$1.33	$0.10	$5.51	$5.27	$15.89	$2.65	$35.22
	Upper Bound (95th %ile)	$1.33	$0.30	$11.14	$5.51	$40.96	$15.17	$69.00
States	Mean	$9.18	$1.39	$0.54	$0.10	$0.52	$0.00	$11.74
	Lower Bound (5th %ile)	$9.18	$0.63	$0.50	$0.07	$0.36	$0.00	$10.87
	Upper Bound (95th %ile)	$9.18	$2.14	$0.59	$0.13	$0.69	$0.01	$12.61
Total	Mean	$10.51	$1.59	$8.67	$5.48	$27.72	$8.32	$62.31
	Lower Bound (5th %ile)	$10.51	$0.74	$6.01	$5.34	$16.26	$2.65	$46.09
	Upper Bound (95th %ile)	$10.51	$2.44	$11.73	$5.64	$41.65	$15.18	$81.61

Table VII-9: Total Annualized Costs to Systems by System Size and Type ($Millions, 2003$)

System Size (Population Served)	At 3%			At 7%		
	Mean Value	90 Percent Confidence Bound		Mean Value	90 Percent Confidence Bound	
		Lower (5th %ile)	Upper (95th %ile)		Lower (5th %ile)	Upper (95th %ile)
Community Water Systems (CWSs)						
<100	$ 2.91	$ 2.13	$ 3.69	$ 2.91	$ 2.16	$ 3.72
101-500	$ 3.61	$ 2.54	$ 4.94	$ 3.59	$ 2.60	$ 4.83
501-1,000	$ 1.45	$ 0.99	$ 1.98	$ 1.44	$ 1.00	$ 1.94
1,001-3,300	$ 1.96	$ 1.29	$ 2.76	$ 1.94	$ 1.30	$ 2.69
3,301-10K	$ 2.23	$ 1.40	$ 3.26	$ 2.26	$ 1.49	$ 3.25
10,001-50K	$ 2.85	$ 1.87	$ 4.06	$ 3.05	$ 2.05	$ 4.41
50,001-100K	$ 1.78	$ 1.01	$ 2.73	$ 1.88	$ 1.11	$ 2.84
100,001-1M	$ 1.89	$ 1.14	$ 2.89	$ 2.12	$ 1.31	$ 3.18
>1 Million	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00	$ 0.00
All Sizes	$ 18.67	$ 12.39	$ 26.31	$ 19.19	$ 13.03	$ 26.87
Nontransient Noncommunity Water Systems (NTNCWSs)						
<100	$ 1.77	$ 1.34	$ 2.27	$ 1.78	$ 1.34	$ 2.26
101-500	$ 1.86	$ 1.21	$ 2.60	$ 1.83	$ 1.23	$ 2.53
501-1,000	$ 0.67	$ 0.43	$ 0.97	$ 0.66	$ 0.42	$ 0.94
1,001-3,300	$ 0.46	$ 0.28	$ 0.68	$ 0.46	$ 0.28	$ 0.67
3,301-10K	$ 0.10	$ 0.05	$ 0.16	$ 0.10	$ 0.06	$ 0.17
10,001-50K	$ 0.04	$ 0.02	$ 0.07	$ 0.04	$ 0.02	$ 0.07
50,001-100K	$ 0.01	$ 0.00	$ 0.01	$ 0.01	$ 0.00	$ 0.01
100,001-1M	$ 0.01	$ 0.00	$ 0.01	$ 0.01	$ 0.00	$ 0.02
>1 Million	$ -	$ -	$ -	$ -	$ -	$ -
All Sizes	$ 4.91	$ 3.33	$ 6.77	$ 4.89	$ 3.36	$ 6.68
Transient Noncommunity Water Systems (TNCWSs)						
<100	$ 17.74	$ 12.87	$ 23.27	$ 17.86	$ 13.11	$ 23.44
101-500	$ 7.07	$ 4.75	$ 9.95	$ 7.00	$ 4.76	$ 9.61
501-1,000	$ 0.98	$ 0.58	$ 1.45	$ 0.96	$ 0.59	$ 1.38
1,001-3,300	$ 0.42	$ 0.25	$ 0.63	$ 0.42	$ 0.26	$ 0.63
3,301-10K	$ 0.13	$ 0.07	$ 0.21	$ 0.14	$ 0.07	$ 0.22
10,001-50K	$ 0.08	$ 0.04	$ 0.14	$ 0.09	$ 0.04	$ 0.15
50,001-100K	$ 0.01	$ 0.00	$ 0.01	$ 0.01	$ 0.00	$ 0.01
100,001-1M	$ 0.01	$ 0.01	$ 0.02	$ 0.01	$ 0.01	$ 0.02
>1 Million	$ -	$ -	$ -	$ -	$ -	$ -
All Sizes	$ 26.44	$ 18.56	$ 35.68	$ 26.49	$ 18.84	$ 35.46
TOTAL	$ 50.02	$ 34.28	$ 68.76	$ 50.57	$ 35.22	$ 69.00

Notes: Detail may not be consistent with summary presentations due to independent statistical analysis.

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Because the exact timing and distribution of problems among systems that may be identified by the sanitary surveys is not known, an average annual GWS cost of correcting significant defects is calculated by summing the cost of correcting all significant deficiencies over the 25-year period of analysis and apportioning them evenly over the period during which they are performed.

For entry points with fecal indicator-positive ground water source samples (from triggered source water monitoring), systems must perform corrective action to comply with the GWR. For cost estimation purposes, the model assumes that for every source water positive sample, at least one additional sample will also be positive (*i.e.*, corrective action ultimately follows every source water positive) (see Chapter 6 of GWR EA (USEPA, 2006d) for a complete discussion of this assumption). For non-disinfecting systems, the model assigns one representative nontreatment corrective action or one disinfection/treatment corrective action (Table VII–10). The cost model assigns nondisinfecting entry points that need to take corrective actions to the treatment category using the current proportion of all entry points providing treatment for different size categories. The current proportion is a range of the estimated existing percentages of treatment entry points among the entry points with less than 4-log disinfection and without disinfection.

For nontreatment corrective actions to comply with the GWR, the cost model assigns equal proportions of entry points to high and low cost scenarios and then assigns a representative corrective action according to the corresponding percentages in that scenario. For entry points predicted to use treatment corrective actions, the cost model assigns one of the possible treatment technologies based on the relative percentage of CWSs currently engaged in those treatment practices. Finally, for entry points that require corrective actions because of source water fecal contamination (from

triggered source water monitoring) and already disinfect, but the disinfection does not achieve at least a 4-log treatment of viruses before or at the first customer, the compliance forecast assigns a corrective action that either increases the dose for hypochlorination or chlorine gas or adds storage. More information regarding the compliance forecasts of corrective actions can be found in Chapter 6 of the GWR EA (USEPA, 2006d).

TABLE VII–10.—REPRESENTATIVE CORRECTIVE ACTIONS

	Representative corrective actions	Note
For Significant Deficiencies at Source Identified by Sanitary Survey.	Replace a Sanitary Well Seal	Low cost option.
	Rehabilitate an Existing Well	High cost option.
For Entry Points with a Fecal Indicator-Positive Ground Water Source Sample.	Non-Treatment Options Rehabilitate an Existing Well Drill a New Well Purchase Water Eliminate Source of Contamination	Interim disinfection is included for costing.
	Treatment Options Disinfection Alternatives or Nanofiltration	Chlorine gas and hypochlorite will be most likely choices for large and small systems, respectively.

In addition to the treatment technique costs, EPA estimated the cost for systems to conduct monitoring. It is important to remember that triggered source water monitoring applies only to systems that do not achieve 4-log treatment of viruses. Compliance monitoring applies to systems that currently provide 4-log treatment of viruses, or those that install treatment as a result of this rule. Assessment source water monitoring is optional and is not included in either the cost or benefit estimates (see Section VII.J.10).

The triggered source water monitoring costs are calculated based on the cost of the test and the operator's time to collect and transport the sample. GWSs have to collect a ground water source sample and analyze it for the selected indicator organism when the system experiences a total coliform-positive under the TCR. If the indicator sample is positive, the system either takes five additional samples or does corrective action immediately. If any of the additional samples is positive, the system must implement a corrective action. Specific issues regarding the monitoring cost estimate are described in Section VII.C.3 of this preamble. The GWR EA has a more detailed discussion of the monitoring cost analysis (USEPA, 2006d).

The cost of compliance monitoring varies with system size. Compliance monitoring is required for any system that currently provides 4-log treatment of viruses or installs treatment as a result of complying with this rule's treatment technique requirements. EPA assumes that systems with treatment technology in place prior to the GWR promulgation incur minimal additional capital or operation and maintenance (O&M) costs for compliance monitoring because GWSs should already have a monitoring program in place and has not included them in the cost analysis. However, the Agency does include costs for systems to notify the State that they achieve at least 4-log treatment of viruses or to notify the State in case of system failure.

For those systems adding a technology that provides 4-log treatment of viruses as a corrective action for source water fecal contamination, EPA assumes that monitoring equipment will also be installed to perform compliance monitoring. The cost varies by system size because the monitoring requirements vary by size category. A more detailed explanation of compliance monitoring schemes is discussed in Section IV.C.

d. *State costs.* As indicated in Table VII–6, EPA estimates that States will incur less than $11.8 million in annualized costs due to the additional sanitary survey requirements in this rule (including increased frequency of sanitary surveys), tracking monitoring information, reviewing action plans, data management, and other activities. Along with system costs, State costs are also summarized in Table VII–8c.

States will incur administrative costs while implementing the GWR. These implementation costs are not directly required by specific provisions of GWR alternatives, but are necessary for States to ensure the provisions of the GWR are properly carried out. States will also be required to spend time responding to PWSs whose ground water sources are found to be fecally contaminated, or have significant deficiencies. These costs include time to review plans and specifications, prepare violation letters, and enter data. States will need to allocate time for their staff to establish and then maintain the programs necessary to comply with the GWR, including developing and adopting State regulations, modifying data management systems to track newly required system reports to the States, and providing ongoing technical assistance to GWSs. For those GWR requirements that include monitoring with a laboratory method not currently required by the State, the State must devote a portion of its staff time to certifying laboratories for the new analytical method. Time requirements for a variety of State agency activities and responses are estimated in Chapter 6 of the GWR EA (USEPA, 2006d).

In addition to these one-time costs, States will use resources to continue activities for the implementation of the GWR unrelated to any specific provision. States with primacy enforcement responsibilities have recordkeeping (§ 142.14) and reporting (§ 142.15) requirements associated with primacy enforcement and must coordinate with EPA for review of the State primacy program. States must also continue to train their personnel and PWS staff, maintain laboratory certifications, and report system compliance information to the Safe Drinking Water Information System (SDWIS).

3. Nonquantifiable Costs

Although EPA has quantified the significant costs of the GWR, there are some costs that the Agency did not quantify. Overall, EPA believes that these nonquantified costs are much smaller than the nonquantified benefits. These nonquantified costs result from uncertainties surrounding rule assumptions and from modeling assumptions. For example, EPA estimated that some systems may need to acquire land if they need to build a treatment facility or drill a new well. This was not considered for most systems because EPA expects that the majority of the technologies that

systems will use to comply with this rule will fit within the existing plant footprint. In addition, if the cost of land is prohibitive, a system may choose another lower cost alternative such as connecting to another source. EPA has also not quantified costs for systems already using disinfection to conduct compliance monitoring because EPA believes that such systems are already incurring these costs.

In addition, the optional assessment source water monitoring provision was not included in the quantitative cost analysis. EPA was not able to quantify either the benefits or costs of this program. Because this provision could potentially increase both benefits and cost, a more complete discussion can be found in Section VII.J of this preamble. Due to lack of information, EPA was unable to quantify the costs (as well as benefits) from the correction of sanitary survey deficiencies in distribution systems and treatment plants. This is discussed in Section VII.J of this preamble.

Also, the Agency did not include the costs for taking five additional samples following a positive source water sample. However, EPA overestimated the cost of triggered source water monitoring because it assumed all systems would take an additional sample beyond the current TCR requirements. However, many small systems (and most GWSs are small) will be able to use one of their TCR repeat samples to also comply with the GWR. Overall, the impact of not including the five additional sample cost (approximately $200,000 per year) is much smaller compared to the overestimate of a few million dollars associated with the initial fecal indicator sampling cost already conducted for TCR monitoring.

4. How Have the Costs Changed Since the Proposal?

The estimated annual quantified costs for the GWR have changed from $183 million and $199 million (year 2000 dollars at proposal, using three and seven percent discount rates, respectively) to $61.8 million and $62.3 million (year 2003 dollars, using three and seven percent discount rates, respectively). The change in quantified costs is due to changes in both the economic analysis estimates (*e.g.*, interpretation of occurrence and other data) and GWR provisions. However, changes in the economic analysis estimates are the dominant factor in explaining the large change in costs from the proposal. The major changes in economic analysis estimates include the following:

- The number of significant deficiencies and corrective actions in wells from sanitary survey provisions;
- State costs for the incremental changes to existing sanitary survey programs;
- The total coliform-positive samples under the TCR and the number of triggered source water monitoring samples required under the GWR;
- The frequency and duration of fecal indicator occurrence in wells;
- The efficiency by which fecally contaminated wells are identified and therefore performing a corrective action;
- Compliance forecasts include a higher percentage of non-treatment corrective actions; and
- Using net present values and then annualizing costs.

EPA believes that the changes made in the GWR EA since proposal substantially improve the basis for quantifying the GWR costs with more available data, a major issue raised by public comments (see Section VII.L of this preamble for further discussion of major public comments).

Changes in the rule provisions also impacted the final cost estimate but these changes are not as significant as the changes made in the economic analysis. In addition, the costs (as well as benefits) for optional assessment source water monitoring and additional fecal indicator sampling following triggered source water monitoring are not included in the final rule analysis. These potential impacts are discussed in Section VII.J.

Another major change in the Economic Analysis since the proposed GWR is a more thorough analysis of the nonquantified costs. Chapter 6 of the GWR EA describes the basis for the analysis (USEPA, 2006d). Rule changes can be found in Section VII.A of this preamble.

E. What Is the Potential Impact of the GWR on Households?

This analysis considers the potential increase in a household's water bill if a CWS passed the entire cost increase resulting from this rule on to their customers. This analysis is a tool to gauge potential impacts and should not be construed as a precise estimate of potential changes to household water bills.

The household cost analysis only considers the impact on CWSs. State costs and costs to TNCWSs and NTNCWSs are not included in this analysis since their costs are not passed through directly to households. Table VII–11 presents the mean expected increases in annual household costs for all CWSs, including those systems that do not have to take corrective action for significant deficiencies or source water fecal contamination. Table VII–11 also presents the same information for CWSs that must take corrective action. Household costs tend to decrease as system size increases, due mainly to the economies of scale for the corrective actions.

As shown in Table VII–11, the mean annual household costs for systems (including those that do not add treatment) range from $0.21 to $16.54 (systems serving fewer households generally have higher average annual household costs). Household costs for the subset of systems that take corrective actions range from $0.45 to $52.38. EPA estimates that, as a whole, households subject to the GWR face minimal increases in their annual costs. The lowest increases in household costs are for those served by larger systems due to significant economies of scale and because many already disinfect. Approximately 66 percent of the households potentially affected by the GWR are customers of systems that serve at least 10,000 people. Households served by small systems that take corrective actions will face the greatest increases in annual costs.

Table VII-11: Summary of Annual Per-Household Costs for the GWR (2003$/Year)

Systems Size (Population Served)	Households	Mean	Median	90th Percentile
All Community Water Systems (CWSs)				
<100	289,222	$ 16.54	$ 2.81	$ 9.31
101-500	1,303,890	$ 3.51	$ 0.64	$ 6.11
501-1,000	1,278,081	$ 0.97	$ 0.16	$ 1.70
1,001-3,300	4,196,105	$ 0.37	$ 0.04	$ 0.61
3,301-10K	6,271,380	$ 0.27	$ 0.03	$ 0.43
10,001-50K	11,468,813	$ 0.21	$ 0.04	$ 0.49
50,001-100K	4,204,584	$ 0.34	$ 0.10	$ 1.02
>100,000	9,755,817	$ 0.21	$ 0.04	$ 0.62
Corrective Action Community Water Systems (CWSs)				
<100	70,563	$ 52.38	$ 18.99	$ 82.21
101-500	312,484	$ 12.00	$ 4.52	$ 25.76
501-1,000	302,557	$ 3.23	$ 1.33	$ 6.56
1,001-3,300	919,133	$ 1.33	$ 0.47	$ 2.59
3,301-10K	1,487,159	$ 0.80	$ 0.25	$ 2.18
10,001-50K	2,871,250	$ 0.45	$ 0.18	$ 1.18
50,001-100K	1,215,544	$ 0.53	$ 0.26	$ 1.36
>100,000	2,283,144	$ 0.68	$ 0.39	$ 1.65

Source: GWR model output.

