ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[WH–FRL–6584–4]

RIN 2040–AA97

National Primary Drinking Water Regulations: Ground Water Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: EPA is proposing to require a targeted risk-based regulatory strategy for all ground water systems. The proposed requirements provide a meaningful opportunity to reduce public health risk associated with the consumption of waterborne pathogens from fecal contamination for a substantial number of people served by ground water sources.

The proposed strategy addresses risks through a multiple-barrier approach that relies on five major components: periodic sanitary surveys of ground water systems requiring the evaluation of eight elements and the identification of significant deficiencies; hydrogeologic assessments to identify wells sensitive to fecal contamination; source water monitoring for systems drawing from sensitive wells without treatment or with other indications of risk; a requirement for correction of significant deficiencies and fecal contamination (by eliminating the source of contamination, correcting the significant deficiency, providing an alternative source water, or providing a treatment which achieves at least 99.99 percent (4-log) inactivation or removal of viruses), and compliance monitoring to insure disinfection treatment is reliably operated where it is used.

EPA believes that the combination of these components strikes an appropriate regulatory balance which tailors the intensity or burden of protective measures and follow-up actions with the risk being addressed. In addition to proposing requirements for ground water systems, EPA requests comment on ways to address the problem of transient providers of water who furnish drinking water to large numbers of people for a limited period of time. One possible solution is to adopt alternative definitions for ''public water systems'' which is currently defined as ''one that serves 25 or more people or has 15 or more service connections and operates at least 60 days per year. EPA is only requesting comment on this issue. The Agency is not today proposing to change the definition of ''public water system ,'' or modify related provisions. If EPA decides to take action on this issue, EPA will publish a proposal at a later date.

DATES: The EPA must receive comments on or before July 10, 2000.

ADDRESSES: References, supporting documents and public comments (and additional comments as they are provided) are available for review at EPA's Drinking Water Docket #W–98–23: 401 M Street, SW, Washington, DC 20460 from 9 a.m. to 4 p.m., Eastern Time, Monday through Friday, excluding Federal holidays.

You may submit comments by mail to the docket at: 1200 Pennsylvania Ave., NW, Washington, DC 20460 or by sending electronic mail (e-mail) to ow-docket@epa.gov. Hand deliveries should be delivered to: EPA's Drinking Water Docket at 401 M Street, SW, Washington, DC 20460.

For access to docket materials, please call 202/260–3027 to schedule an appointment and obtain the room number.

FOR FURTHER INFORMATION CONTACT: For general information, contact the Safe Drinking Water Hotline, telephone (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. Eastern Time. For technical inquiries, contact the Office of Ground Water and Drinking Water (MC 4607), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W. Washington, DC 20460; telephone (202) 260–3309.

SUPPLEMENTARY INFORMATION:

Regulated Entities

Entities potentially regulated by the Ground Water Rule are public water systems using ground water. Regulated categories and entities include:

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 this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in § 141.400(b) of this proposed rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT**.

Abbreviations Used in This Notice

AWWA: American Water Works Association
ASDWA: Association of State Drinking Water Administrators
AWWARF: American Water Works Association Research Foundation
BMP: Best Management Practice
CDC: Centers for Disease Control and Prevention
CT: The residual concentration of disinfectant multiplied by the contact time
CWS: community water system
CWSS: Community Water System Survey
DBP: disinfection byproducts
ELR: Environmental Law Reporter
EPA: Environmental Protection Agency
FR: Federal Register
GAO: Government Accounting Office
GWR: Ground Water Rule
GWS: ground water system
HAA5: Haloacetic acids consisting of the sum of mono-, di-, and trichloroacetic acids, and mono-and dibromoacetic acids
HAV: Hepatitis A Virus
ICR: Information Collection Rule
IESWTR: Interim Enhanced Surface Water Treatment Rule
IT: UV irradiance multiplied by the contact time
m: meter
ml: milliliters
MCL: maximum contaminant level
MCLG: maximum contaminant level goal
mg/L: milligrams per liter
MPN: most probable number
MWCO: molecular weight cut-off
NCWS: non-community water system
NTNCWS: non-transient non-community water system
PCR: polymerase chain reaction
PWS: public water system
RO: reverse osmosis
RT–PCR: reverse-transcriptase, polymerase chain reaction
SBREFA: Small Business Regulatory Enforcement Fairness Act
SDWA: Safe Drinking Water Act
SDWIS: Safe Drinking Water Information System
Stage 1 DBPR: Stage 1 Disinfectants/Disinfection Byproducts Rule
Stage 2 DBPR: Stage 2 Disinfectants/Disinfection Byproducts Rule
SWAPP: Source Water Assessment and Protection Program
SWTR: Surface Water Treatment Rule
TCR: Total Coliform Rule
TNCWS: transient non-community water system
TTHM: total trihalomethanes
UIC: Underground Injection Control
USGS: United States Geological Survey
US EPA: United States Environmental Protection Agency
UV: ultraviolet radiation
WHP: Wellhead Protection

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I. Introduction and Background

The purpose of this section is to provide background on existing regulations that affect ground water systems and current state practices.

A. Statutory Authority

This section discusses the Safe Drinking Water Act (SDWA) requirements which EPA must meet in developing the Ground Water Rule (GWR).

EPA has the responsibility to develop a GWR which not only specifies the appropriate use of disinfection but, just as important, addresses other components of ground water systems to ensure public health protection. Section 1412(b)(8) states that EPA develop regulations specifying the use of disinfectants for ground water systems ''as necessary.'' Under these provisions, EPA has the responsibility to develop a ground water rule which specifies the appropriate use of disinfection, and, in addition, addresses other components of ground water systems to ensure public health protection.

B. Existing Regulations

This section briefly describes the existing regulations that apply to ground water systems. These rules are the baseline for developing the GWR. The regulations that will be discussed include the Total Coliform Rule (TCR)(US EPA, 1989a), Surface Water Treatment Rule (SWTR)(US EPA, 1989b), Interim Enhanced Surface Water Treatment Rule (IESWTR)(US EPA 1998d), Information Collection Rule (ICR)(US EPA, 1996b), Stage 1 Disinfectant/Disinfection Byproducts Rule (Stage 1 DBPR)(US EPA, 1998e), Underground Injection Control Program (US EPA, 1999g) and the Source Water Assessment and Protection Program/Wellhead Protection Program.

1. Total Coliform Rule

The Total Coliform Rule (TCR), promulgated on June 29, 1989 (54 FR 27544)(US EPA,1989a) covers all public water systems. The rule protects public water supplies from disease-causing organisms (pathogens), and it is the most important regulation applicable to drinking water from ground water systems.

Total coliforms are a group of closely related bacteria that are generally free-living in the environment, but are also normally present in water contaminated with human and animal feces. They generally do not cause disease (there are some exceptions). Specifically, coliforms are used as a screen for fecal contamination, as well as to determine the efficiency of treatment and the integrity of the water distribution system. The presence of total coliforms in drinking water indicates that the system is either fecally contaminated or vulnerable to fecal contamination.

The TCR requires systems to monitor their distribution system for total coliforms at a frequency that depends upon the number of people served and whether the system is a community water system (CWS) or non-community water system (NCWS). The monitoring frequency ranges from 480 samples per month for the largest systems to once annually for some of the smallest systems. If a system has a total coliform-positive sample, it must (1) test that sample for the presence of fecal coliform or *E. coli,* (2) collect three repeat samples (four, if the system collects one routine sample or fewer per month) within 24 hours and analyze them for total coliforms (and then fecal coliform or *E. coli,* if positive), and (3) collect at least five routine samples in the next month of sampling regardless of system size.

Under the TCR, a system that collects 40 or more samples per month (generally systems that serve more than 33,000 people) violates the maximum contaminant level (MCL) for total coliforms if more than 5.0% of the samples (routine + repeat) it collects per month are total coliform-positive. A system that collects fewer than 40 samples per month violates the MCL if two samples (routine or repeat samples) during the month are total coliform-positive. For any size system, if two consecutive total coliform-positive samples occur at a site during a month, and one is also fecal coliform/*E. coli*-positive, the system has an acute violation of the MCL, and must provide public notification immediately. The presence of fecal coliforms or *E. coli* indicates that recent fecal contamination is present in the drinking water.

The TCR also requires a sanitary survey every five years (ten years for a protected, disinfected, ground water system) for every system that takes fewer than five samples per month (the monitoring frequency for systems serving 4,100 people or fewer, which is approximately 97% of GWS). Other provisions of the TCR include criteria for invalidating a positive or negative sample and a sample siting plan to ensure that all parts of the distribution system are monitored over time.

2. Surface Water Treatment Rule and Interim Enhanced Surface Water Treatment Rule

The Surface Water Treatment Rule, promulgated in June 29, 1989 (54 FR 27486)(40 CFR Part 141, Subpart H)(US EPA 1989b), covers all systems that use surface water or ground water under the direct influence of surface water. It is intended to protect against exposure to *Giardia lamblia,* viruses, and *Legionella,* as well as many other pathogens. The rule requires all such systems to reduce the level of Giardia by 99.9% (3-log reduction) and viruses by 99.99% (4-log reduction). Under this rule, all surface water systems must disinfect. The vast majority must also filter, unless they meet certain EPA-specified filter avoidance criteria that define high source water quality. More specifically, the SWTR requires: (1) A 0.2 mg/L disinfectant residual entering the distribution system, (2) maintenance of a detectable disinfectant residual in all parts of the distribution system; (3) compliance with a combined filter effluent performance standard for turbidity (*i.e.,* for rapid granular filters, 5 nephelometric turbidity units (NTU) maximum; 0.5 NTU maximum for 95% of measurements (taken every 4 hours) during a month); and 4) watershed protection and other requirements for unfiltered systems. The SWTR set a maximum contaminant level goal (MCLG) of zero for *Giardia,* viruses, and *Legionella.* The MCLG is a non-enforceable level based only on health effects.

On December 16, 1998, EPA promulgated the Interim Enhanced Surface Water Treatment Rule (IESWTR) (63 FR 69478)(US EPA, 1998d). The IESWTR covers all systems that use surface water, or ground water under the direct influence of surface water, that serve 10,000 people or greater. Key provisions include: a 2-log *Cryptosporidium* removal requirement for filtered systems; strengthened combined filter effluent turbidity performance standards (1 NTU maximum; 0.3 NTU maximum for 95% of measurements during a month); individual filter turbidity provisions; disinfection benchmark provisions to ensure continued levels of microbial protection while facilities take the necessary steps to comply with new disinfection byproduct (DBP) standards; inclusion of *Cryptosporidium* in the definition of ground water under the direct influence of surface water and in the watershed control requirements for unfiltered public water systems; requirements for covers on new finished water reservoirs; sanitary surveys for all surface water systems regardless of size; and an MCLG of zero for *Cryptosporidium.* In a parallel rulemaking, EPA has proposed a companion microbial regulation for surface water systems serving less than 10,000 people, the Long Term 1 Enhanced Surface Water Treatment Rule.

3. Information Collection Rule

The Information Collection Rule, promulgated on May 14, 1996 (61 FR 24368)(40 CFR part 141, Subpart M)(US EPA, 1996b), is a monitoring and data reporting rule. The data and information provided by this rule will support development of the Stage 2 Disinfection Byproducts Rule and a related microbial rule, the Long Term 2 Enhanced SWTR, scheduled for promulgation in May 2002.

The ICR applied to large water systems serving at least 100,000 people, and ground water systems serving at least 50,000 people. About 300 systems operating 500 treatment plants were involved. The ICR required systems to collect source water samples, and in some cases finished water samples, monthly for 18 months, and test them for *Giardia, Cryptosporidium,* viruses, total coliforms, and either fecal coliforms or *E. coli.* The ICR also required systems to determine the concentrations of a range of disinfectant and disinfection byproducts in different parts of the system. These disinfection byproducts form when disinfectants used for pathogen control react with naturally occurring total organic compounds (TOC) already present in source water. Some of these byproducts are toxic or carcinogenic. The rule also required systems to provide specified operating and engineering data to EPA. The required 18 months of monitoring under the ICR ended in December 1998.

As noted earlier, the only ground water systems affected by the ICR were those that served at least 50,000 people. These systems had to conduct treatment study applicability monitoring (by measuring TOC levels) and, in some

cases, studies to assess the effectiveness of granular activated carbon or membranes to remove DBP precursors. In addition, ground water systems serving at least 100,000 people had to obtain disinfectant and DBP occurrence and treatment data. EPA is still processing the ICR data, and has not used this information in developing the GWR.

4. Stage 1 Disinfectants/Disinfection Byproducts Rule

The Stage 1 Disinfectants/Disinfection Byproducts Rule (Stage 1 DBPR) (63 FR 69389; December 16, 1998) (US EPA, 1998e) sets maximum residual disinfection level limits for chlorine, chloramines, and chlorine dioxide, and MCLs for chlorite, bromate, and two groups of disinfection byproducts: total trihalomethanes (TTHMs) and haloacetic acids (HAA5). TTHMs consist of the sum of chloroform, bromodichloromethane, dibromochloromethane, and bromoform. HAA5 consist of the sum of mono-, di-, and trichloroacetic acids, and mono- and dibromoacetic acids. The rule requires water systems that use surface water or ground water to remove specified percentages of organic materials, measured as total organic carbon (TOC), that may react with disinfectants to form DBPs. Under the rule, precursor removal will be achieved through a treatment technique (enhanced coagulation or enhanced softening) unless a system meets alternative criteria.

The Stage 1 DBPR applies to all CWSs and non-transient NCWSs, both surface water systems and ground water systems, that treat their water with a chemical disinfectant for either primary or residual treatment. In addition, certain requirements for chlorine dioxide apply to transient water systems.

A ground water system that disinfects with chlorine or other chemical disinfectant must comply with the Stage 1 DBPR by December 2003. Sampling frequency will depend upon the number of people served. Ground water systems not under the direct influence of surface water that serve 10,000 people or greater must take one sample per quarter per treatment plant, and analyze for TTHMs and HAA5; systems that serve fewer than 10,000 people must take one sample per year per treatment plant during the month of warmest water temperature, and analyze for the same chemicals. Systems must monitor for chlorine or chloramines at the same location and time that they monitor for total coliforms. Additional monitoring for other chemicals is required for systems that use ozone or chlorine dioxide.

5. Underground Injection Control Program

In 1980, EPA established an Underground Injection Control (UIC) Program (US EPA, 1999g) to prevent injection practices which contaminate sources of drinking water. The UIC Program protects both underground sources of drinking water and ground water under the direct influence of surface water, which includes at least 41 percent of the streams and rivers in the U.S. during dry periods. Injection is a common and long-standing method of placing fluids underground for disposal, storage, replenishment of ground water, enhanced recovery of oil and gas, and mineral recovery. These fluids often contain contaminants. The EPA sets minimum requirements for effective State programs to ensure that injection practices, or ''injection wells'' as they are called in the UIC Program, are operated safely. EPA or the appropriate State regulatory agency may impose on any injection well, requirements for siting, construction, corrective action, operation, maintenance, monitoring, reporting, plugging and abandonment, and impose penalties on violators. The UIC Program regulations are designed to recognize varying geologic, hydrologic or historic conditions among different States or areas within a State.

The UIC Program regulations are found under Title 40 of the Code of Federal Regulations (CFR), Parts 124, and 144–148. Section 144.6 divides injection practices into five categories or classes of wells. Classes I, II, and III are wells which inject fluids beneath and away from aquifers used by ground water systems into confined geologic formations. These wells are associated with municipal or industrial waste disposal, hazardous waste or radioactive waste sites, oil and gas production, and extraction of minerals. Class IV and most of Class V are wells which inject contaminants, into or above aquifers which may be used by ground water systems. Class IV wells inject hazardous or highly radioactive wastes and are banned by all States and EPA. Class V wells include storm water and agricultural drainage wells, dry wells, floor drains and similar types of shallow disposal systems which discharge directly or indirectly to ground water, but in any case, must not endanger the ground water resources. However, Class V wells which may pose the greatest potential threat to ground water systems include poorly-designed or malfunctioning large-capacity septic tanks, leach fields and cesspools associated with solely sanitary wastewater disposal. Malfunctioning septic systems can result in the release of disease-causing microorganisms including enteric viral and bacterial pathogens to surface and ground water. Multi-family, commercial, manufacturing, recreational, and municipal facilities, particularly those located in unsewered areas sometimes dispose both sanitary waste and process wastewater containing harmful chemicals in Class V wells. This combination can increase the risk of contamination to aquifers used by ground water systems. Approximately half of the States have adopted primary enforcement authority for the regulation in whole or part and, therefore, have primary enforcement responsibility (primacy). State enforcement activities range from notices of improper activities to penalties and well closures. For those States which do not have primacy, the EPA Regional Offices perform the enforcement duties. (Note: the UIC Program does not regulate individual or single family residential septic systems and cesspools which inject solely sanitary wastewater) (40 CFR 144.1(g)(1)(2)). EPA has finalized banning large capacity cesspools in ground water source water protection areas (64 FR 234, December 7, 1999)(USEPA, 1999g).

6. Source Water Assessment and Protection Program (SWAPP) and the Wellhead Protection (WHP) Program

The Wellhead Protection Program (WHP Program) in SDWA section 1428 requires every State to develop a program that protects ground water sources of public drinking water. The intended result of the WHP Program are local pollution prevention programs that reduce or eliminate the threats of contamination to ground water sources of drinking water. To do this, States delineate wellhead protection areas (WHPA) in which sources of contamination are managed to minimize ground water contamination. WHPA boundaries are determined based on factors such as well pumping rates, time-of-travel of ground water flowing to the well, aquifer boundaries, and degree of aquifer protection by the overlying geology. These hydrogeologic characteristics have a direct effect on the likelihood and extent of contamination. Currently, 48 States and two territories have a WHP Program in place.

A new Source Water Assessment and Protection Program (SWAPP) was incorporated into SDWA section 1453 and requires each State to establish a SWAPP that describes how the State will: (1) Delineate source water

protection areas; (2) inventory significant contaminants in these areas; and (3) determine the susceptibility of each public water supply to contamination. This program builds upon the WHP Program; however, it addresses both ground water and surface water sources of public drinking water. The States' SWAPP were approved by EPA by November, 1999. Under the SWAPP, the State must complete source water assessments for all PWSs by November 6, 2001, although EPA may grant an extension to May 6, 2003. A summary of the results of the source water assessments must then be made available to the public in CWSs' Consumer Confidence Reports. The 1996 Amendments to the SDWA do not require States to protect water sources after the assessments are completed.

EPA seeks, in today's proposed GWR, to incorporate the States' SWAPP and WHP Programs into an overall Agency program for protecting ground water sources of public drinking water by encouraging States to use information gathered through these programs in site-specific sanitary surveys and hydrogeologic sensitivity assessments where appropriate.

C. Industry Profile—Baseline Information

1. Definitions and Data Sources

Outlined in the following section are data sources relied upon by the Agency to develop baseline information for the GWR. The baseline information is important to understanding how various regulatory options might affect risk reduction and the cost to small public water systems. The information shows that there is a large number of systems which solely utilize ground water, over 156,000. In addition, most of the ground water systems are small, with 97% serving 3,300 or fewer people. However, 55% of the people served by ground water sources get their drinking water from systems which serve 10,000 or more persons (one percent of the systems).

A public water system (PWS) is one that serves 25 or more people or has 15 or more service connections and operates at least 60 days per year. The following discussion of PWSs is based on the current definition of PWS (i.e., operating at least 60 days a year). A PWS can be publicly owned or privately owned. EPA classifies PWSs as community water systems (CWSs) or non-community water systems (NCWSs). CWSs are those that serve at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents. NCWSs do not have year-round residents, but serve at least 15 service connections used by travelers or intermittent users for at least 60 days each year, or serving an average of 25 individuals for at least 60 days a year. NCWSs are further classified as either transient or non-transient. A non-transient non-community water system (NTNCWS) serves at least 25 of the same persons over six months per year (*e.g.*, factories and schools with their own water source). Transient non-community water systems (TNCWS) do not serve at least 25 of the same persons over six months per year (*e.g.*, many restaurants, rest stops, parks). The majority of ground water systems are NCWSs, with 60% (93,618) transient and 12% (19,322) non-transient. CWSs make up the remaining 28% (44,910) of all ground water systems. Although there are far more NCWSs, CWSs serve a far larger number of people.

Over 88 million people are served by CWSs that use ground water and 20 million people are served by NCWSs that use ground water. An overlap occurs because most people are served by both types of systems which may also include a combination of ground and surface water. For example, a person may be served by a surface water community water system (CWS) at home and by a ground water non-community water system (NCWS) at work.

EPA uses two primary sources of information to characterize the universe of ground water systems: the Safe Drinking Water Information System (SDWIS) and the Community Water System Survey (CWSS) (US EPA, 1997c). EPA's SDWIS contains data on all PWSs as reported by States and EPA Regions. This data reflects both mandatory and optional reporting components. States must report the location of the system, system type (CWS, TNCWS, or NTNCWS), primary raw water source (ground water, surface water or ground water under the direct influence of surface water), and violations. States may also report, at their option, type of treatment and ownership type. EPA does not have complete data on the discretionary items (such as treatment) in SDWIS for every system; this is especially common for NCWSs.

The second source of information, CWSS, is a detailed survey of surface and ground water CWSs conducted by EPA in 1995 (US EPA, 1997c). The CWSS includes information such as the number of system operators, revenues, expenses, treatment practices, source water protection measures, and capacity (*i.e.*, the amount of water the system is designed to deliver). The CWSS contains data from 1,980 water systems, and is stratified to represent CWSs across the U.S. Of the 1,980 water systems that were surveyed by CWSS, 1,020 are ground water systems; 510 are surface water systems; and 450 represent purchased water systems. Among the ground water systems represented, approximately 17% were from systems serving 100 persons or less; 20% were from systems serving 101–500 persons; 13% were from systems serving 501–1,000 persons; 14% were from systems serving 1,001–3,300 persons; 15% were from systems serving 3,301–10,000 persons; 10% were from systems serving 10,001–50,000 persons; and 11% were from systems serving 50,001 or more persons.

Baseline profile data for ground water systems from SDWIS and CWSS are summarized later. The data on system ownership, treatment, and operator information is from the CWSS.

2. Alternate Definition of ''Public Water System'' and the Problem of Short-Term Water Providers

EPA is not today proposing to change the definition of ''public water supply,'' nor proposing additional requirements for short-term water providers. If EPA decides to take either action, EPA will publish a proposal at a later date. However, EPA requests comment on the following issues.

A PWS is one that serves 25 or more people or has 15 or more service connections and operates at least 60 days per year. EPA requests comment on the definition of ''public water system'' specifically, shortening the time period within the regulatory definition (§ 141.2). Section 1401(4)(A) of the SDWA defines public water system as one that ''regularly serves at least twenty-five individuals.'' EPA by regulation defined the minimum time period that a system ''regularly'' serves as 60 days. See 40 FR 59566, December 24, 1975 for a discussion of the definition. The current definition applies after a minimum of 1,500 consumer servings (60 days multiplied by 25 individuals). However, some drinking water providers serve far more people during just a few events. For example, out-door public events may occur at a site just a few days a year but may draw thousands of people to each event. Such drinking water providers thus can affect the public health of a similar number of persons in a short period of time as a system that serves fewer people for a longer period. EPA wants to provide the same public health protection in these situations. Only

contaminants that cause adverse health effects through small volumes or short exposure (*e.g.,* acute contaminants such as microbes, nitrate and nitrite) are of concern at these short term events. Therefore, EPA is considering changing the definition of ''public water system'' by reducing the 60 day time frame to 30 days and including events drawing many people on one or just a few days, specifically by adding the phrase, ''or serves at least 750 people for one or more days'' to the end of the current definition of ''public water system.'' In other words, for short-term providers, the term ''regularly serves'' would be defined in terms of the number of persons served rather than days of service, but the minimum number of persons served would be equivalent to the number of servings for longer-term systems. EPA requests comment on this issue. Rather than the simple total of 750 (30 days times 25 people), should EPA include a minimum of persons served days (calculated by multiplying the average number of individuals served by the number of days the system serves water)? What should that number be? Should there be a sliding scale (*e.g.,* for a system operating one day and serving more than 10,000 consumers, and systems operating more than 30 days and serving 2,000 consumers)? EPA requests comments on defining/identifying systems, implementation, public notice, training, monitoring and record keeping and reporting issues for these systems if they were included.

As an alternate to changing the definition EPA is also considering and requesting comments on requiring under section 1431 of the SDWA or other appropriate authorities that transient water providers or other types of drinking water systems (including those not currently defined as public water systems) monitor for acute contaminants prior to providing water to the public and requiring that any such provider that finds acute contaminants at a level above the MCL not be allowed to serve drinking water until it is corrected. Currently, transient public water systems must currently monitor for total coliforms, nitrate and nitrite. In addition, transient public water systems using surface water or ground water under the direct influence of surface water must comply with the treatment technique requirements of the SWTR. EPA is also considering proposing requiring any non-community water system that is not operated year round monitor for: fecal coliforms, nitrate and nitrate, and that monitoring required to show treatment technique compliance (*e.g., Cryptosporidium*) no more than 30 days prior to beginning operation for that season. EPA requests comment on what time frame the monitoring should be completed prior to beginning operation (*i.e.*, 10 or 15 days).

3. Number and Size of Ground Water Systems

Nationally, SDWIS indicates that there are approximately157,000 public water systems that use ground water solely (SDWIS, 1997). Slightly more than 13,000 additional systems use surface water. SDWIS only describes any system that uses any amount of surface water as a surface water system. SDWIS therefore, does not have information on the number of systems that mix ground water and surface water. Under the SDWA and for purposes of the Regulatory Flexibility Act (RFA) analysis, EPA defines a small system as serving fewer than 10,000 people. According to SDWIS (1997), 96.6% of the 42,413 CWSs and virtually all of the NCWSs that use ground water serve fewer than 10,000 persons and thus are ''small.'' Collectively, 99% of systems serve fewer than 10,000 people. About 97% of the systems (152,555) serve 3,300 people or fewer (totaling over 31 million people nationally). The purpose of these requirements would be to prevent any endangerment to public health that might occur if these short-term, high volume providers dispense drinking water that is untested and potentially contaminated.

4. Location of Ground Water Systems

Ground water systems are located in all 50 States, many tribal lands and most United States territories. The number of ground water systems varies substantially by State. The largest numbers of ground water systems are in the States of Wisconsin, Michigan, Pennsylvania, New York and Minnesota. These five States, each with over 8,000 ground water systems, account for over 50,698 ground water systems—one third of the total number in the U.S. By contrast, Hawaii (126), Kentucky (287), Rhode Island (430), and the United States territories (<254) have the fewest ground water systems (See Table I–1).

5. Ownership of Ground Water Systems

For ground water CWSs, 36% are publicly operated, 35% are owned and operated by private entities whose primary business is providing drinking water, and 29% are ancillary water systems which are operated by entities whose primary business is not providing drinking water, but do so to support their primary business (*e.g.*, mobile home park operators). The distribution of ownership type, however, varies significantly with the size of the system. For example, over 90% of the ground water systems serving less than 100 people are privately owned or are ancillary systems. For systems serving over 100,000 people, only 16% are privately owned and none are ancillary systems.

TABLE I–1.—NUMBER OF GROUND WATER SYSTEMS AND POPULATIONS SERVED BY STATE AND SYSTEM TYPE

State/territory	CWSs		TNCWSs		NTNCWSs	
	Number of systems	Population served	Number of systems	Population served	Number of systems	Population served
Alabama	345	1,283,469	123	11,170	46	21,182
Alaska	511	342,722	906	97,647	0	0
American Samoa	10	48,692	0	0	0	0
Arizona	783	1,308,843	602	120,126	216	100,317
Arkansas	480	1,003,145	442	22,521	57	13,528
California	2,831	14,223,977	3,698	1,301,671	1,018	359,096
Colorado	548	927,917	1,061	153,454	133	34,884
Commonwealth of the Northern Marianas	30	50,769	7	620	6	3,039
Connecticut	537	311,771	3,360	2,980,181	641	121,664
Delaware	225	173,460	215	57,634	86	24,840
District of Columbia	0	0	0	0	0	0
Florida	2,019	13,132,468	3,660	304,865	1,119	286,055
Georgia	1,465	1,484,860	663	127,661	291	80,240
Guam	6	20,220	0	0	2	770

TABLE I–1.—NUMBER OF GROUND WATER SYSTEMS AND POPULATIONS SERVED BY STATE AND SYSTEM TYPE—Continued

State/territory	CWSs		TNCWSs		NTNCWSs	
	Number of systems	Population served	Number of systems	Population served	Number of systems	Population served
Hawaii	109	1,247,315	3	1,125	14	7,437
Idaho	658	579,778	1,033	125,873	265	68,195
Illinois	1,255	2,606,104	3,715	413,000	446	142,655
Indiana	806	1,826,820	2,984	327,229	693	158,102
Iowa	1,033	1,239,902	639	78,653	133	35,715
Kansas	601	747,169	110	4,481	67	23,602
Kentucky	124	271,630	83	9,374	80	21,620
Louisiana	1,211	2,707,805	482	115,804	234	88,070
Maryland	448	519,289	2,509	93,757	495	142,171
Massachusetts	360	1,396,430	863	209,476	229	67,650
Michigan	1,185	1,602,792	8,930	1,187,331	1,718	344,654
Minnesota	919	2,074,843	6,963	252,602	672	49,514
Mississippi	1,253	2,586,680	169	28,006	126	89,416
Missouri	1,194	1,638,152	1,040	138,894	227	76,360
Montana	554	267,597	1,011	140,745	215	38,504
Nebraska	616	811,112	584	22,241	189	26,219
Nevada	250	187,509	273	55,792	91	28,497
New Hampshire	621	262,371	1,012	181,949	421	77,505
New Jersey	516	2,339,500	2,955	346,484	1,009	274,758
New Mexico	600	1,235,920	506	74,256	149	38,101
New York	1,940	4,396,557	5,742	853,533	693	248,223
North Carolina	1,900	1,271,804	5,373	542,400	655	198,136
North Dakota	258	239,874	215	16,910	22	2,349
Ohio	1,129	3,555,876	3,545	533,921	1,116	276,441
Oklahoma	556	671,287	302	34,172	123	20,419
Oregon	677	622,157	1,390	233,477	332	67,531
Pennsylvania	1,788	1,567,696	7,017	922,336	1,251	480,328
Puerto Rico	207	623,958	4	765	43	36,426
Rhode Island	59	127,854	300	48,875	71	25,246
South Carolina	550	671,878	577	54,837	248	71,239
South Dakota	367	250,742	243	42,949	25	3,072
Tennessee	193	1,312,996	503	61,504	58	11,010
Texas	3,613	6,150,001	1,378	245,171	748	253,468
Tribes	685	330,466	0	0	82	20,833
Utah	335	583,506	439	79,371	52	20,969
U.S. Virgin Islands	0	0	0	0	0	0
Vermont	346	154,521	718	523,079	1	25
Virginia	1,199	584,779	1,911	443,920	772	312,422
Washington	2,092	2,299,340	1,498	283,735	287	70,009
West Virginia	297	304,888	644	47,313	182	39,318
Wisconsin	1,117	1,947,016	9,704	731,781	1,049	214,561

D. Effectiveness of Various Best Management Practices in Ground Water Systems

There are numerous sanitation practices, called best management practices (BMPs), to prevent, identify and correct contamination in a water supply. These practices relate to well siting, well construction, distribution system design and operations. Examples of BMPs that form a barrier to ground water contamination include drilling into a protected aquifer; siting a well away from sources of contamination; identifying and controlling contamination sources; and disinfection. BMPs that form a barrier to well contamination include well casing, well seals, and grouting the well. Distribution system BMPs include disinfection; maintaining positive pressure; flushing water mains; and adopting cross connection control programs. Surveillance BMPs such as sanitary surveys are conducted to identify weaknesses in the barriers.

EPA recognizes that BMPs can and do contribute significantly to the safety of drinking water; however, the effectiveness of each individual practice can be difficult to measure. Two studies, State Ground Water Management Practices—Which Practices are Linked to Significantly Lower Rates of Total Coliform Rule Violations? (US EPA, 1997d) and the Analysis of Best Management Practices for Community Ground Water Systems (Association of State Drinking Water Administrators, or ASDWA, 1998), were conducted to examine the relative effectiveness of BMPs in reducing microbial contamination of ground water systems. The EPA study compared BMP implementation at the State level to total coliform MCL violation rates of community ground water systems over a four year period. The ASDWA study compared BMP implementation to detections of both total and fecal coliform in community ground water systems over a two year period.

A third study was conducted by EPA, Ground Water Disinfection and Protective Practices in the United States, (US EPA, 1996a) to review State practices and requirements for the protection of drinking water that has ground water as its source.

1. EPA Report on State Ground Water Management Practices

In the EPA study, State Ground Water Management Practices—Which

Practices are Linked to Significantly Lower Rates of Total Coliform Rule Violations? (US EPA, 1997d), 12 BMPs were compared to the MCL violation rate for total coliform in community water systems by State. The 12 State BMPs were taken from the EPA report Ground Water Disinfection and Protective Practices in the United States (US EPA, 1996a). The study used total coliform MCL violation data in SDWIS for community water systems for Fiscal Years 1993 through 1996. In the study, pairwise and stepwise linear regression analyses were used to determine if there was a statistically significant difference in the TCR MCL violation rates between those States that practice a particular BMP and those that do not. From this perspective, BMPs associated with lower violation rates are considered effective. The 12 BMPs included in the study were well construction codes, well/pump disinfection requirements, sanitary surveys, disinfection of new/repaired mains, cross connection controls, operator certification, minimum setback distances, EPA approved State Wellhead Protection Programs, periodic flushing of mains, wellhead monitoring, hydrogeologic criteria, and disinfection.

Six of the 12 State management practices were unsuitable for pairwise analysis because these practices were present in nearly all States. Therefore, a comparison of TCR MCL violation rates in States with and without these practices could not be made. The BMPs for which analysis were not done were: well construction codes, well/pump disinfection requirements, sanitary surveys, disinfection of new/required mains, cross connection controls, and operator certification. However, these six management practices were evaluated as part of the 1998 Best Management Practices Survey conducted by ASDWA.

Using a pairwise statistical analysis, two of the remaining six practices, disinfection and hydrogeologic criteria, showed a significant statistical relationship (at a .01 and a .05 level of confidence, respectively) in lowering the statewide median TCR violation rates, with disinfection showing the strongest relationship. In this analysis, disinfection is defined as the maintenance of at least a chlorine residual or its equivalent at the entry point or in the distribution system. The report focused its analysis on disinfection practices among 20 States, comparing the 10 highest disinfecting States with the 10 lowest disinfection States. Specifically, the 10 States with the highest percentage of disinfected CWSs had an average MCL violation rate of 16% over the four year period, versus a 33% violation rate for the ten States with the lowest disinfection rates. States that require hydrogeologic criteria for well siting and construction decisions had significantly lower median MCL violation rates than States that do not use these criteria (15.4% vs. 24.6%). The other four practices, minimum setback distances from pollution sources, EPA approved Wellhead Protection Programs, periodic flushing of the distribution system, and wellhead monitoring, did not show a significant relationship in lowering TCR violation rates at the State level. The report does not provide information on the statistical significance of these results.

The four year time frame for the statistical analyses was chosen as a more accurate reflection of the effectiveness of statewide management practices given the high degree of variability in the TCR violation rate from year to year. Different trends emerge when annual rates are compared. There is not enough data to determine if the year to year variability, shown in the FY 96 data, correlates to a change in State management practices.

In a second analysis, stepwise linear regression was used on the six best management practices to further explain the variability among States in their reported TCR MCL violation rates. This analysis examines both the simultaneous effect of several BMPs on the State TCR MCL violation rate and evaluates which of the practices may explain the variability in the TCR violation rate among States. Ascertaining how much of the State-to-State variability can be explained by each of the practices is an important question given that the TCR requirements are the same for all States. The results of this analysis indicate that disinfection is the single largest factor in explaining the difference in the TCR violation rate among States. In general, the higher the rate of disinfection, the lower the rate of TCR MCL violations.

Uncertainties associated with this analysis were: (1) Whether a State's BMP requirements are fully implemented at the system level; (2) what effect the six State BMPs not analyzed had on violation rates; (3) the degree of voluntary implementation of BMPs; and (4) the effect of not including State practices required only under certain circumstances. Nonetheless, this data on State management practices indicates that there is a significant association between disinfection and a lower TCR MCL violation rate.

2. ASDWA Analysis of BMPs for Community Ground Water Systems

In the ASDWA study, The Analysis of Best Management Practices for Community Ground Water Systems (ASDWA, 1998), a working group selected 28 BMPs that represent four major areas of plant operations and developed and distributed a survey to all 50 State drinking water programs. Each State was asked to select eight systems in each of the three following categories: (1) Systems with no detections of total coliform; (2) systems with total coliform detections only; and (3) systems with both total coliform and fecal coliform (or *E. coli*) detections. For each system, the State was asked to report which of 28 BMPs listed were used by the system during a two year period (1995 and 1996). Thirty-six States responded to the survey, each completing up to 24 individual system surveys, providing data for 812 systems.

The survey results were analyzed using both descriptive statistics and two statistical models—pairwise and logistical regression. The descriptive statistics illustrate the characteristics of a system but cannot isolate the effect of a particular BMP from the effects of other BMPs. The statistical models were used to describe the relationship between implementation of individual or a group of BMPs and a reduction in total or fecal coliform detections.

A pairwise association analysis (*i.e.,* comparing a system that implements a particular BMP to one that does not) was used to determine if the use of a BMP reduced the percentage of positive total coliform samples. The analysis determined that a significant association was found between 21 of the 28 BMPs and systems with no total coliform detections. The two BMPs with the strongest correlation to fewer total coliform detections were correction of deficiencies identified by the sanitary survey and operator certification (ASDWA, 1998).

Using pairwise analysis for systems with fecal coliform (based only on those systems with at least one positive total coliform sample), the study found a significant association for eight of the twenty-eight BMPs. These eight BMPs include: system wells constructed according to State regulations, routine disinfection after well or pump repair, treatment for purposes other than disinfection, system maintaining acceptable pressure at all times, water distribution tanks are designed according to State requirements, systems are in compliance with State permitting requirements, systems have corrected deficiencies noted by the State

and system and operators receive routine training and education. According to the results, fewer BMPs are found to be significant in this analysis than the total coliform analysis. These results are expected given that the analysis of fecal coliform and *E. coli* only evaluate systems with at least one total coliform positive detection. Fecal coliform and *E. coli* tests are more specific to organisms found in human and animal feces, whereas total coliform tests indicate the presence of a broader class of enteric organisms. For this reason, there are fewer data points to model the association of BMPs with fecal coliform. Therefore, this analysis sets apart only the BMPs significant in preventing or eliminating fecal contamination.

Using the logistical regression technique, three BMPs were associated with a significant reduction of total coliform-positive samples: (1) Maintaining a disinfectant residual; (2) operator training; and (3) correcting deficiencies identified by the State as part of a sanitary survey. The two BMPs associated with a significant reduction of fecal coliform/*E. coli*-positive samples were treatment for purposes other than disinfection, *e.g.,* iron removal, and operator training. Another analysis was constructed using Logit models for four categories of BMPs to consider the effects of BMPs in groups rather than individually. Out of the four categories (Source Protection/ Construction, Treatment, Distribution System, and Management and Oversight), the Management and Oversight category showed the most significant association with reduced coliform detections.

The ASDWA survey also evaluated the effectiveness of BMPs with regard to system size. For systems serving less than 500 persons, correction of deficiencies identified by the State, and regular training and education of operators were the most significant in reducing microbial contamination. Routine disinfection after well or pump repair had the greatest significance among systems serving between 501 and 3,300 persons, while maintaining a disinfection residual had the greatest significance among systems serving between 3301 and 10,000 persons.

Overall, this study found that the percentage of systems implementing BMPs is highest among systems with no total coliform detections. In addition, systems that routinely educate and train their operators were more likely to implement other BMPs than systems with no regular training. Similarly, those systems that practice disinfection (contact time or maintain disinfection residual) were more likely to implement other BMPs than systems that do not disinfect. Observations about the implementation of BMPs suggests that many BMPs are interrelated, therefore, it is difficult to isolate the effect of an individual BMP.

3. EPA Report on Ground Water Disinfection and Protective Practices

The purpose of the EPA study, Ground Water Disinfection and Protective Practices in the United States, (US EPA, 1996a) was to compile and assess State regulations, guidance, codes, and other materials pertaining to protection of public health from microbial contamination in public water systems using ground water.

The information compiled included the following:

- Wellhead/ground water protection information;
- Ground water disinfection requirements;
- Well siting and construction requirements/guidelines;
- Sanitary survey requirements/ guidelines;
- Distribution system protection requirements/guidelines; and
- Operator certification requirements.

The study found that there are widespread, but diverse requirements for the protection of drinking water that has ground water as its source. Few of these protective practices are used by all States and there is a variety of interpretations of the same practice. For example, 47 States specify minimum setback distances from sources of microbial contamination but show a wide range of setback distances for the same type of contaminant source; 49 States drinking water programs require disinfection of some sort, but when and where disinfection is required varies considerably; and of the 48 States that have well construction codes, 21 States do not require consideration of hydrogeological criteria in the approval of the siting of a well.

Overall, the study found that although many States appear to require similar BMPs, the nature, scope, and detail of these requirements varies considerably at the national level.

E. Outreach Activities

1. Public Meetings

As part of the 1986 amendments to the Safe Drinking Water Act (SDWA) Section 1412(b)(8), Congress directed EPA to promulgate a national primary drinking water regulation (NPDWR) requiring disinfection as a treatment technique for all public water systems, including those served by surface water and ground water. In 1987, EPA began developing a rule to cover ground water systems. This effort included a preliminary public meeting on the issues in 1990 (see 55 FR 21093, May 22, 1990, US EPA, 1990a). In 1992, EPA circulated a strawman draft for comment (see 57 FR 33960, July 31, 1992) (US EPA, 1992a).

From 1990 to 1997, EPA conducted technical discussions on a number of issues, primarily to establish a reasonable means of establishing whether a ground water source was vulnerable to fecal contamination and thus pathogens. This effort was accomplished through *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 addition, technical meetings were held in Irvine, California in July 1996, (US EPA, 1996c) and in Austin, Texas in March 1997 (US EPA, 1997e).

The SDWA was amended in August 1996, and as a result, several statutory provisions were added establishing new drinking water requirements. Specifically, Congress required under section 1412(b)(8) that EPA develop regulations specifying the use of disinfectants for ground water systems ''as necessary.'' These amendments established a new regulatory framework that required EPA to set criteria for States to determine whether ground water systems need to disinfect. In December 1997, EPA held its first of a series of stakeholder meetings to present a summary of the findings resulting both from technical discussions held since 1990 and from information generated by internal EPA working groups with the intention of developing disinfection criteria for ground water systems.

EPA held a preliminary Ground Water Rule meeting on December 18 and 19, 1997, in Washington, DC for the purpose of engaging all interested stakeholders in the analysis of data to support the GWR. The two day meeting covered discussions on the implications of the data, solicited further data from stakeholders, and reviewed EPA's next steps for rule development, data analysis and stakeholder involvement.

Since December 1997, EPA has held GWR stakeholder meetings in Portland, OR, Madison, WI, Dallas, TX, Lincoln, NE, and Washington, DC along with three early involvement meetings with State representatives. In addition, EPA has received valuable input from small system operators as part of an Agency outreach initiative under the Small Business Regulatory Enforcement Fairness Act. See section VI for more

information on the SBREFA process. Taken together, these stakeholder meetings have been crucial both in obtaining feedback and getting additional information as well as in guiding the Agency's consideration and development of different regulatory components.

The Agency's goal in developing the GWR is to reduce the risk of illness caused by microbial contamination in public water systems relying on ground water. The series of GWR stakeholder meetings were beneficial in assisting EPA in understanding how State strategies fit together as part of a national strategy. For more information see the (Stakeholders Meeting Summary, Resolve, July 27, 1998).

Portland, OR, GWR Stakeholder Meeting

There were four different regulatory approaches presented in the first of a series of stakeholder meetings held in Portland, OR, in May 1998: the Barrier Assessment Approach, the Existing State Practices Approach, the Setback Approach, and the Checklist Approach (Stakeholder Meetings Summary, Resolve, July 27, 1998). All approaches address, to varying degrees, three main areas: minimum program requirements or baseline measures, identification of high risk wells, and corrective action. Discussions on the potential approaches centered around determining triggers that could place a well in a high priority category and which minimum set of BMPs should be implemented at high risk wells.

Madison, WI GWR Stakeholder Meeting

There were three approaches presented in a June 9, 1998, GWR stakeholder meeting held in Madison, WI: Status Quo Approach, Baseline Approach, and Disinfection Approach. Regulatory approaches were revised in response to stakeholder input from the earlier GWR stakeholder meetings, representing a continuum of requirements, from Existing Status Quo to mandatory disinfection for all ground water systems. EPA emphasized that existing occurrence data does not appear to support mandatory disinfection across the board, but that the Agency would still appreciate stakeholder input on a range of options. The approaches presented were based on monitoring, inspections, BMPs and disinfection.

Dallas, TX GWR Stakeholder Meeting

A third GWR meeting on June 25, 1998 in Dallas, TX, provided slight modifications to the regulatory approaches, but for the most part the regulatory approach remained unchanged from the Madison meeting held in early June. EPA continued to emphasize the need to identify and strengthen the potential barriers to contamination. Among the three approaches, (Status Quo, Progressive and Universal Disinfection) the Progressive approach was considered the more viable regulatory option to ensure public health protection among public water systems.

Early Involvement Meetings

ASDWA held three early involvement meetings (EIMs) on the GWR. The first EIM followed the May 5, 1998 stakeholder meeting in Portland, OR. The second EIM meeting was held in Washington, DC on July 14 and 15, 1998 and the third meeting was held in Chicago, IL on April 7 and 8, 1999. Representatives from 12 States, four EPA Regions, ASDWA and EPA Headquarters participated in the May 6 and 7, 1998 meeting in Portland, OR. The second EIM involved 10 State representatives, ASDWA, and EPA Headquarters. The third EIM included one Region, seven State representatives, ASDWA and EPA Headquarters. The purpose of the meetings was to review the findings and comments from the stakeholder meetings and to work together to further refine GWR regulatory options. EPA and States discussed a range of issues including risk, exposure, strategies for identifying high risk systems, occurrence data, and regulatory implementation barriers.

2. Review and Comment of Preliminary Draft GWR Preamble

EPA developed a preliminary draft preamble reflecting a wide range of input from numerous stakeholders across the country including four public meetings, three EIMs with State representatives, in addition to valuable input received from small system operators as part of the outreach process established by SBREFA.

To facilitate the rule development process, the preliminary draft preamble was made available to the public via the Internet through EPA's website site on February 3, 1999. Approximately 300 copies were mailed to participants of the public meetings or to those who requested a copy. EPA welcomed any comments, suggestions, or concerns reviewers had on either the general direction or the technical basis of the proposal. EPA closed the email box on February 23, 1999 and continued to receive written comments through the mail through March 17, 1999. Because this was an informal process, EPA did not prepare a formal response to the comments. Nonetheless, the Agency carefully reviewed and evaluated all comments and technical suggestions and greatly appreciated the input and feedback provided by these outreach efforts.

Eighty individual comment letters were received. Commenters included: State and local government representatives, trade associations, academic institutions, businesses and other Federal agencies. Microbial monitoring received the most individual comments. Sanitary survey, sensitivity assessment and treatment issues were next, respectively.

II. Public Health Risk

The purpose of this section is to discuss the health risk associated with pathogens in ground waters. More detailed information about pathogens may be found in three EPA drinking water criteria documents for viruses (US EPA 1985a; 1999b; 1999c), three EPA criteria documents for bacteria (US EPA 1984a, b; 1985b) and the GWR Occurrence and Monitoring Document (US EPA, 1999d). EPA requests comment on all the information presented in this section, and the potential impact of proposed regulatory provisions on public health risk.

A. Introduction

Enteric viral and bacterial pathogens are excreted in the feces of infected individuals. Many bacterial pathogens can infect both humans and animals. Bacterial pathogens that infect humans can also be found in animal feces. In contrast, enteric viruses that are human pathogens generally only infect humans, and thus are only found in human feces. These organisms are able to survive in sewage and leachate derived from septic tanks (septage) and sewer lines. When sewage and septage are released into the environment, they are a source of fecal contamination. Fecal contamination is a very general term that includes all of the organisms found in feces, both pathogenic and non-pathogenic, as well as chemicals.

Fecal contamination of ground water can occur by several routes. First, fecal contamination can reach the ground water source from failed septic systems, leaking sewer lines, and from land discharge by passage through soils and fissures. Twenty-five million households in the United States use conventional onsite wastewater treatment systems, according to the 1990 Census. These systems include systems with septic systems and leach fields. A national estimate for 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, 1997f). 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. Third, fecal contamination may also enter the distribution system when cross connection controls fail or when negative pressure in a leaking pipe allows contaminant infiltration.

Biofilms in distribution systems may harbor bacterial pathogens, especially the opportunistic pathogens that cause illness primarily in individuals with weakened immune systems. These bacterial pathogens may have entered the distribution system as part of fecal matter from humans or other animals. Biofilms may also harbor viral pathogens (Quignon *et al.,* 1997), but, unlike some bacterial pathogens, viruses do not grow in the biofilm. However, a biofilm may protect the viruses against disinfectants and help them survive longer.

Although not the basis for today's proposed rule, there are additional waterborne pathogens that EPA is currently evaluating. These include bacterial pathogens that may be free-living in the environment, and thus not necessarily associated with fecal contamination. These pathogens include *Legionella* (causes Legionnaires Disease and Pontiac Fever), *Pseudomonas aeruginosa,* and *Mycobacterium avium-intracellulare*. Many of these bacteria can colonize pipes of the distribution system and plumbing systems and may play a role in causing waterborne disease that is currently under study. EPA recognizes the potential risk of such organisms, but believes that more research needs to be conducted before they can be considered for regulation. Also, the Agency is aware that *Giardia* and *Cryptosporidium* have occurred in ground water systems (GWSs) (Hancock *et al.*, 1998), causing outbreaks in such systems (Solo-Gabriele and Neumeister, 1996). However, by definition under § 141.2 ground waters with significant occurrence of large diameter pathogens such as *Giardia* or *Cryptosporidium* are considered ground water under the direct influence of surface water and are already subject to the SWTR and IESWTR. The Agency is also not addressing in the GWR the important issue of toxic or carcinogenic chemicals in the GWR. This issue is instead covered in other regulations that address chemicals.

In order to assess the public health risk associated with drinking ground water, EPA has evaluated information and conducted analysis in a number of important areas discussed in more detail later. These include: (1) Recent waterborne disease outbreak data; (2) dose-response data and other health effects data from a range of pathogens; (3) occurrence data from ground water studies and surveys; (4) an assessment of the current baseline ground water protection provided by existing regulations; and (5) an analysis of risk.

B. Waterborne Disease Outbreak Data

The purpose of this section is to present a detailed review of waterborne disease outbreaks associated with ground waters. Outbreak characterization is useful for indicating relative degrees of risk associated with different types of source water and systems.

The Centers for Disease Control and Prevention (CDC) maintains a database of information on waterborne disease outbreaks in the United States. The database is based upon responses to a voluntary and confidential survey form that is completed by State and local public health officials. CDC defines a waterborne disease outbreak as occurring when at least two persons experience a similar illness after ingesting a specific drinking water (Kramer *et al.,* 1996). Data from the CDC database appears in Tables II–1, II–2, II–3, and II–4.

The National Research Council strongly suggests that the number of identified and reported outbreaks in the CDC database (both for surface and ground waters) represents a small percentage of actual waterborne disease outbreaks (Safe Water From Every Tap, National Research Council, 1997; Bennett *et al.,* 1987; Hopkins *et. al.,* 1985 for Colorado data). In practice, most waterborne outbreaks in community water systems are not recognized until a sizable proportion of the population is ill (Perz *et al.,* 1998; Craun 1996), perhaps 1% to 2% of the population (Craun, 1996). Some of the reasons for the lack of recognition and reporting of outbreaks, most of which were noted by the National Research Council (1997), are as follows:

- Some States do not have active disease surveillance systems. Thus, States that report the most outbreaks may not be those in which the most outbreaks occur.
- Even in States with effective disease surveillance systems, health officials may not recognize the occurrence of small outbreaks. In cities, large outbreaks are more likely to be recognized than sporadic cases or small outbreaks in which ill persons may consult different physicians. Even so, health authorities did not recognize the massive outbreak (403,000 illnesses) of waterborne cryptosporidiosis that occurred in Milwaukee, WI, in 1993, until the disease incidence was near or at its peak (MacKenzie *et al.,* 1994). The outbreak was recognized when a pharmacist noticed that the sale of over-the-counter diarrheal medicine was very high and consequently notified health authorities.
- Most cases of waterborne disease are characterized by general symptoms (diarrhea, vomiting, *etc.*) that cannot be distinguished from other sources (*e.g.,* food).
- Only a small fraction of people who develop diarrheal illness seek medical assistance.
- Many public health care providers may not have sufficient information to request the appropriate clinical test.
- If a clinical test is ordered, the patient must comply, a laboratory must be available and proficient, and a positive result must be reported in a timely manner to the health agency.
- Not all outbreaks are effectively investigated. Outbreaks are included in the CDC database only if water quality and/or epidemiological data are collected to document that drinking water was the route of disease transmission. Monitoring after the recognition of an outbreak may be too late in detecting intermittent or a one-time contamination event.
- Some States do not always report identified waterborne disease outbreaks to the CDC. Reporting outbreaks is voluntary.
- The vast majority of ground water systems are non-community water systems (NCWSs). Outbreaks associated with NCWSs are less likely to be recognized than those in community water systems because NCWSs generally serve nonresidential areas and transient populations.

There is also the issue of endemic waterborne disease. Endemic waterborne disease may be defined as any waterborne disease not associated with an outbreak. A more precise definition is the normal level of waterborne disease in a community. Under this definition, an outbreak would represent a spike in the incidence of disease. Based on this definition, the level of endemic waterborne disease in a community may be quite high. For example, 14%-40% of the normal gastrointestinal illness in a community in Quebec was associated

with drinking treated water from a surface water source (Payment *et al.,* 1997). Significant levels of endemic disease could also be associated with ground waters. Because endemic waterborne disease may be a significant and substantially preventable source of health risk, under the directive of the 1996 SDWA Amendments, EPA is jointly pursuing with CDC a multi-city study of waterborne disease occurrence in an effort to provide greater understanding of this risk. EPA believes that some meaningful percentage of the nationwide occurrence of endemic waterborne disease is in ground water systems (GWSs). EPA believes that the prudent policy of prevention embodied in this proposal with regard to identified sources of substantial microbial risk to GWSs gains further justification as a counter to the endemic occurrence of waterborne disease. EPA solicits comment and any data that can increase knowledge of these endemic risks, in particular any studies on such risk in GWSs.

CDC Waterborne Disease Outbreak Data

Outbreak data collected by CDC are presented in Tables II–1, II–2 , II–3, and II–4. Table II–1 provides outbreak data for all public water systems (surface and ground water). Table II–2 shows sources of waterborne disease outbreaks for GWSs. Table II–3 identifies the etiology of waterborne outbreaks in GWSs. Table II–4 shows causes associated with waterborne disease outbreaks and illnesses in GWSs.

According to CDC, between 1971 and 1996 a total of 643 outbreaks and 571,161 cases of illnesses were reported (see Table II–1); however, the total includes 403,000 cases from a single surface water outbreak caused by *Cryptosporidium* in Milwaukee, WI in 1993. Excluding the Milwaukee outbreak from the data set, 642 outbreaks and 168,161 cases of illness were reported during the same period of time. Ground water sources were associated with 371 (58%) of the total outbreaks and 16% of the associated illness (54% of the illness if the Milwaukee outbreak is excluded). In comparison, surface water sources were associated with 216 (33%) of the total outbreaks and 82% of the associated illness (40% of the illness if the Milwaukee outbreak is excluded). Although the data in Table II–1 indicate that NCWSs using ground water had twice as many outbreaks as CWSs using ground water, this may reflect the fact that there are over twice as many NCWSs as CWSs.