F. What Are the Incremental Costs and Benefits of the GWR?

The GWR regulatory alternatives achieve increasing levels of benefits at increasing levels of costs. The regulatory alternatives for this rule, in rank order of increasing costs and benefits are as follows:

- Alternative 1: Sanitary Survey and Corrective Action.
- Alternative 2: Risk-Targeted Approach.
- Alternative 3: Multi-Barrier Approach.
- Alternative 4: Across-the-Board Disinfection.

More information about the alternatives is provided in the GWR EA (USEPA, 2006d).

Incremental costs and benefits are those that are incurred or realized in reducing viral illnesses and deaths 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 alternatives considered by the Agency. Generally, the goal of an incremental analysis is to identify the regulatory alternatives 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 as in the case with the GWR. Also, as pointed out by the Environmental Economics Advisory Committee of the Science Advisory Board, efficiency is not the only appropriate criterion for social decisionmaking (USEPA, 2000d).

For the GWR, 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 bacterial illness and deaths (see Section VII.C.4).

Table VII–12a and Table VII–12b present the four regulatory alternatives in order of increasing level of reduction in waterborne pathogens or increasing level of protection from illness. All values are annualized mean present values expressed in year 2003 dollars. The lower and upper bounds of a 90 percent confidence interval are shown below the mean numbers. As shown in Tables VII–12a and b, incremental net benefits for all alternatives are negative. The nonquantified bacterial illness benefits would add benefits to all alternatives without any increase in costs. EPA estimated that the total benefits could increase by more than a factor of five by accounting for additional deaths and hospitalizations caused by reduced bacterial illness alone. These nonquantified benefits have a significant positive impact on the incremental benefits and incremental net benefits. Both Alternative 3 and Alternative 2 could have positive incremental net benefits if the bacterial benefits are considered. The next highest alternative, Alternative 4, has such highly negative incremental net benefits, and the difference is so substantial, that nonquantified benefits would be unlikely to compensate. However, comparisons between Alternative 4 and the other alternatives may be between two separate sets of benefits, in the sense that they may be distributed to somewhat different populations.

TABLE VII–12a.—INCREMENTAL NET BENEFITS BY RULE ALTERNATIVE—ENHANCED COI

[Annualized Present Value Mean, $Millions, 2003$]

Rule alternatives	Annual quantified costs	Annual quantified benefits (enhanced COI)	Incremental costs	Incremental benefits*	Incremental net benefits*
	A	B	C	D	E = D − C
Three Percent Discount Rate (in dollars)					
Alternative 1: Sanitary Survey and Corrective Action	15.3 (11.8–19.2)	3.6 (0.9–9.3)	15.3	3.6	−11.7
Final Rule: Risk-targeted Approach**	61.8 (45.2–81.4)	19.7 (6.5–45.4)	46.5	16.1	−30.4
Alternative 3: Multi-Barrier Approach	67.9 (49.4–89.5)	21.3 (7.1–48.7)	6.1	1.6	−4.5
Alternative 4: Across-the-Board Disinfection	686.4 (636.8–735.4)	70.2 (18.3–177.0)	618.5	48.9	−569.6
Seven Percent Discount Rate (in dollars)					
Alternative 1: Sanitary Survey and Corrective Action	15.3 (11.9–19.0)	2.9 (0.7–7.5)	15.3	2.9	−12.4
Final Rule: Risk-targeted Approach**	62.3 (46.1–81.6)	16.8 (5.5–38.6)	47.0	13.9	−33.1
Alternative 3: Multi-Barrier Approach	69.4 (51.0–90.6)	18.2 (6.0–41.6)	7.1	1.4	−5.7
Alternative 4: Across-the-Board Disinfection	665.3 (612.3–717.0)	61.9 (16.1–156.3)	595.9	43.8	−552.2

*Does not include significant nonquantified benefits. See GWR EA Section 5.4 (USEPA, 2006d).
**Benefits and costs are also not included for optional assessment source water monitoring.

TABLE VII–12b.—INCREMENTAL NET BENEFITS BY RULE ALTERNATIVE—TRADITIONAL COI

[Annualized Present Value Mean, $Millions, 2003$]

Rule alternatives	Annual quantified costs	Annual quantified benefits (traditional COI)	Incremental costs	Incremental benefits*	Incremental net benefits*
	A	B	C	D	E = D − C
Three Percent Discount Rate (in dollars)					
Alternative 1: Sanitary Survey and Corrective Action	15.3 (11.8–19.2)	1.9 (0.3–5.5)	15.3	1.9	−13.5
Final Rule: Risk-targeted Approach**	61.8 (45.2–81.4)	10.0 (2.2–27.0)	46.5	8.2	−38.3
Alternative 3: Multi-Barrier Approach	67.9 (49.4–89.5)	10.8 (2.5–28.9)	6.1	0.8	−5.3
Alternative 4: Across-the-Board Disinfection	686.4 (636.8–735.4)	35.5 (6.5–102.4)	618.5	24.7	−593.8
Seven Percent Discount Rate (in dollars)					
Alternative 1: Sanitary Survey and Corrective Action	15.3 (11.9–19.0)	1.5 (0.2–4.5)	15.3	1.5	−13.8
Final Rule: Risk-targeted Approach**	62.3 (46.1–81.6)	8.6 (1.9–23.0)	47.0	7.1	−39.9
Alternative 3: Multi-Barrier Approch	69.4 (51.0–90.6)	9.3 (2.1–24.8)	7.1	0.7	−6.4
Alternative 4: Across-the-Board Disinfection	665.3 (612.3–717.0)	31.5 (5.7–90.8)	595.9	22.2	−573.7

*Does not include significant nonquantified benefits. See GWR EA Section 5.4 (USEPA, 2006d).
**Benefits and costs are also not included for optional assessment source water monitoring.
Notes: The Traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production and caregiver time for sick children). The Enhanced COI also factors in valuations for lost personal time (non-worktime) such as child care and homemaking (to the extent not covered by the traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway.
Source: Chapter 8 of the GWR EA (USEPA, 2006d). Ranges in parentheses are the 90 percent confidence bounds.

G. Are There Any Benefits From Simultaneous Reduction of Co-Occurring Contaminants?

As discussed in Section VII.B.2, the GWR is expected to reduce not only viral illnesses and deaths (the monetized rule benefit) but also bacterial illnesses and deaths. This rule is also expected to decrease the risk of outbreaks that would reduce illnesses and deaths and other outbreak-related costs. Additional health benefits of this rule include the reduction in illnesses and deaths associated with reduced incidence of upsets or failures among disinfecting supplies and reduced incidence of distribution system contamination among disinfecting and non-disinfecting systems. EPA anticipates reductions in disease incidence in these areas to result from the sanitary survey provisions and the treatment and monitoring provisions pertaining to disinfected supplies.

If a system chooses to install treatment, it may choose a technology that would also address other drinking water contaminants. If a system had an iron or manganese problem, for example, the addition of an oxidant and filtration could treat this problem as well as fecal contamination. Also, some membrane technologies installed to remove bacteria or viruses can reduce or eliminate many other drinking water contaminants, including arsenic. EPA recognizes that some systems will choose these more expensive treatment technologies. EPA has included them in the decision tree in the cost analysis, but no estimate of the additional benefit from reducing co-occurring contaminants has been made.

H. Is There Any Increase in Risk From Other Contaminants?

It is unlikely that the GWR will result in a significant increase in risk from other contaminants, although adding disinfection to currently non-disinfecting systems could result in some increased risk. When disinfection is first introduced into a previously undisinfected system, the disinfectant can react with pipe scale, causing increased risk from some contaminants and other water quality problems. Contaminants that could be released include lead, copper, and arsenic. It could also possibly lead to a temporary discoloration of the water as the scale is loosened from the pipe. These risks can be addressed by gradually phasing in disinfection to the system, by targeted flushing of distribution system mains, and by maintaining a proper corrosion control program.

Using a chemical disinfectant could also result in an increased risk from disinfection byproducts (DBPs). Risk from DBPs has already been addressed in the *Stage 1 Disinfection Byproducts Rule* (DBPR) (USEPA, 1998c) and additional consideration of DBP risk has been addressed in the recently published final *Stage 2* DBPR (USEPA, 2006g). In general, GWSs are less likely to experience high levels of DBPs than surface water systems because they have lower levels of naturally occurring organic materials (generally represented by total organic carbon (TOC)) that contribute to DBP formation. For the most part, GWSs with high levels of TOC in their ground water source are located in States that already require GWSs to disinfect, therefore decreasing the chance that significant disinfection byproduct problems would result from this rule.

I. What Are the 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 estimates that the average annual baseline illnesses and deaths associated with viruses in ground water are about 185,000 and 3, respectively (Table VII–4). The general population typically experiences GI illness when exposed to waterborne viral and bacterial pathogens, although other severe diseases such as kidney failure can also occur. Sensitive subpopulation exposure to these pathogens can result in more severe illness than in the general population, and sometimes death.

Examples of sensitive subpopulations include pregnant women, infants, elderly (over 65), cancer patients, and AIDS patients (Gerba *et al.*, 1996). Gerba estimates that these groups represent almost 20 percent of the U.S. population. The purpose of this section is to discuss the potential health effects associated with sensitive population groups, especially children, pregnant women, and the elderly.

1. Risk of Acute Viral Illness to Children and Pregnant Women

The risk of acute illness and death due to viral contamination of drinking water depends on several factors, including the age of the exposed individual. Infants and young children have higher rates of infection and disease from enteroviruses than other age groups (USEPA, 1999). Several enteroviruses that can be transmitted through water can have serious health consequences in children. Enteroviruses (which include poliovirus, coxsackievirus, and echovirus) have been implicated in cases of flaccid paralysis, myocarditis, encephalitis, hemorrhagic conjunctivitis, and diabetes mellitis (CDC, 1997; Modlin, 1997; Melnick, 1996; Cherry, 1995; Berlin *et al.*, 1993; Smith, 1970; Dalldorf and Melnick, 1965). Women may be at increased risk from enteric viruses during pregnancy (Gerba *et al.*, 1996). Enterovirus infections in pregnant women can also be transmitted to the unborn child late in pregnancy, sometimes resulting in severe illness in the newborn (USEPA, 2000e).

a. *Children's Environmental Health.* To comply with Executive Order 13045, EPA calculated the baseline risk and reduction of risk from waterborne viral illness and death for children as a result of this rule. To address the disproportionate risk of waterborne viral illness and death affecting children, EPA used age-specific morbidity data in the risk assessment. The risk assessment first estimated the proportion of the population that falls into several age categories for which data are available for two model viruses: Type A (represented by rotavirus data) and Type B (represented by enterovirus or echovirus data).

While bacterial illnesses are not addressed in the quantified benefits analysis, EPA believes that the nonquantified benefits associated with consumption of undisinfected bacterially contaminated PWS well water could be significant in sensitive subpopulations. In an alternative analysis to the quantified benefits calculation, EPA estimated that roughly 16,805 bacterial illnesses and 11 bacterial deaths annually could be avoided in the general population. See Section 5.4.3 of the GWR EA for details of the analysis (USEPA, 2006d). Children and the elderly are particularly vulnerable to kidney failure (hemolytic uremic syndrome) caused by the bacterium *E. coli* O157:H7. Waterborne outbreaks due to *E. coli* O157:H7 have caused kidney failure in children and the elderly as the result of disease outbreaks from consuming ground water in Cabool, Missouri (Swerdlow *et al.*, 1992); Alpine, Wyoming (Olsen *et al.*, 2002); Washington County, New York (NY State DOH, 2000); and Walkerton, Ontario, Canada (Health Canada, 2000).

Type A viruses of high infectivity (Type A, *e.g.*, rotavirus) disproportionately affect children less than three years of age. Thus, the age categories used in the hazard analysis were less than three years of age and greater than three years of age. Based on rotavirus data, it was assumed that 10 to

88 percent of children less than three years old would become ill once infected with high infectivity viruses and that 10 to 50 percent of the population over three years of age would become ill.

For viruses of low-to-medium infectivity (Type B, *e.g.*, echovirus), children are again disproportionately at risk of becoming ill once infected. For this virus type, the age categories used in the hazard analysis were less than five years of age, five to 19 years of age, and greater than 19 years of age. Based on echovirus data, EPA estimated that 50 to 78 percent of children less than five years old would become ill once infected with low-to-medium infectivity viruses, 12 to 57 percent of children five to 19 years of age and 12 to 33 percent of people over 19 years of age would become ill once infected.

In addition to illness, EPA also considered child mortality attributable to waterborne viral illness. For viruses of high infectivity (Type A), EPA estimates 0.00057 to 0.00073 percent of the ill population (including children) will die (Tucker *et al.*, 1998). This value, based on rotavirus data from children less than five years of age (20 deaths from 2,730,000 to 3,500,000 illnesses), was applied to individuals of all ages because data for older individuals are not available. For low-to-medium infectivity viruses (Type B), EPA estimates that 0.92 percent of children less than one month of age who become ill will die based on data from Jenista *et al.* (1984), Modlin (1986) and Kaplan *et al.* (1983). For those individuals greater than one month in age, 0.02 percent who become ill will die based on the EPA assumption that one percent of enterovirus illnesses are severe and two percent of severe illnesses result in death. The low-to-medium infectivity viruses result in a higher mortality rate than the high infectivity viruses because they can cause more serious health effects.

To estimate the benefits to children from this rule, the Agency calculated the number of endemic, acute viral illnesses and deaths avoided after rule implementation for children less than five years old and for children ages five through 15 years old. Table VII–13 shows the estimates for annual illnesses avoided in young children due to this rule. Overall, this rule will result in about 2,780 fewer endemic, acute viral illnesses per year caused by Type A (represented by rotavirus data) and Type B (represented by enterovirus or echovirus data) viruses and 0.06 deaths in children less than five years of age. For older children aged five to 15 years of age, this rule will result in 4,856 fewer acute illnesses per year (see Chapter 5 of the GWR EA (USEPA, 2006d)). In addition to endemic, acute viral illnesses avoided, EPA estimates that there will be fewer deaths (less than one death) in children of all ages.

Of the total annual avoided gastrointestinal illnesses predicted as the result of this rule, approximately 18 percent (7,636) of the mean annual illnesses avoided occur in children aged 15 years or younger. Children are disproportionately represented in the average annual number of illnesses avoided. Because children are often likely to be exposed via exposure pathways other than water in schools and day care centers (including fomites, respiratory, dermal, and person-to-person), the waterborne proportion probably does not dominate in total exposure but it may represent a significant fraction. More serious waterborne illnesses, such as hemolytic uremic syndrome (kidney failure), disproportionately affect children but this calculation only considers gastrointestinal illness.

TABLE VII–13.—ANNUAL VIRAL ILLNESSES AVOIDED BY THE GWR IN CHILDREN, THE ELDERLY, AND THE IMMUNOCOMPROMISED

Virus type	Health effect	Infants and young children <5 years old	Elderly adults >65 years old	Immunocompromised (all ages)	Total sensitive subgroups
Type A (Rotavirus)	Illness ...	2,588	Illness: 5,559	Illness: 126	Illness: 8,465.
	Death ...	0.02			
Type B (Enterovirus or Echovirus)	Illness ...	191	Deaths: 0.10	Deaths: 0.002	Deaths: 0.15.
	Death ...	0.04			

Note: Detail may not sum due to independent statistical analyses and rounding. The figures presented represent only the quantifiable benefits of the GWR. The nonquantified benefits are expected to comprise a significant portion of the overall benefits of the GWR and are presented in Section 5.4 of the GWR EA (USEPA, 2006d). The immunocompromised population includes bone marrow transplant recipients, AIDS patients, and organ transplant patients.

Source: Number of Illnesses Avoided, Deaths Avoided, and Annual Benefits from GWR Model Output.

2. Risk of Viral Illness to the Elderly and Immunocompromised

The elderly are particularly at risk from diarrheal diseases (Glass *et al.*, 2000), such as those associated with waterborne microbial pathogens. Fifty-three percent of diarrheal deaths occur among those older than 74 years of age, and 77 percent of diarrheal deaths occur among those older than 64 years of age. In Cabool, Missouri (Swerdlow *et al.*, 1992), a waterborne E. coli O157:H7 outbreak in a GWS resulted in four deaths, all among the elderly. One death occurred from hemolytic uremic syndrome (kidney failure); the others from gastrointestinal illness. Table VII–13 shows that this rule's estimates for avoided viral illnesses and deaths per year in the elderly population (> 65 years old) are approximately 5,559 and 0.1, respectively.