The outbreak data indicate that the major deficiency in ground water systems was source water contamination—either untreated or inadequately treated ground water (see Table II–2). Contaminated source water was the cause of 86% of the outbreaks in ground water systems. Contamination due to source water was the cause of 68% of the outbreaks for CWSs, while for NCWSs it was 92%. Distribution system deficiencies were associated with 29% of the outbreaks in CWSs and in five percent of the NCWSs.

Of the 371 outbreaks in ground water systems, 91 (25%) were associated with specific viral or bacterial pathogens, while 22 (6%) were associated with chemicals (see Table II–3). Etiologic agents were not identified in 232 (63%) outbreaks. The diversity of disease agents is similar to that of surface water, with a variety of protozoa, viruses, and bacteria. As stated previously, a ground water with *Cryptosporidium* or *Giardia* is, by definition, a ''ground water under the direct influence of surface water'', and is thus subject to the microbial treatment requirements of a surface water system (*i.e.,* SWTR or IESWTR). According to CDC's data, bacterial pathogens were responsible for more outbreaks (57) than were viral pathogens (34). However, EPA suspects that many, perhaps a majority, of the outbreaks where an agent was not determined (232) were virus-caused, given the fact that it is generally more difficult to analyze for viral pathogens than bacterial pathogens. The fecal bacterial pathogen, *Shigella,* caused far more reported outbreaks (eight percent) than any other single agent.

Table II–4 shows outbreak data since 1991, the year in which the TCR became effective. Untreated ground water and inadequate treatment were collectively associated with 73% of the outbreaks in ground water systems between 1991–1996.

Large outbreaks are rarely associated with ground water systems because most ground water systems are small. However, one large outbreak occurred in Georgetown, TX, in 1980 (Hejkal *et al.,* 1982) where 7,900 people became ill. Coxsackievirus and hepatitis A virus were found in the raw well water in a karst hydrogeologic setting; the outbreak was the result of source water contamination. Another occurred in 1965, in Riverside, CA, where about 16,000 illnesses resulted from exposure to *Salmonella typhimurium* in the source water (Boring, 1971).

Most of the outbreaks were caused by agents of gastrointestinal illness. Normally, the disease is self-limiting and the patient is well within one week or less. However, in some cases, deaths have occurred. In 1989, four deaths (243 illnesses) occurred in Cabool, MO, as a result of distribution system contamination by *E. coli* 0157:H7 (Swerdlow *et al.,* 1992; Geldreich *et al.,* 1992). In 1993, seven deaths (650 illnesses) occurred in Gideon, MO, as a result of distribution system contamination by Salmonella typhimurium (Angulo, 1997). Both cases involved ground water systems. Waterborne disease in ground water systems has also caused serious illness such as hemolytic uremic syndrome (six reported cases in two outbreaks), which includes kidney failure, especially in children and the elderly. Two cases of hemolytic uremic syndrome were reported during the Cabool outbreak, the affected individuals being three and 79 years of age. Deep wells are not immune from contamination; for example, an outbreak of gastroenteritis caused by the Norwalk virus (900 illnesses) was associated with a 600-foot well (Lawson *et al.,* 1991).

Collectively, the data indicate that outbreaks in ground water systems are a problem and that source contamination and inadequate treatment (or treatment failures) are responsible for the great majority of outbreaks. The outbreaks are caused by a variety of pathogens, most of which cause short term gastrointestinal disease.

TABLE II–1.—COMPARISON OF OUTBREAKS AND OUTBREAK-RELATED ILLNESSES FROM GROUND WATER AND SURFACE WATER FOR THE PERIOD 1971–1996 [1] [2]

Water source	Total outbreaks[1]	Cases of illnesses	Outbreaks in CWSs	Outbreaks in NCWSs	Total CWS[4]	Total NCWS[4]
Ground	371 (58%)	90,815 (16%)	113	258	43,908	112,940
Surface	216 (33%)	469,721[2] (82%)	142	43	10,760	2,848
Other	56 (9%)	10,625 (2%)	29	19	.....	.....

TABLE II–1.—COMPARISON OF OUTBREAKS AND OUTBREAK-RELATED ILLNESSES FROM GROUND WATER AND SURFACE WATER FOR THE PERIOD 1971–1996 [1] [2]—Continued

Water source	Total outbreaks[1]	Cases of illnesses	Outbreaks in CWSs	Outbreaks in NCWSs	Total CWS[4]	Total NCWS[4]
All Systems[3]	643 (100%)	571,161 (100%)	284	320	54,668	115,788

[1] Modified from Craun and Calderon, 1994, plus 1995–1996 data.
[2] Includes 403,000 cases of illness from a single outbreak in Milwaukee, Wisconsin, 1993.
[3] Includes outbreaks in CWSs + NCWSs + Private wells.
[4] Safe Drinking Water Information System, 1998.

TABLE II–2.—SOURCES OF WATERBORNE DISEASE OUTBREAKS, PUBLIC GROUND WATER SYSTEMS, 1971–1996 [1,2].

Type of contamination	Total	Percent of total	CWSs	Percent of total	NCWSs	Percent of total
Source	274	86	53	68	221	92
Untreated	150	47	20	26	130	54
Disinfected	122	38	31	40	91	38
Filtered	2	1	2	3	0	0
Distribution System	35	11	23	29	12	5
Unknown Cause	9	3	2	3	7	3
Total	318	100	78	100	240	100

[1] Source water could not be identified for 29 CWSs and 19 NCWSs with outbreaks, and thus these systems are not included in the table.
[2] Excludes outbreaks caused by protozoa and chemicals.

TABLE II–3.—ETIOLOGY OF OUTBREAKS IN GROUND WATER SYSTEMS, 1971–96, CWSS AND NCWSS

Causative agent	Outbreaks	Percent
Undetermined	*232*	*63*
Chemical	*22*	*6*
Giardia	[1] 21	6
Cryptosporidium	[1] 4	1
E. histolytica	1	<1
Total Protozoa	*26*	*7*
Hepatitis A	18	5
Norwalk Agent	16	5
Total Virus	*34*	*9*
Shigella	30	8
Campylobacter	10	3
Salmonella, non-typhoid	10	3
E. coli	4	1
S. typhi	1	<1
Yersinia	1	<1
Plesiomonas shigelloides	1	<1
Total Bacteria	*57*	*15*
Total	*371*	*100*

[1] Ground waters with *Giardia* and *Cryptosporidium* are regulated under the SWTR and IESWTR. These systems would likely not be considered ground water systems for purposes of this rule.

TABLE II–4.—CAUSES OF OUTBREAKS IN GROUND WATER SYSTEMS, 1991–1996

Cause	Number of outbreaks	Cases of illness	Percent of outbreak-related illnesses
Untreated Ground Water	18	2924	51
Distribution System Deficiency	6	944	17
Treatment Deficiency	17	1260	22
Miscellaneous, Unknown Cause	3	568	10
Total	44	5696	100

[1] Excludes protozoa and chemicals.

C. Ground Water Occurrence Studies

The purpose of this section is to present data on the occurrence of waterborne pathogens and indicators of fecal contamination in ground water supplying PWS wells. These data are important to GWR development because they provide insight on: (1) The extent to which ground water may be contaminated; (2) possible fecal indicators for source water monitoring under the GWR; and (3) a national estimate of ground water pathogen occurrence. In addition, determining the occurrence of microbial contaminants in ground water sources of drinking water is necessary to yield a quantified national estimate of public health risk.

EPA has reviewed data from13 recent or on-going studies of pathogen and/or fecal indicator occurrence in ground waters that supply PWSs. While most of these studies were not designed to yield a nationally representative sample of ground water systems, one of the studies (Abbaszadegan *et al.,* 1999, or the ''AWWARF study'') was later expanded to include a nationally representative range of hydrogeologic settings. This study was used as the basis of EPA's quantitative assessment of baseline risk from viral contamination of ground water, which is also a component of the quantitative benefits assessment for the proposed rule. Short narratives on each of the studies are provided in the next sections. The study design and results for each study are summarized in Table II–6, at the end of the narratives. The Agency decided not to combine the data from these studies, because of the different method protocols and scopes.

Each occurrence study investigated a combination of different pathogenic and/or indicator viruses and bacteria. Indicator viruses and bacteria may be non-pathogenic but are associated with fecal contamination and are transmitted through the same pathways as pathogenic viruses and bacteria. The samples analyzed in each study were tested for viral pathogens such as enteroviruses (a group of human viruses also referred to as ''total cultureable viruses'') and/or bacterial pathogens such as *Legionella* and *Aeromonas.* Several studies used the polymerase chain reaction (PCR) as part of the method for determining the presence of pathogenic viruses. Bacterial indicators of fecal contamination tested included enterococci (or fecal streptococci, which are closely related), and fecal coliforms (or *E. coli,* which is closely related), and *Clostridium perfringens.* Most studies tested for total coliforms, which are not considered a direct fecal indicator since they also include coliforms that live in soil. Viral indicators of fecal contamination were all bacteriophage, which are viruses that infect bacteria. Among the bacteriophage tested were somatic coliphage and/or male-specific coliphage, both of which infect the bacterium *E. coli.* Bacteroides phage were tested in two studies and *Salmonella* phage in one study.

While this section presents a summary of each study, a more detailed explanation of one study (Abbaszadegan *et al.*, 1999) (AWWARF Study) is provided, as it is the broadest study in scope. The hydrogeology of individual wells is mentioned in addition to the microbial results, because EPA considers hydrogeology an important factor in source water contamination. Hydrogeology is discussed in greater detail in section III.B.

1. Abbaszadegan et al. (1999) (AWWARF Study)

Of the 13 studies, the AWWARF study sampled the largest number of wells, examined the widest array of well and system characteristics, and tested sites in 35 States across the U.S., located in hydrogeologic settings representative of national hydrogeology. The objectives of the AWWARF study were to: (1) Determine the occurrence of virus contamination in source water of public ground water systems; (2) investigate water quality parameters and occurrence of microbial indicators in ground water and possible correlation with human viruses; and (3) develop a statistically-based screening method to identify wells at risk of fecal contamination. A summary of AWWARF results are presented in Tables II–5 and II–6.

Many of the initial sites were selected to evaluate the effectiveness of a method based on the reverse-transcriptase, polymerase chain reaction (RT–PCR) technique to detect pathogenic viruses in ground water. Sites for this portion of the study were selected based on the following criteria: (1) Ground water sites with high concentrations of minerals, metals, or TOC; (2) sites with a previous detection of any virus or bacteria in the ground water source; (3) sites with potential exposure to contaminants due to agricultural activities near the well, industrial activities near the well, or septic tanks near the well; and (4) sites with different pH values, temperatures, depths, production capacities and aquifer types. Sites were selected for the virus occurrence project based upon their geological characteristics to balance out the range of geologies so that the sites in aggregate more closely matched the national geologic profile of ground water sources. Sites for the virus occurrence study were selected from an initial mailing to 500 utilities that currently disinfect their water; 160 utilities with 750 wells volunteered to be included in the study. In total, 448 wells were sampled for the study. AWWARF excluded sites from the investigation if: (1) It was known to be under the influence of surface water; (2) the well log records were not available; or (3) it was considered poorly constructed.

EPA subsequently compared nitrate concentrations from a national database of nitrate concentrations in ground water (Lanfear, 1992) with nitrate data measured in the AWWARF study wells. The purpose of the comparison was to determine if there was any statistically significant difference between the nitrate levels in the AWWARF wells as compared with the national distribution of nitrate concentration data. Nitrate was chosen for this comparison because there is a large, national database available. Each data set contained 216 samples selected so that proportionately, wells of equal depth were analyzed in each comparison. The national data were selected randomly from a database of more than 100,000 wells; all available AWWARF data were used. In analyzing the data, EPA noted that the national data is biased by multiple sampling of many shallow monitoring wells in farming regions leading to a few wells having exceptionally high nitrate levels. In order to minimize the impact of these wells on the analysis, EPA chose a small random subset comparable in size to the sample in the AWWARF study. Thus, the data are not directly comparable with PWS wells. Census data were used to divide the national nitrate database into urban and rural components. The analysis showed that the AWWARF wells had nitrate concentrations that were not significantly different from the national data or from the urban and rural components. Thus, using nitrate concentration as a surrogate, EPA concludes that, by this measure, the AWWARF wells are nationally representative.

All samples were collected by the systems. AWWARF provided a sample kit containing all needed equipment and a video illustrating the details of appropriate sampling and storage procedures. A total of 539 samples were collected from 448 sites in 35 States. The preliminary results indicate that of the 448 wells sampled, about 64% were located in unconsolidated aquifers, 27% in consolidated aquifers including consolidated sedimentary strata, and 9% in unknown geology. Unconsolidated aquifers are made of

loosely packed (uncemented) particles, such as sand grains or gravel, while consolidated aquifers are comprised of compacted (cemented) particles or crystalline rock (*e.g.,* granite, limestone). As discussed further in section III.B., the degree and type of consolidation may affect the transport of pathogens from a source of fecal contamination to the well. The percentages of sites sampled from these geologic settings are similar to those of national ground water production from unconsolidated and consolidated hydrogeologic settings (modified by AWWARF, from United States Geological Survey (USGS) Circular 1081, 1990). The data indicate that 174 sites (39%) were within 150 feet of a known sewage source, and an additional 127 sites (28%) were within 550 feet of a known sewage source. There is no comparable data on the distribution nationally of wells relative to sewage sources. EPA notes however, that the proximity to these sources is not inconsistent with State standards across the country. For example, 41 States have setback distances (the minimum distance between a source of contamination and a well) that are less than or equal to 100 feet for sources of microbial contaminants. Only five States appear to require setback from all sewage sources of more than 200 feet. The preliminary results also indicated that a total of 25 sites were sampled more than once. Most sites were from systems that serve greater than 3,300 people, and almost all systems maintain a disinfectant residual.

In the study, systems collected at least 400 gallons (1,512 liters) of water and concentrated it using a filter-adsorption and elution method. The concentrated samples were then sent to the researchers for analysis. The presence of enteroviruses was determined by two procedures: a cell culture assay and a procedure using the RT–PCR technique. The RT–PCR technique was also used to determine the presence of hepatitis A virus, rotavirus, and Norwalk virus. The researchers also tested each well for total coliforms, enterococci, *Clostridium perfringens,* somatic coliphage, and male-specific coliphage to establish their relationship with enterovirus and to get a better indication of the percentage of fecally contaminated wells.

Preliminary results indicated that fecal contamination occurs in a subset of PWS wells (see Table II–5). The investigators detected pathogenic viruses, either by cell culture or RT–PCR analyses, in a significant percentage of samples.

TABLE II–5.—PRELIMINARY RESULTS OF AWWARF STUDY

Assay	Percent of wells positive (number positive/samples analyzed)
Enteroviruses (cell culture)	4.8% (21/442)
Bacterial Indicators	15.1%
Total coliforms	9.9% (44/445)
enterococci	8.7% (31/355)
Clostridium perfringen spores	1.8% (1/57)
Coliphage Indicators	20.7%
Male-specific coliphage (*Salmonella* WG–49 host)	9.5% (42/440)
Somatic coliphage (*E. coli* C host)	4.1% (18/444)
Somatic and male-specific coliphage (*E. coli* C–3000 host)	10.8% (48/444)
PCR	31.5%
Norwalk viruses (PCR)	0.96% (3/312)
Enteroviruses (PCR)	15.9% (68/427)
Rotaviruses (PCR)	14.6% (62/425)
Hepatitis A viruses (PCR)	7.2% (31/429)

2. Lieberman et al., (1994, 1999) (EPA/AWWARF Study)

The study objectives included the following: (1) develop and evaluate a molecular biology (PCR) monitoring method; (2) obtain occurrence data for human enteric viruses and *Legionella* (a bacterial pathogen) in ground water; and (3) assess the microbial indicators of fecal contamination. These objectives were accomplished by sampling vulnerable wells nominated by States to confirm the presence of fecal indicators (Phase I) and then choosing a subset of these for monthly sampling for one year (Phase II).

In Phase I, well vulnerability was established using historical microbial occurrence data and waterborne disease outbreak history, known sources of human fecal contamination in close proximity to the well, and sensitive hydrogeologic features (*e.g.,* karst). Ninety-six of the 180 potentially vulnerable wells were selected for additional consideration. Selected wells were located in 22 States and 2 US territories. Additional water quality information was then successfully obtained for 94 of the wells through use of a single one liter grab sample which was subsequently tested for several microbial indicators (see Table II–6). The wells from Phase I served as the well selection pool for Phase II sampling.

In Phase II, 23 of the Phase I wells were selected for monthly sampling for one year. Seven additional wells were selected from a list of state-nominated wells for a total of 30 wells, located in 17 States and 2 US territories. The additional seven wells were based on other criteria, including historical water quality data, known contaminant sources in proximity to the well, hydrogeologic character or to replace wells that were no longer available for sampling. Samples were analyzed for enteroviruses, *Legionella,* enterococci, *E. coli, Clostridium perfringens,* total coliforms, somatic coliphage, male-specific coliphage and Bacteroides phage. For each sample analyzed for enteric viruses and bacteriophages, an average of approximately 6,000 liters of water were filtered and analyzed by cell culture.

Twenty samples from seven wells were enterovirus positive and were speciated by serotyping. Coxsackievirus and echovirus, as well as reovirus, were identified. The range in virus concentration in enterovirus-positive samples was 0.9–212 MPN/100 liters (MPN, or most probable number, is an estimate of concentration).

The hydrogeologic settings for the seven enterovirus-positive wells were

karst (3), a gravel aquifer (1), fractured bedrock (2), and a sandy soil and alluvial aquifer (1). The karst wells were all positive more than once. The gravel aquifer was also enterovirus-positive more than once, with 4 of 12 monthly samples positive.

3. Missouri Ozark Aquifer Study #1

The purpose of this study was to determine the water quality in recently constructed community public water system wells in the Ozark Plateau region of Missouri. This largely rural region is characterized by carbonate aquifers, both confined and unconfined, with numerous karst features throughout. A confining layer is defined in this study as a layer of material that is not very permeable to ground water flow and that overlays an aquifer and acts to prevent water movement into the aquifer.

The US Geological Survey, working with the Missouri Department of Natural Resources, selected a total of 109 wells, in both unconfined and confined aquifers (Davis and Witt, 1998, 1999). In order to eliminate poorly constructed wells from the study, most of the selected wells had been constructed within the last 15 years. Wells were also selected to obtain good coverage of the aquifer and to reflect the variability in land use. All wells were sampled twice, in summer and winter. Evidence of fecal contamination was found in a number of wells. Thirteen wells had samples that were PCR-positive for enterovirus.

4. Missouri Ozark Aquifer Study #2

The purpose of this study is to determine the water quality in older (pre-1970) CWS wells in the Ozark Plateau region of Missouri to supplement the Missouri Ozark Aquifer Study #1, by Davis and Witt (1998, 1999). This largely rural region is characterized by carbonate aquifers, both confined and unconfined, with numerous karst features throughout.

The US Geological Survey, working with the Missouri Department of Natural Resources, sampled a total of 106 wells (Femmer, 1999), in both unconfined and confined aquifers. Wells (all of which were constructed before 1970) were selected for monitoring to obtain good coverage of the aquifer, and to reflect the variability in land use. Priority was given to wells that had completion records, well operation and maintenance history and wells currently being used. Each well was sampled once (during the spring). No wells were enterovirus-positive by cell culture.

5. Missouri Alluvial Aquifer Study

The purpose of this study was to determine water quality in wells located in areas that were subjected to recent flooding. The wells are located primarily in the thick, wide alluvium of the Missouri and Mississippi rivers. Sampling (117 samples) occurred during the period of March through June 1996. Twelve wells served as control wells (uncontaminated) and were sited in ''deep rock'' aquifers or upland areas. A total of 64 wells were sampled.

Many of the wells had been flooded. Fifty-five were affected by a flood in 1995. In addition, some of the wells sampled had been flooded around the surface well casing prior to the sampling event, and several were flooded at the time of sampling (Vaughn, 1996).

6. Wisconsin Migrant Worker Camp Study

The purpose of this study was to determine the quality of drinking water in the 21 public ground water systems serving migrant worker camps in Wisconsin (US EPA, 1998a). These transient, non-community water systems are located in three geographic locations across the State. Each well was sampled monthly for six months, from May through November, 1997. The study conducted sampling for male-specific coliphage, total coliforms and *E. coli.* When detections of coliforms occurred, the specific type of coliform was further identified (speciated). One total coliform positive sample was identified to contain *Klebsiella pneumoniae.* Along with the microbial indicators, nitrate and pesticides were also measured.

Other factors were compared to the microbial and chemical sampling results of the study. Well construction records were available for 14 of the wells. The mean casing depth was 109 feet (range 40 to 282 feet) and the mean total well depth was 155 feet (range 44 to 414 feet). Most of these 14 wells are also reported to terminate in a sand or sandstone formation.

Investigators detected male-specific coliphage in 20 of 21 wells during the six-month sampling period, but never detected *E. coli.* In addition, four wells had nitrate levels that exceeded the EPA MCL for nitrate.

7. EPA Vulnerability Study

The purpose of this study was to conduct a pilot test of a new vulnerability assessment method by determining whether it could predict microbial monitoring results (U.S. EPA 1998b). The vulnerability assessment assigned low or high vulnerability to wells according to their hydrogeologic settings, well construction and age, and distances from contaminant sources. A total of 30 wells in eight States were selected to represent ten hydrogeologic settings. Selection was based on the following criteria: (1) Wells representing a variety of conditions relevant to the vulnerability predictions; (2) wells with nearby sources of potential fecal contamination; and (3) wells with sufficient well and hydrogeologic information available.

Samples were taken and tested for enteroviruses (both by cell culture and PCR), hepatitis A virus (HAV) (by PCR), rotavirus (by PCR), Norwalk virus (by PCR), and several indicators (total coliforms, enterococci, male-specific coliphage, and somatic coliphage). The only positive result was one PCR sample positive for HAV.

8. US-Mexico Border Study

The purpose of this study was to determine water quality in wells sited in alluvium along the Rio Grande River between El Paso, Texas and the New Mexico border (U.S. EPA, in preparation). The 17 wells selected were perceived to be the most vulnerable, based on well depth, chloride concentration and proximity to contamination sources, especially the Rio Grande River.

The wells tested are relatively shallow and all serve less than 10,000 people. One well serves 8,000 people, while seven wells serve fewer than 100 people. Well depths range from 65 feet to 261 feet, but most are about 150 feet deep. This signifies that water was collected from the middle aquifer, a shallow but potable aquifer. Wells shallower than 65 feet contain chloride concentrations prohibitively high for drinking water.

Samples were collected from each well and tested for enteroviruses (by cell culture), somatic coliphage, and male-specific coliphage. None of the sites were positive for any of the viruses tested.

9. Whittier, CA, Coliphage Study

The purpose of this study was to determine the presence of fecal contamination in all wells located within 500 feet down-gradient of a water recharge infiltration basin (Yanko *et al.,* 1999). The 23 wells were sampled once per month for six months.

The wells are sited in similar hydrogeologic settings, although they vary in age and depth. The hydrogeologic setting is primarily a thick layer of unconsolidated sand, with lesser amounts of other sized grains. About 30% of the recharge volume to

the wells is reclaimed water. Wells were all constructed between 1919 and 1989 and produce water from depths ranging from 60–888 feet.

The wells were sampled monthly for a six month period. The samples were tested for total coliforms and indicators of fecal contamination, including male specific coliphage, somatic coliphage, and *E. coli*. Coliphage were found in all wells, and repeatedly in 20 of the 23 wells.

10. Oahu, HI Study

The purpose of this study was to establish a water quality monitoring program to assess the microbial quality of deep ground water used to supply Honolulu (Fujioka and Yoneyama, 1997). A total of 71 wells were sampled, 32 of which were sampled for viruses and 39 of which were sampled for bacteria. The wells are located in carbonate or basalt aquifers.

Each of the wells was tested for several pathogens and indicators of fecal contamination. Bacterial samples taken from 39 wells (79 samples) were tested for total coliforms, fecal streptococci, *Clostridium perfringens*, heterotrophic bacteria (by m-HPC), and *Legionella* (by PCR). Sample volumes were 100 mL for *C. perfringens* and heterotrophic bacteria, and both 100 mL and 500 mL for coliforms and fecal streptococci. For FRNA coliphage (male-specific coliphage), one liter samples from 32 wells (35 samples) were tested by membrane adsorption-elution method, while 24 wells (24 samples) were tested by an enrichment technique developed by Yanko. None of the wells were coliphage-positive, and only one sample each was positive for *E. coli* and fecal streptococci.

11. New England Study

The purpose of this study was to: (1) Determine the prevalence of enteric pathogens in New England's public water supply wells; (2) assess the vulnerability of different systems; and (3) evaluate various fecal indicators.

Wells were selected based on the following criteria: (1) Must have constant withdrawal throughout the year; (2) must be near septic systems, (3) should have, if possible, a history of violations of the MCL for total coliforms or elevated nitrate levels; and (4) must not have direct infiltration by surface water (Doherty, 1998).

Wells were nominated, characterized, selected and sampled by regulatory staff of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. The selection process considered wells in different hydrogeologic settings. Of the 124 total wells, 69 (56%) were located in unconfined aquifers, 31 (25%) were located in bedrock aquifers, 10 (8%) were located in confined aquifer hydrogeologic settings, and 14 (11%) were located in unknown aquifer settings. Each well was sampled quarterly for one year. Enterococci were identified in 20 of 124 wells (16%) and in 6 of 31 (19%) bedrock aquifer wells. Two wells were enterovirus-positive using cell culture methods, both in unconsolidated aquifers. One of these two wells is 38 feet deep and the other well is 60 feet deep. Final results from this study are not yet available.

12. California Study

The purpose of this research is two-fold: (1) To assess the vulnerability of ground water to viral contamination through repeated monitoring, and (2) to assess the potential for bacteria and coliphages to serve as indicators of the vulnerability of ground water to viral contamination (Yates 1999).

Eighteen wells were tested monthly for human enteroviruses (by cell culture (direct RT–PCR, Immunomagnetic separation reverse transcriptase (IMS–RT–PCR) and integrated cell culture RT–PCR) and PCR), HAV (by PCR), rotaviruses (by PCR), somatic and male-specific coliphage, and total coliforms and fecal streptococci. The depth of the wells is variable, but is on the order of about 200 feet (the deeper the well, the less likely contamination). There are some intermittent confining layers.

Of the 230 samples tested for enteroviruses, 6 samples from 6 of the 18 wells were cell culture positive for enteroviruses. Final results from this study are not yet available.

13. Three State PWS Study (Wisconsin, Maryland and Minnesota)

The purpose of the three-state study is to characterize the extent of viral contamination in PWS wells by testing wells in differing hydrogeologic regions and considering contamination over time (Battigelli, 1999). Wells were sampled quarterly for one year in Wisconsin (25 wells), Minnesota (25 wells), and will be sampled in Maryland (up to 35 wells).

Three wells in Wisconsin were positive for enteroviruses by cell culture. Final results for this study are not yet available.

TABLE II–6.—GROUND WATER MICROBIAL OCCURRENCE STUDIES/SURVEYS

Study	Number of PWS wells sampled and location	Sampling frequency/volume	Indicators monitored (number of POS. wells/number of wells total, unless otherwise indicated)	Pathogenic viruses, *Legionella* (number of POS. wells/number of wells total, unless otherwise indicated)
1. AWWARF Study.	448 wells; 35 States.	Sampled once (25 wells sampled twice); 539 samples total, not all analyses conducted on all samples. Sampling volumes: 1512L eluated for virus analyses (5 liter equivalent for RT–PCR, 600L for cell culture), Coliphage 15L, Bacteria 200 mL.	Male-sp. coliphage, host *Salmonella* WG–49 (42/440); Somatic coliphage, host *E. coli C* (18/444); Coliphage, host *E. coli* C–3000 (48/444); Total coliform (44/445); enterococci (31/355); *C. perfringens* (1/57).	*Cell Culture:* Enterovirus (21/442); *PCR:* Rotavirus (62/425), Hepatitis A virus (31/429), Norwalk virus (3/312), Enterovirus (68/427).
2a. EPA/AWWARF Phase I Study.	94 wells; 22 States plus PR and USVI.	One sample, 1 L	Somatic coliphage 5/94; 1*; Total coliform 31/94; 9*; *E. coli* 18/94; 5*; enterococci 17/94; 3*; *C. perfringens* 4/94; 0*; *indicates number of wells positive in Phase I which were not positive or not sampled in Phase II.	

TABLE II–6.—GROUND WATER MICROBIAL OCCURRENCE STUDIES/SURVEYS—Continued

Study	Number of PWS wells sampled and location	Sampling frequency/volume	Indicators monitored (number of POS. wells/number of wells total, unless otherwise indicated)	Pathogenic viruses, *Legionella* (number of POS. wells/number of wells total, unless otherwise indicated)
2b. EPA/ AWWARF—Phase II Study.	30, of which 23 were from Phase I; 17 States plus PR and USVI.	Monthly for one year; Average volume filtered: 6,037 L; Microscopic Particulate Analysis (MPA) data available for each well.	Somatic coliphage (16/30); Male specific coliphage (6/30); *Bacteroides* bacteriophage (6/30); Somatic *Salmonella* bacteriophage (6/30); Total coliform (24/30); enterococci (21/30); *C. perfringens*(10/30); *E. coli* (15/30); *E. coli* H7:O157 (0/7).	*Cell Culture*: Enterovirus (7/30); *PCR*: polio, entero, Hepatitis A, Norwalk, rota (results not available), (300+ samples from 30 wells; several wells cell culture positive multiple times); *Legionella* sp. (14/30), *Legionella pneumophila* (6/30).
3. Missouri Ozark Plateau Study #1 (Davis and Witt, 1999).	109 wells	Two samples/well, 25 wells sampled once for tritium, 200–300 L ground water filtered at the well head.	Somatic coliphage (1/109); Male specific coliphage (10/109); Fecal streptococci (1/109); Fecal coliform (2/109); *E. coli* (0/109).	*Cell Culture*: Enterovirus (0/109); *PCR*: Enterovirus (13/109).
4. Missouri Ozark Plateau Studies #2 (Femmer, 1999) (pre-1970 wells).	106 wells	One sample, 200–300 L filtered at the well head.	Somatic coliphage (3/106); Male specific coliphage (3/106); Fecal streptococci (8/106); Fecal coliform (8/106); *E. coli* (9/106).	Study in progress; *Cell Culture*: Enterovirus (0/106).
5. Missouri Alluvial Study.	64 wells	Sampling occurred during a four month period. Some sampling done during flooding.	Somatic coliphage (1/81); Male specific coliphage (1/81); *Bacteroides* bacteriophage (1/81); Total coliform (33/81); Fecal coliform (5/81); Fecal streptococci (12/81).	*Cell Culture*: Enterovirus (1//81).
6. Wisconsin Migrant Worker Camp Study.	21 wells	Monthly: Bacteria—6 mos.; Phage—5 mos.; Bacteria—100 mL; Phage—1L.	Male specific coliphage (20/21); Total coliform (14/21); *E. coli* (0/21); *K. pneumoniae* (1/21).	
7. EPA Vulnerability Study.	30 wells in 8 States.	Each well visited once. Two 1L grab samples and 1500–L sample Equiv. vol. 650L for enterovirus, 100 mL for bacteria, 10 mL to 100L for coliphage, PCR?.	Male specific coliphage (0/30); Somatic coliphage (2/24; large volume); Total coliform (4/30); enterococci (0/30).	*Cell Culture*: enterovirus (0/30); *PCR*: HAV (1/30), Rota (0/30), Norwalk (0/30), enterovirus (0/30).
8. US-Mexico Border Study (TX and NM).	17 wells	3 (300–1000 gallon) samples/well	Male specific coliphage (0/17); Somatic coliphage (0/17).	*Cell Culture*: Enterovirus (0/17).
9. Whittier, CA, Coliphage Study.	23 wells	Once a month for 6 months; 4L samples.	Male specific coliphage (18/23); Somatic coliphage (23/23); Total coliform (4/23); *E. coli* (0/23).	
10. Oahu, Hawaii Study.	Virus—32 wells Bacteria—39 wells.	Each well sampled 1–4 times; total 79 samples, Virus—1–L; *C. perfringens*, HPC—0.1L; Coliforms, fecal strep—0.1L and 0.5L.	Male specific coliphage (0/32); Somatic coliphage (0/32); Total Coliform (3/39); *E. coli* (1/39); Fecal Streptococci (1/39); *C. perfringens* (0/39).	*Legionella* sp. (PCR; 15/26), *Legionella pneumophila* (PCR; 1/27).
11. New England Study.	124 wells; 6 States.	Each well sampled four times over one year; Up to 1500–L sample for virus.	Study in progress; Male specific coliphage (4/79); Somatic coliphage (1/70); Total coliform (27/124); Aeromonas hydrophila (19/122); *C. perfringens* (6/119); *E. coli* (0/124); enterococci (20/124).	Study in progress; *Cell Culture*: Enterovirus (2/122); *PCR*: Enterovirus (results not available).
12. California Study.	18 wells	14 of 18 wells sampled 12 to 22 times (monthly); Average sample volume 1784 L (range 240–3331 L) 1 l grab sample for indicators; (Coliphage analyzed using 10 mL grab samples, 1–L enrichment samples, IMDS filter eluates and filter concentrates).	Study in progress; Male specific coliphage: (hosts *E. coli* FAMP, S. *typhimurium* WG–49) (4/18); Somatic coliphage: host *E. coli* 13706 (13/18); Total coliform (7/18); Fecal streptococci (0/18).	Study in progress; *Cell Culture*: enterovirus (6/18); *PCR*: HAV (0/18), Rota (0/18), enterovirus (direct RT–PCR) (6/18), IMS–RT–PCR (10/18), Integrated *Cell Culture* PCR enterovirus (4/18)).
13. Three-State Study (Wisconsin, Maryland, Minnesota).	50 wells (25 from MN, 25 from WI, additional wells from MD).	Each well sampled four times over one year.	Study in progress; Somatic coliphage; Male specific coliphage; Total coliform; enterococci; *C. perfringens*; *E. coli*.	Study in progress; *Cell Culture*: enterovirus (3/25).

D. Health Effects of Waterborne Viral and Bacterial Pathogens

To assess the public health risk associated with a waterborne pathogen, or group of pathogens, both occurrence data and health effects data are needed. The previous section discussed the occurrence in ground water of pathogens and indicators of fecal contamination. This section discusses the health effects associated with waterborne pathogens, first viral agents and then bacterial.

Viral Pathogens

Table II–7 and II–8 list viral and bacterial pathogens that have caused waterborne disease in ground waters. Unlike some bacterial pathogens, viruses cannot reproduce or proliferate outside a host cell. Viruses that infect cells lining the human gut are enteric viruses. With a few exceptions, viruses that can infect human cells typically cannot infect the cells of other animals and vice versa. This contrasts with many bacterial pathogens, which often have a broader host range. Some enteric viral pathogens associated with water may infect cells in addition to those in the gut, thereby causing mild or serious secondary effects such as myocarditis, conjunctivitis, meningitis or hepatitis. There is also increasing evidence that the human body reacts to foreign invasion by viruses in ways that may also be detrimental. For example, one hypothesis for the cause of adult onset diabetes is that the human body, responding to coxsackie B5 virus infection, attacks pancreatic cells in an auto-immune reaction as a result of similarities between certain pancreas cells and the viruses (Solimena and De Camilli, 1995).

When humans are infected by a virus that infects gut cells, the virus becomes capable of reproducing. As a result, humans shed viruses in stool, typically for only a short period (weeks to a few months). Shedding often occurs in the absence of any signs of clinical illness. Regardless of whether the virus causes clinical illness, the viruses being shed may infect other people directly (by person-to-person spread, contact with infected surfaces, *etc.*) and is referred to as secondary spread. Waterborne viral pathogens thus may infect others via a variety of routes.

TABLE II–7.—SOME ILLNESSES CAUSED BY FECAL VIRAL PATHOGENS

Enteric virus	Illness
Poliovirus	*Paralysis.*
Coxsackievirus A	*Meningitis*, fever, respiratory disease.
Coxsackievirus B	*Myocarditis*, congenital heart disease, rash, fever, *meningitis*, encephalitis, *pleurodynia*, diabetes melitis, *eye infections*.
Echovirus	*Meningitis*, encephalitis, *rash, fever, gastroenteritis.*
Norwalk virus and other caliciviruses	*Gastroenteritis.*
Hepatitis A virus	*Hepatitis.*
Hepatitis E virus	*Hepatitis.*
Small round structured viruses (probably caliciviruses)	*Gastroenteritis.*
Rotavirus	*Gastroenteritis.*
Enteric Adenovirus	Respiratory disease, *eye infections*, gastroenteritis.
Astrovirus	*Gastroenteritis.*

(Data from the 1994 Encyclopedia of Microbiology, *Underline*indicates disease causality rather than association)(Lederberg, 1992).

Bacterial Pathogens

Bacterial pathogens may be primary pathogens (those that can cause illness in most individuals) or secondary or opportunistic pathogens (those that primarily cause illness only in sensitive sub-populations). Unlike most primary pathogens, some opportunistic bacterial pathogens can colonize and grow in the biofilm in water system distribution lines. Some waterborne bacterial agents cause disease by rapid growth and dissemination (*e.g., Salmonella*) while others primarily cause disease via toxin production (*e.g., Shigella, E. coli* O157, *Campylobacter jejuni*). *Campylobacter, E. coli* and *Salmonella* have a host range that includes both animals and humans; *Shigella* is associated with humans and some other primates (Geldreich, 1996). As noted previously, some waterborne bacterial pathogens can survive a long time outside their hosts.

Most of the waterborne bacterial pathogens cause gastrointestinal illness, but some can cause severe illness too. For example, *Legionella* causes Legionnaires Disease, a form of pneumonia that has a fatality rate of about 15%. It can also cause Pontiac Fever, which is much less severe than Legionnaires Disease, but causes illness in almost everyone exposed. A few strains of *E. coli* can cause severe disease, including kidney failure. One strain, *E. coli* O157:H7 has caused several waterborne disease outbreaks since 1990. It is a prime cause of bloody diarrhea in infants, and can cause hemorrhagic colitis (severe abdominal cramping and bloody diarrhea). In a small percentage of cases, hemorrhagic colitis can lead to a life-threatening complication known as hemolytic uremic syndrome (HUS), which involves destruction of red blood cells and acute kidney failure. From 3% to 5% of HUS cases are fatal (CDC, 1999), and most commonly found in young children and the elderly. Some of the opportunistic pathogens can also cause a variety of illnesses including meningitis, septicemia, and pneumonia (Rusin *et al.*, 1997).

TABLE II–8.—SOME ILLNESSES CAUSED BY MAJOR WATERBORNE BACTERIAL PATHOGENS

Bacterial pathogen	Illnesses
Campylobacter jejuni	Gastroenteritis, meningitis, associated with reactive arthritis and Guillain-Barre paralysis.
Shigella species	Gastroenteritis, dysentery, hemolytic uremic syndrome, convulsions in young children, associated with Reiters Disease (reactive arthropathy).
Salmonella species	Gastroenteritis, septicemia, anorexia, arthritis, cholecystitis, meningitis, pericarditis, pneumonia, typhoid fever.

TABLE II–8.—SOME ILLNESSES CAUSED BY MAJOR WATERBORNE BACTERIAL PATHOGENS—Continued

Bacterial pathogen	Illnesses
Vibrio cholerae	Cholera (dehydration and kidney failure).
Escherichia coli (several species)	Gastroenteritis, hemolytic uremic syndrome (kidney failure).
Yersinia entercolitica	Gastroenteritis, acute mesenteric lymphadenitis, joint pain.
Legionella species	Legionnaires Disease, Pontiac Fever

(Data from the 1994 Encyclopedia of Microbiology, Underline indicates disease causality rather than association)(Lederberg, 1992).

E. Risk Estimate

1. Baseline Risk Characterization

This section provides an estimate of the number of people that may be at risk of microbial illness associated with consumption of fecally contaminated drinking water in populations served by ground water systems. EPA has prepared estimates of the numbers of people at risk of viral illness (and possibly death) from three conditions in which fecal contamination may be introduced to ground water systems: fecal contamination in the source water of systems without disinfection; fecal contamination in the source water of systems with inadequate (less than 4-log as discussed later) or failed disinfection; and fecal contamination of the distribution system.

The first condition in which EPA characterizes the baseline risk is for source contaminated ground water systems which do not have disinfection treatment. EPA characterizes the risk to consumers in these systems in five steps: (1) Calculating the population served by undisinfected systems using ground water sources; (2) determining the occurrence of the pathogens of concern in these systems; (3) assessing the exposure to the pathogens of concern; (4) determining the pathogenicity (likelihood of infection) based on dose-response information for each of the pathogens characterized; and (5) calculating the number of illnesses among the population served resulting from consumption of water containing the pathogens.

EPA then estimates additional illnesses resulting from systems with inadequate or failed disinfection treatment and fecally contaminated source water, and systems in which fecal contamination is introduced into the distribution system. These additional illnesses are estimated based on the causes of contamination which lead to waterborne disease outbreaks reported to the CDC in ground water systems from 1991 to 1996. To estimate these additional illnesses, EPA calculated the ratio of the outbreak illnesses in systems with inadequate or failed disinfection treatment to outbreak illnesses in systems without any disinfection, and the ratio of outbreak illnesses in systems with distribution system contamination to outbreak illnesses in systems without any disinfection.

2. Summary of Basic Assumptions

This risk assessment uses a number of assumptions to arrive at an estimate of the number of people at risk of illness or death due to consumption of water from systems with fecal contamination. Some of these assumptions are necessary because data in these areas simply does not exist.

The feasibility of performing a risk analysis on each and every microbial contaminant is diminished when considering the wide range of different microbial contaminants that exist, and that detection methods for all of these contaminants do not exist. Therefore, the risk assessment assumes that the only people exposed to viral contamination are the people served by those wells which test positive for the two viruses used in the risk assessment model, and the exposed population will be exposed to the virus concentration throughout the entire year. The assumption that the population is exposed only to viruses which are accurately described by the model viruses may lead to an underestimation of exposure.

The model viruses which were chosen to act as surrogates for all viruses fall into two categories; those viruses which have low-to-moderate infectivity but relatively severe health effects, and those viruses which have high infectivity but relatively mild health effects. Exposure to viruses that do not fall into these categories may result in an underestimate or overestimate of risk. Risks are not directly quantified for bacterial contaminants because EPA does not have sufficient data to directly model bacterial risk. However, EPA has adjusted its risk estimate for viral illness to approximate for the risk of bacterial illness.

The simplifying assumptions used in this risk assessment, as well as assessing the exposure in only the positive wells, yields an estimated average risk that EPA assumes is a best estimate of the actual risk given available data.

3. Population Served by Untreated Ground Water Systems

EPA estimates there are 44,000 community ground water systems (CWS) serving 88 million people; 19,000 non-transient, non-community ground water systems (NTNCWS) serving five million people; and 93,000 transient non-community ground water systems (TNCWS) serving 15 million people (SDWIS, 1997a). Of these systems, EPA estimates that 68% percent of CWSs are disinfected (CWSS, 1997) (US EPA, 1997c). Larger CWSs are more likely to practice disinfection than are smaller CWSs (*e.g.,* 81% of CWSs serving more than 100,000 people are disinfected while 45% of systems serving less than 100 people disinfect. Estimates of treatment for noncommunity water systems are not as detailed. However, based upon information from State drinking water programs, EPA estimates 28% of NTNCWS and 18% of TNCWS disinfect (US EPA, 1996a).

Based upon the number of people served by ground water systems, and the percentage of systems which disinfect, EPA estimates that 18 million people are served untreated ground water from CWSs, four million people are served untreated water from NTNCWSs, and 13 million people are served untreated water from TNCWSs. There is a potential for double or triple counting of the same people within these estimates since a number of people may be served ground water from more than one of the system type categories. For example, a person may consume water from a CWS at home, and a NTNCWS at work or a TNCS while on vacation. EPA has addressed the potential for double counting in the analysis by assuming that individuals do not consume water from each system type every day (see section V).

4. Pathogens Modeled

EPA is concerned about ground water systems which are fecally contaminated since drinking water in these systems may contain pathogenic viruses and/or bacteria. A wide number of viral and bacterial pathogens have been associated with waterborne disease in ground water systems. However, there are inadequate data for EPA to

characterize the risk attributable to each pathogen because detection methods are not available for all pathogens. Additionally, detection methods which are available may be insensitive and incapable of detecting the presence of viruses at very low concentrations. However, even at low concentrations, viruses in drinking water can result in infection. To the extent that detection methods do not exist for a particular pathogen, there may be a resultant underestimation of the risk of illness and death.

In this analysis, EPA estimates the number of illnesses annually associated with two types of pathogenic viruses found in fecally contaminated ground water. These two types of viruses are designated as Type A and Type B viruses for this analysis. Type A viruses represent those viruses which are highly infective, yet have relatively mild symptoms (*e.g.,* gastroenteritis). For this analysis, rotavirus is used as a surrogate for all Type A viruses because rotavirus has been detected in drinking water sources, dose-response data have been prepared for rotavirus and rotavirus has been implicated as the etiologic agent in incidents of waterborne disease. Type B viruses represent those viruses which have low-to-moderate infectivity, yet have potentially more severe symptoms (*e.g.,* myocarditis), and are represented by echovirus. Echovirus also has available dose-response data (Regli *et al,* 1991) and has been implicated in a waterborne disease outbreak (Haefliger *et al.,* 1998).

The risk assessment used model viruses as surrogates of the actual viruses present. As a result, the risk assessment provides an estimation of risks. The additional risks from other viruses may be higher or lower depending on their occurrence or pathogenicity. For example, if the risk assessment estimated the risks from exposure to Norwalk virus (a Type A virus), using rotavirus as a surrogate, the morbidity rate may be higher for adults than the rate assumed in the model. An outbreak in an Arizona resort in 1989 was believed to be caused by a Norwalk-like virus. This agent may have been responsible for an outbreak which caused illness in 110 out of 240 guests of all ages (Lawson *et al,* 1991), a 46% morbidity rate. This is much higher than the morbidity rate of 10% for Type A virus among people older than two. National occurrence data do not exist for many of the other pathogens that may occur in drinking water; therefore, EPA has limited its estimation of risk to only those viral pathogens for which occurrence data and dose response data are available.

Occurrence studies show a significant occurrence of bacterial indicators in ground water wells; for example, almost 9% percent of the wells sampled in the AWWARF study tested positive for the presence of enterococci (Abbaszadegan *et al.,* 1999). However, EPA cannot directly estimate national illnesses from bacterial pathogens such as *Salmonella,* due to a lack of occurrence data for those pathogens. EPA believes that the majority of waterborne illnesses due to unknown etiological agents are caused by viruses because viruses move more readily in the ground, remain viable longer and are more infectious than bacteria. Also, more methodologies exist for the identification of bacterial pathogens than for viral pathogens and therefore bacterial pathogens are more likely to be identifiable. The CDC data shows that for every 100 viral or unknown etiological agent illnesses there were 20 bacterial illnesses. Therefore, EPA estimates that the number of viral illnesses can be increased by 20% to account for bacterial illnesses in ground water systems.

5. Microbial Occurrence and Concentrations

EPA reviewed the ground water viral occurrence data (see discussion of occurrence studies in section II. C.) to develop estimates of: the portion of ground water sources which are contaminated with viruses, the period of time in which the wells are contaminated, and the concentration of viruses within the contaminated wells. EPA believes that improperly constructed wells may have significantly higher virus occurrence and concentrations than properly constructed wells (wells which do not comply with State well construction codes). Improperly constructed wells are likely to have more pathways for the introduction of viruses and less natural filtration by the overlying hydrogeologic material. Therefore, the exposure and risks from consumption of water from improperly constructed wells will most likely be higher. As a result, the exposure and risks should be assessed separately for properly and improperly constructed wells in order to develop a range reflecting national conditions.

EPA determined that the study conducted by AWWARF represents conditions in properly constructed wells and the EPA/AWWARF (Lieberman *et al.,* 1994, 1999) study represents conditions in improperly constructed wells. EPA selected the AWWARF study as representative of properly constructed wells (*e.g.,* wells with casing and grout to confining layers, sanitary seals, *etc.*) because it excluded wells of improper construction and the wells sampled were representative of hydrogeologic conditions for water supply wells in the United States. However, the wells selected may not have been representative of the probability of fecal contamination in ground water wells nationally. As noted in section II.C.1., one-third of the wells in this study were originally selected for the purpose of evaluating the effectiveness of the PCR method based on criteria that may over represent high risk wells. The remaining two-thirds were selected to balance the sample with wells that were representative of hydrogeologic conditions for drinking water wells nationally. EPA requests comment and data which would help assess the representativeness of the wells in the AWWARF study sample. However, EPA believes that the AWWARF study data represents the best currently available data on occurrence of viral pathogens in properly constructed wells and has thus used it as the basis of baseline incidence estimates.

EPA selected the EPA/AWWARF study to be representative of wells of improper construction because it sampled wells which were determined to be vulnerable to contamination. The EPA/AWWARF study considered wells as vulnerable based on one or more of the following considerations: hydrogeology, well construction, State nominations, microbial sampling results, close proximity to known sources of fecal contamination, and water quality history. For the purposes of the risk assessment, all wells determined to be vulnerable were used as surrogates for improperly constructed wells. The results from this study may over estimate the risks from improperly-constructed wells generally, since it included only wells that were deliberately selected through a several step process to be highly vulnerable to contamination (see section II.C.2.). EPA estimated that 83% of systems have properly constructed wells based upon data from ASDWA's Survey of Best Management Practices for Community Ground Water Systems (ASDWA, 1998).

The AWWARF study data include viral cell culture assay results which detect the presence of viable enterovirus (including echovirus and other Type B viruses) in the samples. Twenty-one of the 442 wells sampled (4.8%) tested positive for the Type B viral cell culture. EPA determined that this data can be used to estimate the percentage of properly constructed wells which are contaminated at a given point in time with Type B viruses. The AWWARF

study data also include rotavirus PCR results which indicate that 62 of the 425 (14.6%) wells sampled contained rotavirus genetic material. EPA determined that the PCR results may be an overestimation of the portion of wells with viable Type A viruses since PCR methods do not distinguish between viable and non-viable viruses. To calculate the portion of PCR positive wells which contain viable viruses EPA compared the enterovirus (Type B) cell culture results to the enterovirus (Type B) PCR analysis and found that for every enterovirus cell culture positive well, there were 3.3 PCR enterovirus positive wells. EPA estimated that the 1/3.3 rotavirus PCR wells contained viable virus, and therefore 4.4% (14.6%/3.3) of all properly constructed wells were contaminated with Type B viruses at any one time. Viral and bacterial indicator data indicate there are a greater percentage of wells in the study which were fecally contaminated than contained the viral pathogens at the time of sampling. For example, almost 16% of all wells tested positive for viral cell culture, male specific coliphage or enterococci.

The EPA/AWWARF study sampled wells vulnerable to contamination monthly for a one year period and found that 6.0% of the samples tested positive for enterovirus (Type B) cell culture. Since cell culture methods are not available for rotavirus (the representative of Type A viruses), the EPA/AWWARF study tested samples using PCR methods for the presence of rotavirus to estimate the occurrence of Type A viruses in improperly constructed wells. However, the PCR data is still under review by researchers and unavailable for consideration in this analysis. EPA therefore based the estimate of occurrence of viable Type A viruses in improperly constructed wells on the ratio of viable Type A virus in the AWWARF study (4.4%) to Type B viruses in the AWWARF study (4.7%). Applying this ratio (4.4%/4.7%) to the percentage of improperly constructed wells containing Type B viruses (6.0%), EPA estimates the percentage of improperly constructed wells with Type A virus contamination is 5.5%.

EPA estimated Type A and Type B virus concentrations are 0.36 viruses/100L for properly constructed wells based on the mean enterovirus concentration in the AWWARF study. EPA also estimated Type A and Type B virus concentrations to be 29 viruses/100L for improperly constructed wells based on the mean enterovirus concentration in EPA/AWWARF study. Although these studies determined the concentrations of enteroviruses (Type B viruses) only, for the purposes of this analysis EPA assumed the concentrations of Type A viruses and Type B viruses were equivalent.

6. Exposure to Potentially Contaminated Ground Water

EPA developed estimates of the population potentially exposed to viral pathogens based upon the estimates of population served by undisinfected systems and the portions of those systems which are estimated to be virally contaminated. In CWS, 18 million people are served undisinfected ground water. Assuming 17% of wells serving these people are improperly constructed (and 83% are properly constructed) from the results of the ASDWA BMP Survey (ASDWA, 1997), and Type A viruses occur in 4.4% of properly constructed wells and 5.5% of improperly constructed wells, the population potentially exposed to Type A viruses in CWS is 842,000. Similar calculations can be conducted to obtain the population exposed to Type A viruses in NTNCWS, as well as Type B viruses in all ground water systems. EPA's estimates of the population potentially exposed to the viruses are presented in Table II–9. Many of the people exposed to the Type A viruses are also exposed to the Type B viruses, therefore these number cannot be added.

TABLE II–9.—POPULATION POTENTIALLY EXPOSED TO VIRALLY CONTAMINATED DRINKING WATER IN UNDISINFECTED GROUND WATER SYSTEMS

System type	Population potentially exposed to type A virus	Population potentially exposed to type B virus
CWS	842,000	918,000
NTNCWS ..	175,000	191,000
TNCWS	567,000	619,000

To estimate the risk of illness from consumption of undisinfected ground water, EPA estimated people consume an average 1.2 liters of water per day based upon the 1994–1996 USDA Continuing Survey of Food Intakes by Individuals (US EPA, 2000a). EPA accounted for the variability in consumption by modeling consumption as a custom distribution fit to age groups in the survey data. EPA also assumed that people consume water from CWSs 350 days per year; from NTNCWSs 250 days per year; and from TNCWSs 15 days per year. EPA notes that these assumptions may allow for some double counting of exposure, but EPA is not aware of data to allow a more refined breakdown of consumption. EPA requests comment on these assumptions.

7. Pathogenicity

After estimating the population potentially exposed to untreated (i.e., not disinfected) contaminated ground water and the amount of water consumed, the next step is to assess the pathogenicity of the viruses. Once viruses are consumed, the likelihood of infection and illness varies depending on the virus.

For this analysis, the likelihood of infection from ingestion of one or more Type A or Type B viruses are estimated based on dose response equations developed for rotavirus (Ward *et al.,* 1986) and echovirus (Schiff *et al.*, 1984), respectively. These equations estimate the annual probability of infection following consumption of a specified virus and are based on studies of healthy volunteers. The volunteers for these studies are typically between the ages of 20 and 50, and therefore, may underestimate the probability of infection in sensitive subpopulations (*e.g.*, children and elderly) and the immunocompromised (*e.g.*, nursing home residents and AIDS patients). Rotavirus dose-response information was used to represent Type A viruses, while echovirus dose-response information was used to represent Type B viruses.

Once a person becomes infected, the likelihood of illness (morbidity) varies, depending on the pathogen and the sensitivity of the consumer. For Type A viruses, EPA assumed the percent of people becoming ill once infected is 88% for children under the age of two (Kapikian and Chanock, 1996). EPA assumed a morbidity rate of 10% for all other populations based upon a study of a rotavirus outbreak (Foster *et al.*, 1980) and incidents of rotavirus in families with infants ill with rotavirus (Wenman *et al.*, 1979).

EPA assumed the percent of people infected with Type B viruses who become ill also varies with age: 50% for children five years of age and less, 57% for individuals between 5 and 16 years of age, and 33% for people older than 16. EPA estimated these age-specific morbidity values based on data from a community-wide echovirus type 30 epidemic (Hall *et al.*, 1970) and from the New York Viral Watch (Kogon *et al.*, 1969).

Secondary illnesses result from individuals being exposed to individuals who contracted the illness from drinking water. For this analysis, EPA estimates the additional number of

people who become ill as a result of secondary spread. For Type A viruses, EPA assumed that an additional 0.55 people will become ill from every child that becomes ill through consumption of drinking water. This assumption is based on a study of children under five years old, ill with rotavirus, who spread the illness to others in their households (Kapikian and Chanock, 1996). For Type B viruses EPA assumed that 0.35 additional people will become ill through secondary spread. This assumption was based on a review of various epidemiological studies for echovirus (Morens *et al.*, 1991). There is some uncertainty as to the exact rate of secondary spread for Type B viruses, so EPA has assumed that the secondary spread rates range from 0.11 to 0.55.