Most epidemiological studies focus on nursing homes because the cluster of individuals improves data collection. Nursing home populations are typically, but not exclusively, elderly. Gerba *et al.* (1996) compiled data to show that, for the various waterborne microbial pathogens, nursing home mortality rates are significantly higher than in the general population. In Gideon, Missouri, a waterborne *Salmonella typhimurium* outbreak (Angulo *et al.*, 1997) resulted in seven deaths from gastrointestinal illness, all among nursing home residents.

Hospitalizations due to diarrheal disease are higher in the elderly (Glass *et al.*, 2000). Average hospital stays for individuals older than 74 years of age due to diarrheal illness are 7.4 days compared to 4.1 days for individuals aged 20 to 49 (Glass *et al.*, 2000).

For another significant sensitive subpopulation, the immunocompromised, Gerba *et al.* (1996) summarized the literature and reported that enteric adenovirus and rotavirus are the two waterborne viruses most commonly isolated in the stools of AIDS patients. For patients undergoing bone-marrow transplants, several

studies cited by Gerba *et al.* (1996) reported mortality rates greater than 50 percent among patients infected with enteric viruses. Table VII–13 shows that this rule's estimates for avoided illnesses and deaths in the immunocompromised groups (all ages) are approximately 126 and 0.002, respectively.

Overall, this rule will provide protection from waterborne viral and bacterial illness to both the general population and sensitive subpopulations. To capture the impact of the rule on both populations, the Agency considered the different severities of illness when valuing reductions in illness that will result from this rule.

J. What Are the Uncertainties in the Risk, Benefit, and Cost Estimates for the GWR?

Many uncertain values are used to derive estimates of baseline risk, risk reductions, and costs of this rule. Most, but not all, of these are mathematically modeled so that a ''realization'' is selected for them in each ''uncertainty iteration'' of EPA's probabilistic economic analysis. These uncertainties then propagate through the derivation of final estimates so the total uncertainty of those final estimates can be understood. Each of those uncertainties, or the assumption that is made by not modeling it mathematically, is summarized in Sections 5.6 (for benefits) and 6.7 (for costs) in the GWR EA (USEPA, 2006d) for its importance and tendency to contribute systematically to an over-or understatement of the final estimate. The paragraphs that follow discuss the most important of these uncertain quantities.

1. The Baseline Numbers of Ground Water Systems, Populations Served, and Associated Disinfection Practice

The baseline number of systems is uncertain because of data limitations in the Safe Drinking Water Information System (SDWIS). For example, some systems use both ground and surface water, but because of other regulatory requirements, they are labeled in SDWIS as surface water systems. In addition, the SDWIS data on NCWSs do not reflect a consistent reporting convention for population served. Some States may report the population served by TNCWSs over the course of a year, while others may report the population served on an average day. For example, a State park may report the population served yearly instead of daily. Thus, SDWIS data may, in some cases, overestimate the daily population served. Also, SDWIS does not require States to provide information on current disinfection practices, resulting in uncertainty in the percentage of disinfecting systems providing 4-log or greater virus treatment. Although these different factors influencing the baseline estimates are uncertain, EPA believes that their relative degree of uncertainty in influencing the estimates within the GWR EA is small compared to other uncertain components of the Economic Analysis, so these are not treated probabilistically in the analysis.

2. The Numbers of Wells Designated as More Versus Less Vulnerable

For the purposes of the GWR EA, contaminated wells are classified as more or less vulnerable, which determines the assumptions used for the concentrations of virus as discussed in Section VII.B.1.c of this preamble. The numbers of systems falling into these two categories is uncertain and is also modeled as an uncertain variable.

3. The Baseline Occurrence of Viruses and *E. coli* in Ground Water Wells

EPA's occurrence analysis is based on monitoring data from over 1,200 public drinking water supply wells that were tested for culturable virus, *E. coli,* or both. Compiled from 15 ground water surveys that were designed for different purposes, these wells are believed to be representative of ground water wells. Although the number of wells is large, the number of assays per well is small, and most wells were sampled only once for either virus or *E. coli.* Because of the limited amount of data, these data do not provide precise occurrence estimates. EPA's analysis recognizes the limitations of the data, producing a large ''uncertainty sample'' of estimates that are consistent with the data. This uncertainty sample is an input to the probabilistic economic analysis, where these uncertainties are combined with the uncertainties of other inputs to portray total uncertainty in the GWR cost and benefit estimates. EPA's occurrence model includes concentration differences between more and less vulnerable wells, but applies the same hit rate model to both types of wells. Also, because of data limitations, EPA was unable to make an assessment of aquifer sensitivity as part of the final rule and, therefore, no difference in hit rates or concentration levels between sensitive and nonsensitive wells is assumed. The GWR EA addresses uncertainty about these assumptions in a qualitative discussion (USEPA, 2006d).

4. For the Sanitary Survey Provisions, the Percentage of Systems Identified as Having Significant Deficiencies, the Percentage of These Deficiencies That Are Corrected, and State Costs for Conducting Surveys

For the sanitary survey provisions, EPA estimated the impacts associated with well deficiencies. EPA used data from the 1998 ASDWA survey to estimate the percentage of wells with deficiencies (ASDWA, 1997). To estimate benefits, EPA assumed that if a correction of a well defect occurred at a virally contaminated well, some, but not all of these virally contaminated wells would no longer have viral contamination. EPA used an uncertainty distribution for this estimate.

To estimate costs for significant deficiencies detected at or near the source, EPA chose two representative corrective actions to use in the cost model: replacement of a sanitary well seal or rehabilitation of an existing well. Because the corrections of significant deficiencies are dependent upon the deficiencies defined as significant by States and the conditions of specific systems, both of which are highly variable, EPA used a high and low scenario to bound the cost estimates. The low-cost scenario assumes a greater percentage of the systems with significant deficiencies will have deficiencies that are less expensive to correct (*e.g.*, more systems will have to replace their sanitary well seal than will have to perform a complete rehabilitation of their well). This high/low bounding provides an estimate of the uncertainty with respect to the percentages of each type of defect to be corrected.

While the sanitary survey provisions will also result in identification and correction for deficiencies associated with treatment or distribution system deficiencies, due to insufficient data, EPA did not quantify either costs or benefits for these types of deficiencies. In the GWR EA, EPA qualitatively discusses these impacts (USEPA, 2006d).

Finally, EPA assumes that most States are already conducting sanitary surveys that include the eight required elements, and that many States are already conducting sanitary surveys for GWSs that meet the frequency requirements in the GWR, so EPA estimated incremental costs for these activities in only a relatively small subset of States.

5. The Predicted Rates at Which Virally Contaminated (and Non-Contaminated) Wells Will Be Required To Take Action After Finding *E. coli* Ground Water Sources

EPA's occurrence model estimates the percentage of wells that have only virus present, both *E. coli* and virus present, or only *E. coli* present. The occurrence model also includes parameters that describe how often contaminated wells actually have the contaminant present. For example, some contaminated wells have *E. coli* present less than one percent of the time, while others have *E. coli* present more than 10 percent of the time (some of which will also have sometime viral presence). When *E. coli*-contaminated wells are tested for the first time, those with frequent *E. coli* occurrence are the most likely to be identified as contaminated. As these problems are addressed and corrected, there should be fewer and fewer wells with frequent *E. coli* occurrence (as well as viral occurrence since a fraction of *E. coli* wells will also have sometime viral presence; see Section III.C.2 for further elaboration). This diminishing rate of fecal contamination identification is included in the GWR EA (USEPA, 2006d). Uncertainty about the diminishing rate is due to uncertainty about the EPA's estimates of how often *E. coli* occurs in contaminated wells. As with other key uncertain inputs, this uncertainty is represented by an uncertainty sample of the relevant parameters. Again, EPA assumes no difference based on vulnerability or sensitivity. The GWR EA qualitatively discusses uncertainty of this assumption (USEPA, 2006d).

Undisinfected wells are subjected to triggered source water monitoring. The rate at which triggered source water monitoring identifies a well as fecally-contaminated depends on both the fraction of time that *E. coli* is present in the well and the frequency at which the well is sampled. Data verification (DV) data on total coliform occurrence in distribution systems provide the basis for estimates of sampling frequency in different types and sizes of systems. Although the data are limited, EPA has not modeled these as uncertain estimates. Compared to other uncertain parameters, these have relatively little uncertainty and are expected to make only minor contributions to the total uncertainty in the GWR EA.

EPA also did not consider the cost impacts of additional fecal indicator sampling following triggered source water monitoring on corrective action costs. The analysis assumes that for every triggered source water monitoring positive, at least one additional fecal indicator sample will also be positive, resulting in corrective action. The rationale for this assumption is explained in Chapter 6 of the GWR EA. However, it is possible that some systems will not have a positive additional fecal indicator sample and will therefore not incur costs for corrective action. Accounting for this would reduce the costs of the rule associated with corrective actions and, to the extent that these systems actually do have viral or bacterial pathogens present, would reduce the benefits of the rule as well.

EPA assumes that the occurrence of fecal contamination will remain constant throughout the implementation of the rule. However, this might not be the case if increased development results in fecal contamination of a larger number of aquifers in areas served by GWSs or if other rules, such as Concentrated Animal Feeding Operations (CAFO) and Class V Underground Injections Control (UIC) Well regulations, result in decreased fecal contamination. This uncertainty is not mathematically modeled in the GWR Economic Analysis.

6. The Infectivity of Echovirus and Rotavirus Used To Represent Viruses That Occur in Ground Water

EPA does not have dose-response data for all viruses associated with previous ground water disease outbreaks. For viral illness, the Agency used echovirus and rotavirus as surrogates for all pathogenic viruses from fecal contamination that can be found in ground water. By using these two viruses, the Agency is capturing the effects of both high infectivity (Type A) viruses that cause mild illness and low-to-medium infectivity (Type B) viruses that may cause more severe illness but not the range of infectivity within each type. Further, there is additional uncertainty in the dose-response functions used, even for these two viruses. The dose-response relationship was modeled in two steps. First, infectivity, or the percentage of people in the different age groups who become infected after exposure to a given quantity of water with a given concentration of viruses, was estimated. Then morbidity, or the percentage of infected people who actually become ill, was estimated. EPA models uncertainty for morbidity within different age categories and differences in morbidity across different age categories (variability).

7. The Costs of Illnesses Due to Ingestion of Contaminated Ground Water

There is also uncertainty in the valuation of risk reduction benefits. For this analysis, EPA used a cost of illness (COI) approach based on the direct medical care costs as well as the indirect costs of becoming ill. However, there is uncertainty in these estimates and variability in the COI across populations and geographic regions.

8. The Costs of Taking Action After Finding *E. coli* in Ground Water Sources

EPA recognizes that there are both variability and uncertainty in unit cost estimates for treatment. Variability is expected in the actual costs that will be experienced by different water systems with similar flows installing the same treatment technology. Otherwise similar systems may experience different capital and/or O&M costs due to site-specific factors. Inputs to unit costs such as water quality conditions, labor rates, and land costs can be highly variable and increase the system-to-system variability in unit costs. In developing the unit cost estimates, there is insufficient information to fully characterize what the distribution of this variability will be on a national scale for all of the treatments and all possible conditions.

The unit costs for the GWR EA are developed as average or representative estimates of what these unit costs will be nationally. That is, in developing unit costs, design criteria for the technologies were selected to represent typical, or average, conditions for the universe of systems. As a result, there is uncertainty inherent in these unit cost estimates since they are based on independent assumptions with supporting data and vendor quotes, where available, rather than on a detailed aggregation of State, regional, or local estimates based on actual field conditions. EPA quantifies the uncertainty in these national average unit cost factors for specific technologies. The percentage uncertainty bounds used to characterize unit costs were developed based on input from engineering professionals and reflect recommendations from the National Drinking Water Advisory Council (NDWAC, 2001) in its review of the national cost estimation methodology for the Arsenic Rule. EPA believes that the uncertainties in capital and O&M costs for a given treatment technology are independent of one another and that uncertainties across all technologies are independent.

9. Nonquantifiable Benefits

A major uncertainty concerns the number of baseline bacterial illnesses caused by ground water contamination. The bacterial risk could not be modeled because of the lack of occurrence and dose-response data; therefore, the Agency was unable to include these benefits in the primary analysis. Many other nonquantifiable endpoints (as discussed in Section VII.C.4 of this preamble and in the GWR EA Chapter 5 (USEPA, 2006d) cause further uncertainty. In summary, the quantified benefits may be small as compared with the total benefits. EPA's analysis of benefits from avoided bacterial illnesses and deaths suggests that these benefits could exceed the monetized benefits by a factor of five.

10. Optional Assessment Source Water Monitoring

The Agency was not able to estimate the benefits or costs resulting from the optional assessment source water monitoring program. States can determine which systems they deem most vulnerable to fecal contamination and require these systems to conduct assessment source water monitoring. Systems would incur additional costs from monitoring and reporting results as well as any corrective action associated with fecal indicator-positives. States would incur additional costs for determining what systems would be required to monitor, assisting systems with corrective action decisions, and recordkeeping. The types of illnesses avoided would be similar to those already described in this preamble such as reduced viral and bacterial illness.

11. Corrective Actions and Significant Deficiencies

The Agency also did not develop costs for corrective actions for all conceivable significant deficiencies that a system may encounter. Instead, representative actions that span the range of low cost to expensive actions were used as shown in Table VII–10. The corrective actions that are a result of significant deficiencies identified during sanitary surveys do not include the ones performed within the treatment plant or in the distribution system due to lack of adequate data. Exclusion of these costs from the cost analysis results in an underestimate of potential rule costs, though the magnitude of the underestimate is unknown. Data limitations also exclude quantifying any benefits that may be realized from these corrective actions. More information regarding these costs and benefits can be found in the GWR EA (USEPA, 2006d) (see Chapter 6.6 for cost and Chapter 5.4.7 and 5.4.8 for benefits).

12. Uncertainty Summary

Overall, EPA recognizes that there is uncertainty in various parts of its estimates. The Agency has, however, been careful to use the best available data to account for uncertainty quantitatively when possible, and to avoid any consistent biases in assumptions and the use of data. The primary known bias is that some benefits and costs have not been quantified, and therefore are not included in the quantitative comparison of regulatory alternatives. However, as explained above and in the EA, EPA believes that the nonquantified benefits are significantly greater than the quantified benefits. In summary, EPA believes that the analyses presented represent a solid foundation for the decisions made for this rule.

K. What Is the Benefit/Cost Determination for the GWR?

As required by the SDWA, at the time of proposal, the Agency determined that the benefits of this rule justify the costs. In making this determination, EPA considered both quantified and nonquantified benefits and costs as well as the other components of the HRRCA outlined in section 1412 (b)(3)(C) of the SDWA.

For the final rule, as shown in Table VII–14, for the regulatory alternative being finalized in this rule, the annualized mean quantified benefits are approximately $20 million ($10 million using traditional cost-of-illness values) and the annualized mean quantified costs are approximately $62 million using a three percent discount rate ($17/$9 million and $62 million, respectively, using a seven percent discount rate). Overall, the GWR will reduce the risk of fecal contamination reaching the consumer. The monetized costs of these provisions were compared to the monetized benefits that result from the reduction in some viral illnesses and deaths. In addition, other non-monetized benefits further justify the costs of this rule. For example, including bacterial illness would significantly increase the benefits without any increases in costs.

Table VII–15 shows the net benefits for this rule as well as the three regulatory alternatives considered. The net benefits include only the monetized values (*i.e.*, nonquantified costs and benefits are not considered). The nonquantified benefits are likely to be significantly greater than the quantified benefits (and also much greater that the nonquantified costs). Thus, the net benefits of each of the options may be higher than shown in these estimates. Nonquantified costs are also not included.

TABLE VII–14.—ESTIMATED ANNUALIZED NATIONAL BENEFITS AND COSTS FOR THE GWR

[$Millions, 2003$]

	3% Discount rate			7% Discount rate		
	Mean	90 percent confidence bound		Mean	90 percent confidence bound	
		Lower (5th %ile)	Upper (95th %ile)		Lower (5th %ile)	Upper (95th %ile)
Enhanced COI:						
Benefits	$19.7	$6.5	$45.4	$16.8	$5.5	$38.6
Costs	61.8	45.2	81.4	62.3	46.1	81.6
Net Benefits	−42.1	Note 1	Note 1	−45.5	Note 1	Note 1
Traditional COI:						
Benefits	10.0	2.2	27.0	8.6	1.9	22.9
Costs	61.8	45.2	81.4	62.3	46.1	81.6
Net Benefits	−51.8	Note 1	Note 1	−53.7	Note 1	Note 1
Nonquantified Benefits	Decreased incidence of other acute viral disease endpoints. Decreased incidence of bacterial illness and death. Decreased incidence of chronic bacterial or viral illness sequellae.					