The probability that an ill person will die as a result of an illness is referred to as mortality. EPA expects Type A viruses to result in far fewer deaths than Type B viruses. EPA assumed a mortality rate for all age groups of 0.00073 percent. This assumption was based on an estimate of 20 rotavirus deaths per year out of 2,730,000 cases of rotavirus diarrhea in children 0–4 years old (Tucker *et al.*, 1998). EPA assumed the mortality rate for Type B viruses be 0.92 percent for infants one month or less. This assumption was based upon studies of hospitalized infants (Kaplan and Klein, 1983). For the rest of the population, EPA assumed that 0.04 percent of people ill from Type B viruses will die. These estimates may underestimate the number of infant deaths due to Type B viral illnesses, since Jenista et al. (1984) and Modlin (1986) reported a three percent case fatality rate for infants (one month or less) which is three times the value used in the model.

8. Potential Illnesses

EPA estimates, based upon the assumptions described earlier, that 98,000 viral illnesses each year are caused by consuming drinking water in undisinfected public ground water systems. EPA further estimates that nine of these people die each year.

EPA believes there are additional waterborne illnesses and deaths among consumers of drinking water from public ground water systems beyond those estimated due to contaminated source waters in undisinfected systems. Between 1991 and 1996 there were 1,260 waterborne outbreak illnesses reported to CDC which were attributed to microbial contamination of the source and inadequate or interrupted disinfection, and 944 waterborne illnesses reported to CDC which were attributed to distribution system contamination in ground water systems. In that same period there were 2,924 reported outbreak illnesses in source contaminated undisinfected system. This results in 0.43 (1,260/2,924) additional illnesses in source contaminated, ground water systems with failed disinfection for every illness from undisinfected, fecally contaminated ground water. Based on similar analysis, there are also 0.32 (944/2,924) additional illnesses due to distribution system contamination for every one illness due to source contamination in undisinfected ground water systems. (This ratio does not apply to transient noncommunity water systems, because they do not have distribution systems.) EPA assumed the ratios of the causes of reported outbreak illnesses is equal to the ratio of the causes of all waterborne illnesses. Therefore, EPA estimates, based upon these ratios, that an average of 42,000 additional illnesses and four additional deaths occur each year as a result of source contamination and inadequate or interrupted disinfection. EPA also estimates that an average of 28,000 additional illnesses and three additional deaths are caused each year by distribution system contamination. Table II–10 presents the estimates of viral illness and death under current conditions.

TABLE II–10.—ESTIMATES OF BASELINE VIRAL ILLNESS AND DEATH DUE TO CONTAMINATION OF PUBLIC GROUND WATER SYSTEMS

Cause of contamination	No. of type A virus illnesses	No. of type A virus deaths	No. of type B virus illnesses	No. of type B virus deaths	total illnesses types A & B	Total deaths types A & B
Source contamination/undisinfected system	78,000	1	20,000	8	98,000	9
Source contamination/disinfected system	34,000	.....	8,000	4	42,000	4
Distribution system contamination	22,000	.....	6,000	3	28,000	3
All Causes	134,000	1	34,000	14	168,000	16

Because of a lack of occurrence data for bacterial pathogens in ground water, risks from bacterial contamination of ground water sources and distribution systems are not quantified in this assessment. Although it is believed that viruses are more readily transported through the subsurface than bacteria (Sinton *et al.*, 1997), ground water system disease outbreaks caused by bacterial pathogens such as *Shigella, Salmonella* spp., and *Campylobacter* spp. and *E. coli* O157:H7 have been reported. For the period 1971–1996, 56 outbreaks, resulting in more than 10,000 illnesses and 11 deaths, were attributed to bacterial pathogen contamination of public ground water systems. More than 20% of these bacterial outbreaks occurred since 1991, and several outbreaks were attributed to gross fecal contamination of distribution lines.

As previously stated, there may be an additional 20% of illnesses caused by bacterial pathogens (in the absence of viral pathogens) in fecally contaminated ground water. Therefore, the numbers of illnesses and deaths presented in Table II–10 may underestimate the true numbers of annual illnesses and deaths by 20% (an estimated 34,000 additional illnesses and three additional deaths).

9. Summary of Key Observations

In conclusion, EPA believes that at any one point in time (most approximately 90 percent) ground water systems provide uncontaminated water. However, the risk characterization described herein indicates that a subset of ground water systems represent a potential risk to public health, which clearly supports the need to proceed with regulation of these systems. According to the assessment, EPA estimates that approximately 168,000 people are at risk to viral illness and 16 people are at risk of death, annually. It is noted that this analysis focuses primarily on the potential of gastrointestinal illness caused by exposure to viruses, therefore; the potential for additional illnesses from ground water contaminated only by pathogenic bacteria also exists and may account for an additional 34,000 illnesses and three deaths annually.

Therefore, the estimate of illnesses represents a potential underestimate of the actual illnesses attributed to consumption of water from ground water systems. Based on this analysis EPA believes that risk of microbial illness exists for a substantial number of people served by ground water systems. Consequently, EPA believes that the proposed regulatory provisions discussed later provide a meaningful opportunity for public health risk reduction.

10. Request for Comments

EPA seeks comment on the data, criteria and methodology used in the risk assessment, and where any different approaches may be appropriate. EPA also seeks comment on the assumptions used in this assessment, as well as the conclusions reached, and any additional data that commenters may be able to provide on occurrence, exposure, infectivity, morbidity, or mortality associated with microbial pathogens in ground water.

F. Conclusion

In EPA's judgment, the data and information presented in previous sections relating to outbreaks, occurrence, adverse microbial health effects, exposure, and risk characterization demonstrate that there are contaminants of concerns that exist in ground water at levels and at frequencies of public health concern. Moreover, as discussed in detail later, the Agency believes there are targeted risk-based regulatory strategies that provide a meaningful opportunity to reduce public health risk for a substantial number of people served by ground water sources.

EPA recognizes that there are particular challenges associated with developing an effective regulatory approach for ground water systems. These include first, the large number of ground water systems; second, the fact that only a subset of these systems appear to have microbial contamination (although a larger number are likely to be vulnerable); and third, that most ground water systems range from being small to very small in terms of population served. These factors combine to underscore the fact that a one-size-fits-all approach cannot work. This point was made repeatedly by participants in public stakeholder meetings across the country, and EPA agrees. The task therefore is to develop a protective public health approach which ensures a baseline of protection for all consumers of ground water and sets in place an increasingly targeted strategy to identify high risk or high priority systems that require greater scrutiny or further action.

III. Discussion of Proposed GWR Requirements

The information outlined earlier indicates that the primary causes of waterborne related illnesses are associated with source water contamination and untreated ground water, source water contamination and unreliable treatment, water system deficiencies, and a subset of waterborne disease outbreaks of unknown causes. The requirements and options proposed today address each of these areas through a multiple-barrier approach which relies upon five major components: periodic sanitary surveys of ground water systems requiring the evaluation of eight elements and the identification of significant deficiencies; hydrogeologic assessments to identify wells sensitive to fecal contamination; source water monitoring for systems drawing from sensitive wells without treatment or with other indications of risk; a requirement for correction of significant deficiencies and fecal contamination through the following actions: eliminate the source of contamination, correct the significant deficiency, provide an alternative source water, or provide a treatment which achieves at least 99.99 percent (4-log) inactivation or removal of viruses, and compliance monitoring to insure disinfection treatment is reliably operated where it is used.

A. Sanitary Surveys

1. Overview and Purpose

A key element of the multiple-barrier approach is periodic inspection of ground water systems through sanitary surveys. According to the Total Coliform Rule (TCR), a sanitary survey is an onsite review of the water source, facilities, equipment, operation and maintenance of a public water system for the purpose of evaluating the adequacy of such source, facilities, equipment, operation and maintenance for producing and distributing safe drinking water (40 CFR 141.2). The Agency believes that periodic sanitary surveys, along with appropriate corrective actions, are indispensable for assuring the long-term quality and safety of drinking water. When properly conducted, sanitary surveys can provide important information on a water system's design and operations and can identify minor and significant deficiencies for correction before they become major problems. By taking steps to correct deficiencies exposed by a sanitary survey, the system provides an additional barrier to microbial contamination of drinking water.

The Agency proposes the following sanitary survey requirements: (1) States, or authorized agents, conduct sanitary surveys for all ground water systems at least once every three years for CWSs and at least once every five years for NCWSs; (2) sanitary surveys address all eight elements set out in the EPA/State Joint Guidance on sanitary surveys (outlined later in this section); (3) States provide systems with written notification which describes and identifies all significant deficiencies no later than 30 days of the on-site survey; and (4) systems consult with the State and take corrective action for any significant deficiencies no later than 90 days of receiving written notification of such deficiencies, or submit a schedule and plan to the State for correcting these deficiencies within the same 90 day period; and (5) States must confirm that the deficiencies have been addressed within 30 days after the scheduled correction of the deficiencies.

A ground water system that has been identified as having significant deficiencies must do one or more of the following: eliminate the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer. Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness. The ground water system must consult with the State to determine which of the approaches, or combination of approaches, are appropriate for meeting the treatment technique requirement. Ground water systems unable to address the significant deficiencies in 90 days, must develop a specific plan and schedule for meeting this treatment technique requirement, submit them to the State, and receive State approval before the end of the same 90-day period. For the purposes of this paragraph, a ''significant deficiency'' includes, : 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.

Sanitary surveys provide a comprehensive and accurate record of the components of water systems, assess the operating conditions and adequacy of the water system, and determine if

past recommendations have been implemented effectively. The purpose of the survey is to evaluate and document the capabilities of the water system's sources, treatment, storage, distribution network, operation and maintenance, and overall management in order to ensure the provision of safe drinking water. In addition, sanitary surveys provide an opportunity for State drinking water officials or approved third party inspectors to visit the water system and educate operators about proper monitoring and sampling procedures, provide technical assistance, and inform them of any changes in regulations.

Sanitary surveys have historically been conducted by State drinking water programs as a preventative tool to identify water system deficiencies that could pose a threat to public health. In 1976, EPA regulations established, as a condition of primacy, that States develop a systematic program for conducting sanitary surveys, with priority given to public water systems not in compliance with drinking water regulations (40 CFR 142.10 (b)(2)). This primacy requirement did not define the scope of sanitary surveys or specify minimum criteria.

In 1989, the TCR included a provision that requires systems that serve 4,100 people or less and collecting fewer than five routine total coliform samples per month to conduct a periodic sanitary survey every five years, with an exception made for NCWS that use protected and disinfected ground water to conduct the survey every ten years. The TCR, however, does not establish what must be addressed in a sanitary survey or how such a survey should be conducted. The responsibility is on the system rather than the State for completing the sanitary survey (40 CFR 141.21(d)(2)). The TCR requires systems to use either a State official or an agent approved by the State to conduct the sanitary survey.

The IESWTR (63 FR 69478, December 16, 1998), established requirements for primacy States to conduct sanitary surveys for all systems using surface water or ground water under the direct influence of surface water. The rule also requires States to have the appropriate authority for ensuring that systems address significant deficiencies. The State must perform a survey at least once every three years for CWSs and every five years for NCWSs. These surveys must encompass the eight major areas defined by the EPA/State Joint Guidance (discussed in section 3).

This GWR proposal and the IESWTR differ in the requirements for a system to correct any significant deficiency. In the IESWTR, States are specifically required to have the appropriate rules or other authority to require systems to respond in writing to significant deficiencies outlined in a sanitary survey report within at least 45 days. A system, under this 45-day time frame, is required to notify the State in writing how and on what schedule it will address significant deficiencies noted in the survey. This GWR proposal differs from the IESWTR by proposing to require ground water systems to correct significant deficiencies and to do so within 90 days or seek a State approved schedule for plans requiring longer than 90 days.

2. General Accounting Office Sanitary Survey Investigation

In 1993, the US General Accounting Office (US GAO) investigated State sanitary survey practices. The US GAO found that many sanitary surveys were deficient, and that follow-up on major problems was often lacking. This investigation, which is described next, was published as a report, *Key Quality Assurance Program is Flawed and Underfunded* (US GAO 1993).

US GAO was directed by Congress to review State sanitary survey programs due to congressional concern that many States were cutting back on these programs, and thus undermining public health. Congress asked US GAO to determine in its report whether sanitary surveys are comprehensive enough to determine if a water system is providing safe drinking water and what the results indicate about water systems nationwide.

As part of this effort, GAO sent a detailed questionnaire to 49 States to attain a nationwide perspective on whether the States were conducting sanitary surveys, the frequency and comprehensiveness of the surveys, and what the survey results indicate about the operation and condition of water systems. To obtain more detailed information, the GAO also focused on 200 specific sanitary surveys conducted on CWSs in four States (Illinois, Montana, New Hampshire and Tennessee). This information was summarized in the GAO's report (US GAO 1993). The GAO report presented a number of key concerns, as discussed next.

Frequency Varies Among States and is Declining Overall. At least 36 States had a policy to conduct surveys of CWSs at intervals of three years or less; however, only 21 of these States were conducting surveys at this frequency. The remaining 15 States reported they were unable to implement this policy because their inspectors had other competing responsibilities that often took precedence over non-mandated requirements (*e.g.,* sanitary surveys). Overall, the frequencies of the surveys vary from quarterly to 10 years. According to the report, States have reduced the frequency of surveys since 1988, a downward trend that is expected to continue.

Comprehensiveness of Sanitary Surveys is Inconsistent. The report indicates that a comprehensive sanitary survey, as recommended in Appendix K of EPA's SWTR Guidance Manual (US EPA, 1990b), is frequently not conducted. Forty-five out of 48 States omitted one or more key elements defined in the 1990 guidance manual. The GAO noted wide variation among States in the comprehensiveness of their sanitary surveys. Some States, for example, omit inspections of water distribution systems and/or other key components or operations of water systems, others do not provide complete documentation of sanitary survey results. Based on a review of the 200 sanitary surveys, survey results which identify deficiencies were found to be inconsistently interpreted from one surveyor to another. In some cases, systems' deficiencies that could have been detected during a comprehensive survey may not be found until after water quality is affected and the root cause(s) investigated. By that time, however, consumers may already have ingested contaminated water (US GAO, 1993).

Limited Efforts to Ensure that Deficiencies are Corrected. The GAO found that follow-up procedures for deficiencies were weak. The detailed review of the four States' sanitary surveys indicated that deficiencies frequently go uncorrected. Of the 200 surveys examined, about 80% disclosed deficiencies and 60% cited deficiencies that had already been identified in previous surveys. Of particular concern was the GAO finding that smaller systems (serving 3,300 or less) are in greatest need of improvements. Small systems compose a significant majority of all ground water systems. Ninety-nine percent (approximately 154,000) of ground water systems serve fewer than 10,000 people and ninety-seven percent (approximately 151,000) serve 3,300 or fewer people.

Results Poorly Documented. The GAO also found variation in how States document and interpret survey results. Proper documentation would facilitate follow-up on the problems detected.

GAO recommended EPA work with States to establish minimum criteria on how surveys should be conducted and documented and to develop procedures

to ensure deficiencies are corrected. This proposal addresses these recommendations.

3. ASDWA/EPA Guidance on Sanitary Surveys

Recognizing the essential role of sanitary surveys and the need to define the broad areas that all sanitary surveys should cover, EPA and ASDWA prepared a joint guidance on sanitary surveys entitled EPA/State Joint Guidance on Sanitary Surveys (1995). The guidance identified the following eight broad components that should be covered in a sanitary survey: source, treatment, distribution system, finished water storage, pumps and pump facilities and controls, monitoring/reporting/data verification, water system management and operations, and operator compliance with State requirements. The EPA/State Joint Guidance does not provide detailed instructions on evaluating criteria under the eight elements; however, EPA has recently issued detailed supplementary information as technical assistance (April 1999, Guidance Manual for Conducting Sanitary Surveys of Public Water Systems)(US EPA, 1999e).

—Source. The water supply source is the first opportunity for controlling contaminants. The reliability, quality, and quantity of the source should be evaluated during the sanitary survey using available information including results of source water assessments or other relevant information. A survey should assess the potential for contamination from activities within the watershed as well as from the physical components and condition of the source facility.

—Treatment. The treatment phase should consider evaluation of the handling, storage, use and application of treatment chemicals if the system includes application of any chemicals. A review of the treatment process should include assessment of the operation, maintenance, record keeping and management practices of the treatment system.

—Distribution System. Given the potential for contamination to spread throughout the distribution system, a thorough inspection of the distribution network is important. Review of leakage that could result in entrance of contaminants, monitoring of disinfection residual, installation and repair procedures of mains and services, as well as an assessment of the conditions of all piping and associated fixtures are necessary to maintain distribution system integrity.

—Finished Water Storage. A survey of the storage facilities is critical to ensuring the availability of safe water, and the adequacy of construction and maintenance of the facilities.

—Pumps/Pump Facilities and Controls. Pumps and pump facilities are essential components of all water systems. A survey should verify that the pump and its facilities are of appropriate design and properly operated and maintained.

—Monitoring/Reporting/Data Verification. Monitoring and reporting are needed to determine compliance with drinking water provisions, as well as to verify the effectiveness of source protection, preventative maintenance, treatment, and other compliance-related issues regarding water quality or quantity.

—Water System Management/Operations. The operation and maintenance of any water system is dependent on effective oversight and management. A review of the management process should ensure continued and reliable operation is being met through adequate staffing, operating supplies, and equipment repair and replacement. Effective management also includes ensuring the system's long-term financial viability.

—Operator compliance with State requirements. A system operator plays a critical role in the reliable delivery of safe drinking water. Operator compliance with State requirements includes state-specific operation and maintenance requirements, training and certification requirements, and overall competency with on-site observations of system performance.

4. Other Studies

As previously described (see section I.D.2.), ASDWA examined 28 different BMPs to determine the effectiveness of each BMP in controlling microbial contamination. Within this study, 91.4% of systems surveyed had implemented a sanitary survey within the previous five years. The ASDWA survey found no significant association with systems that conducted sanitary surveys and no total coliform detections. The insignificance of the association between sanitary surveys and the detection of bacteria may be due to the fact that State sanitary surveys are designed to identify problems (ASDWA, 1998). However, correction of sanitary survey deficiencies was correlated with lower levels of total coliform, fecal coliform, and *E. coli.*

EPA conducted a survey published in Ground Water Disinfection and Protective Practices in the United States (US EPA 1996a), which confirmed the GAO finding that considerable variability among States exists with regard to the scope and comprehensiveness of sanitary surveys.

The Environmental Law Reporter (ELR), a private database of State and Federal statutes and regulations, provides some information on current State regulations for ground water systems. According to the ELR, only the State of Washington does not require sanitary surveys under the TCR requirement at 40 CFR 141.21(d). However, most State regulations found in the ELR are general in nature and do not specifically address the eight EPA/State Joint Guidance sanitary survey components. State regulations vary considerably in terms of types of systems surveyed, the content of the survey, and who is designated to conduct the surveys (*e.g.*, a sanitarian). The database indicates that the majority of States (46 out of 50) do not specifically require systems to correct deficiencies. Significantly, a number of States do not appear to have legal authority to require correction of deficiencies. The ELR findings contained in the Baseline Profile Document for the Ground Water Rule (US EPA, 1999f) indicate that many sanitary survey provisions do not appear in State regulations. The GAO report confirmed that many States incorporated sanitary survey requirements into policy, thereby undercutting their legal enforceability.

5. Proposed Requirements

EPA proposes to require periodic State sanitary surveys for all ground water systems specifically addressing all of the applicable sanitary survey elements noted earlier, regardless of population size served.

With regard to the frequency of sanitary surveys, EPA proposes to require the State or a state-authorized third party to conduct sanitary surveys for all ground water systems at least once every three years for CWSs and at least once every five years for NCWSs. This approach would be consistent with the requirements of the IESWTR. CWSs would be allowed to follow a five-year frequency if the system either treats to 4-log inactivation or removal of viruses or has an outstanding performance record in each of the applicable eight areas documented in previous inspections and has no history of TCR MCL or monitoring violations since the last sanitary survey. A State must, as part of its primacy application, include how it will decide whether a system has outstanding performance and is thus eligible for sanitary surveys at a reduced frequency.

The Agency believes that periodic sanitary surveys, along with appropriate corrective measures, are indispensable for ensuring the long-term safety of drinking water. By taking steps to correct deficiencies exposed by a sanitary survey, the system provides an additional barrier to pathogens entering the drinking water.

The definition of a sanitary survey used in the GWR differs from the definition of a sanitary survey in 40 CFR 141.2 by a parenthetical clause. For the purpose of Subpart S, a sanitary survey is ''an onsite review of the water source (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.'' This reflects a recommendation by the 1997 M/DBP Federal Advisory Committee Act that sanitary inspectors should use source water assessments and other information where available as part of the overall evaluation of systems. This change in definition reflects the value of Source Water Assessment and Protection Programs (SWAPPs) required by Congress in the 1996 SDWA amendments and the importance of utilizing information generated as a result of that activity.

EPA is also proposing to require that State inspectors, as part of each sanitary survey, evaluate all applicable components defined in the EPA/State Joint Guidance on Sanitary Surveys and identify any significant deficiencies. Some stakeholders have suggested the comprehensiveness of sanitary surveys be tailored based upon system size and type. EPA requests comment on whether this would be an appropriate approach and if so, what factors or criteria should be considered in tailoring the scope or complexity of the sanitary survey.

Individual components of a sanitary survey may be separately completed as part of a staged or phased State review process as part of ongoing State inspection programs within the established frequency interval. In its primacy package, a State which plans to complete the sanitary survey in such a staged or phased review process must indicate which approach it will take and provide the rationale for the specified time frames for sanitary surveys conducted on a staged or phased approach basis.

EPA proposes to regard the requirements for sanitary surveys under the GWR as meeting the requirements for sanitary surveys under the TCR (40 CFR 141.21). The reason for this is that the frequency and criteria of a sanitary survey under the GWR is more stringent than that for the TCR. For example, the TCR does not define a sanitary survey as precisely as the GWR, which requires an evaluation of eight elements. In addition, the frequency of the sanitary survey under the TCR for CWSs is every five years, compared to three years (at least initially) under the GWR. Also, the TCR requires a survey every ten years for disinfected NCWSs using protected ground waters, as compared to every five years under the GWR. The scope of the systems that must conduct a sanitary survey also differs; under the TCR only systems that collect fewer than five routine samples per month and serve less than 4,100 persons are required to undergo a sanitary survey, compared to all ground water systems under the GWR. Given that the proposed sanitary survey requirements under the GWR are more stringent than those under the TCR, EPA notes that a survey under the TCR cannot replace one conducted under the GWR, unless that survey meets the criteria specified in the GWR.

As part of today's rule, a ''significant deficiency'' as identified by a sanitary survey includes: 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. This is a working definition developed by the EPA GWR workgroup.

The Agency proposes to require the State to provide the system with written notification which identifies and describes any significant deficiencies found in a sanitary survey no later than 30 days after completing the on-site survey. States would not be required, in this rule, to provide the system with a complete sanitary survey report within the 30 days of completing the on-site survey. Rather, this rule requires that, at a minimum, the State provide the system a written list which clearly identifies and describes all significant deficiencies as identified during the on-site survey.

EPA proposes to require a system to: (1) Correct any significant deficiencies identified in a sanitary survey as soon as possible, but no later than 90 days of receiving State written notification of such deficiencies, or (2) to submit a specific schedule and receive State approval on the schedule for correcting the deficiencies within the same 90-day period. The system must consult the State within this 90-day period to determine the corrective action approach appropriate for that system, consistent with the State's general approach outlined in their primacy package. In performing a corrective action, the system must eliminate the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer. Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness. There are cases in which one or more of the corrective actions listed previously may be inappropriate for the nature of the problem, and in these cases only appropriate corrective actions must be taken. For example, a system with a significant deficiency in the distribution system should not install treatment at the source water as the corrective action; that system should correct the problem in the distribution system. There may also be fecal sources that a State does not identify as a significant deficiency, however the State may choose to use their authority to require source water monitoring to monitor the influence of that fecal source. Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness. States must confirm that the deficiency has been corrected, either through written confirmation from systems or a site visit by the State, within 30 days after the 90-day or scheduled correction of the deficiency. Systems providing 4-log inactivation or removal of viruses need not undergo a hydrogeologic sensitivity assessment or monitor their source water for fecal indicators.

As noted earlier, States would be required to have the appropriate rules or other authority to: (1) Ensure that public ground water systems correct any significant deficiencies identified in the written notification provided by the State (including providing an alternative source or 4-log inactivation or removal of viruses); and (2) ensure that a public ground water system confirm in writing any significant deficiency corrections made as a result of sanitary survey findings.

The requirements in today's rule do not preclude a State from enforcing corrective action on any significant deficiencies whether or not they are identified through a sanitary survey.

EPA is also proposing to require States, as part of their primacy application, to indicate how they will

define what constitutes a significant deficiency found in a sanitary survey for purposes of this rule. EPA believes that this requirement would provide the State sufficient latitude to work within their existing programs in addressing significant deficiencies yet provide facilities and the public with clear notice as to what kinds of system conditions constitute a significant deficiency. EPA recognizes the importance of enabling States the flexibility to identify and define sanitary survey deficiencies in broad categories under this requirement (*e.g.*, unsafe source, improper well construction, *etc.*).

Also, in its primacy application, States must specify if and how they will integrate SWAPP susceptibility determinations into the sanitary survey or the definition of significant deficiencies.

Based upon input from a number of State and EPA Regional office experts, significant deficiencies of ground water systems may include but are not limited, to the following types of deficiencies:

—Unsafe source (*e.g.*, septic systems, sewer lines, feed lots nearby);
—Wells of improper construction;
—Presence of fecal indicators in raw water samples;
—Lack of proper cross connection control for treatment chemicals;
—Lack of redundant mechanical components where chlorination is required for disinfection;
—Improper venting of storage tank;
—Lack of proper screening of overflow pipe and drain;
—Inadequate roofing (*e.g.*, holes in the storage tank, improper hatch construction);
—Inadequate internal cleaning and maintenance of storage tank;
—Unprotected cross connection (*e.g.*, hose bibs without vacuum breakers);
—Unacceptable system leakage that could result in entrance of contaminants;
—Inadequate monitoring of disinfectant residual and TCR MCL or monitoring violations.

6. Reporting and Record Keeping Requirements

The GWR does not change the requirements on the system and the State to maintain reports and records of sanitary survey information as specified in 40 CFR 141.33(c) and 142.14(d)(1).

7. Request for Comments

EPA requests comment on all the information presented earlier and the potential impacts on public health and regulatory provisions of the GWR. In addition, EPA specifically requests comments on alternative approaches.

Alternative Approaches

a. Content of a Sanitary Survey

i. Grandfathering and Scope of Sanitary Survey

EPA requests comment on ''grandfathering'' of surveys conducted under the TCR if those surveys addressed all eight EPA/State Joint Guidance on Sanitary Surveys components. Under what circumstances should grandfathering be allowed? Are there circumstances under which grandfathering should be allowed even if the survey did not address all eight components?

EPA is seeking comment on the level of detail EPA should use in establishing the sanitary survey requirement which addresses the eight sanitary survey components.

ii. Definition of Significant Deficiency

EPA is also seeking comment on the proposed definition of ''significant deficiencies.'' In this regard, EPA is requesting comment on whether or not the Agency should promulgate a minimum list of specific significant deficiencies for all States to use in their programs.

iii. Well Construction and Age

EPA considered specifying, in addition to sanitary survey elements, well construction deficiencies and well age as surrogate measures of well performance as part of the hydrogeologic sensitivity assessment (HSA) or as an independent component from the sanitary survey or HSA. EPA considered identifying older wells as those more likely to be contaminated because of degradation to the construction materials over time. EPA concluded that wells may have been constructed adequately to protect public health, but records to document such construction may no longer be available. Given these circumstances, EPA recognizes that down-hole test methods to evaluate well construction, as required for some hazardous waste disposal methods, is neither desirable nor feasible for PWS wells. In addition, EPA found that there were few data to support the concept that older wells were more likely to be contaminated. In fact, data from two studies encompassing more than 200 wells in Missouri suggest that newer wells were more likely to be contaminated than older wells (Davis and Witt, 1998, 1999 and Femmer, 1999). Thus, EPA decided not to include well construction and age as measures of the potential fecal hazard to PWS wells.

Almost all States have well construction standards, and trade associations, such as the American Water Works Association and the National Ground Water Association, have also provided recommendations for well construction. EPA recognizes the importance of designing, constructing and maintaining wells so as to maximize well life and yield and to minimize potential harmful contamination. Therefore, the Agency requests comment on whether well construction and age should be considered as a required element within a sanitary survey or specifically identified by States as a significant deficiency. EPA also requests comment on criteria for evaluating well construction and age.

b. Frequency

EPA believes that a sanitary survey cycle of at least once every three years for CWSs (with certain exceptions discussed previously) and at least once every five years for NCWSs most properly balances public health protection and State burden issues and is consistent with the frequency required for surface water systems. However, the Agency seeks comment on whether other alternative time cycles might be appropriate together with any applicable rationale that supports that alternative frequency cycle. Specifically, EPA requests comment on requiring States to conduct sanitary surveys for all ground water systems every five years. EPA also requests comment on allowing States to conduct sanitary surveys less often than once every 5 years if the system provides 4-log inactivation or removal. The Agency requests comment on the resource implications for States and small systems to perform these surveys with a frequency of 3–5 years.

In addition, the Agency seeks comment on requiring the State to conduct a sanitary survey for new systems prior to the system serving water to the public. This requirement would serve as an added public health measure to ensure new systems are in compliance with the GWR sanitary survey provisions.

c. Follow-Up Requirements

EPA requests comment on requiring States to schedule an on-site inspection as follow-up to verify correction of significant deficiencies, rather than allowing States to accept written certification from systems to verify the correction. EPA requests comment on alternative approaches for a State to verify that a significant deficiency has

been corrected. EPA notes that follow-up in this context only applies to significant deficiencies.

d. Public Involvement

EPA requests comment on including public involvement and/or meetings for certain systems to discuss the results of sanitary surveys. Congress wrote requirements for extensive public information and involvement in programs and decisions affecting drinking water safety throughout the 1996 amendments to SDWA. For example, in addition to the new requirement for CWSs to produce and distribute annually a Consumer Confidence Report, the public notice requirements for PWSs regarding violations of a national drinking water standard were made more effective, and States were required to ''make readily available to the public'' an annual report to the Administrator on the statewide record of PWS violations, see (SDWA 1414(c)(1)–(3)). Each State's triennial report to the Governor on the effectiveness of and progress under the capacity development strategy must also be available to the public. (See SDWA section 1420(c)(3)). EPA must make the information from the occurrence database ''available to the public in readily accessible form.'' (See SDWA section 1445(g)(5)). The public must be provided with notice and an opportunity to comment on the annual priority list of projects eligible for State Revolving Fund (SRF) assistance that States will publish as a part of their SRF intended use plans (See SDWA section 1452(b)(3)(B)). States ''shall make the results of the source water assessments * * * available to the public.'' (See SDWA section 1453(a)(7)). And, under several specific provisions of the SDWA as well as the Administrative Procedure Act, EPA generally must publish and make regulations, and a number of guidance and information documents, available for public notice and comment.

These requirements, and others like them, are integral to both the philosophy and operation of the amended SDWA. They reflect Congress' view that public confidence in drinking water safety and informed support for any needed improvements must rest on full disclosure of all significant information about water system conditions and quality, from source to tap.

The 1996 SDWA Amendments, and EPA's implementation of them, consistently provide for such disclosure and involvement by means that are informative, timely, understandable, and practicable for each size group of PWSs subject to them. EPA believes that the principles of public information and involvement must apply with equal validity to the GWR, and is considering including in the final rule provisions to apply these principles, for disclosure and involvement. EPA believes that the following approach meets both tests and principles, but solicits comment on alternative means of doing so.

EPA requests comment on what approaches might be practicable, not burdensome and workable to involve the public in working with their system to address the results of their system's sanitary survey. Specifically, EPA requests comment on requiring ground water CWSs to notify their consumers, as part of the next billing cycle, of the completion of any sanitary survey, and any significant deficiency(s) and corrective action(s) identified. The system would also have to make information concerning the sanitary survey available to the public upon request. Alternatively, the system might be required to notify customers of the availability of the survey only, and provide copies on request, or include information about the survey in the annual Consumer Confidence Report (CCR). EPA requests comment on whether this approach should be extended to transient and nontransient NCWSs as well. EPA also requests comment on what approaches might be practicable, not burdensome and workable to involve the public in working with their system to address the results of their system's sanitary survey.

B. Hydrogeologic Sensitivity Assessment

1. Overview and Purpose

Occurrence data collected at the source from public ground water systems suggest that a small percentage of all ground water systems are fecally contaminated. Because of the large number of ground water systems (156,000), the GWR carefully targets the high priority systems and has minimal regulatory burden for the remaining low priority systems. The GWR screens all systems for priority and only requires corrective action for fecally contaminated systems and systems with significant deficiencies. Thus, the challenge of the hydrogeologic sensitivity assessment is to identify ground water wells sensitive to fecal contamination. The assessment supplements the sanitary survey by evaluating the risk factors associated with the hydrogeologic setting of the system. EPA believes requiring hydrogeologic sensitivity analysis for all non-disinfecting ground water systems will reduce risk of waterborne disease by identifying systems with incomplete natural attenuation of fecal contamination. EPA bases the following requirements on: CDC outbreak case studies, USGS studies of ground water flow, State vulnerability maps, and US National Research Council reports on predicting ground water vulnerability.

For the purposes of this rulemaking, EPA intends the term ''well'' to include any method or device that conveys ground water to the ground water system. The term ''well'' include springs, springboxes, vertical and horizontal wells and infiltration galleries so long as they meet the general applicability of the GWR (see section 141.400). The GWR does not apply to PWSs that are designated ground water under the direct influence of surface water; such systems are subject to the SWTR and IESWTR. EPA requests comment on this definition of ''well.''

The hydrogeologic sensitivity assessment is a simple, low burden, cost-effective approach that will allow States to screen for high priority systems. Systems that are situated in certain hydrogeologic settings are more likely to become contaminated. EPA believes that a well obtaining water from a karst, fractured bedrock or gravel hydrogeologic setting is sensitive to fecal contamination unless the well is protected by a hydrogeologic barrier. A State may add additional sensitive hydrogeologic settings (*e.g.*, volcanic aquifers) if it believes that it is necessary to do so to protect public health. A hydrogeologic barrier is defined as the physical, biological and chemical factors, singularly or in combination, that prevent the movement of viable pathogens from a contaminant source to a public supply well. In this proposal, a confining layer is one example of a hydrogeologic barrier. The strategy is for a State to consider hydrogeologic sensitivity first. If ground water systems not treating to 4-log inactivation of viruses are located in sensitive hydrogeologic settings, then the strategy allows the State to consider the presence of any existing hydrogeologic barriers that act to protect public health. If a hydrogeologic barrier is present, then the State can nullify the determination that a system is located in a sensitive hydrogeologic setting. If no suitable hydrogeologic barrier exists, then the GWR requires the system to conduct monthly fecal indicator source water monitoring. Finally, for those systems where monitoring results are positive for the presence of fecal indicators, under the proposed GWR, States may require systems to eliminate

the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer. GWSs which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness.

The States have experience implementing a wide variety of methods suitable for identifying hydrogeologically sensitive systems. Also, the States may collect hydrogeologic information through their SWAPP (see section I.B.) that is useful for the hydrogeologic sensitivity assessments under the GWR. EPA believes that it would be beneficial if the States coordinate their SWAPP analysis with the GWR. By using the information generated in the SWAPP for the GWR hydrogeologic sensitivity assessment, States can effectively reduce the burden associated with this requirement.

EPA-approved vulnerability assessments conducted for the purpose of granting waivers under the Phase II and Phase V Rules may also serve as sources of hydrogeologic information useful to the State in assessing the hydrogeologic sensitivity of its GWSs under the GWR. Under the Phase II (56 FR 30268, July 1, 1991d)(US EPA,1991) and Phase V (57 FR 31821, July 17, 1992)(US EPA,1992b) Rules, monitoring waivers may be granted to individual systems for specific regulated chemicals (*e.g.*, PCBs and cyanide). Monitoring frequencies may be reduced or eliminated by the State if the system obtains a waiver based on previous sampling results and/or an assessment of the system's vulnerability to each Phase II and V contaminant. This evaluation must include the sampling results of neighboring systems, the environmental persistence and transport of the contaminant(s) under review, how well the source is protected by geology and well design, Wellhead Protection Assessments, and proximity of potential contamination sites and activities.

2. Hydrogeologic Sensitivity

Sensitive hydrogeologic settings occur in aquifer types that are characterized by large interconnected openings (void space) and, therefore, may transmit ground water at rapid velocities with virtually no removal of pathogens. Sensitive aquifers may be present at or near the ground surface or they may be covered by overlying aquifers or soils. An aquifer is sensitive, independent of its depth or the nature of the overlying material, because average water velocities within that aquifer are rapid. This allows microbial contaminants to be transported long distances from their source at or near the surface and especially in the absence of a hydrogeologic barrier. In the following paragraphs, each sensitive aquifer type is briefly characterized. It is often difficult to determine the actual contaminant removal capabilities of an aquifer and the and ground water velocities within an aquifer. Consequently, the aquifer rock type can be a surrogate measure in the hydrogeologic sensitivity assessment. All soil and rocks have void space, but aquifers have the largest interconnected void space. The voids are filled with water that is tapped by a well. Without these interconnections, the water could not flow to a well. In those aquifers with the largest interconnected void space, ground water velocities can be comparable to the velocity of a river, and the rate of travel can be measured in kilometers per day (US EPA, 1997b). Compared to velocities in fine-grained granular aquifers (aquifers that are not considered sensitive under the GWR), ground water velocities in fractured media are large (Freeze and Cherry, 1979). Sensitive aquifers allow fecal contaminants to travel rapidly to a well, with little loss in number due to inactivation or removal.

In the GWR, three aquifer types are identified as sensitive: (1) Karst aquifers, (2) fractured bedrock aquifers, and (3) gravel aquifers. Each aquifer type is characterized by the differing nature and origin of the interconnected void space. These distinctions are important to hydrogeologists identifying these aquifer types. To meet the requirements of the hydrogeologic sensitivity assessment of the GWR, it is sufficient for States to identify the aquifer type supplying a system. Karst, fractured bedrock and gravel aquifer types are at high risk to fecal contamination by virtue of their capability to rapidly transmit fecal contamination long distances over short time periods.

Several means can be used to evaluate wells to determine if they are located in one of the three sensitive hydrogeologic settings proposed under the GWR. For example, hydrogeologic data are available from published and unpublished materials such as maps, reports, and well logs. The United States Geologic Service (USGS), U.S. Department of Agriculture's Natural Resource Conservation Service, USGS Earth Resources Observation System Data Center, the EPA Source Water Assessment and Protection Program and Wellhead Protection Program, State geological surveys, and universities have substantial amounts of regional and site-specific information. The USGS has published a national karst map (USGS, 1984) on which States can locate karst settings. Karst and other aquifers may also be identified on finer scale maps published by States or counties. For example, the State of Kentucky contains substantial karst terrain, documented in complete geologic maps at the scale of one inch: 2000 feet (7.5 minute quadrangles).

States can base assessments on available information about the age and character of the regional geology, regional maps and rock outcrop locations. For example, in a karst setting, the State may have some additional information such as: (1) Observations of typical karst features such as sinkholes and disappearing streams; (2) well driller logs which noted the presence of limestone or crystalline calcite (a mineral that grows into openings in rock) or a drop in the drill string as it penetrated a karst opening; or (3) geologic reports (or unpublished geological observations) which identify the presence of limestone in rock outcrops in the vicinity of the well.

(a) Karst Aquifers

Karst aquifers are aquifers formed in soluble materials (limestone, dolomite, marble and bedded gypsum) that have openings at least as large as a few millimeters in radius (EPA 1997b). Over geologic time periods, infiltrating precipitation (especially acid rain) moving through the aquifer has enlarged, by dissolution, the small openings that existed when the rock was formed. In mature karst terrain, characterized by relatively pure limestone located in regions with high precipitation, caves or caverns are formed in the subsurface, often large enough for human passage. Ground water has the potential to flow rapidly through karst because the void spaces are large and have a high degree of interconnection. In addition to the openings created by solution removal, karst aquifers, like all consolidated geologic formations, also contain fractures that transmit ground water. The size of these fractures may be small, but the fractures may also be more numerous than solution-enhanced openings. The fractures may or may not have a high degree of interconnection, and the degree of interconnection is a primary factor that controls the velocity of the ground water.

Quinlan (1989) suggests that about 20 percent of the U.S. is underlain by limestone or dolomite which may be karst aquifers. East of the Mississippi River, almost forty percent of the U.S. is underlain by limestone, dolomite or marble that may be karst aquifers (Quinlan, 1989). Karst areas are often identified by the formation of sinkholes at the ground surface. A sinkhole forms when the roof of a cave collapses and the material that was overlying the cave is dissolved or otherwise carried away by streams flowing through the cave. Sinkholes may also form or become enlarged as the direct result of vertical ground water flow dissolving the rock material to form a vertical passageway. Sinkholes represent direct pathways for fecal contamination to enter the aquifer from the surface. The surface topography may also be characterized by dry stream valleys in regions of high rainfall, by streams that flow on the ground surface but suddenly sink below ground to flow within a cave and by large springs where underground streams return to the surface. The degree of karst development in Missouri has been defined by Davis and Witt (1998) as primary and secondary karst: primary containing more than ten sinkholes per 100 square miles and secondary karst containing between one and ten sinkholes per 100 square miles. Other features suitable for identifying karst aquifers are described in EPA (1997b).

The most direct method for ground water velocity determinations consists of introducing a tracer substance at one point in the ground water flow path and observing its arrival at other points in the path, usually at monitoring wells (Freeze and Cherry, 1979). Using tracer studies, ground water velocities in karst aquifers have been measured as high as 0.5 kilometers (km) per hour (US EPA, 1997b). In Florida, ground water velocities surrounding a well have been measured at several hundred meters (m) per hour (US EPA, 1997b). At Mammoth Cave, Kentucky, ground water velocities have been measured at more than 300 m per hour (US EPA, 1997b). In a confined karst aquifer in Germany, ground water traveled 200 m in less than 4 days (Orth *et al.,* 1997). In the Edwards Aquifer, Texas, Slade *et al.*, (1986) reported that dye traveled 200 feet in ten minutes. The water level in one well (582 feet deep with a water table 240 feet deep) began rising within one hour after a rainfall (Slade *et al.,* 1986). These data suggest that ground water flows extremely rapidly through karst aquifers. Because ground water flows rapidly through karst aquifers, these aquifers are considered to be hydrogeologically sensitive aquifers under the GWR.

(b) Fractured Bedrock

Bouchier (1998) characterizes a fractured bedrock aquifer as an aquifer which has fractures that provide the dominant flow-path. Although all rock types have fractures, the rock types most susceptible to fracturing are igneous and metamorphic rock types (US EPA, 1991c).

Freeze and Cherry (1979) report void space as high as 10 percent of total volume in igneous and metamorphic rock. These rock types readily become fractured in the shallow subsurface as a result of shifts in the Earth's crust. Most fractures are smaller than one millimeter (mm) in width but each fracture's capability to transmit ground water varies significantly with the width of the fracture. A one mm fracture will transmit 1,000 times more water than a 0.1 mm fracture, provided that other factors are constant (*e.g.*, hydraulic gradient) (Freeze and Cherry, 1979). Data presented in Freeze and Cherry (1979) suggest that the first 200 feet beneath the ground surface produces the highest water yields to wells. These data suggest that the fractures are both more numerous and more interconnected in the first 200 feet interval. The rate of ground water travel in fractured rock can be estimated through the results of tracer tests. Malard *et al.*, (1994) report that dye traveled 43 m in a fractured aquifer in two hours. Becker *et. al.*, (1998) report that water traveled 36 m in about 30 minutes. Therefore, ground water may travel as quickly as several hundreds of meters per day in fractured bedrock, comparable to travel times in karst aquifers.

Aquifers that are comprised of igneous or metamorphic rock are often fractured bedrock aquifers, and their size is typically larger than a few tens or hundreds of square miles in area. EPA (1991c) has compiled a map showing the distribution of fractured bedrock aquifers in the U.S. Because ground water flows rapidly through fractured bedrock aquifers, these aquifers are considered to be hydrogeologically sensitive aquifers under the GWR.

(c) Gravel Hydrogeology

Gravel aquifers are deposits of unconsolidated gravel, cobbles and boulders (material larger in size than pebbles). Due to the large grain sizes of gravel aquifers, ground water travels rapidly within these aquifers with little to no removal or filtration of contaminants from the ground water. Such gravel aquifers are typically produced by catastrophic floods, physical weathering by glaciers, flash-floods at the periphery of mountainous terrain or at fault-basin boundaries. For example, glacial flooding has produced the Spokane-Rathdrum Prairie aquifer which extends from Spokane, Washington to Coeur d'Alene, Idaho. Another gravel aquifer is associated with glacial flooding along the Umatilla River in Milton-Freewater, Oregon. The boulder zone in the Jacobs Sandstone and Baraboo Quartzite near Baraboo, Wisconsin may represent another example. Typically, these aquifers are small.

Gravel aquifers are generally not alluvial aquifers. Alluvial aquifers, associated with typical river processes, normally have high proportions of sand mixed with the gravel. Sand or finer materials provide a higher probability of microorganism removal by the aquifer particles (Freeze and Cherry, 1979), and, therefore, greater public health protection. Because ground water flows rapidly through gravel aquifers, these aquifers are considered to be hydrogeologically sensitive aquifers under the GWR.

3. Hydrogeologic Barrier

The second part of the hydrogeologic sensitivity assessment is determining the presence of a hydrogeologic barrier. Under the GWR, the States perform an initial screen for hydrogeologic sensitivity by determining whether a PWS utilizes a fractured bedrock, karst or gravel aquifer. States would then examine systems located in these sensitive aquifers and determine whether a hydrogeologic barrier is present. A hydrogeologic barrier consists of physical, chemical, and biological factors that, singularly or in combination, prevent the movement of viable pathogens from a contaminant source to a public water supply well. If the State determines that a hydrogeologic barrier is present, the hydrogeologic setting is no longer considered sensitive to fecal contamination. If no such barrier is present or if insufficient information is available to make such a determination, the system would be identified as a sensitive system.

It is difficult to describe a single, detailed methodology for identifying a hydrogeologic barrier that can be used on a national basis. Geological and geochemical conditions, climate, and land uses are highly variable throughout the United States. In its primacy application, each State seeking consideration of a proposed hydrogeologic barrier under the rule may identify an approach for

determining the presence of a hydrogeologic barrier that addresses its own unique set of these variables (*e.g.,* geological and geochemical conditions, climate, and land uses). In determining the presence of a hydrogeologic barrier, the State should evaluate specific characteristics of the hydrogeologic setting, discussed in more detail in the following paragraphs.

Examples of characteristics to be considered in determining the presence of a hydrogeologic barrier include, but are not limited to: (1) Subsurface vertical and horizontal ground water travel times or distances sufficiently large so that pathogens become inactivated as they travel from a source to a public water supply well, or (2) unsaturated geological materials sufficiently thick so that infiltrating precipitation mixed with fecal contaminants is effectively filtered during downward flow to the water table.

A confining layer is one type of hydrogeologic barrier EPA has identified which can result in sufficient protection in many settings. A confining layer may protect sensitive aquifers from fecal contamination. It is defined as a layer of material that is not very permeable to ground water flow which overlies an aquifer and acts to prevent water movement into the aquifer (US EPA, 1991b). Confined aquifers are bounded by confining layers and, therefore, generally occur at depth, separated from the water table aquifer at the surface. Confining layers are typically identified by the high water pressures in the underlying aquifer. Where present, a confining layer will separate an aquifer of high pressure from an overlying aquifer of lower pressure. The high water pressure in a confined aquifer can force water to flow naturally (without pumping) to heights greater than the ground surface, as in an artesian well. The confining layer is comprised of fine-grained materials such as clay particles, either as an unconsolidated layer or as a consolidated rock (*e.g.,* shale). The small size of clay particles restricts the movement of water across or through the clay layer. Freeze and Cherry (1979) determined that water would take almost 10,000 years to pass through a 10 meters-thick unfractured layer of silt and clay deposited at the bottom of a glacial lake, such as the layers present in the northern part of the United States and the southern part of Canada. Therefore, the presence of a confining layer can provide public health protection.

However, confining layers may be breached and, therefore, unprotective. Breaches may be natural (*e.g.,* partly removed by erosion, sinkholes, faults, and fractures) or caused by humans (*e.g.,* wells, mines, and boreholes). For example, an unplugged, abandoned well that breaches the confining layer is capable of providing a pathway through the confining layer, allowing water and contaminant infiltration into ground water. A thicker, unpunctured confining layer is considered most protective of the underlying aquifer. The State should consider such confined aquifer characteristics in determining the adequacy of a confining layer as a hydrogeologic barrier.

EPA proposes to use the presence of a confining layer that is protective of the aquifer to act as a hydrogeologic barrier and nullify a sensitivity determination. Where the confining layer integrity is compromised by breaches or if the aquifer appears at the surface near the water supply well, the State shall determine if the layer is performing adequately to protect the well, and, therefore, public health. EPA estimates approximately 15 percent of undisinfected ground water system sources will be determined to be hydrogeologically sensitive (see RIA section 6.2.1.1).

4. Alternative Approaches to Hydrogeologic Sensitivity Assessment

EPA recognizes that the States have substantial experience characterizing hydrogeology. Most States require some hydrogeologic information for reasons such as to delineate wellhead protection areas, manage ground water extraction or assess ground water contamination. EPA recognizes that there is no single approach for identifying systems at risk from source water contamination. In the GWR, a selected subset of hydrogeologic settings (karst, fractured bedrock and gravel aquifers) is hydrogeologically sensitive. These hydrogeologic settings are identified through regional and local maps that show the general distribution of these settings. Other approaches considered by EPA to identify sensitive systems, but not selected, require additional data that may not be available to all States. In the following paragraphs, alternative methods to identify sensitive systems are discussed, including the data requirements for implementing each approach.

(a) Horizontal Ground Water Travel Time

Horizontal ground water travel time is the time that a water volume requires to travel through an aquifer from a fecal contamination source to a well. Viruses are longer lived than bacteria. Therefore, the ground water travel time should allow sufficient virus die-off to take place such that the concentration of viruses in the well water would be at or below a 1 in 10,000 annual risk level (Regli *et. al.,* 1991). However, travel time determinations are site specific, and some methods are expensive and/or difficult to perform. Therefore, EPA is not prescribing a particular travel time as a hydrogeologic sensitivity assessment criterion under the GWR. Travel time information may be useful for evaluating hydrogeologic barrier performance, and States may make use of this information where available.

Ground water travel time measurement methods include conservative tracer tests (*e.g.,* dyes, stable isotopes), and travel time calculations. Conservative tracer tests may be used in all aquifer types including karst and fractured bedrock, as well as porous media aquifers. Tracer tests are expensive and difficult to perform. Ground water travel time calculations are only suitable for porous media aquifers. Because travel time methods are site-specific and their associated levels of uncertainty vary, EPA is not prescribing one travel time number or method to be used nationally.

In evaluating whether to require a specific ground water travel time, EPA recognized that there are three problems with requiring this method for all States. First, all ground water travel time calculations require measurement of the aquifer porosity (void space). Aquifer porosity data are rare and usually must be estimated based on the aquifer character (*e.g.,* sand, or sand and gravel). Second, ground water travel time calculations require knowledge of the distance traveled and water velocity; however, calculating travel time is complicated because ground water does not travel in a straight line. The ground water's flow path can be nearly straight, as in the case of cavernous karst or it can be very convoluted as found in fractured media. Third, the ground water travel time value represents the average travel time of a large water volume moving toward a well. Some water arrives more quickly than the average. Because viruses and bacteria are small in size their charge effects become important. As a result, some fecal contaminants may take the fastest path from source to well and arrive faster than the average water volume. Fecal contaminants introduced into an aquifer may or may not be channeled into flow paths that move faster than the average water volume. Thus, a calculation of the average ground water travel time is not as protective as the calculation of the first arrival time of the

ground water volume. Because of the additional uncertainty in calculating first arrival times, average travel times must be augmented with a safety factor. Travel time data, where available, may assist States in evaluating hydrogeologic barriers for localities where all sources of fecal contamination have been identified.

(b) Setback Distance

A setback distance is the distance between a well and a potential contamination source. Many States already use setback distances around a well as exclusion zones in which septic tanks are prohibited.

EPA compiled data on State sanitary setback distances for PWS wells. EPA found that there is little uniformity among the States. State setback distances from septic tanks or drain fields for new PWS wells range from 50 to 500 feet. Moreover, some States have differing setback distances depending on the well type (*e.g.,* CWS versus NTNCWS and TNCWS), the well pumping rate (*e.g.,* greater or less than 50 gallons per minute) or the microbial contaminant source type (*e.g.,* 50 feet from a septic tank and 10 feet from a sewer line).

EPA considered using a strategy that included the setback distance as an element in determining the potential fecal hazard to systems. In this strategy, wells located near contamination sources are at risk. EPA concluded that it would be difficult to implement this strategy on a national scale for two reasons. First, the differing State setback distance requirements suggests that there is substantial disagreement among the States about an appropriate setback distance. Second, any setback distance selected for use in the GWR must be sufficiently large so as to protect a well from fecal contamination. The complexity of the processes that govern virus and bacterial transport in ground water and the variability of ground water velocity in sensitive hydrogeologic settings make it difficult, if not impossible, for EPA to specify setback distances that will be protective of public health for all hydrogeologic settings. Thus, EPA concluded that there was insufficient scientific data to mandate national setback distances in the GWR.

(c) Well and Water Table Depth

Well depth is the vertical distance between the ground surface and the well intake interval or the bottom of the well. Water table depth is the vertical distance between the ground surface and the water table. Infiltrating ground water can require substantial time to reach a deep well or a deep water table because precipitation infiltrating downward to the water table and vertical ground water flow within an aquifer are typically slow, and thus the long infiltration path to a deep well or water table provides opportunities for inactivation or removal of pathogens and is protective against source water contamination.

EPA considered identifying well depth and water table depth as alternative hydrogeologic sensitivity methods. Two key pieces of information would then be needed for each well: (1) Aquifer measurements that describe its capability to vertically transmit ground water and (2) measurements from the soil and other material overlying the water table that describe its capability to transmit infiltrating precipitation mixed with fecal contamination. EPA believes that few data are available to describe vertical ground water flow or infiltration on a national level. Thus, EPA concluded that there was insufficient data available to determine a well depth at which there exists a fecal contamination risk for all systems on a national scale.

5. Proposed Requirements

(a) Assessment Criteria

Today's proposal provides that States shall identify high priority systems through a hydrogeologic sensitivity assessment. In this assessment, wells located in karst, fractured bedrock or gravel hydrogeologic settings are determined to be sensitive. The information provided in previous paragraphs shows that the wells located in these hydrogeologic settings are potentially at risk of fecal contamination because ground water velocities are high and fecal contamination can travel long distances over a short time. A hydrogeologic barrier can protect a sensitive aquifer, and if present, can nullify the sensitivity determination. In its primacy application, a State shall identify its approach to determine the presence of a hydrogeologic barrier. For example, a State may choose to consider a specific depth, hydraulic conductivity, and the presence of improperly abandoned wells. For systems with one or more wells that potentially produce ground water from multiple aquifers, the State shall identify its approach to making separate hydrogeologic sensitivity determinations and, if appropriate, hydrogeologic barriers identifications, for each well. For example, a State may choose to consider a specific depth and hydraulic conductivity, improperly abandoned wells. The system shall provide to the State or EPA, at its request, any pertinent existing information that would allow the State to perform a hydrogeologic sensitivity analysis. The hydrogeologic sensitivity assessment does not necessarily require an on-site visit by the State, provided the State has adequate information (geologic surveys, *etc.*) to make the assessment without a site visit.