TABLE VII–14.—ESTIMATED ANNUALIZED NATIONAL BENEFITS AND COSTS FOR THE GWR—Continued

[$Millions, 2003$]

	3% Discount rate			7% Discount rate		
	Mean	90 percent confidence bound		Mean	90 percent confidence bound	
		Lower (5th %ile)	Upper (95th %ile)		Lower (5th %ile)	Upper (95th %ile)
	Decreased incidence of waterborne disease outbreaks and epidemic illness. Decreased illness through minimizing treatment failures or fewer episodes with inadequate treatment. Potential decreased use of bottled water and point-of-use devices (material costs). Decreased time spent on averting behavior. Avoided costs associated with outbreak response. Perceived improvement in drinking water quality and reduction in risk associated with ingestion. Benefits from optional Assessment Source Water Monitoring. Benefits from correction of sanitary survey deficiencies identified in the distribution systems and treatment plant.					
Nonquantified Costs	Costs for optional Assessment Source Water Monitoring. Costs from correction of sanitary survey deficiencies identified in the distribution systems and treatment plant. Some land costs depending on the treatment technology. Cost for five additional samples but this is small compared to the overestimate of cost for the initial fecal-indicator sample that systems would take. Costs for compliance monitoring at some systems that already disinfect.					

Note 1: Because benefits and costs are calculated using different model modules, bounds are not calculated on net benefits.

Note 2: The Traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The Enhanced COI also factors in valuations for lost personal time (non-worktime) such as child care and homemaking (to the extent not covered by the traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway.

TABLE VII–15.—ANNUALIZED NET BENEFITS ($MILLIONS, 2003$) BY REGULATORY ALTERNATIVE

Rule alternative	Annualized value	
	3% discount rate (dollars)	7% discount rate (dollars)
Enhanced COI:		
Alternative 1	−11.7	−12.4
Final Rule	−42.1	−45.5
Alternative 3	−46.6	−51.2
Alternative 4	−616.2	−603.4
Traditional COI:		
Alternative 1	−13.5	−13.8
Final Rule	−51.8	−53.7
Alternative 3	−57.1	−60.1
Alternative 4	−650.9	−633.8
Nonquantified Benefits	Decreased incidence of other acute viral disease endpoints. Decreased incidence of bacterial illness and death. Decreased incidence of chronic bacterial or viral illness sequellae. Decreased incidence of waterborne disease outbreaks and epidemic illness. Decreased illness through minimizing treatment failures or fewer episodes with inadequate treatment. Potential decreased use of bottled water and point-of-use devices (material costs). Decreased time spent on averting behavior. Avoided costs associated with outbreak response. Perceived improvement in drinking water quality and reduction in risk associated with ingestion. Benefits from optional Assessment Source Water Monitoring. Benefits from correction of sanitary survey deficiencies identified in the distribution systems and treatment plant.	
Nonquantified Costs	Costs for optional Assessment Source Water Monitoring. Costs from correction of sanitary survey deficiencies identified in the distribution systems and treatment plant. Some land costs depending on the treatment technology. Cost for five additional samples but this is small compared to the overestimate of cost for the initial fecal-indicator sample that systems would take. Cost for compliance monitoring at some systems that already disinfect.	

In addition to examining the net benefits of this rule, the Agency used several other techniques to compare benefits and costs. For example, Table VII–16 shows the cost of the rule per viral illness 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 avoided may not result in the greatest net benefits. The cost effectiveness analysis, as with the net benefits, is limited because the Agency was able to only partially quantify and monetize the benefits of the GWR. This rule achieves the lowest cost per viral illness avoided. Additional information about this analysis and other methods used to compare benefits and costs can be found in Chapter 8 of the GWR EA (USEPA, 2006d).

TABLE VII–16.—COST PER CASE OF VIRAL ILLNESS OR DEATH AVOIDED BY REGULATORY ALTERNATIVE

[2003$]

Rule alternative	Cost per viral illness avoided	
	3% (dollars)	7% (dollars)
Alternative 1	2,045	2,044
Final Rule	1,476	1,488
Alternative 3	1,495	1,527
Alternative 4	4,420	4,284

Note: Calculated using mean costs of illness avoided.

Overall, the measures described above are very close for the Final Rule and Alternative 3 and EPA believes that the nonquantified benefits of the rule would result in positive net benefits for either option. The Final Rule allows States to implement the assessment source water monitoring provision, which would have been mandatory if EPA had chosen Alternative 3, on a voluntary basis. The final GWR is more flexible, targeted, and protective than Alternative 3 (see Section VII.A of this preamble and Chapter 8 of the GWR EA (USEPA, 2006d) for more details). The level at which additional costs will be incurred and benefits realized under the voluntary provision is dependent on the rate at which States elect to adopt the provisions, and thus is not quantified as part of the Economic Analysis.

L. What Were Some of the Major Comments Received on the Economic Analysis and What Are EPA's Responses?

1. Costs

EPA requested comment on all aspects of cost analysis for the proposed GWR, particularly on the flow estimate for NTNCWSs and TNCWSs and handling mixed systems. In addition to these two issues, EPA also received numerous comments on the following analyses: sanitary survey costs, estimate of treatment baseline, costs of corrective actions, and compliance costs for small systems or NCWSs.

a. *Flow estimate for NTNCWSs and TNCWSs.* EPA received a few comments on NTNCWS and TNCWS flow estimates. Some commenters indicated that the alternative approach described in the preamble of the proposed rule would lead to greater disparities from the true values. The other commenters supported using the alternative approach. For this rule, EPA continues to apply the CWS regression equations to NCWSs, recognizing that this may overestimate flow and, therefore, costs. This overestimate is addressed as part of the uncertainties, which is discussed in Chapter 4 of the GWR EA (USEPA, 2006d). Further discussion of the alternative approach is also presented there.

b. *Mixed systems.* EPA received comments that regulatory impacts on mixed systems were not adequately characterized because either their costs were underestimated or the methodology for deriving the costs was unclear. Since the available data was insufficient to directly account for ground water entry points in mixed systems, EPA based the cost estimate for mixed systems on the primarily ground water mixed system inventory report. Primarily ground water mixed systems are systems using ground water for more than 50 percent of their source water; the remainder of their source water is surface water. The primarily ground water-mixed CWSs identified by this calculation were added to the solely GWS inventory to produce the total baseline number of GWSs used in the economic analysis. Because NTNCWSs and TNCWSs are typically a single building or located in a small area, a simplifying assumption was made for this analysis that all NCWSs draw from a single source water type.

The total baseline number of GWSs is treated as ground water-only systems throughout subsequent analyses. This methodology, treating mixed systems as ground water-only systems, may overestimate costs and benefits (*i.e.*, some surface water entry points are now counted as ground water entry points). However, the ground water entry points in the excluded mixed surface water inventory (those mixed systems using less than 50 percent ground water) are not included in the analysis, potentially underestimating costs and benefits. The contrasting over- and under-accounting for ground water entry points are expected to offset one another to some extent in the cost and benefit analyses. Data are not available to quantify the direction or magnitude of the final effect on overall national cost estimates, but the effect is expected to be small. Chapter 4 of the GWR EA (USEPA, 2006d) contains a detailed description of the methodology for impact analysis of mixed systems.

c. *Sanitary survey costs.* EPA received comments that the sanitary survey costs were inadequately estimated because of lack of considerations of the surveys currently performed by States and travel times needed for conducting surveys. The sanitary survey cost estimates used in this rule analysis have been updated based on data that became available after the proposed GWR. For the proposed GWR, EPA used the same unit costs as the ones used in a previous economic analysis (IESWTR) for estimating costs of full sanitary surveys. Fifty percent of full survey costs was applied to all systems as the incremental costs resulting from the GWR sanitary survey provision. This percentage was used to account for the more comprehensive survey coverage (*i.e.*, evaluation of eight elements) under the GWR than under existing requirements of the TCR.

For the final rule, EPA revised its cost analysis for conducting sanitary surveys

based on new information from States. First, EPA revised its estimates for conducting full sanitary surveys specifically for GWSs with and without treatment. Second, EPA estimated the number of additional full sanitary costs (including travel time costs) that would result from the higher frequency of sanitary surveys required under the GWR, over the number that is currently being implemented. This number of additional sanitary surveys was multiplied by the sanitary survey unit costs to estimate national costs for this effect.

Third, for those sanitary surveys already being conducted, EPA estimated the percentage of systems for which sanitary surveys would need to be increased in scope to ensure that all 8 elements were being implemented. Because all States currently have sanitary surveys in place under the IESWTR, TCR, or other State programs, most States are now conducting sanitary surveys at the frequencies and scope required by the GWR. The revised sanitary survey costs thus assume no incremental unit costs in most States and are substantially lower than the estimates costed for the proposed GWR. Chapter 6 of the GWR EA (USEPA, 2006d) contains a detailed discussion of sanitary survey costing assumptions.

d. *Treatment baseline.* EPA received comments that the percentage of disinfecting systems currently achieving 4-log virus inactivation was overestimated. For the proposed rule, EPA based the estimate of systems achieving 4-log inactivation (77 percent) on the data from the AWWA disinfection survey for community GWSs. EPA recognizes the limited data resources; AWWA data was the only source available on a national level and the disinfection rate estimate used in the proposed rule is likely to bias high due to relatively small sample size and question complexity for the survey.

In the final GWR EA, EPA re-evaluated the AWWA data and made a conservative assumption that those community GWSs providing insufficient information for the CT calculation in the AWWA survey are not currently achieving 4-log virus inactivation. As a result, the 4-log disinfection rate was revised downward to 52 percent. A similar change was made for NCWSs. Chapter 4 of the GWR EA (USEPA, 2006d) provides the detailed discussion of current disinfection rates.

e. *Corrective action costs.* EPA received comments that corrective action costs were underestimated, especially the costs for installing disinfection units. The commenters questioned the cost estimates of the additional land required and the addition of storage tanks for achieving sufficient CT values for 4-log virus inactivation. EPA believes that the unit costs of technologies provided in the *Technology and Cost Document for the Final Ground Water Rule* (USEPA, 2006h) (T&C document) are adequate to derive the costs for complying with the GWR corrective action provisions because the costs were derived using the best available published data, vendor estimates and best professional judgment.

EPA understands that some technologies used to comply with this rule will not fit within the existing plant footprints for some systems. When land costs become expensive, systems have the flexibility to consider other non-treatment options such as well rehabilitation or purchasing water. EPA further recognizes the land costs as part of nonquantified costs in the GWR EA (USEPA, 2006d).

The T&C document presents the unit costs of disinfection apart from the unit costs for storage tanks because consultation with the field experts indicates that some systems have existing storage tanks or certain lengths of pipes before the first costumers. Systems that do not have existing storage tanks will need to consider the costs for them in cases when they would need to meet the CT values for 4-log inactivation of viruses. The detention times in existing facilities could be sufficient for achieving the 4-log CT values with disinfectant doses within a typical range. For these cases, EPA assumes that no additional storage will be required for installing disinfection or that an increase of disinfectant doses will be feasible for increasing viral disinfection levels to 4-logs.

EPA also recognizes that disinfection and conducting compliance monitoring may not be preferred by some systems (particularly for small systems) because of distribution system size and configuration or operational complexity (including compliance monitoring) and costs. After further consultation with State representatives, EPA revised the compliance forecasts for this rule by lowering the percentages of systems taking treatment actions (and raising percentages of systems taking non-treatment actions) and adding a range of estimates to quantify the uncertainty around the compliance forecasts. The consultation also resulted in the addition of interim disinfection for systems taking corrective actions due to a fecal indicator-positive ground water source sample. This is because some immediate protection measures may have to be in place prior to completing corrective actions. Chapter 6 of the GWR EA (USEPA, 2006d) contains a detailed discussion of the corrective action costs.

f. *Compliance costs for small systems or NCWSs.* Some commenters questioned whether EPA appropriately considered the costs to small systems. As part of the GWR regulatory development process, EPA participated in extensive consultations with small system representatives to develop risk-based rule requirements that would minimize the time and financial burden on small systems. To address concerns over the potential cost of additional monitoring for small systems, the GWR leverages the existing TCR monitoring framework to the extent possible (*e.g.*, by using the results of the TCR monitoring to determine if triggered source water monitoring is required and by allowing small systems to use TCR repeat samples to satisfy GWR requirements). In addition, the implementation schedule for the sanitary survey requirement is staggered (*e.g.*, every three to five years for CWSs and every five years for NCWSs), providing some relief for small systems since there are many more small NCWSs than CWSs. In addition to the targeted requirements for minimizing small systems burden, financial assistance to small systems may be available from programs administered by EPA or other Federal agencies (*http://www.epa.gov/safewater/dwsrf/index.html*).

Some commenters noted that systems may break into smaller units to fall below SDWA regulatory thresholds. Specifically, they noted that if a system is no longer classified as a PWS, it would be able to opt out of the GWR requirements. However, EPA believes that systems would most likely consolidate with other systems to defray costs rather than split up and lose economies of scale and put the public health at risk. Systems would also have to consider the transaction costs associated with dissolving into smaller units such as drilling new wells and separating distribution systems.

EPA also received a number of comments questioning if the Agency considered the costs to NCWSs (*i.e.*, NTNCWSs and TNCWSs). EPA did consider the costs to NTNCWSs and TNCWSs. The baseline number of systems subject to GWR requirements was derived from all CWSs, NTNCWSs, and TNCWSs listed in the SDWIS inventory. The new occurrence database also includes NCWSs. Costs were estimated by system size and type corresponding to applicable GWR requirements and schedules and typical operating characteristics (*e.g.*, population served, treatment in place,

flows, etc.). Detailed descriptions of all costing procedures are presented in the GWR EA (USEPA, 2006d). More specifically, NTNCWS and TNCWS cost estimates are presented by system size in Exhibit 6.40 of the GWR EA.

2. Benefits

a. *Use of occurrence data in risk assessment.* Some commenters questioned the basis for EPA using the data from the Lieberman *et al.* (2002) and Abbaszadegan (Abbaszadegan, 2002 and Abbaszadegan *et al.*, 1999a–c and 2003) studies to represent national microbial occurrence in the risk assessment. Issues raised included use of the studies to represent all CWSs and NCWSs on a national level, use of the Abbaszadegan *et al.* data set to represent ''properly constructed wells,'' and use of the Lieberman data set to represent ''poorly constructed wells.''

Upon re-examination of all available occurrence data, EPA has made several changes to the occurrence analysis used to support the risk assessment. The Agency has made changes to achieve better representation of viral and fecal indicator occurrence among all PWS wells in the U.S. as described in Section VII.B.

Data from all the studies used in the occurrence analysis of the GWR EA were cited in the NODA (USEPA, 2006e) and made publicly available. EPA believes that use of occurrence data from the cited studies in Section VII.A rather than using only the two studies used in the GWR EA under the proposal (Lieberman *et al.*, 2002; Abbaszadegan, 2002 and Abbaszadegan *et al.*, 1999a–c and 2003) provides a better national estimate of intermittent enterovirus occurrence in support of the GWR risk assessment.

Under the proposed rule, EPA used the Lieberman *et al.* (2002) data set to estimate enteric virus occurrence for poorly constructed wells and the Abbaszadegan (Abbaszadegan, 2002; Abbaszadegan *et al.*, 1999a–c and 2003) data set to estimate enteric virus occurrence in properly constructed wells. In this rule, due to data limitations, EPA assumes the same enterovirus occurrence and percent time of viral presence (as described in Section VII.B of this preamble) for all wells.

In this rule, EPA uses the terminology ''more vulnerable'' and ''less vulnerable'' wells as categories for differing enteric virus concentration assumptions in differing groups of wells. Since the wells sampled from the Lieberman *et al.* (2002) data were selected because of likely vulnerability to fecal contamination, the enteric virus concentration data from Lieberman *et al.* (2002) is assumed to be characteristic of ''more vulnerable'' wells. Since the wells from the Abbaszadegan *et al.* (2002) and Lindsey *et al.* (2002) studies were not selected with a bias toward greater likelihood of fecal contamination, enteric viral concentrations from these two studies were assumed to be characteristic of ''less vulnerable'' wells. A more complete description of this analysis is available in Chapters 4 and 5 of the GWR EA (USEPA, 2006d).

b. *Variability and uncertainty.* Some commenters suggested that EPA could do more to address uncertainty and variability when calculating the benefits of this rule. As a result of these comments, EPA re-evaluated the data used to support the proposed GWR and the newer data published since the proposal. EPA determined that the values and/or analysis used in the proposed rule should be revised to better capture variability and uncertainty. The following discussion describes the significant changes that were made in the analysis supporting this rule as a result of the public comments and EPA's re-analysis.