Discussions of proposed monitoring requirements for hydrogeologically sensitive systems are found in section III.D., and corrective action requirements are found in section III.E.

(b) Frequency of Assessment

The States, or their authorized agent, shall conduct one hydrogeologic sensitivity assessments for each GWS that does not provide treatment to 4-log inactivation or removal of viruses. States shall conduct the hydrogeologic sensitivity assessment for all existing CWSs no later than three years after publication of the final rule in the **Federal Register** and for all existing NCWSs no later than five years after publication of the final rule in the **Federal Register**. States shall complete the hydrogeologic sensitivity assessment prior to a new ground water system providing drinking water for public consumption. EPA requests comment on these time frames. Some stakeholders have indicated that an assessment for hydrogeologically sensitive areas (karst, gravel, fractured rock) of a State can be quickly performed at the State level. If such data can be quickly gathered and an assessment easily performed, EPA questions putting off the routine monitoring requirements and public health protection that it would bring for three or five years. EPA requests comment on requiring the State to perform the hydrogeologic sensitivity assessment within one year of the effective date of the final GWR.

(c) Reporting and Record Keeping Requirements

The State shall keep records of the supporting information and explanation of the technical basis for determinations of hydrogeologic sensitivity and of the presence of hydrogeologic barriers. The State shall keep a list of ground water systems which have had a sensitivity assessment completed during the previous year, a list of those systems which are sensitive, a list of those systems that are sensitive, but for which the State has determined a hydrogeologic barrier exists at the site sufficient for protecting public health, and a record of an annual evaluation of the State's program for conducting hydrogeologic sensitivity assessments.

6. Request for Comments

EPA requests comments on all the information presented earlier and the potential impacts on public health and the regulatory provisions of the GWR.

a. Routine Monitoring Without State Assessment

EPA requests comment on requiring systems to perform routine monitoring if the State fails to conduct a hydrogeologic sensitivity assessment. Under this provision, if the State fails to conduct a hydrogeologic sensitivity assessment within the time frame specified by the GWR, the systems would conduct fecal indicator monitoring once per month for every month they serve water to the public (see section § 141.403(d), microbial analytical methods). The time frame for completing sensitivity assessments for all existing CWSs is no later than three years after the date of publication of the final rule in the **Federal Register**, and the time frame for all existing NCWSs is no later than five years after the date of publication of the final rule in the **Federal Register**. The systems could discontinue monitoring only after the State conducts a hydrogeologic sensitivity assessment and determines that the systems are not sensitive, or if the systems initiate and continue treatment to achieve 4-log inactivation or removal of viruses.

b. Vulnerability Assessment

EPA requests comment on a detailed, on-site vulnerability investigation as an alternative to the Hydrogeologic Sensitivity Assessment. The alternative hydrogeologic investigation will assess the performance of all existing hydrogeologic barriers such as unsaturated zone thickness and composition (including the soil), the saturated zone thickness and composition above the well, intake interval, the frequency, duration and intensity of precipitation for all aquifer types, and will also require a detailed investigation of the well construction conditions by a certified well technician and a review of the well construction-related documentation from the sanitary survey and SWAPP assessment. The results of the detailed investigation must demonstrate that the existing hydrogeologic barriers, aquifer type and the well construction function to prevent the movement of viable pathogens from a contaminant source to a public water supply well. The demonstration may include ground water age dating, natural or artificial tracer test data, or ground water modeling results. See EPA 1998b for more information on vulnerability assessments.

c. Sandy Aquifers

EPA is proposing to require States to identify systems in karst, gravel and fractured rock aquifer settings as sensitive and these systems must perform routine source water monitoring. On March 13, 2000, the Drinking Water Committee of the Science Advisory Board (DWCSAB) reviewed this issue and made several recommendations to EPA concerning a draft of this proposal. EPA requests comment on two DWCSAB recommendations concerning the hydrogeologic sensitivity assessment. The committee recommended that all ground water sources be required to monitor for bacterial indicators and coliphage for at least one year—regardless of sensitivity determination. As an alternative approach, the committee recommended sand aquifers be included as sensitive settings. This recommendations was based on column studies of virus transport in soils that showed that viruses move rapidly through sandy soils and field studies of virus transport from septic tanks showing rapid movement into ground water from sandy coastal plains.

C. Cross Connection Control

EPA is concerned about introduction of fecal contamination through distribution systems; however, EPA has not proposed cross connection control requirements in the GWR. EPA will work with the Microbial/DBP FACA to consider whether cross connection control should be required in future microbial regulations, particularly during the development of the Long Term 2 ESWTR, in the context of a broad range of issues related to distribution systems. EPA will also request input from the FACA on whether to require systems to maintain disinfection residual throughout the distribution system. EPA seeks comments or additional supporting data related to cross connection control or other distribution system issues. In particular to cross connections, the Agency requests public comment on: (1) Whether EPA should require States and/or systems to have a cross connection control program, (2) what specific criteria, if any, should be included in such a requirement, (3) how often a program should be evaluated, (4) and whether EPA should limit any requirement to only those connections identified as a cross connection by the public water system or the State. The Agency also requests comment on what other regulatory measures EPA should consider to prevent contamination of drinking water in the distribution system.

D. Source Water Monitoring

1. Overview and Purpose

As previously stated, EPA recognizes that there are particular challenges associated with developing an effective regulatory approach for ground water systems. These include the large number of ground water systems that would be regulated, the fact that only a subset of these systems appear to have fecal contamination (although a larger number are likely to be sensitive), and that most ground water systems range from small to very small in terms of the population served. These factors combine to underscore the limitations of an across-the-board disinfection approach to regulation.

As part of the multiple-barrier approach, EPA proposes source water monitoring requirements that fulfill the need for a targeted risk-based regulatory strategy by identifying those systems with source water contamination and systems with high sensitivity to possible fecal contamination—specifically undisinfected systems located in hydrogeologically sensitive aquifers. EPA believes that the proposed requirements provide a meaningful opportunity to reduce public health risk for a substantial number of people served by ground water sources. This section provides detailed information on current monitoring requirements, monitoring data, indicators of fecal contamination, co-occurrence issues, and describes the proposed requirements.

EPA proposes the following source water monitoring requirements for systems that do not treat 4-log removal and/or inactivation of viruses: (1) A system must collect a source water sample within 24 hours of receiving notification of a total coliform-positive sample taken in compliance with the TCR, and test for the presence of *E. coli,* enterococci or coliphage; and (2) any system identified by the State as hydrogeologically sensitive through a sensitivity assessment (see § 141.403) must conduct routine monthly monitoring, during the months the system supplies water to the public, and analyze for *E. coli,* enterococci or coliphage. In either case, if any sample is fecal indicator-positive, the system would have to notify the State immediately and then the system must take corrective action.

Currently, all systems must comply with the TCR (see section I.B.1.) and the MCL for nitrates and nitrites. In

addition, CWSs and NTNCWSs must monitor at the entrance of the distribution system for 15 additional inorganic chemicals associated with an MCL (*e.g.,* antimony, arsenic) and sometimes other inorganic chemicals not associated with an MCL (calcium, orthophosphate, silica, sodium, sulphate; 40 CFR 141.23(b) and (c)). Systems will also have to comply with the Stage 1 DBPR, if they use a chemical disinfectant. CWSs must additionally monitor for certain organic chemicals and certain radionuclides. Ground water systems under the direct influence of surface water must satisfy the requirements of the SWTR and IESWTR.

Microbial monitoring plays an important role in detecting fecal contamination in source waters, as well as in assessing best management practices, including in-place disinfection adequacy and distribution system integrity. It is the most direct way to determine the presence of fecal contamination. However, because of limitations on sample volume, monitoring frequency, and the species of microorganisms that can reasonably be monitored, non-detection of a fecal indicator does not necessarily mean fecal contamination is absent (see Tables III–2 and 3).

2. Indicators of Fecal Contamination

Two approaches for determining whether a well is contaminated are to monitor for the presence of either specific pathogens or more general indicators of fecal contamination. Monitoring for individual pathogens, however, is impractical because the large number and variety of pathogens require extensive sampling and numerous analytical methods. This is a process which is extremely time-consuming, expensive, and also technically demanding. Moreover, methods are not available for some pathogens and pathogen concentrations in water are usually sufficiently small so as to require analysis of large-volume samples, which significantly increases analytical costs. For these reasons, EPA is focusing on indicators of fecal contamination as a screening tool rather than on individual pathogens themselves. The Agency is considering several promising fecal indicators: *E. coli,* enterococci, somatic coliphage, and male-specific coliphage. Because these indicators are closely associated with fecal contamination, EPA believes that even a single positive sample should require urgent State notification and other follow-up activities.

EPA considered three bacterial microorganisms as indicators of fecal contamination: *E. coli,* enterococci, and *C. perfringens. E. coli* and enterococci are both closely associated with fresh fecal contamination and are found in high concentrations in sewage and septage. Analytical methods are commercially available, simple, reliable, and inexpensive. *E. coli* is monitored under the TCR, and *E. coli* and enterococci are recommended by EPA as indicators for fecally contaminated recreational waters. A drawback is that these two groups may die out more quickly or be less mobile in the subsurface environment than some waterborne pathogens.

As with *E. coli* and enterococci, *C. perfringens* is common in sewage (about 10^6 organisms per liter) and is associated with fecal contamination. Methods of detection are commercially available, simple, reliable, and relatively inexpensive. *C. perfringens* forms protective spores (endospores), and these spores survive much longer in some environments than most pathogens. Thus, these spores may be present in old fecal contamination where fecal pathogens are no longer viable. EPA rejected *C. perfringens* as an indicator of fecal contamination for GWSs based on co-occurrence data showing that the organism is seldom present in ground water when other fecal indicators are present (Lieberman *et. al.,* 1999).

Enteric viruses, much smaller in size than bacteria such as *E. coli,* may be more mobile than bacteria because they can slip through small soil pores more rapidly. Thus, viral pathogens may sometimes be present in ground water in the absence of bacterial indicators of fecal contamination. However, other factors such as sorption to soil and aquifer particles are also important in affecting the relative transport of viruses and bacteria in ground water.

The coliphage are viruses that infect the bacterium *E. coli.* Because they do not often infect other bacteria, they (like *E. coli*) are closely associated with recent fecal contamination. Because they are viruses, their stability and transport within soil and under aquifer environmental conditions may be similar to the fate and transport of pathogenic viruses. There are two categories of coliphage—somatic coliphage and male-specific coliphage. The somatic coliphage are a heterogenous group that enters the cell wall of *E. coli.* The male-specific (also called the F-specific) phage are those that only enter through tiny hair-like appendages (pili) to the cell wall.

There are issues about using coliphage as an indicator of fecal contamination in small communities. Individuals do not consistently shed coliphage. For example, Osawa *et al.* (1981) found that only 2.3% of infected individuals shed male-specific phage. Thus, the occurrence of these viruses in small septic tanks, which is an important source of fecal contamination in ground water wells, is uncertain. The issue of frequency and abundance is important because a primary source of fecal contamination in wells is thought to be nearby leaking septic tanks.

To answer this question, EPA funded a study to determine (Deborde, 1998, 1999) the frequency and density of coliphage occurrence in household septic tanks. Deborde (1998) collected and analyzed a sample from each of 100 sites in the Northwest and from each of 12 sites in the Midwest (3), Southwest (3), Northeast (3), and Southeast (3). All 112 samples were analyzed for male-specific coliphage, while 33 were also analyzed for somatic coliphage. Table III–1 shows that male-specific coliphage are present in about one-third of the septic tank samples, while somatic coliphage are present in two thirds of the samples tested. However, when found, the male-specific coliphage are present at a slightly higher level. The number of possible people per household (and therefore the number of virus sources) varied from one to seven, with an average of 2.8. In the next phase of the study, Deborde (1999), selected ten of the 112 sites (five coliphage-positive, five coliphage-negative) and collected three quarterly samples from each. The data indicate that significant changes in density occur over time. For the male-specific phage, the number of positive sites was 40%, 60% and 40% for quarter 2, 3, and 4, respectively. For the somatic phage, the number of positive sites was 70%, 80% and 50% during these same three quarters. As in the first phase, somatic phage were detected more frequently and the male-specific phage were (when detected) more abundant.

The data indicate that household septic tanks often (50–80%) contain measurable levels of somatic coliphage, suggesting that the somatic coliphage may be an appropriate indicator of fecal contamination in nearby source waters. However, the male-specific coliphage were present in the septic tanks in slightly less than half the sites at any one time. Based on these data, male-specific phage may not be suitable for detecting fecal contamination in source waters if the most likely contamination source is a household septic tank.

TABLE III–1.—FREQUENCY AND DENSITY OF COLIPHAGE IN HOUSEHOLD SEPTIC TANKS, PRELIMINARY RESULTS (DEBORDE, 1998)

Coliphage	Presence	Density [1]
Male-specific.	36% (44/112)	9.7×10^5 PFU [1]/L
Somatic	67% (22/33)	1.3×10^5 PFU [1]/L

[1] Plaque-Forming Units (PFU).

Analytical methods for coliphage are available and are far less expensive than methods for pathogenic virus detection. However, the coliphage detection methods are still somewhat more expensive than those for the common indicator bacteria. EPA is in the process of funding the development of more sensitive, less expensive analytical methods for the somatic and male-specific coliphage.

EPA also considered methods using polymerase chain reaction (PCR) for identifying specific viruses. PCR amplifies the nucleic acid of the targeted virus, which then can be detected and identified by various procedures. An advantage of this method over those for coliphage is that it can identify the presence of specific viruses pathogenic to humans. Methods using PCR may be specific, sensitive, and much more rapid than other methods for pathogenic virus. However, current PCR technology cannot yet determine whether a virus is viable or infectious and is significantly more expensive than the culture methods for the above fecal indicators (currently about $250–300 per sample). EPA expects substantial reductions in this cost as the method is further developed. Nevertheless, in spite of the current limitations of PCR, a positive result in a ground water sample would strongly imply that a pathway exists for virus contamination of ground water.

EPA did not consider total coliform bacteria or heterotrophic bacteria as fecal indicators because both groups grow naturally in soil and water, and thus are not specific indicators of fecal contamination.

According to a survey of ground water data by the AWWARF study (see Table II–6), *C. perfringens* was only detected in one of 57 samples (1.8%). Thus, EPA eliminated this organism from consideration. See Tables III–2 and 3 for occurrence data on candidate indicators.

TABLE III–2.—PRESENCE/ABSENCE OF INDICATORS AT ENTEROVIRUS-POSITIVE SITES (GENERALLY, ONE SAMPLE/SITE)

Study	Number of positive enterovirus sites	Total coliforms (100 mL)	*E. coli or* fecal coliforms	Enterococci or fecal streptococci (100 mL)	Somatic phage (100 L)	F–specific phage (100 L)
AWWARF Study	22	4	NA	[1] 2	[2] 0	[2] 2 (3)
Missouri Alluvial Study	11	5	3	5	1	0
Missouri Ozark Plateau	10	0	0	0	0	2

[1] Only 11 enterovirus-positive sites tested.
[2] 15 liter samples.

TABLE III–3.—DATA FROM EPA/AWWARF STUDY. NUMBER OF TIMES INDICATOR WAS POSITIVE IN 12 MONTHLY SAMPLES AT ENTEROVIRUS-CONTAMINATED SITES [1]

Enterovirus-positive site (≥ 1/12 pos)	Total coliform-positive	*E. coli* positive	Enterococci-positive	Somatic coliphage-positive [2]	F–specific coliphage positive [2]
029	12	12	12	12	11
031	12	6	5	9	3
047	12	10	12	12	4
061	11	11	10	11	8
091	10	3	5	12	0
097	5	0	1	4	0
099	2	0	1	0	1
Total	64	42	46	60	27

[1] Sample volume: bacteria 300 mL; coliphage most between 10–100L; enterovirus: average of 6,037 L.
[2] Host for somatic coliphage: *E. coli* C; host for F-specific coliphage: WG49.

The data strongly shows that a single negative sample is usually not sufficient to demonstrate the absence of fecal contamination, and that repeated sampling is necessary. Based on the data, EPA does not believe that one fecal indicator is clearly superior to the others.

The coliphage sample volume in the studies in Table III–3 ranged from 10L to 100L (compared to 100–300 mL for the bacterial indicators). EPA believes that it would be unreasonable to expect systems to collect and transport these high water volumes. However, as stated earlier, several sensitive coliphage methods have been developed that can be used with a more reasonable volume (100–1000 mL).

Thus, for the reasons indicated earlier, EPA is proposing *E. coli,* coliphage and enterococci as appropriate monitoring tools for source water. Because these three fecal indicators are closely associated with fecal contamination, the Agency believes that a single source water positive *E. coli,* coliphage or enterococci sample is sufficient to consider the source water as fecally contaminated. Repeated sampling is proposed for routine monitoring (described in the next section) since it may take more than one sample to identify intermittent contamination. Additional support for this approach is provided by Christian and Pipes (Christian and Pipes, 1983), who found that coliforms follow a lognormal distribution pattern in small distribution systems (*i.e.,* coliforms are not uniformly distributed). EPA has no reason to suspect that this non-uniform pattern should be different in source waters. Only one additional sample is proposed after triggered monitoring (described in the next section) since the

sample is taken immediately after an indication of contamination.

The Agency recognizes that errors in sample collection and testing may contaminate a sample, and therefore would allow the State to invalidate such samples, on a case-by-case basis, in the same manner required under the TCR (141.21(c)(1)(i) and (iii) for invalidating total coliform samples. However, EPA believes that errors in sample collection rarely lead to contamination. This is based on a study by Pipes and Christian (Pipes and Christian, 1982), where water samplers and other individuals tried to contaminate 111 sample bottles containing 100-mL of sterile dechlorinated tap water by placing a finger into the mouth of each bottle and shaking the bottle vigorously for about 5 seconds. Only 5.4% of the samples were found to contain total coliforms.

Thus, the Agency believes that States should invalidate positive samples sparingly. Under the GWR, the State would be allowed to invalidate a positive source water sample if (1) the laboratory establishes that improper sample analysis caused the positive result or (2) the State has substantial grounds to believe that a positive result is due to a circumstance or condition which does not reflect source water quality, documents this in writing, and signs the document. In this case, another source water sample must be taken within 24 hours of receiving notice from the State.

3. Proposed Requirements

a. Routine Source Water Monitoring

EPA stated in the previous section on hydrogeology that a State would be required to determine the hydrogeological sensitivity of each system not treating to 4-log inactivation or removal of viruses. If the State determines that the well(s) serving such a system draws water from a sensitive aquifer, that system would be required to collect a source water sample each month that it provides water to the public and test the sample for the fecal indicator specified. If any sample contains a fecal indicator, the system would be required to notify the State immediately and address the contamination within 90 days unless the State has approved a longer schedule (see § 141.404).

Under the GWR, if a system detects no fecal indicator-positive samples after 12 monthly samples, the State would be allowed to reduce routine source water monitoring to quarterly. The State would be allowed, after the first year of monthly samples, to waive source water monitoring altogether for a system if the State determines that fecal contamination of the well(s) is highly unlikely, based on sampling history, land use pattern, disposal practices in the recharge area, and proximity of septic tanks and other fecal contamination sources. PWSs that do not operate year-round would need to conduct monthly sampling for more than one year to collect the twelve monthly samples. EPA requests comment on allowing such systems to monitor monthly for only one seasonal period when the system is in operation.

b. Source Water Sample After a Total Coliform-Positive Under the TCR

EPA proposes that when a non-disinfecting ground water system is notified that a sample is total coliform-positive under the TCR, that system would have to collect, within 24 hours of being notified, at least one source water sample. This requirement would be in addition to all monitoring and testing requirements under the TCR. The source water sample would be tested for either *E. coli*, coliphage or enterococci, as determined by the State. A system that chooses to first test for total coliforms in the source water, and then test any total coliform-positive culture for *E. coli* would meet the requirement.

If any sample is *E. coli*-positive, coliphage-positive or enterococci-positive, the system would be required to meet § 141.404. EPA believes that a total coliform-positive sample in the distribution system, followed by a fecal indicator-positive sample in the source water, indicates a serious contamination problem.

The Agency would allow the State to waive source water monitoring for any system, on a case-by-case basis, if the State determines that the total coliform-positive is associated solely with a distribution system problem. In this case, a State official would be required to document the decision, including the rationale for this decision, in writing, and sign the document.

c. Confirmation of Positive Source Water Sample

The Agency recognizes that false-positive results may occasionally occur with most microbial methods (*i.e.,* a non-target microbe is identified by the method as a target microbe). For example, the false-positive rate for *E. coli* is 7.2% for the E*Colite Test, 2.5% for the ColiBlue24 Test, and 4.3% for the membrane filter test using MI Agar.

Therefore, EPA would allow the State to invalidate a positive source water sample where a laboratory establishes that improper sample analyses caused the positive result or if the State has substantial grounds to believe that a positive result was due to a circumstance or condition that did not reflect source water quality and documents this in writing. For example, a State may invalidate a positive source water sample if a subsequent validation step for the same sample fails to confirm the presence of the fecal indicator being used. These provisions are consistent with the invalidation criteria under the TCR (40 CFR 141.21(c)).

EPA believes that, in the interest of public health, a positive sample by any of the methods listed in Table III–4 should be regarded as a fecal indicator-positive source water sample. This assumption is supported by the Pipes and Christian study (Pipes and Christian, 1982) study mentioned previously, which shows that sample collector handling error is rarely a cause of fecal contamination. Nevertheless, the Agency recognizes that contamination during sampling and analysis may occur, albeit rarely, and is proposing to allow the State to invalidate a fecal indicator-positive in a routine monitoring sample under certain circumstances in the manner described in this section. EPA is also proposing to allow confirmation of a fecal indicator-positive routine source water sample. Specifically, the rule would permit the State to allow a system to waive compliance with the treatment technique in § 141.404, after a single fecal indicator-positive source water sample on a case-by-case basis, if—

(1) The system collects five repeat source water samples within 24 hours after being notified of a source water-positive result;

(2) The system has the samples analyzed for the same fecal indicator as the original sample;

(3) All the repeat samples are fecal indicator-negative; and

(4) All required source water samples (routine and triggered) during the past five years were fecal indicator-negative.

Under this approach, a system would not necessarily have to comply with the specified treatment requirements on the basis of a single, isolated fecal indicator-positive sample if all additional monitoring showed that no problem exists. The Agency believes that this limited level of confirmation would not undermine public health protection. Conversely, the Agency believes that two fecal indicator-positive source water samples at a site provides strong evidence that the source water has been fecally contaminated.

The Agency is also proposing that a total coliform-positive sample in the

distribution system accompanied by a fecal indicator-positive source water sample be sufficient grounds for requiring compliance with the treatment requirements. The Agency argues that it would be unreasonable to expect a sample collector to accidently contaminate two samples taken at least one day apart, and also contends that the likelihood of a false-positive result occurring in both of two samples is much lower than in a single sample. Thus, the Agency believes that, in this circumstance, there is a significant probability that the source water is indeed fecally contaminated. Moreover, the Agency notes that, under the TCR, two consecutive total coliform-positive samples, one of which is *E. coli*-positive, is sufficient grounds for an acute violation of the MCL for total coliforms. For these reasons, EPA believes that it is reasonable to require a system with a total coliform-positive sample in the distribution system followed by a fecal indicator-positive source water sample to comply with the treatment requirements. However, EPA also recognizes that, by itself, a positive total coliform result is not always an indication of fecal contamination (even if the sample result is not a false positive). EPA requests comment on waiving compliance of the treatment techniques after a single positive triggered monitoring source water sample based upon five negative repeat samples as described previously in this section.

4. Analytical Methods

EPA proposes to approve the following methods (listed in 141.403), with the sample volume of 100 mL, for source water monitoring of *E. coli*, enterococci and coliphage. A system would have to use one of these methods. Most of the proposed analytical methods for *E. coli* for source water monitoring are consensus methods described in Standard Methods for the Examination of Water and Wastewater (19th and 20th ed.). 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. Information about these methods is available in the **Federal Register** (63 FR 41134–41143, July 31, 1998; 64 FR 2538–2544, January 14, 1999) and in the EPAWater Docket. Of the three enterococci methods, two are consensus methods in Standard Methods; while the third (Enterolert) was described in a peer-reviewed journal article (Budnick *et al.*, 1996). The description for each of the proposed *E. coli* and enterococci methods state explicitly that the method is appropriate for fresh waters or drinking waters.

EPA is proposing the approval of two newly developed coliphage methods for detecting fecal contamination.

The Agency has conducted performance studies on the two proposed methods, using ten laboratories: a new two-step enrichment method and a single-agar layer method used for decades, but recently optimized for ground water samples. For the two-step enrichment method, using 100-mL spiked water samples (reagent water and ground water) and two *E. coli* hosts (CN–13 and F_{amp}), laboratories detected one plaque-forming unit (PFU) 60–90% of the time. For the optimized single-agar layer method, using the same water type and volume (but higher coliphage spike) and same two *E. coli* hosts, recoveries ranged from 61% to 178%, based upon a coliphage spike level determined by a standard double-agar layer test.

Based upon the results of performance testing, EPA believes that these two coliphage tests are satisfactory for monitoring ground water in compliance with this rule. The two test protocols and study results are available for review in EPA's Water Docket.

EPA is proposing requiring that systems collect and test at least a 100-mL sample volume. The Agency recognizes that a 1–L sample volume will provide ten times more sensitivity than a 100-mL sample. However, the Agency also understands that the greater sample volume would also weigh ten times more, and thus cost more to ship to a laboratory. Data exists that indicate more frequent smaller-volume samples are better in detecting fecal contamination than a smaller number of high volume samples (Haas,1993). AWWARF is funding a study on this issue, and data should be available shortly. The Agency requests comment on the most appropriate sample volume.

For any of the methods described previously, the maximum allowable time between ground water sample collection and the initiation of analysis in the certified laboratory, is 30 hours. This would be consistent with the TCR. The Agency would prefer a shorter time, but believes that a sizable percentage of small systems have difficulty getting their samples to a certified laboratory within 30 hours. In addition, unlike the SWTR where the density is measured, EPA is proposing in the GWR to require analysis for microorganism detection alone. The Agency believes that the detection of an organism is less sensitive to change than measurement of density, and thus a 30-hour transit time would be reasonable.

5. Request for Comments

EPA requests comments on proposed indicators of fecal contamination and analytical methods. In addition, EPA requests comments on the following alternative approaches.

(a) Source Water Samples after an MCL Violation of the TCR

EPA requests comment on requiring a system that violates the MCL for total coliforms, or detects a single fecal coliform/*E. coli*-positive sample under the TCR, to collect five source water samples, rather than a single source water sample as proposed. The Agency believes this alternative approach would be reasonable, given that both events are sufficiently important to require the system to notify the State (and, for a MCL violation, the public) as opposed to a single total coliform-positive sample which does not require notification. Under this approach, systems would be required to collect five source water samples within 24 hours for every MCL violation or positive *E. coli* or fecal coliform sample in the distribution system and test them for one of the EPA-specified fecal indicators. If any source water sample were positive, the system would have to treat or otherwise protect the drinking water. This monitoring requirement would be in addition to requirements under the TCR.

(b) Sampling of Representative Wells

EPA recognizes that most CWSs have more than one well, raising the question about whether the system would need to monitor all wells or just one representative well. One approach would be to require a system to sample all wells because this approach provides more reliable public health protection. However, the Agency notes that wells belonging to a system may vary in their sensitivity to fecal contamination.

If a system is drawing water from more than one well in a hydrogeologically sensitive aquifer, EPA believes that all such wells should be sampled routinely, unless the State can identify a single representative well or, the well (or subset of wells) sensitive to fecal contamination. If a system is required to collect a source water sample as a result of a total coliform-positive sample in the distribution system (triggered monitoring), EPA believes that all wells should be sampled, unless the State can identify a single representative well or the well (or

subset of wells) most vulnerable to fecal contamination. Alternatively, if the total coliform-positive sample was found in a part of the distribution system supplied by a single well, then it might be acceptable to sample that specific well alone. The Agency seeks comment on these alternatives and other approaches.