EPA has significantly revised its modeling of virus and indicator (*E. coli*) occurrence in ground water sources of drinking water in response to public comments. Section VII.B describes additional surveys and their use to produce a national assessment of occurrence. The modeling framework features probabilistic treatments of both variability and uncertainty.

In this rule, EPA modified the mathematical expression that describes the human challenge studies with infectious rotavirus (infectivity of the virus). The purpose of the challenge study was to determine the rotavirus dose required to cause infection in humans. Previously, EPA used an approximation to the exact Beta-Poisson distribution in describing the dose-response data to simplify the Monte-Carlo simulation computational requirements. EPA's primary analysis now recognizes that the approximation is poor for some combinations of dose and parameter values and when used to predict low dose risk. As a result, EPA is using the exact expression for this rule. In an alternative analysis, EPA utilizes only data from the lowest dose used in the study. That dose (0.9 infectious units) is nearest the most relevant environmental number ingested: exactly one infectious unit. An exponential dose-response model is applied in the alternative analysis and the small number of subjects (seven exposed at this dose) results in considerable uncertainty about the model parameter.

In this rule, EPA maintains as its primary analysis a Beta-Poisson dose-response model (Pareto approximation) utilizing the full echovirus data set but now includes an alternative analysis in which an exponential model is utilized with data from all but the two highest dose levels. Subjects who were not infected at the high dose levels demonstrate that different individuals have different levels of susceptibility (a feature of the Beta-Poisson model), but without the high dose data, the remaining subjects appear equally susceptible (a feature of the exponential model). The alternative analysis predicts significantly lower risk at environmental exposure levels. EPA's two analyses demonstrate considerable uncertainty with respect to model and data selection.

In this rule, EPA revised the morbidity value for rotavirus illness in adults. The Agency now recognizes that the variability in this value is considerable and has included a range of uncertainty in the morbidity estimate. Because of limited data on common source rotavirus outbreaks involving adults, under the proposal, EPA had assumed that most adults remain immune due to multiple repeat infections, or if infected, do not often become ill. Under the proposal, EPA used a low value for the adult rotavirus morbidity rate (0.10). However, EPA re-examined the Ward *et al.* (1986) data and concluded that one-half of the subjects in the dose-response study became ill after infection. Also, since the proposal, Griffin *et al.* (2002) analyzed previous outbreaks and identified one rotavirus genotype that is associated with outbreaks involving adults in the U.S. This new knowledge suggests that the morbidity value for adults can be much more variable than previously believed depending on which rotavirus genotype is consumed. EPA now uses a range in the rotavirus adult morbidity value from 0.10–0.50 and a uniform distribution. The distribution selected reflects the variability among rotavirus genotypes.

EPA obtained additional echovirus (Type B) morbidity data to improve the analysis described in the proposal. The proposal used only Echovirus type 30 morbidity data from the Seattle Virus Watch Study (Hall *et al.*, 1970) based on the assumption that data from a single strain would minimize variability among the general population. In this rule, EPA uses multiple echovirus serotype data from both the Seattle and New York Virus Watch Studies (Kogon *et al.*, 1969) to determine the range of

morbidity rates in the general population.

c. *Are the benefits and the data used to estimate the benefits of the GWR sufficient to justify regulatory action?* EPA received several comments that addressed the calculation of benefits. Most commenters questioned whether the GWR benefits are sufficient to justify regulatory action. In particular, comments suggested that the probability of an outbreak is low and there is no linkage between undisinfected ground water and waterborne disease. EPA also received several comments about the overall lack of information suitable for estimating health benefits.

In general, EPA recognizes that the health effects data available for use in calculating GWR benefits are limited because there are no national epidemiological studies to identify waterborne disease from ground water nor is there any national system for reporting waterborne disease once it is identified.

EPA has substantially revised its benefits analysis to use a combination of measured data, calculated values, and reasonable assumptions to make predictions about benefits. The benefits determined for the GWR are based on measurement of pathogenic enteric viruses in public drinking water wells, so these data are directly applicable to making predictions about possible avoided illnesses due to elimination of these pathogens from the drinking water supply. Furthermore, it should be recognized that, in the benefits calculation, EPA does not assume that pathogen occurrence automatically results in illness in all individuals consuming water from that drinking water supply well. EPA used dose-response data from human feeding studies to determine the probability that an individual would become infected by consuming water with a range of pathogen concentrations. For echovirus (one of the enteroviruses), illness rates and ranges were determined from epidemiology studies on the general population. For rotavirus, illness rates and ranges were determined from epidemiology studies on the general population and from the symptomatic response to infection in human challenge studies.

d. *Transparency of regulatory impact analysis.* Some commenters expressed that the Regulatory Impact Analysis for the proposed GWR (USEPA, 2000f) did not provide a clear description of the critical assumptions underlying the cost and benefit analysis.

EPA believes that it has made the GWR EA for the final rule more transparent than the analysis done for the proposal. Changes include (1) Expanded text on the basis for most of the assumptions used in the analysis, (2) expanded text and new diagrams describing how the different steps in the analysis are combined to produce an aggregate analysis, and (3) expanded text on how the nonquantified benefits complement the quantified benefits analysis.

3. Risk Management

a. *What is EPA's response to comments that EPA chose the wrong option and that the benefits do not justify the cost or that the rule is not cost-effective?* Consistent with EPA's statutory requirements, the Agency carefully considered benefits and costs in proposing and promulgating the GWR. The Agency's decision for the final rule is described in VII.A. The Agency believes that this rule provides benefits at a cost that is justified. In making decisions for the final rule, EPA considered both quantified and nonquantified benefits and costs as well as the other components of the Health Risk Reduction and Cost Analysis (HRRCA) outlined in section 1412(b)(3)(C) of the SDWA.

In the proposal, the Multi-Barrier approach (Regulatory Alternative 3) had net benefits similar to the proposed regulatory Alternative 2, Sanitary Survey and Triggered Monitoring. However, the Multi-Barrier approach provided a greater reduction in illnesses and deaths, especially to children. After an exhaustive review of the benefits and cost estimates used in the proposal resulting from public comments, peer review, and the NDWAC Arsenic Review panel, the Agency updated both the benefit and cost analysis for each rule option. The risk-targeted approach, which was selected for the final rule, has lower net benefits than Alternative 1, but more than Alternatives 3 and 4. EPA believes that the additional benefits realized under Alternative 2 justify its selection over Alternative 1, despite the lower net benefits.

Other commenters noted that the proposed rule is not cost-effective. The mean cost per viral illness avoided for the final rule ranges from $1,476 to $1,488, at three percent and seven percent discount rates respectively. These represent the lowest values of all alternatives considered and are much lower than either Alternative 1 or Alternative 4. Thus, Alternative 2 is the most cost-effective rule alternative by this measure.

b. *Did the Agency consider that some systems may have negative net benefits, and did the Agency conduct an incremental analysis by system size and type?* Some commenters noted that the costs may exceed benefits for smaller size systems. EPA agrees that for some drinking water regulations the costs may exceed the benefits because the populations served by these systems are much smaller. Generally, large systems benefit from economies of scale which eases the relative impact on these systems. In addition, many GWR benefits remain nonquantified.

Other commenters suggested that EPA should exclude or set different standards for small systems based on benefit and cost analysis, including incremental analysis, by system size or type. However, the SDWA does not generally provide a basis for establishing tailored drinking water standards as these commenters suggest. Rather, the SDWA is designed to ensure uniform levels of public health protection across the country (except as specifically provided for in variances from the standard).

Thus EPA disagrees with the suggestion that the level of the final standard be altered to address system size or type. However, as discussed in detail in the preamble of this rule, the rule provides flexibility that reduces burden on small systems and reflects individual system conditions. Financial and technical assistance is also available through various funding authorities. Regarding affordability, variances based on affordability are not allowed by the SDWA for regulations addressing microbial contamination, and as a result EPA did not conduct an affordability analysis. However, EPA has considered the SAB review of the Arsenic Rule and the suggestions of the NDWAC Arsenic Cost Working Group regarding the further disaggregation of the analyses. The NDWAC group recommended calculation and presentation of cost information in multiple size categories, which is done in the GWR EA (USEPA, 2006d).

In addition, the Agency took many steps to reduce the burden on small systems where possible. More information regarding this effort can be found in Chapter 6 of the GWR EA (USEPA, 2006d).

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a ''significant regulatory action''. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in

response to OMB recommendations have been documented in the docket for this action.

In addition, EPA has prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in the *Economic Analysis for the Final Ground Water Rule* (USEPA, 2006d). A copy of the analysis is available in the docket for this action and the analysis is briefly summarized in Section VII of this preamble.

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 2040–0271.

The information collected as a result of this rule will allow the States and EPA to make decisions and evaluate compliance with the rule. For the first three years after the promulgation of the GWR, the major information requirements are for States and PWSs to prepare for implementation of the rule. The information collection requirements are described in 40 CFR part 141, for systems, and part 142, for States, and are mandatory. The information collected is not confidential.

EPA estimates that the annual burden on PWSs and States for reporting and recordkeeping will be 385,264 hours. This annual burden is based on an estimate that 57 States and territories will each need to provide one response each year with an average of 2,193 hours per response, and that 49,110 systems will each provide two responses each year with an average of 2.6 hours per response. The total reporting and recordkeeping cost over the three-year period of the Information Collection Request is $30,274,266 (labor costs) (USEPA, 2006a). It should be noted, however, that much of the paperwork burden of the rule will be incurred only after the three-year time horizon covered in this analysis. Subsequent ICR submissions will address future burden for activities such as triggered and compliance monitoring. There are no operation, maintenance or capital costs estimated for the first three years. The labor burden is estimated for the following activities: reading and understanding the rule, planning, training, and meeting primacy requirements. 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 rule.

C. Regulatory Flexibility Act (RFA)

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

The RFA provides default definitions for each type of small entity. Small entities are defined as: (1) A small business as defined by the Small Business Administration'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 Counsel for Advocacy.

For purposes of assessing the impacts of the final GWR on small entities, EPA considered defining ''small entities'' in its regulatory flexibility assessments under the RFA 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 applies to this regulation as well.

Pursuant to section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule (see 65 FR 30193, May 10, 2000) and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the regulated small entities (USEPA, 2000a). A detailed discussion of the Panel's advice and recommendations is found in the Panel Report (docket number EPA–HQ–OW–2002–0061; document number W–98–23–I.E–2). A summary of the Panel's recommendations is presented in the GWR proposal at 65 FR 30253, May 10, 2000 (USEPA, 2000a).

As required by section 604 of the RFA, we also prepared a final regulatory flexibility analysis (FRFA) for the final GWR. The FRFA addresses the issues raised by public comments on the IRFA, which was part of the proposal of this rule. The FRFA is available for review in the docket and is summarized below.

EPA is issuing this final rule to comply with section 1412(b)(8) of the SDWA, which directs EPA to ''promulgate national primary drinking water regulations requiring disinfection as a treatment technique for all public water systems, including surface water systems and, as necessary, ground water systems.'' The need for this final rule is based upon the substantial likelihood that fecal contamination of ground water supplies is occurring at frequencies and levels that present public health concern. Fecal contamination refers to the contaminants, particularly the microorganisms, contained in human or animal feces. These microorganisms may include bacterial and viral pathogens, which can cause illnesses in the individuals that consume them. The objective of the final GWR is to identify those systems with fecal contamination and undertake corrective action to eliminate or address that contamination.

Two significant issues were raised in comments on the IRFA for the proposed rule. First, several commenters wrote

that small water systems lack the customer base to defray the costs of installing new treatment, such as disinfection, or the cost of a new source. EPA notes that the final GWR does not mandate disinfection, but rather is a flexible regulation, targeting those high-risk systems or sources that are vulnerable to contamination. EPA also notes that financial assistance is available to small systems through programs such as the Drinking Water State Revolving Fund, the Loan and Grant program of the U.S. Department of Agriculture's Rural Utilities Services (RUS) and the Community Development Block Grant Program of the Department of Housing. The second significant issue raised in comments on the IRFA was a recommendation that EPA allow the States flexibility to consider competing fiscal impacts on small systems when implementing the rule. EPA believes the final rule has greater flexibility and is less burdensome for States and small systems than the proposal. For example, a GWS serving 1,000 people or fewer may use a repeat sample collected from a ground water source to meet the TCR to satisfy the GWR triggered source water monitoring requirements if the State approves the use of *E. coli* as a fecal indicator for ground water source monitoring.

EPA assessed the potential impact of the final GWR on small entities. There are 147,330 CWSs, NTNCWSs, and TNCWSs providing potable ground water to the public; 145,580 (99 percent) are classified by EPA as small entities. EPA has determined that all small systems are impacted by the sanitary survey requirement and a substantial number these systems will be impacted by additional requirements of the final GWR, including the triggered source water monitoring requirements and the corrective action requirements.

In addition, in the final GWR there are a number of recordkeeping and reporting requirements for all GWSs (including small systems). To minimize the burden with these provisions, the final rule uses a risk-based regulatory strategy, whereby the monitoring requirements are based on system characteristics and not directly related to system size. In this manner, the rule takes a system-specific approach to regulation.

To prevent conflict and overlap with other Federal rules, this final rule leverages the existing TCR monitoring framework to the extent possible (*e.g.*, by using the results of the routine TCR monitoring to determine if source water monitoring is required). GWSs that do not reliably treat to 4-log inactivation or removal of viruses are required to collect a source water sample following a total coliform-positive sample in the distribution system. Additionally, systems may utilize one of the follow-up monitoring samples required under the TCR to meet the triggered source water sampling requirements of this final rule.

As a result of the input received from stakeholders, the EPA workgroup, and other interested parties, EPA constructed four regulatory options: The sanitary survey option, the sanitary survey and triggered monitoring option, the multi-barrier option, and the across-the-board disinfection option. In developing this final rule, EPA considered the recommendations to minimize the cost impact to small systems. A risk-targeted approach, based on sanitary surveys and triggered source water monitoring (which only requires corrective action if the GWS has a sanitary survey significant deficiency or source water fecal contamination), was selected as the option to protect public health and to reduce burden. Assessment source water monitoring, part of the preferred proposal option (the multi-barrier option), has been finalized as a discretionary requirement as determined by the State, allowing further flexibility and burden reduction.

To mitigate the associated compliance cost increases across water systems, this final rule also provides States with considerable flexibility when implementing other requirements of the rule. This flexibility will allow States to consider the characteristics of individual systems when determining an appropriate corrective action. For example, States have the flexibility to allow systems to fix existing wells, drill a new well, obtain a new source, or use any disinfection treatment technology that achieves 4-log inactivation or removal of viruses. States may also determine that the source of contamination has been eliminated if, after thorough investigation by the State and the system, the State concludes that contamination is unlikely to reoccur.

As required by section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA), EPA also is preparing a Small Entity Compliance Guide to help small entities comply with this rule. This guide will be available on EPA's Web site at *http://www.epa.gov/safewater/disinfection/gwr/index.html* or by calling the Safe Drinking Water Hotline at (800) 426–4791.

D. Unfunded Mandates Reform Act (UMRA)

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 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 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 does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, or Tribal governments in the aggregate, or the private sector in any one year (see Table VIII–1). The rule is estimated to cost State, local and Tribal governments $41.5 to $41.9 million. Public water systems that are privately owned will incur total costs of $20.3 to $20.4 million per year. A more detailed description is presented in the Economic Analysis for the Final Ground Water Rule (USEPA, 2006d), which is available in the water docket. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Table VIII-1: Ground Water System, State, and Tribal Estimated Costs

(Note: Detail may not add up to totals due to independent rounding)

	3% Discount Rate	7% Discount Rate	Percent of 3% Grand Total Costs	Percent of 7% Grand Total Costs
Ground Water Systems Costs	$ 29.5	$ 30.0	48%	48%
State Costs	$ 11.8	$ 11.7	19%	19%
Tribal Costs	$ 0.2	$ 0.2	0%	0%
Total Public	**$ 41.5**	**$ 41.9**	**67%**	**67%**
Ground Water Systems Costs	$ 20.3	$ 20.4	33%	33%
Total Private	**$ 20.3**	**$ 20.4**	**33%**	**33%**
GRAND TOTAL	**$ 61.8**	**$ 62.3**	**100%**	**100%**

In developing this rule, EPA consulted with small governments pursuant to its interim plan established under section 203 of the UMRA to address impacts of regulatory requirements in the rule that might significantly or uniquely affect small governments. EPA held four public meetings for all stakeholders. Because of the GWR's impact on small entities, the Agency convened a Small Business Advocacy Review (SBAR) Panel in accordance with the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to address small entity concerns, including small local governments specifically. EPA consulted with small entity representatives prior to convening the Panel to get their input on the GWR. Of the 22 small entity participants, five represented small governments. EPA also made presentations on the GWR to the national and some local chapters of the American Water Works Association, the Ground Water Foundation, the National Ground Water Association, the National Rural Water Association, and the National League of Cities.

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 the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This rule does not contain a ''significant Federal government mandate'' under section 202 of the UMRA, nor does it have a significant impact on small governments. Thus, Executive Order 13132 does not apply to this rule.

Although Section 6 of Executive Order 13132 does not apply to this rule, EPA did consult with State and local officials in developing this rule (65 FR 30203 and 30263, May 10, 2000) (USEPA, 2000a). A summary of the concerns raised during that consultation and EPA's response to those concerns are provided in the proposal. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed rule from State and local officials.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop ''an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' 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. This rule will significantly affect communities of Tribal governments because 87 percent of PWSs in Indian Country are GWSs. Accordingly, EPA provides the following Tribal summary impact statement as required by section 5(b).

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 (see the proposed rule, 65 FR 30259, May 10, 2000) (USEPA, 2000a). Two consultations took place at national conferences; one for the National Indian Health Board and the other for the National Tribal Environmental Council. A third consultation was conducted in conjunction with the Inter-Tribal Council of Arizona, Inc. EPA received one comment on the proposed rule from a Tribal organization. The organization is concerned that the GWR will have a negative impact on their ability to provide infrastructure improvements by taking funding resources away from new water supply construction programs and applying these funds to cover compliance costs for existing water systems. EPA recognizes that the GWR will increase the compliance burden for some Tribal PWSs, however, EPA believes that the GWR will provide public health benefits that justify the increase in burden. To offset some of this burden, EPA has provided flexibility for small systems through various mechanisms. For a detailed discussion, please see Section IV of this preamble.

As required by section 7(a), EPA's Tribal Consultation Official has certified that the requirements of this Executive Order have been met in a meaningful and timely manner. A copy of the certification is 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 Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

While this final rule is not subject to the Executive Order because it is not economically significant as defined under Executive Order 12866, we nonetheless have reason to believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. As a matter of EPA policy, we therefore assessed the environmental health or safety effects of viruses on children. The results of this assessment are contained in Section VII.I.1 of the preamble of this rulemaking as well as in the final GWR EA (USEPA, 2006d).

H. Executive Order 13211: Actions 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.

1. Energy Supply

The GWR does not regulate power generation, either directly or indirectly. The public and private PWSs that the GWR regulates do not, in general, generate power. Further, the cost increases borne by customers of PWSs as a result of the GWR represent a small percentage of the total cost of water, except for a very few small systems that will need to spread the cost of installing advanced technologies 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 GWR. In summary, the GWR does not regulate the supply of energy, does not generally regulate the utilities that supply energy, and is unlikely to significantly affect the customer base of energy suppliers. Thus, the GWR will not adversely affect the supply of energy.

2. Energy Distribution

The GWR does not regulate any aspect of energy distribution. PWSs that are regulated by the GWR already have electrical service. The rule is projected to increase peak electricity demand at PWSs by only 0.001 percent (see below). Therefore, EPA assumes that the existing connections are adequate and that the GWR has no discernable adverse effect on energy distribution.

3. Energy Use

Some PWSs are expected to add treatment technologies that use electrical power. This potential impact of the GWR on the use of energy was evaluated. The analyses that underlay the estimation of costs are national in scope and do not identify specific plants or systems that may install treatment in response to the GWR. As a result, no analysis of the effect on specific energy suppliers is possible with the available data. Further data are required to evaluate the effect on specific energy suppliers. The approach used to estimate the impact of energy use, therefore, focuses on national-level impacts. In this approach, EPA estimates the additional energy use due to the GWR and compares that to the national levels of power generation in terms of average and peak loads.

The first step is to estimate the energy used by the technologies or corrective action expected to be installed as a result of the GWR. Energy use is not directly estimated in the *Technology and Cost Document for the Final Ground Water Rule* (USEPA, 2006h), but the annual cost of energy for each technology and corrective action addition or upgrade necessitated by the GWR 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 per kilowatt hour per year (kWh/y) (USDOE EIA, 2002). The energy use per plant for each flow range and technology or corrective action 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. An incremental national annual energy usage of 4,521 megawatt hours (mWh) was calculated.

The total increase in energy usage by water systems as a result of the GWR is predicted to be approximately 4.5 million kWh/y, which is less than one-ten-thousandth of one percent of the total energy produced in 2003. While the rule may have some adverse energy effects, EPA does not believe that this constitutes a significant adverse effect on the energy supply. See the *Economic Analysis for the Final Ground Water Rule* (USEPA, 2006d) for further detail.

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, 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 standards 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 identified some consensus standards and developed or modified methods for the remaining methods requirements. These methods are listed in § 141.402(c).

Most of the methods that EPA is approving for the detection of *E. coli* in source waters are consensus methods described in *Standard Methods for the Examination of Water and Wastewater (20th Edition)* (APHA, 1998). The three *E. coli* methods that are not consensus methods are newly developed: MI agar (a membrane filter method), the ColiBlue 24 test (a membrane filter method) and the E*Colite test (a defined dehydrated medium to which water is added). EPA has already evaluated and approved these three methods for use under the TCR. Of the three enterococci methods EPA is approving in this rule, two are consensus methods in *Standard Methods*; the third (Enterolert) was described in a peer-reviewed journal article (Budnick *et al.*, 1996).

The two methods EPA proposed for the detection of coliphage in source water are not consensus methods. For the coliphage tests, EPA is approving the use of two methods: *EPA Method 1601* (Two-Step Enrichment Presence-Absence Procedure) (USEPA, 2001a) and *EPA Method 1602* (Single Agar Layer Procedure) (USEPA, 2001b). *EPA Method 1601* is a new method optimized for the detection of a single coliphage in a small (100–1,000 mL) water sample. EPA did not use the consensus method for coliphage in *Standards Methods* (20th edition) (Method 9211D) (APHA, 1998) rather, EPA modified and optimized Method 9211D to improve its sensitivity and versatility.

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

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

The Environmental Justice Executive Order requires the Agency to consider environmental justice issues in the rulemaking and to consult with minority and low-income stakeholders. The Agency has considered environmental justice issues concerning the potential impacts of this action and has consulted with minority and low-income stakeholders. The GWR applies to all PWSs (CWSs, NTNCWSs, and NTCWSs) that use ground water as their source water. Consequently, the health protection benefits provided by this rule are equal across all income and minority groups served by these systems. Existing regulations such as the SWTR, IESWTR, and LT2ESWTR provide similar health benefit protection to communities that use surface water or ground water under the direct influence of surface water.

Nonetheless, the Agency held a stakeholder meeting on March 12, 1998, to address various components of pending drinking water regulations and how they may impact sensitive sub-populations, minority populations, and low-income populations. See the discussion of this meeting in the proposed rule for further information (65 FR 30261, May 10, 2000) (USEPA, 2000a).

K. 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 January 8, 2007.

L. Analysis of the Likely Effect of Compliance With the GWR on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of SDWA, as amended, requires that in promulgating an NPDWR, the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, managerial, and financial capacity of public water systems. This analysis can be found in the GWR Economic Analysis (USEPA, 2006d). Analyses reflect only the impact of new requirements, as established by the GWR; the impacts of previously established requirements on system capacity are not considered.

IX. Consultation With Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services; and Peer Review

In accordance with sections 1412(d) and 1412(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.

In addition, this rule was supported by influential scientific information. Therefore, the Agency conducted a peer review in accordance with OMB's Final Information Quality Bulletin for Peer Review (OMB, December 15, 2004). EPA developed charge questions related to the statistical approach used to characterize national occurrence of viral pathogens and fecal indicators; risk characterization including dose-response modeling; characterization of morbidity, mortality, and severity for Type A and Type B viruses; characterization of nonquantified benefits; and national risk reduction (benefits) and costs for the GWR. The Peer Review Report is located in the docket for this rule.

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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: October 11, 2006.

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 by adding entries § 141.401–141.405'', § 142.14(d)(17)'', § 142.15(c)(7)'' and § 142.16(o)'' in numerical order, as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * * * *	
National Primary Drinking Water Regulations	
* * * * * * *	
141.401–141.405	2040–0271
* * * * * * *	
National Primary Drinking Water Regulations Implementation	
* * * * * * *	
142.14(d)(17)	2040–0271
* * * * * * *	
142.15(c)(7)	2040–0271
* * * * * * *	
142.16(o)	2040–0271

* * * * *

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 141.21 is amended by adding paragraph (d)(3) to read as follows:

§ 141.21 Coliform sampling.

* * * * *

(d) * * *

(3) Sanitary surveys conducted by the State under the provisions of § 142.16(o)(2) of this chapter may be used to meet the sanitary survey requirements of this section.

* * * * *

■ 5. Section 141.28 is amended by revising paragraph (a) to read as follows:

§ 141.28 Certified laboratories.

(a) For the purpose of determining compliance with § 141.21 through 141.27, 141.30, 141.40, 141.74, 141.89 and 141.402, samples may be considered only if they have been analyzed by a laboratory certified by the State except that measurements of alkalinity, calcium, conductivity, disinfectant residual, orthophosphate, pH, silica, temperature and turbidity may be performed by any person acceptable to the State.

* * * * *

■ 6. Section 141.153 is amended by adding a new paragraph (h)(6) to read as follows:

§ 141.153 Content of the reports.

* * * * *

(h) * * *

(6) Systems required to comply with subpart S. (i) Any ground water system that receives notice from the State of a significant deficiency or notice from a laboratory of a fecal indicator-positive ground water source sample that is not invalidated by the State under § 141.402(d) must inform its customers of any significant deficiency that is uncorrected at the time of the next report or of any fecal indicator-positive ground water source sample in the next report. The system must continue to inform the public annually until the State determines that particular significant deficiency is corrected or the fecal contamination in the ground water source is addressed under § 141.403(a). Each report must include the following elements.

(A) The nature of the particular significant deficiency or the source of the fecal contamination (if the source is known) and the date the significant deficiency was identified by the State or the dates of the fecal indicator-positive ground water source samples;

(B) If the fecal contamination in the ground water source has been addressed under § 141.403(a) and the date of such action;

(C) For each significant deficiency or fecal contamination in the ground water source that has not been addressed under § 141.403(a), the State-approved plan and schedule for correction, including interim measures, progress to date, and any interim measures completed; and

(D) If the system receives notice of a fecal indicator-positive ground water source sample that is not invalidated by the State under § 141.402(d), the potential health effects using the health effects language of Appendix A of subpart O.

(ii) If directed by the State, a system with significant deficiencies that have been corrected before the next report is issued must inform its customers of the significant deficiency, how the deficiency was corrected, and the date of correction under paragraph (h)(6)(i) of this section.

* * * * *

■ 7. Appendix A to subpart O is amended by adding a new entry ''Fecal Indicators (enterococci or coliphage)'' to read as follows:

APPENDIX A TO SUBPART O OF PART 141—REGULATED CONTAMINANTS

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
Microbiological Contaminants:						
*	*	*	*	*	*	*
Fecal Indicators (enterococci or coliphage).	TT		TT	N/A	Human and animal fecal waste.	Fecal indicators are microbes whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term health effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
*	*	*	*	*	*	*

* * *

TT=Treatment Technique.

■ 8. Section 141.202 is amended by redesignating entry (8) in Table 1 in paragraph (a) as entry (9); and adding a new paragraph (8) to read as follows:

§ 141.202 Tier 1 Public Notice—Form, manner, and frequency of notice.

(a) * * *

Table 1 to § 141.202—Violation Categories and Other Situations Requiring a Tier 1 Public Notice

* * * * *

(8) Detection of *E. coli*, enterococci, or coliphage in source water samples as specified in § 141.402(a) and § 141.402(b).

* * * * *

■ 9. Section 141.203 is amended by adding entry (4) to Table 1 in paragraph (a) to read as follows:

§ 141.203 Tier 2 Public Notice—Form, manner, and frequency of notice.

(a) * * *

Table 1 to § 141.203—Violation Categories and Other Situations Requiring a Tier 2 Public Notice

* * * * *

(4) Failure to take corrective action or failure to maintain at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer under § 141.403(a).

* * * * *

■ 10. Appendix A to Subpart Q of Part 141 is amended to read as follows:

■ a. Adding I.A.11;

■ b. Redesignating entry IV.F as entry IV.G; and

■ c. Adding a new entry IV.F in alphabetical order:

APPENDIX A TO SUBPART Q OF PART 141—NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE [1]

Contaminant	MCL/MRDL/TT violations [2]		Monitoring and testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
I. Violations of National Primary Drinking Water Regulations (NPDWR): [3] A. Microbiological Contaminants				
* * * *	*	*	*	*
11. Ground Water Rule violations	2	141.404	3	141.402(h). 141.403(d).

APPENDIX A TO SUBPART Q OF PART 141—NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE [1]—Continued

Contaminant	MCL/MRDL/TT violations [2]		Monitoring and testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
* * * * * * *				
IV. Other Situations Requiring Public Notification				
* * * * * * *				
F. Source Water Sample Positive for GWR Fecal indicators: E. coli, enterococci, or coliphage	1	141.402(g)	N/A	N/A
* * * * * * *				

[1] Violations and other situations not listed in this table (*e.g.*, failure to prepare Consumer Confidence Reports) do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (*e.g.*, Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under § 141.202(a) and § 141.203(a).

[2] MCL—Maximum contaminant level, MRDL—Maximum residual disinfectant level, TT—Treatment technique.

[3] The term Violations of National Primary Drinking Water Regulations (NPDWR) is used here to include violations of MCL, MRDL, treatment technique, monitoring, and testing procedure requirements.

* * * * *

■ 11. Appendix B of Subpart Q of Part 141 is amended by adding entries A.1.c and A.1.d in numerical order to read as follows:

APPENDIX B TO SUBPART Q OF PART 141—STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

Contaminant	MCLG [1] mg/L	MCL [2] mg/L	Standard health effects language for public notification
National Primary Drinking Water Regulations (NPDWR) **A. Microbiological Contaminants**			
* * * * * * *			
1c. Fecal indicators (GWR):			
i. E. coli	Zero	TT	Fecal indicators are microbes whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term health effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
ii. enterococci	None	TT	
iii. coliphage	None	TT	
1d. Ground Water Rule (GWR) TT violations	None	TT	Inadequately treated or inadequately protected water may contain disease-causing organisms. These organisms can cause symptoms such as diarrhea, nausea, cramps, and associated headaches.
* * * * * * *			

[1] MCLG—Maximum contaminant level goal.

[2] MCL—Maximum contaminant level.

* * * * *

■ 12. Appendix C to Subpart Q is amended by adding the following abbreviations in alphabetical order:

Appendix C to Subpart Q of Part 141—List of Acronyms Used in Public Notification Regulations

* * * * *

GWR Ground Water Rule

* * * * *

■ 13. A new subpart S is added to read as follows:

Subpart S—Ground Water Rule

Subpart S—Ground Water Rule

§ 141.400 General requirements and applicability.

(a) *Scope of this subpart.* The requirements of this subpart S constitute National Primary Drinking Water Regulations.

(b) *Applicability.* This subpart applies to all public water systems that use ground water except that it does not apply to public water systems that combine all of their ground water with surface water or with ground water under the direct influence of surface water prior to treatment under subpart

H. For the purposes of this subpart, ''ground water system'' is defined as any public water system meeting this applicability statement, including consecutive systems receiving finished ground water.

(c) *General requirements.* Systems subject to this subpart must comply with the following requirements:

(1) Sanitary survey information requirements for all ground water systems as described in § 141.401.

(2) Microbial source water monitoring requirements for ground water systems that do not treat all of their ground water to at least 99.99 percent (4-log) treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer as described in § 141.402.

(3) Treatment technique requirements, described in § 141.403, that apply to ground water systems that have fecally contaminated source waters, as determined by source water monitoring conducted under § 141.402, or that have significant deficiencies that are identified by the State or that are identified by EPA under SDWA section 1445. A ground water system with fecally contaminated source water or with significant deficiencies subject to the treatment technique requirements of this subpart must implement one or more of the following corrective action options: correct all significant deficiencies; provide an alternate source of water; eliminate the source of contamination; or provide treatment that reliably achieves at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer.

(4) Ground water systems that provide at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer are required to conduct compliance monitoring to demonstrate treatment effectiveness, as described in § 141.403(b).

(5) If requested by the State, ground water systems must provide the State with any existing information that will enable the State to perform a hydrogeologic sensitivity assessment. For the purposes of this subpart, ''hydrogeologic sensitivity assessment'' is a determination of whether ground water systems obtain water from hydrogeologically sensitive settings.

(d) *Compliance date.* Ground water systems must comply, unless otherwise noted, with the requirements of this subpart beginning December 1, 2009.

§ 141.401 Sanitary surveys for ground water systems.

(a) Ground water systems must provide the State, at the State's request, any existing information that will enable the State to conduct a sanitary survey.

(b) For the purposes of this subpart, a ''sanitary survey,'' as conducted by the State, includes but is not limited to, an onsite review of the water source(s) (identifying sources of contamination by using results of source water assessments or other relevant information where available), facilities, equipment, operation, maintenance, and monitoring compliance of a public water system to evaluate the adequacy of the system, its sources and operations and the distribution of safe drinking water.

(c) The sanitary survey must include an evaluation of the applicable components listed in paragraphs (c)(1) through (8) of this section:

(1) Source,

(2) Treatment,

(3) Distribution system,

(4) Finished water storage,

(5) Pumps, pump facilities, and controls,

(6) Monitoring, reporting, and data verification,

(7) System management and operation, and

(8) Operator compliance with State requirements.

§ 141.402 Ground water source microbial monitoring and analytical methods.

(a) *Triggered source water monitoring.*—(1) *General requirements.* A ground water system must conduct triggered source water monitoring if the conditions identified in paragraphs (a)(1)(i) and (a)(1)(ii) of this section exist.

(i) The system does not provide at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for each ground water source; and

(ii) The system is notified that a sample collected under § 141.21(a) is total coliform-positive and the sample is not invalidated under § 141.21(c).

(2) *Sampling Requirements.* A ground water system must collect, within 24 hours of notification of the total coliform-positive sample, at least one ground water source sample from each ground water source in use at the time the total coliform-positive sample was collected under § 141.21(a), except as provided in paragraph (a)(2)(ii) of this section.

(i) The State may extend the 24-hour time limit on a case-by-case basis if the system cannot collect the ground water source water sample within 24 hours due to circumstances beyond its control. In the case of an extension, the State must specify how much time the system has to collect the sample.

(ii) If approved by the State, systems with more than one ground water source may meet the requirements of this paragraph (a)(2) by sampling a representative ground water source or sources. If directed by the State, systems must submit for State approval a triggered source water monitoring plan that identifies one or more ground water sources that are representative of each monitoring site in the system's sample siting plan under § 141.21(a) and that the system intends to use for representative sampling under this paragraph.

(iii) A ground water system serving 1,000 people or fewer may use a repeat sample collected from a ground water source to meet both the requirements of § 141.21(b) and to satisfy the monitoring requirements of paragraph (a)(2) of this section for that ground water source only if the State approves the use of *E. coli* as a fecal indicator for source water monitoring under this paragraph (a). If the repeat sample collected from the ground water source is *E.coli* positive, the system must comply with paragraph (a)(3) of this section.

(3) *Additional Requirements.* If the State does not require corrective action under § 141.403(a)(2) for a fecal indicator-positive source water sample collected under paragraph (a)(2) of this section that is not invalidated under paragraph (d) of this section, the system must collect five additional source water samples from the same source within 24 hours of being notified of the fecal indicator-positive sample.

(4) *Consecutive and Wholesale Systems.* (i). In addition to the other requirements of this paragraph (a), a consecutive ground water system that has a total coliform-positive sample collected under § 141.21(a) must notify the wholesale system(s) within 24 hours of being notified of the total coliform-positive sample.

(ii) In addition to the other requirements of this paragraph (a), a wholesale ground water system must comply with paragraphs (a)(4)(ii)(A) and (a)(4)(ii)(B) of this section.

(A) A wholesale ground water system that receives notice from a consecutive system it serves that a sample collected under § 141.21(a) is total coliform-positive must, within 24 hours of being notified, collect a sample from its ground water source(s) under paragraph (a)(2) of this section and analyze it for

a fecal indicator under paragraph (c) of this section.

(B) If the sample collected under paragraph (a)(4)(ii)(A) of this section is fecal indicator-positive, the wholesale ground water system must notify all consecutive systems served by that ground water source of the fecal indicator source water positive within 24 hours of being notified of the ground water source sample monitoring result and must meet the requirements of paragraph (a)(3) of this section.

(5) *Exceptions to the Triggered Source Water Monitoring Requirements.* A ground water system is not required to comply with the source water monitoring requirements of paragraph (a) of this section if either of the following conditions exists:

(i) The State determines, and documents in writing, that the total coliform-positive sample collected under § 141.21(a) is caused by a distribution system deficiency; or

(ii) The total coliform-positive sample collected under § 141.21(a) is collected at a location that meets State criteria for distribution system conditions that will cause total coliform-positive samples.

(b) *Assessment Source Water Monitoring.* If directed by the State, ground water systems must conduct assessment source water monitoring that meets State-determined requirements for such monitoring. A ground water system conducting assessment source water monitoring may use a triggered source water sample collected under paragraph (a)(2) of this section to meet the requirements of paragraph (b) of this section. State-determined assessment source water monitoring requirements may include:

(1) Collection of a total of 12 ground water source samples that represent each month the system provides ground water to the public,

(2) Collection of samples from each well unless the system obtains written State approval to conduct monitoring at one or more wells within the ground water system that are representative of multiple wells used by that system and that draw water from the same hydrogeologic setting,

(3) Collection of a standard sample volume of at least 100 mL for fecal indicator analysis regardless of the fecal indicator or analytical method used,

(4) Analysis of all ground water source samples using one of the analytical methods listed in the in paragraph (c)(2) of this section for the presence of *E. coli*, enterococci, or coliphage,

(5) Collection of ground water source samples at a location prior to any treatment of the ground water source unless the State approves a sampling location after treatment, and

(6) Collection of ground water source samples at the well itself unless the system's configuration does not allow for sampling at the well itself and the State approves an alternate sampling location that is representative of the water quality of that well.

(c) *Analytical methods.* (1) A ground water system subject to the source water monitoring requirements of paragraph (a) of this section must collect a standard sample volume of at least 100 mL for fecal indicator analysis regardless of the fecal indicator or analytical method used.

(2) A ground water system must analyze all ground water source samples collected under paragraph (a) of this section using one of the analytical methods listed in the following table in paragraph (c)(2) of this section for the presence of *E. coli*, enterococci, or coliphage:

ANALYTICAL METHODS FOR SOURCE WATER MONITORING

Fecal indicator [1]	Methodology	Method citation
E. coli	Colilert [3]	9223 B.[2]
	Colisure [3]	9223 B.[2]
	Membrane Filter Method with MI Agar	EPA Method 1604.[4]
	m-ColiBlue24 Test [5]	
	E*Colite Test [6]	
	EC–MUG [7]	9221 F.[2]
	NA–MUG [7]	9222 G.[2]
Enterococci	Multiple-Tube Technique	9230B.[2]
	Membrane Filter Technique	EPA Method 1600.[8]
	Enterolert [9]	
Coliphage	Two-Step Enrichment Presence-Absence Procedure.	EPA Method 1601.[10]
	Single Agar Layer Procedure	EPA Method 1602.[11]

Analyses must be conducted in accordance with the documents listed below. The Director of the Federal Register approves the incorporation by reference of the documents listed in footnotes 2–11 in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the documents may be obtained from the sources listed below. Copies may be inspected at EPA's Drinking Water Docket, EPA West, 1301 Constitution Avenue, NW., EPA West, Room B102, Washington DC 20460 (Telephone: 202–566–2426); 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.*

[1] The time from sample collection to initiation of analysis may not exceed 30 hours. The ground water system is encouraged but is not required to hold samples below 10°C during transit.

[2] Methods are described in Standard Methods for the Examination of Water and Wastewater 20th edition (1998) and copies may be obtained from the American Public Health Association, 1015 Fifteenth Street, NW., Washington, DC 20005–2605.

[3] Medium is available through IDEXX Laboratories, Inc., One IDEXX Drive, Westbrook, Maine 04092.

[4] EPA Method 1604: Total Coliforms and *Escherichia coli* in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium); September 2002, EPA 821–R–02–024. Method is available at *http://www.epa.gov/nerlcwww/1604sp02.pdf* or from EPA's Water Resource Center (RC–4100T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

[5] A description of the m-ColiBlue24 Test, ''Total Coliforms and *E. coli* Membrane Filtration Method with m-ColiBlue24® Broth,'' Method No. 10029 Revision 2, August 17, 1999, is available from Hach Company, 100 Dayton Ave., Ames, IA 50010 or from EPA's Water Resource Center (RC–4100T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

[6] A description of the E*Colite Test, ''Charm E*Colite Presence/Absence Test for Detection and Identification of Coliform Bacteria and *Escherichia coli* in Drinking Water, January 9, 1998, is available from Charm Sciences, Inc., 659 Andover St., Lawrence, MA 01843–1032 or from EPA's Water Resource Center (RC–4100T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

[7] EC–MUG (Method 9221F) or NA–MUG (Method 9222G) can be used for *E. coli* testing step as described in § 141.21(f)(6)(i) or (ii) after use of Standard Methods 9221 B, 9221 D, 9222 B, or 9222 C.

[8] EPA Method 1600: Enterococci in Water by Membrane Filtration Using membrane-Enterococcus Indoxyl–β–D–Glucoside Agar (mEI) EPA 821–R–02–022 (September 2002) is an approved variation of Standard Method 9230C. The method is available at *http://www.epa.gov/nerlcwww/1600sp02.pdf* or from EPA's Water Resource Center (RC–4100T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. The holding time and temperature for ground water samples are specified in footnote 1 above, rather than as specified in Section 8 of EPA Method 1600.

[9] Medium is available through IDEXX Laboratories, Inc., One IDEXX Drive, Westbrook, Maine 04092. Preparation and use of the medium is set forth in the article ''Evaluation of Enterolert for Enumeration of Enterococci in Recreational Waters,'' by Budnick, G.E., Howard, R.T., and Mayo, D.R., 1996, Applied and Environmental Microbiology, 62:3881–3884.

[10] EPA Method 1601: Male-specific (F+) and Somatic Coliphage in Water by Two-step Enrichment Procedure; April 2001, EPA 821–R–01–030. Method is available at *http://www.epa.gov/nerlcwww/1601ap01.pdf* or from EPA's Water Resource Center (RC–4100T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

[11] EPA Method 1602: Male-specific (F+) and Somatic Coliphage in Water by Single Agar Layer (SAL) Procedure; April 2001, EPA 821–R–01–029. Method is available at *http://www.epa.gov/nerlcwww/1602ap01.pdf* or from EPA's Water Resource Center (RC–4100T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

(d) *Invalidation of a fecal indicator-positive ground water source sample.* (1) A ground water system may obtain State invalidation of a fecal indicator-positive ground water source sample collected under paragraph (a) of this section only under the conditions specified in paragraphs (d)(1)(i) and (ii) of this section.

(i) The system provides the State with written notice from the laboratory that improper sample analysis occurred; or

(ii) The State determines and documents in writing that there is substantial evidence that a fecal indicator-positive ground water source sample is not related to source water quality.

(2) If the State invalidates a fecal indicator-positive ground water source sample, the ground water system must collect another source water sample under paragraph (a) of this section within 24 hours of being notified by the State of its invalidation decision and have it analyzed for the same fecal indicator using the analytical methods in paragraph (c) of this section. The State may extend the 24-hour time limit on a case-by-case basis if the system cannot collect the source water sample within 24 hours due to circumstances beyond its control. In the case of an extension, the State must specify how much time the system has to collect the sample.

(e) *Sampling location.* (1) Any ground water source sample required under paragraph (a) of this section must be collected at a location prior to any treatment of the ground water source unless the State approves a sampling location after treatment.

(2) If the system's configuration does not allow for sampling at the well itself, the system may collect a sample at a State-approved location to meet the requirements of paragraph (a) of this section if the sample is representative of the water quality of that well.

(f) *New Sources.* If directed by the State, a ground water system that places a new ground water source into service after November 30, 2009, must conduct assessment source water monitoring under paragraph (b) of this section. If directed by the State, the system must begin monitoring before the ground water source is used to provide water to the public.

(g) *Public Notification.* A ground water system with a ground water source sample collected under paragraph (a) or (b) of this section that is fecal indicator-positive and that is not invalidated under paragraph (d) of this section, including consecutive systems served by the ground water source, must conduct public notification under § 141.202.

(h) *Monitoring Violations.* Failure to meet the requirements of paragraphs (a)–(f) of this section is a monitoring violation and requires the ground water system to provide public notification under § 141.204.

§ 141.403 Treatment technique requirements for ground water systems.

(a) *Ground water systems with significant deficiencies or source water fecal contamination.*

(1) The treatment technique requirements of this section must be met by ground water systems when a significant deficiency is identified or when a ground water source sample collected under § 141.402(a)(3) is fecal indicator-positive.

(2) If directed by the State, a ground water system with a ground water source sample collected under § 141.402(a)(2), § 141.402(a)(4), or § 141.402(b) that is fecal indicator-positive must comply with the treatment technique requirements of this section.

(3) When a significant deficiency is identified at a Subpart H public water system that uses both ground water and surface water or ground water under the direct influence of surface water, the system must comply with provisions of this paragraph except in cases where the State determines that the significant deficiency is in a portion of the distribution system that is served solely by surface water or ground water under the direct influence of surface water.

(4) Unless the State directs the ground water system to implement a specific corrective action, the ground water system must consult with the State regarding the appropriate corrective action within 30 days of receiving written notice from the State of a significant deficiency, written notice from a laboratory that a ground water source sample collected under § 141.402(a)(3) was found to be fecal indicator-positive, or direction from the State that a fecal indicator'positive collected under § 141.402(a)(2), § 141.402(a)(4), or § 141.402(b) requires corrective action. For the purposes of this subpart, significant deficiencies include, but are not limited to, defects in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that the State determines to be causing, or have potential for causing, the introduction of contamination into the water delivered to consumers.

(5) Within 120 days (or earlier if directed by the State) of receiving written notification from the State of a significant deficiency, written notice from a laboratory that a ground water source sample collected under § 141.402(a)(3) was found to be fecal indicator-positive, or direction from the State that a fecal indicator-positive sample collected under § 141.402(a)(2), § 141.402(a)(4), or § 141.402(b) requires corrective action, the ground water system must either:

(i) Have completed corrective action in accordance with applicable State plan review processes or other State guidance or direction, if any, including State-specified interim measures; or

(ii) Be in compliance with a State-approved corrective action plan and schedule subject to the conditions specified in paragraphs (a)(5)(ii)(A) and (a)(5)(ii)(B) of this section.

(A) Any subsequent modifications to a State-approved corrective action plan and schedule must also be approved by the State.

(B) If the State specifies interim measures for protection of the public health pending State approval of the corrective action plan and schedule or pending completion of the corrective action plan, the system must comply with these interim measures as well as

with any schedule specified by the State.

(6) *Corrective Action Alternatives.* Ground water systems that meet the conditions of paragraph (a)(1) or (a)(2) of this section must implement one or more of the following corrective action alternatives:

(i) Correct all significant deficiencies;

(ii) Provide an alternate source of water;

(iii) Eliminate the source of contamination; or

(iv) Provide treatment that reliably achieves at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for the ground water source.

(7) *Special notice to the public of significant deficiencies or source water fecal contamination.* (i) In addition to the applicable public notification requirements of § 141.202, a community ground water system that receives notice from the State of a significant deficiency or notification of a fecal indicator-positive ground water source sample that is not invalidated by the State under § 141.402(d) must inform the public served by the water system under § 141.153(h)(6) of the fecal indicator-positive source sample or of any significant deficiency that has not been corrected. The system must continue to inform the public annually until the significant deficiency is corrected or the fecal contamination in the ground water source is determined by the State to be corrected under paragraph (a)(5) of this section.

(ii) In addition to the applicable public notification requirements of § 141.202, a non-community ground water system that receives notice from the State of a significant deficiency must inform the public served by the water system in a manner approved by the State of any significant deficiency that has not been corrected within 12 months of being notified by the State, or earlier if directed by the State. The system must continue to inform the public annually until the significant deficiency is corrected. The information must include:

(A) The nature of the significant deficiency and the date the significant deficiency was identified by the State;

(B) The State-approved plan and schedule for correction of the significant deficiency, including interim measures, progress to date, and any interim measures completed; and

(C) For systems with a large proportion of non-English speaking consumers, as determined by the State, information in the appropriate language(s) regarding the importance of the notice or a telephone number or address where consumers may contact the system to obtain a translated copy of the notice or assistance in the appropriate language.

(iii) If directed by the State, a non-community water system with significant deficiencies that have been corrected must inform its customers of the significant deficiencies, how the deficiencies were corrected, and the dates of correction under paragraph (a)(7)(ii) of this section.

(b) *Compliance monitoring*—(1) *Existing ground water sources.* A ground water system that is not required to meet the source water monitoring requirements of this subpart for any ground water source because it provides at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for any ground water source before December 1, 2009, must notify the State in writing that it provides at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for the specified ground water source and begin compliance monitoring in accordance with paragraph (b)(3) of this section by December 1, 2009. Notification to the State must include engineering, operational, or other information that the State requests to evaluate the submission. If the system subsequently discontinues 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for a ground water source, the system must conduct ground water source monitoring as required under § 141.402.

(2) *New ground water sources.* A ground water system that places a ground water source in service after November 30, 2009, that is not required to meet the source water monitoring requirements of this subpart because the system provides at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for the ground water source must comply with the requirements of paragraphs (b)(2)(i), (b)(2)(ii) and (b)(2)(iii) of this section.

(i) The system must notify the State in writing that it provides at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for the ground water source. Notification to the State must include engineering, operational, or other information that the State requests to evaluate the submission.

(ii) The system must conduct compliance monitoring as required under § 141.403(b)(3) of this subpart within 30 days of placing the source in service.

(iii) The system must conduct ground water source monitoring under § 141.402 if the system subsequently discontinues 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for the ground water source.

(3) *Monitoring requirements.* A ground water system subject to the requirements of paragraphs (a), (b)(1) or (b)(2) of this section must monitor the effectiveness and reliability of treatment for that ground water source before or at the first customer as follows:

(i) *Chemical disinfection*—(A) *Ground water systems serving greater than 3,300 people.* A ground water system that serves greater than 3,300 people must continuously monitor the residual disinfectant concentration using analytical methods specified in § 141.74(a)(2) at a location approved by the State and must record the lowest residual disinfectant concentration each day that water from the ground water source is served to the public. The ground water system must maintain the State-determined residual disinfectant concentration every day the ground water system serves water from the ground water source to the public. If there is a failure in the continuous monitoring equipment, the ground water system must conduct grab sampling every four hours until the continuous monitoring equipment is returned to service. The system must resume continuous residual disinfectant monitoring within 14 days.

(B) *Ground water systems serving 3,300 or fewer people.* A ground water system that serves 3,300 or fewer people must monitor the residual disinfectant concentration using analytical methods specified in § 141.74(a)(2) at a location approved by the State and record the residual disinfection concentration each day that water from the ground water source is served to the public. The ground water system must maintain the State-determined residual disinfectant concentration every day the ground water system serves water from the ground water source to the public. The ground water system must take a daily grab sample during the hour of peak flow or at another time specified by the State. If any daily grab sample

measurement falls below the State-determined residual disinfectant concentration, the ground water system must take follow-up samples every four hours until the residual disinfectant concentration is restored to the State-determined level. Alternatively, a ground water system that serves 3,300 or fewer people may monitor continuously and meet the requirements of paragraph (b)(3)(i)(A) of this section.

(ii) *Membrane filtration.* A ground water system that uses membrane filtration to meet the requirements of this subpart must monitor the membrane filtration process in accordance with all State-specified monitoring requirements and must operate the membrane filtration in accordance with all State-specified compliance requirements. A ground water system that uses membrane filtration is in compliance with the requirement to achieve at least 4-log removal of viruses when:

(A) The membrane has an absolute molecular weight cut-off (MWCO), or an alternate parameter that describes the exclusion characteristics of the membrane, that can reliably achieve at least 4-log removal of viruses;

(B) The membrane process is operated in accordance with State-specified compliance requirements; and

(C) The integrity of the membrane is intact.

(iii) *Alternative treatment.* A ground water system that uses a State-approved alternative treatment to meet the requirements of this subpart by providing at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer must:

(A) Monitor the alternative treatment in accordance with all State-specified monitoring requirements; and

(B) Operate the alternative treatment in accordance with all compliance requirements that the State determines to be necessary to achieve at least 4-log treatment of viruses.

(c) Discontinuing treatment. A ground water system may discontinue 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for a ground water source if the State determines and documents in writing that 4-log treatment of viruses is no longer necessary for that ground water source. A system that discontinues 4-log treatment of viruses is subject to the source water monitoring and analytical methods requirements of § 141.402 of this subpart.

(d) Failure to meet the monitoring requirements of paragraph (b) of this section is a monitoring violation and requires the ground water system to provide public notification under § 141.204.

§ 141.404 Treatment technique violations for ground water systems.

(a) A ground water system with a significant deficiency is in violation of the treatment technique requirement if, within 120 days (or earlier if directed by the State) of receiving written notice from the State of the significant deficiency, the system:

(1) Does not complete corrective action in accordance with any applicable State plan review processes or other State guidance and direction, including State specified interim actions and measures, or

(2) Is not in compliance with a State-approved corrective action plan and schedule.

(b) Unless the State invalidates a fecal indicator-positive ground water source sample under § 141.402(d), a ground water system is in violation of the treatment technique requirement if, within 120 days (or earlier if directed by the State) of meeting the conditions of § 141.403(a)(1) or § 141.403(a)(2), the system:

(1) Does not complete corrective action in accordance with any applicable State plan review processes or other State guidance and direction, including State-specified interim measures, or

(2) Is not in compliance with a State-approved corrective action plan and schedule.

(c) A ground water system subject to the requirements of § 141.403(b)(3) that fails to maintain at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for a ground water source is in violation of the treatment technique requirement if the failure is not corrected within four hours of determining the system is not maintaining at least 4-log treatment of viruses before or at the first customer.

(d) Ground water system must give public notification under § 141.203 for the treatment technique violations specified in paragraphs (a), (b) and (c) of this section.

§ 141.405 Reporting and recordkeeping for ground water systems.

(a) *Reporting.* In addition to the requirements of § 141.31, a ground water system regulated under this subpart must provide the following information to the State:

(1) A ground water system conducting compliance monitoring under § 141.403(b) must notify the State any time the system fails to meet any State-specified requirements including, but not limited to, minimum residual disinfectant concentration, membrane operating criteria or membrane integrity, and alternative treatment operating criteria, if operation in accordance with the criteria or requirements is not restored within four hours. The ground water system must notify the State as soon as possible, but in no case later than the end of the next business day.

(2) After completing any corrective action under § 141.403(a), a ground water system must notify the State within 30 days of completion of the corrective action.

(3) If a ground water system subject to the requirements of § 141.402(a) does not conduct source water monitoring under § 141.402(a)(5)(ii), the system must provide documentation to the State within 30 days of the total coliform positive sample that it met the State criteria.

(b) *Recordkeeping.* In addition to the requirements of § 141.33, a ground water system regulated under this subpart must maintain the following information in its records:

(1) Documentation of corrective actions. Documentation shall be kept for a period of not less than ten years.

(2) Documentation of notice to the public as required under § 141.403(a)(7). Documentation shall be kept for a period of not less than three years.

(3) Records of decisions under § 141.402(a)(5)(ii) and records of invalidation of fecal indicator-positive ground water source samples under § 141.402(d). Documentation shall be kept for a period of not less than five years.

(4) For consecutive systems, documentation of notification to the wholesale system(s) of total-coliform positive samples that are not invalidated under § 141.21(c). Documentation shall be kept for a period of not less than five years.

(5) For systems, including wholesale systems, that are required to perform compliance monitoring under § 141.403(b):

(i) Records of the State-specified minimum disinfectant residual. Documentation shall be kept for a period of not less than ten years.

(ii) Records of the lowest daily residual disinfectant concentration and records of the date and duration of any failure to maintain the State-prescribed minimum residual disinfectant concentration for a period of more than

four hours. Documentation shall be kept for a period of not less than five years.

(iii) Records of State-specified compliance requirements for membrane filtration and of parameters specified by the State for State-approved alternative treatment and records of the date and duration of any failure to meet the membrane operating, membrane integrity, or alternative treatment operating requirements for more than four hours. Documentation shall be kept for a period of not less than five years.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

■ 14. 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.

■ 15. Section 142.14 is amended by adding paragraph (d)(17) to read as follows:

§ 142.14 Records kept by States.

* * * * *

(d) * * *

(17) Records of the currently applicable or most recent State determination, including all supporting information and an explanation of the technical basis of each decision, made under the following provisions of 40 CFR part 141, subpart S and 40 CFR part 142.

(i) Section 142.16(o)(2)(v). Records of written notices of significant deficiencies.

(ii) Section 141.403(a)(5)(ii) of this chapter. Records of corrective action plans, schedule approvals, and State-specified interim measures.

(iii) Section 142.16(o)(4). Records of confirmations under § 141.403(a) of this chapter that a significant deficiency has been corrected or the fecal contamination in the ground water source has been addressed.

(iv) Section 141.402(a)(5) of this chapter. Records of State determinations and records of ground water system's documentation for not conducting triggered source water monitoring.

(v) Section 141.402(d) of this chapter. Records of invalidations of fecal indicator-positive ground water source samples.

(vi) Section 141.402(a)(2)(ii) of this chapter. Records of State approvals of source water monitoring plans.

(vii) Section 142.16(o)(4)(ii). Records of notices of the minimum residual disinfection concentration (when using chemical disinfection) needed to achieve at least 4-log virus inactivation before or at the first customer.

(viii) Sections 142.16(o)(4)(iv) and 142.16(o)(4)(v) Records of notices of the State-specified monitoring and compliance requirements (when using membrane filtration or alternative treatment) needed to achieve at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log inactivation and removal) before or at the first customer.

(ix) Sections 141.403(b)(1) and 141.403(b)(2) of this chapter. Records of written notices from the ground water system that it provides at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for a ground water source.

(x) Section 142.16(o)(4)(vi). Records of written determinations that the ground water system may discontinue 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log inactivation and removal).

* * * * *

■ 16. Section 142.15 is amended by adding paragraph (c)(7) to read as follows:

§ 142.15 Reports by States.

* * * * *

(c) * * *

(7) *Ground water rule.* (i) *Sanitary surveys.* The month and year in which the most recent sanitary survey was completed or, for a State that uses a phased review process, the date the last element of the applicable eight elements was evaluated under § 142.16(o)(2) for each ground water system.

(ii) *Corrective action requirements.* For any corrective action under § 141.403(a) of this chapter, the date the ground water system completed corrective action.

(iii) *Compliance monitoring.* All ground water systems providing at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for any ground water source(s).

* * * * *

■ 17. Section 142.16 is amended as follows:

■ a. Revise paragraph (a)(2)(iii), and

■ b. Add paragraph (o) to read as follows:

§ 142.16 Special primacy requirements.

(a) * * *

(2) * * *

(iii) *Table 1 of 40 CFR 141.202(a) (Items (5), (6), and (9))*—To require public water systems to give a Tier 1 public notice (rather than a Tier 2 or Tier 3 notice) for violations or situations listed in Appendix A of Subpart Q of Part 141 of this chapter;

(o) *Requirements for States to adopt 40 CFR part 141, subpart S.* In addition to the general primacy requirements specified elsewhere in this part, including the requirement that State regulations are no less stringent than the Federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subpart S, must contain the information specified in this paragraph (o).

(1) *Legal authority.* The application for primacy must demonstrate the State has:

(i) The authority contained in statute or regulation to ensure that ground water systems conduct source water monitoring under § 141.402(a)(2), § 141.402(a)(3) and § 141.402(a)(4)(ii)(A) of this chapter.

(ii) The authority contained in statute or regulation to ensure that ground water systems take the appropriate corrective actions including interim measures, if necessary, needed to address significant deficiencies.

(iii) The authority contained in statute or regulation to ensure that ground water systems take the appropriate corrective actions, including interim measures if necessary, to address any source water fecal contamination identified during source water monitoring under § 141.402 of this chapter.

(iv) The authority contained in statute or regulation to ensure that ground water systems consult with the State regarding corrective action(s).

(2) *State practices or procedures for sanitary surveys.* In addition to the general requirements for sanitary surveys contained in § 142.10(b)(2), a primacy application must describe how the State will implement a sanitary survey program that meets the requirements of paragraph (o)(2)(i) of this section. A ''sanitary survey,'' as conducted by the State, includes but is not limited to, an onsite review of the water source(s) (identifying sources of contamination by using results of source water assessments or other relevant information where available), facilities, equipment, operation, maintenance, and monitoring compliance of a public water system to evaluate the adequacy of the system, its sources and operations and the distribution of safe drinking water.

(i) The State must conduct sanitary surveys that address the eight sanitary survey components listed in this section no less frequently than every three years

for community water systems, except as provided in paragraph (o)(2)(iii) of this section, and every five years for non-community water systems. The State may conduct more frequent sanitary surveys for any system. The initial sanitary survey for each community water system must be conducted by December 31, 2012, unless the system meets the requirements of paragraph (o)(2)(iii) of this section. The initial sanitary survey for each community water system that meets the requirements of paragraph (o)(2)(iii) of this section and for each non-community water system must be conducted by December 31, 2014. The sanitary survey must include an evaluation of each of the following elements as applicable:

(A) Source,

(B) Treatment,

(C) Distribution system,

(D) Finished water storage,

(E) Pumps, pump facilities, and controls,

(F) Monitoring, reporting, and data verification,

(G) System management and operation, and

(H) Operator compliance with State requirements.

(ii) The State may use a phased review process to meet the requirements of (o)(2)(i) of this section if all the applicable elements of paragraphs (o)(2)(i)(A) through (o)(2)(i)(H) of this section are evaluated within the required interval.

(iii) The State may conduct sanitary surveys once every five years for community water systems if the system either provides at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log inactivation and removal) before or at the first customer for all its ground water sources, or if it has an outstanding performance record, as determined by the State and documented in previous sanitary surveys and has no history of total coliform MCL or monitoring violations under § 141.21 of this chapter since the last sanitary survey. In its primacy application, the State must describe how it will determine whether a community water system has an outstanding performance record.

(iv) The State must define and describe in its primacy application at least one specific significant deficiency in each of the eight sanitary survey elements in paragraphs (o)(2)(i)(A) through (o)(2)(i)(H) of this section. Significant deficiencies include, but are not limited to, defects in design, operation, or maintenance, or a failure or malfunction of the sources, treatment, storage, or distribution system that the State determines to be causing, or have potential for causing, the introduction of contamination into the water delivered to consumers.

(v) As a condition of primacy, the State must provide ground water systems with written notice describing any significant deficiencies no later than 30 days after the State identifies the significant deficiency. The notice may specify corrective actions and deadlines for completion of corrective actions. The State may provide the written notice at the time of the sanitary survey.

(3) *State practices or procedures for source water microbial monitoring.* The State's primacy application must include a description of the following:

(i) The criteria the State will use under §§ 141.402(a)(2)(i) and 141.402(d)(2) of this chapter for extending the 24-hour time limit for a system to collect a ground water source sample to comply with the source water monitoring requirements.

(ii) The criteria the State will use under §§ 141.402(a)(5)(i) and 141.402(a)(5)(ii) of this chapter to determine whether the cause of the total coliform-positive sample taken under § 141.21(a) of this chapter is directly related to the distribution system.

(iii) The criteria the State will use for determining whether to invalidate a fecal indicator-positive ground water source sample under § 141.402(d)(1)(ii) of this chapter.

(iv) The criteria the State will use to allow source water microbial monitoring at a location after treatment under § 141.402(e)(1) of this chapter.

(4) *State practices or procedures for treatment technique requirements.* As a condition of primacy, the State must verify that significant deficiencies or source water fecal contamination have been addressed. The State must verify within 30 days after the ground water system has reported to the State that it has completed corrective action. The State must verify either through written confirmation from the ground water system or a site visit by the State. Written notice from the ground water system under § 141.405(a)(2) of this chapter may serve as this verification. The State's primacy application must include the following:

(i) The process the State will use to determine that a ground water system achieves at least a 4-log treatment of viruses (using inactivation, removal, or a combination of inactivation and removal) before or at the first customer for a ground water source for systems that are not subject to the source water monitoring requirements of § 141.402(a) of this chapter because the ground water system has informed the State that it provides at least 4-log treatment of viruses.

(ii) The process the State will use to determine the minimum residual disinfectant concentration the system must provide prior to the first customer for systems using chemical disinfection.

(iii) The State-approved alternative technologies that ground water systems may use alone or in combination with other approved technologies to achieve at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log inactivation and removal) before or at the first customer for a ground water source.

(iv) The monitoring and compliance requirements the State will require for ground water systems treating to at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of inactivation and removal) before or at the first customer for State-approved alternative treatment technologies.

(v) The monitoring, compliance and membrane integrity testing requirements the State will require to demonstrate virus removal for ground water systems using membrane filtration technologies.

(vi) The criteria, including public health-based considerations and incorporating on-site investigations and source water monitoring results the State will use to determine if a ground water system may discontinue 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of inactivation and removal) before or at the first customer.

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