EPA recognizes that systems may have storage tanks or other water holding tanks between the wellhead and the distribution system. Therefore the Agency also requests comment on whether further definition is needed for exactly where source water samples should be taken; *e.g.*, at the well, the tank, or at any point before the water enters the distribution system. The Agency seeks comment on where source water samples should be collected.

(c) Distribution System Monitoring for Fecal Indicators

One alternative approach for distribution system monitoring is to augment total coliform/*E. coli* testing in the distribution system with one or more additional fecal indicators. For example, under this approach, a system would be required to monitor coliphage or enterococci at the same frequency as it monitors for total coliforms. This approach recognizes that fecal indicators differ in their effectiveness in detecting fecal contamination, and that this effectiveness may vary with environmental conditions. Thus, more than one fecal indicator should stand a greater likelihood of detecting fecal contamination than a single indicator (*i.e., E. coli* under the TCR). This approach would be more expensive for systems, but may be counterbalanced by the greater likelihood of detecting fecal contamination. EPA seeks comment on this monitoring approach.

(d) Persistent Monitoring Non-Compliers

EPA requests comment on defining a persistent non-complier of monitoring requirements and, specifically what any additional monitoring, public notification or treatment requirements should pertain to them.

(e) Monitoring of Disinfecting Systems

Some States currently require disinfected systems to monitor their source water to ensure that the system would be protected against the potential risk of fecal contamination in the event of a disinfectant failure. The Agency requests comment on requiring a disinfected system to test its source water periodically.

The Agency also requests comment on requiring all ground water systems (including those that disinfect to 4-log removal/ inactivation of viruses) to collect a source water sample after a total coliform-positive in the distribution system (triggered monitoring). Systems may want or need to change their disinfection practices or take other source water protection actions based on discovering that their source water is contaminated.

(f) Multiple Fecal Indicators

EPA is proposing to require ground water systems to monitor coliphage, *E. coli,* or enterococci, as determined by the State, in the source water. On March 13, 2000, the Drinking Water Committee of the Science Advisory Board (DWCSAB) made a few recommendations to EPA concerning a draft of this proposal.

The DWCSAB recommended unanimously, and the Agency is requesting comment on, requiring monitoring for both bacterial and viral indicators for both routine and triggered monitoring. Specifically, EPA is requesting comment on whether systems that must monitor their source water be required to monitor for both a bacterium (*E.coli* or enterococci) and virus (male specific and somatic coliphage). As discussed earlier, occurrence data show that fecal indicators differ in their scope and this may vary with environmental conditions. The DWCSAB noted that the scientific literature documents significant differences between transport and survival of bacteria and viruses. Coliphage and human viruses are smaller than bacterial indicators and thus under certain conditions may travel faster through the ground than bacteria; alternately, bacterial indicators are often at much higher concentrations in fecal matter than coliphage, and thus may be a more sensitive indicator than coliphage relatively near the contamination source. The use of both bacteria and coliphage indicators could provide better ability to detect fecal contamination and greater protection of human health. However it would also entail a higher probability of false positive results, and higher sampling costs to the systems.

The DWCSAB believed that the proposed indicators (*E.coli,* enterococci, and coliphage) are appropriate. The DWCSAB noted that both *E. coli* and enterococci are effective bacterial indicators. *E. coli* methods may be more familiar to many laboratories which may be advantageous. The enterococci may be somewhat hardier in terms of environmental persistence and perhaps more fecal specific. The media for enterococci is more selective and less subject to background growth with regards to the viral indicators. The DWCSAB recommended both somatic and male-specific coliphage be required when viral monitoring of the source water is conducted because they will detect a larger population of coliphage. The DWCSAB stated that laboratory methods are available to detect both coliphages and that they believe that a method can be made available to detect both coliphages on a single host (using a single host such as *E. coli* C3000) so that it would not be necessary to collect and test two samples for coliphage.

(g) Monitoring Frequency and Number of Samples To Identify Fecal Contamination

As stated previously, the proposed rule would require systems with sensitive wells to conduct monthly routine monitoring. The Agency believes that monitoring more frequently than monthly would increase the probability for detecting fecal indicator organisms sooner in a fecally contaminated well. However, the Agency also recognizes that more intensive monitoring could be overly burdensome to many small systems. Less than monthly monitoring would likely delay fecal contamination detection, and thus continue a possible health risk for a longer time. EPA concludes that monthly monitoring is the most appropriate balance between monitoring costs and prompt fecal contamination detection.

The total number of samples needed to determine whether a ground water is fecally contaminated depends on the fecal indicator used, the sample volume, and the level and duration of fecal contamination in the source water. Because the EPA/AWWARF study described in section II.C.2. monitored contaminated wells repeatedly, the results of this study were used to assess the likelihood (95%, 99%, 99.9% confidence) of detecting fecal contamination with different indicators, number of samples and level of fecal contamination actually in the ground water. The Agency then determined the minimum number of samples necessary to detect contamination, allowing for a small percentage of samples where fecal contamination is not detected. The EPA/AWWARF study operated in two phases. In Phase I, the EPA/AWWARF researchers identified a set of 93 wells thought to be vulnerable to fecal contamination. In Phase II, the researchers conducted further analysis, including monthly monitoring for virus and bacteria, on a subset of 23 of the Phase I wells which demonstrated total coliform and/or fecal bacteria contamination and on an additional 7

wells chosen for their unique physical or chemical characteristics.

From the wells tested in Phase II of the EPA/AWWARF study, seven sites tested positive for enterovirus in at least one sample of the twelve collected during the year. These seven waters are considered to be representative of ground water that are highly fecally contaminated at least part of the year. In such waters, a good indicator should be present in almost every sample, therefore, the number of non-detects should be very low. Combining the monthly results for these seven waters, there are 84 results for each indicator. Table III–5 shows the proportion of positives among the 84 results for each of four indicators.

TABLE III–5.—INDICATOR PERFORMANCE IN SEVEN HIGHLY-CONTAMINATED WATERS

Indicator	Samples positive (percent) (N=84)
E. coli	50
Enterococci	54.8
Somatic Coliphage	71.4
F-Specific Coliphage	32.1

N = number of samples.

If P is the probability of a positive sampling result (a detect) for a single indicator sample assay, then the probability of at least one positive result for N repeated independent samples is $1–(1–P)^N$. The probability of ''N'' non-detects is $(1–P)^N$. Table III–6 shows the probabilities of ''N'' non-detects for the same indicators as a function of the number of independent sample assays (N).

TABLE III–6.—PROBABILITY OF NON-DETECTS IN GROUND WATER THAT IS HIGHLY FECALLY CONTAMINATED AT LEAST PART OF THE YEAR (WHERE 'N' IS THE NUMBER OF INDEPENDENT ASSAYS)

Indicator [1]	Number of samples (N)								
	N = 1 (percent)	N = 2 (percent)	N = 4 (percent)	N = 6 (percent)	N = 12 (percent)	N = 24 (percent)	N* 5 percent	N*1 1 percent	N* 0.1 percent
E.coli	50	25	6.3	1.6	<0.1	<0.1	5	7	10
Enterococci	45.2	20.5	4.2	0.9	<0.1	<0.1	4	6	9
Somatic Coliphage	28.6	8.2	0.7	0.1	<0.1	<0.1	3	4	6
F-Specific Coliphage	67.9	46	21.2	9.8	<1.0	<0.1	8	12	18

Sample volume was 300 ml for *E. coli* and enterococci, 10–100L for coliphage
N* = Smallest number of samples for which the error rate is less than or equal to the specified percentage (5%, 1%, 0.1%).

Table III–6 shows that six to18 source water samples are needed, depending on the fecal indicator (and sample volume used), to determine with a 99.9% probability that a fecal indicator positive will be detected in ground water that is highly contaminated at least part of the year.

A similar analysis was conducted using the results for the 10 waters that tested positive for *E. coli* at least once (N=12), but negative for enterovirus. These waters were defined as moderately contaminated during at least part of the year. Because these waters probably do not contain enteroviruses at easily detectable levels, the incidence of waterborne disease is probably less. Table III–7 shows the probabilities of ''N'' non-detects for different numbers of independent sample assays (N).

TABLE III–7.—PROBABILITY OF NON-DETECTS IN GROUND WATER THAT IS MODERATELY FECALLY CONTAMINATED AT LEAST PART OF THE YEAR (WHERE 'N' IS THE NUMBER OF INDEPENDENT ASSAYS)

Indicator	Number of samples (N)								
	N = 1 (percent)	N = 2 (percent)	N = 4 (percent)	N = 6 (percent)	N = 12 (percent)	N = 24 (percent)	N* 5 percent	N* 1 percent	N* 0.1 percent
E.coli	71.7	51.4	26.4	13.5	1.8	<0.1	9	14	21
Enterococci	67.5	45.6	20.8	9.55	0.9	<0.1	8	12	18
Somatic	72.5	52.6	27.6	14.5	2.1	<0.1	10	15	22
F-Specific	96.7	93.4	87.3	81.6	66.6	44.3	89	136	204

Sample volume was 300 ml for *E. coli* and enterococci, 10–100L for coliphage
N* = Smallest number of samples for which the error rate is less than or equal to 5.0%, 1% and 0.1%.

Table III–7, shows that 8 to 89 samples are needed, depending on the indicator selected, to determine with a 95% probability that a fecal indicator positive will be detected in a well that is moderately contaminated at least part of the year.

Based on the data described previously and statistics, EPA concludes that, given a margin of safety for the analysis, 12 samples would be sufficient for determining the presence of fecal contamination in sensitive wells. For systems operating year round, 12 monthly samples will provide data throughout the year, increasing the likelihood of detecting the seasonal presence of fecal contamination.

EPA requests comment on the monitoring approach discussed previously and the analysis and the assumptions used.

(h) Triggered Monitoring in Systems Without a Distribution System

EPA believes that circumstances exist that might not require the collection of a source water sample after a total coliform-positive sample in the distribution system. For example, if an

undisinfected system does not have a distribution system, any sample taken for compliance with the TCR is essentially a source water sample. Therefore, the Agency is requesting comment on whether to allow States to waive ''triggered'' source water sampling for systems without distribution systems if the system is also taking TCR samples at least quarterly. If the total coliform-positive sample from the distribution system is fecal coliform- or *E. coli*-positive, the system would be required to meet the treatment technique. There might also be provisions for repeat sampling in this case.

(i) Routine Monitoring in Systems Without a Distribution System.

EPA requests comment on whether to allow States to substitute TCR monitoring for routine monitoring in hydrogeologically sensitive systems if the system does not have a distribution system and takes at least one total coliform sample per month under the TCR for every month it provides water to the public. Such a system would be monitoring source water under the TCR. The State would be allowed to reduce or waive monthly monitoring after twelve negative monthly samples. The rule would require a system that has a total coliform-positive sample that is also *E. coli* (or fecal coliform)-positive to meet the treatment requirements in § 141.404.

(j) Source Water Monitoring for All Systems

EPA is proposing to require source water monitoring requirements for systems that do not treat to 4-log inactivation or removal of viruses and have either a total coliform-positive sample taken in compliance with the TCR, or any system identified by the State as hydrogeologically sensitive. On March 13, 2000 the Drinking Water Committee of the Science Advisory Board (DWCSAB) reviewed this issue and made several recommendations to EPA concerning a draft of this proposal. The DWCSAB raised concerns that under this approach many untreated ground water systems will not be monitored at the source, particularly in light of available occurrence data indicating contamination between 4 and 31 percent of ground water systems, a number of which many not be located in hydrogeologically sensitive areas. DWCSAB unanimously recommended that all ground water systems monitor for both bacterial and viral indicators. EPA requests comment on whether routine source water samples should be required for all ground water systems that do not notify the State that they achieved 4-log inactivation or removal of virus. EPA also requests comment upon the appropriate frequency (monthly or quarterly) for routine monitoring if it were required for all systems. EPA also requests comment upon whether this monitoring should be performed in conjunction with sanitary surveys so as to provide data for the sanitary survey and to reduce the capacity burden on laboratories by taking advantage of the phased timing of sanitary surveys (every 3 years for CWSs and every 5 years for NCWs).

E. Treatment Techniques for Systems With Fecally Contaminated Source Water or Uncorrected Significant Deficiencies

1. Overview and Purpose

EPA proposes that a public ground water system with uncorrected significant deficiencies or fecally contaminated source water must apply a treatment technique or develop application for a longer State-approved treatment technique within 90 days of notification of the problem. Under the SDWA, the State may extend the 90 day deadline up to two additional years if the State determines that additional time is necessary for capital improvements (SDWA, 1412(b)(10)). As part of this requirement and in consultation with the State, systems must eliminate the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer. Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness.

EPA is proposing 99.99% (4-log) virus inactivation or removal as the minimum level of treatment since it is the level required of surface water systems under the SWTR and because, the World Health Organization (WHO) states that disinfection processes must achieve at least 4-log reduction of enteric viruses (WHO, 1996). Which treatment technique approach is chosen will depend on existing State programs, policies or regulations. States must describe in their primacy application the treatment technique they will require and under what circumstances. If the treatment technique is not provided within 90 days, or if it is not implemented by the system in accordance with schedule requirements, the system is in violation of the treatment technique requirements of the GWR.

States and systems can select a number of treatment technologies to achieve 4-log virus inactivation or removal. The treatment technologies which have demonstrated the ability to achieve 4-log virus inactivation are chlorine, chlorine followed by ammonia (chloramines), chlorine dioxide, ozone, ultraviolet radiation (UV) and anodic oxidation. Reverse osmosis (RO) and nanofiltration (NF) have demonstrated the ability to achieve 4-log removal of viruses.

The Agency is also proposing requirements for systems that treat to monitor the disinfection and State notification requirements any time a system fails to disinfect to 4-log inactivation or removal of viruses. As part of this proposal, systems serving 3,300 or more people per day must monitor the disinfection continuously. Systems serving fewer than 3,300 people per day must monitor the disinfection by taking daily grab samples. When a system continuously monitors chemical disinfection, the system must notify the State any time the residual disinfectant concentration falls below the State-determined residual disinfectant concentration and is not restored within four hours. When a system monitors chemical disinfection by taking daily grab samples the system must maintain the State-determined residual disinfectant concentration in all samples taken. If any sample does not contain the required concentration, the system must take follow-up samples every four hours until the required residual disinfectant concentration is restored. The system must notify the State any time the system does not restore the disinfectant concentration to the required level within 4 hours.

a. Background

A key element of the multiple-barrier approach is disinfection where fecal contamination or significant deficiencies are not or cannot be corrected. EPA recognizes that the GWR must provide system-specific flexibility due to the diverse configuration and variability of the numerous public ground water systems in operation and allow for State-specific flexibility. Therefore, the proposed treatment technique requirements are designed to support the multiple-barrier approach, yet provide flexibility to meet system-specific concerns.

EPA recognizes that States use varying approaches and that a State's preferred approach comes from extensive experience in dealing with uncorrected significant deficiencies and

contaminated source water. States may require systems to take differing approaches to providing treatment techniques, depending upon many factors, including the system's configuration, or State policies or regulations. Therefore, the proposed GWR attempts to build on the strengths of existing State programs, yet provide requirements which ensure safe drinking water for all consumers. Under the proposed GWR, States may require systems to eliminate the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer. Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness. For example, a State may have a policy or regulation requiring a system to consider an alternative source of safe drinking water before considering the use of disinfection. Alternatively, the State may require the system to disinfect to 4-log virus inactivation without first considering the use of corrective BMPs or alternative sources of safe drinking water. The approach the State will use to require a treatment technique for uncorrected significant deficiencies or fecally contaminated source water must be described in the State's primary enforcement application (primacy). EPA expects a State to build upon existing ground water programs to meet today's proposed regulations. In any case, systems which do not provide the appropriate State-determined treatment technique within the 90 day deadline, and do not have a State-approved plan in place for complying with the treatment technique requirement within 90 days, are in violation of the treatment technique requirements of the GWR.

b. Corrective Action Background Information

This section presents background information used by EPA to develop the proposed treatment technique requirements for ground water systems with uncorrected sanitary survey significant deficiencies or fecally contaminated source water. Specifically discussed is information related to current State treatment technique requirements, and the protectiveness of treatment techniques, as well as a discussion of disinfection as it relates to uncorrected significant deficiencies and fecally contaminated source water.

i. Alternative Sources of Safe Drinking Water

Limited data exists on the effectiveness of systems using an alternative source as a treatment technique against uncorrected significant deficiencies or fecally contaminated source water. However, since many States require a wide range of BMPs to be followed prior to placing an alternative source into service, it is believed that this treatment technique would be effective. In addition, some States require the local hydrogeology or sources of contamination to be considered for all new sources of drinking water, and would, therefore, provide some assurance that an alternative source as a treatment technique is effective. Several States require systems with source water contamination to provide an alternative source, if possible.

ii. Background Information on Eliminating the Source of Contamination

As with the effectiveness of providing alternative source water as a treatment technique for uncorrected significant deficiencies or fecally contaminated source water, limited data exists on the effectiveness of eliminating the source of contamination as a treatment technique. The report on the Analysis of Best Management Practices for Community Ground Water Systems Survey Data Collected by the Association of State Drinking Water Administrators (ASDWA, 1998) provides information on the effectiveness of BMPs in reducing total coliform positives, however, it does not address those BMPs used in response to a source water fecal contamination event. The report does show that when correcting significant deficiencies, a significant pairwise association exists in reducing both total and fecal coliform positive samples. A wide range of State requirements exist for the use of BMPs, with some States requiring the use of one or more BMPs in response to contamination events.

iii. Disinfection

Under today's proposal, disinfection is defined as the inactivation or removal of fecal microbial contamination. As noted earlier, corrective actions to met the GWR treatment technique includes disinfection. Chemical disinfection of viruses involves providing a dosage of a disinfectant for a period of time for the purposes of inactivating the viruses. For most treatment strategies, the level of inactivation achieved varies depending on the target microorganism, residual disinfectant concentration, ground water temperature and pH, water quality and the contact time. The CT value is the residual disinfectant concentration multiplied by the contact time. Specifically, the contact time is the time in minutes it takes the water to move between the point of disinfectant application and a point before or at the first customer during peak hourly flow. The concentration is the residual disinfectant concentration in mg/L before or at the first customer, but at or after the point the contact time is measured. A system compares the CT value achieved to the published CT value for a given level of treatment (*e.g.*, 4-log inactivation of viruses) to determine the level of treatment attained. As long as the CT value achieved by the system meets or exceeds the CT value needed to inactivate viruses to 4-log, the system meets the treatment technique requirement.

Four-log virus inactivation can also be achieved by UV disinfection, which differs from some other treatment technologies, in that providing a residual concentration is not possible. When using UV disinfection, a light dosage is applied to the water to target the attainment of IT values (measured in mWs/cm^2). IT is the light irradiance (measured in mW/cm^2) to which the target organisms are exposed, multiplied by the time for which the irradiance is applied (measured in seconds). A system compares the IT value achieved to the published IT value for a given level of treatment (*e.g.*, 4-log inactivation of viruses) to determine the level of treatment attained. Systems required to disinfect with UV disinfection under the GWR must provide 4-log inactivation of viruses at a minimum. As long as the system attains IT values necessary for 4-log virus inactivation, the system meets the treatment technique requirement.

Removal, in the context of treatment of microbially contaminated ground water, is the physical straining of the microbial contamination, and is usually accomplished through filtration. For the purposes of disinfection of microbially contaminated ground water, removal is accomplished by membrane processes. Membrane processes physically remove viruses from the water based on the size of the virus and the size of the membrane's pores. When the absolute size of the membrane's pores (the molecular weight cut-off, or MWCO) are substantially smaller than the diameter of the virus, removal of the virus can be achieved. Therefore, membrane filtration technologies with MWCO substantially less than the diameter of

viruses can be effective treatment technologies for 4-log virus removal.

iv. State Requirements

EPA used the Baseline Profile Document for the Ground Water Rule (USEPA, 1999f) to assess current State treatment technique requirements. The EPA survey Ground Water Disinfection and Protective Practices in the United States (US EPA, 1996a) was used where the Baseline Profile Document for the Ground Water Rule (USEPA, 1999f) lacked certain information. These data are important in illustrating the wide range of State requirements that exists in ground water systems. The GWR attempts to build on existing State practices and provide State flexibility to address system-specific concerns.

Based on an analysis of information in the Baseline Profile Document for the Ground Water Rule (USEPA, 1999f), there is great variability nationwide in State statutes, regulations, and policies for when and how systems must apply treatment techniques. The variability ranges from 11 States requiring across-the-board disinfection, several other States requiring systems to attempt to eliminate the real or potential source of fecal contamination before considering disinfection, to some States requiring systems with fecally contaminated source water to provide an alternative source of safe drinking water. Almost all of the States have statutes, regulations, or policies for treatment techniques that define under what circumstances treatment techniques are necessary. Twenty-eight of the 39 States which do not require across-the-board disinfection require application of treatment techniques based on the microbial quality of the water and 12 of the 39 require application of treatment techniques based on the sanitary quality of the system.

How a system applies treatment techniques also varies considerably from State to State. For example, 36 of the 50 States specify requirements on the use of disinfectant residuals in the distribution system, while five States require 4-log inactivation of viruses at the source.

v. Disinfection Technologies

In ground water systems, 4-log inactivation of viruses can be accomplished by disinfection with free chlorine, chloramines, chlorine dioxide, ozone, on-site oxidant generation (anodic oxidation) or ultraviolet radiation (UV). Reverse osmosis (RO) and nanofiltration (NF) can achieve 4-log removal of viruses. Chlorine, chloramines, chlorine dioxide, ozone, UV, RO and NF are all listed as small system compliance technologies for the SWTR. EPA also suggests that small systems consider on-site oxidant generation for SWTR compliance purposes (US EPA, 1998c).

Chemical disinfection technologies are commonly used to provide disinfection prior to distribution, and must attain specific CT values (which vary depending on the technology) to achieve 4-log virus inactivation. Free chlorine disinfection is the most commonly practiced chemical disinfection technology, and requires a CT value of four to provide 4-log inactivation of viruses at a water temperature of 15°C, and a pH of 6–9 (USEPA, 1991a).

The required CT values for 4-log virus inactivation when using chloramines or chlorine dioxide are higher than when using free chlorine (Table III–8). The CT values for 4-log inactivation of viruses at a pH of 6–9 and a temperature of 15°C are 16.7 mg-min/L for chlorine dioxide and 994 mg-min/L for chloramines (US EPA, 1991a). The CT value for chloramines applies to systems which generate chloramines by the addition of free chlorine, followed by the addition of ammonia. This chloramine CT value for 15°C was obtained by extrapolating CT values from a study performed by Sobsey, *et al*, (1988) at 5°C. These CT values for chlorine and chloramines studied HAV, which, compared to other viruses which occur in fecally contaminated ground water, is relatively resistant to chlorine disinfection. The CT value for chlorine dioxide was obtained from a study of chlorine dioxide inactivation of HAV by chlorine dioxide at 5°C (Sobsey, *et al.*, 1988). The CT value obtained in this study was adjusted to 15°C, and had a safety factor of two applied. Considering that chlorine dioxide has a higher CT value than chlorine and due to site specific situations, chlorine dioxide may not be a feasible disinfection technology for all systems. Additional studies have been conducted using free chlorine on Coxsackie virus B5 and poliovirus 1 (Kelly and Sanderson, 1958), and information on these studies is provided in Table III–8. Although the CT values for HAV were included in the guidance manual to the SWTR intended for surface water systems, the CT values are applicable to ground water systems, since they are based on disinfectant residual (*i.e.*, after demand) concentrations.

Many systems apply free chlorine disinfection in a contact basin prior to distribution for virus inactivation, followed by ammonia addition prior to distribution (to form chloramines) to protect the water as it travels through the distribution system, since chloramines provide a longer lasting residual than free chlorine. Due to the high CT value for chloramines, some additional disinfection prior to distribution would probably be needed.

A system that must disinfect may also need to increase the CT value attained if the CT value attained does not achieve the 4-log inactivation of viruses. Under some circumstances, this can be accomplished by providing a higher disinfectant dosage (and hence, a higher disinfectant residual), or a longer contact time (by providing additional storage). Data from the CWSS (1995) suggests that many CWSs (and some NCWSs) served by ground water may already have storage in place and may be able to achieve 4-log virus inactivation without additional storage. According to the CWSS, 59% of community ground water systems have distribution system storage tanks, including 34% of systems serving less than 100 people (CWSS, 1995). This number increases to 95% for systems serving 10,001–100,000 people. Twenty-eight percent of ancillary community ground water systems were found to have storage. According to the CWSS, ancillary systems are those systems for which providing drinking water is not their primary business (*e.g.*, restaurants).

TABLE III–8. DISINFECTION STUDIES USING CHLORINE, CHLORINE DIOXIDE AND CHLORAMINES ON VIRUSES

Studies conducted			Effectiveness		Additional notes	
Disinfectant	Virus studied	Reference & date	Log removal	CT	Residual	Comments
Chlorine	HAV	Sobsey *et al.*, 1988	4	[1] 4	Y	safety factor = 3
		Sobsey *et al.*, 1988	4	[1] 30	Y	$_{p}$H = 10 safety factor = 3
	Coxsackie B5	Kelly & Sanderson, 1958	4	~1.07	Y	$_{p}$H = 6, T = 28°C

TABLE III–8. DISINFECTION STUDIES USING CHLORINE, CHLORINE DIOXIDE AND CHLORAMINES ON VIRUSES—Continued

Studies conducted			Effectiveness		Additional notes	
Disinfectant	Virus studied	Reference & date	Log removal	CT	Residual	Comments
	[1] Poliovirus	Kelly & Sanderson, 1958	4	~7.8	Y	4-log at 5°C
Chloramine	HAV	Sobsey *et al.*, 1988	4	[1] 994	Y	
[2] Chlorine dioxide	HAV	Sobsey *et al.*, 1988	4	[1] 16.7	Y	safety factor = 2

[1] CT values are for 15°C and a $_{p}$H of 6–9, unless otherwise noted.
[2] Table adapted from Technologies and Costs for Ground Water Disinfection (USEPA, 1993).

Ozone, unlike chlorine dioxide and chloramines, is a stronger disinfectant than chlorine and would require less contact time (and less storage) at a similar dosage (Table III–9) to inactivate viruses. The CT value for 4-log inactivation of HAV using ozone is 0.6 mg-min/L at a pH of 6–9 and a temperature of 15°C (US EPA, 1991a). The CT data for ozone were obtained from a study by Roy *et al.*, (1982). This study obtained data for 2-log inactivation of poliovirus 1 at 5°C. The CT value for 4-log virus inactivation listed in Table III–8 is an extrapolation of the 2-log inactivation value assuming first-order kinetics, as well as an adjustment for inactivation at 15°C. In addition, a safety factor of three was applied to the CT values. However, the CT value required for 4-log virus inactivation may depend on the virus. Poliovirus 1 (Kaneko, 1989) and enteric viruses (Finch *et al.*, 1992) have demonstrated other CT requirements in studies; however, it is uncertain whether or not all other experimental conditions were the same (*e.g.*, temperature) .

Numerous studies on viral inactivation using UV have been conducted, with Table III–9 presenting some of the findings. According to these studies, 4-log UV disinfection of HAV requires an IT of between 16 mWs/cm^2 (Battigelli *et. al.*, 1993) and 39.4 mWs/cm^2 (Wilson *et al.*, 1992). IT is the UV light irradiance multiplied by the contact time. Other studies have shown variable IT values, depending on the virus studied (Table III–9). Harris *et al.* (1987) found that an IT of 120 mWs/cm^2 (including a safety factor of 3) was required for 4-log inactivation of poliovirus. Unlike many of the other alternative treatment technologies, the efficacy of UV disinfection is not dependent on the temperature and $_{p}$H.

TABLE III–9.—DISINFECTION STUDIES USING OZONE, MEMBRANE FILTERS AND UV ON VIRUSES

Studies conducted			Effectiveness		Additional notes	
Disinfectant	Virus studied	Reference E & date	Log removal	CT	Residual	Comments
[4] Ozone	Poliovirus	Roy *et al.*,1982	4	[1] 0.6	N	safety factor = 3.
	Poliovirus	Herbold *et al.*,1989	4–6	.008	N	T = 10°C.
		Kaneko, 1989	4	5	N	
	enterics	Finch *et al.*,1992	4	3	N	
	HAV	Hall & Sobsey, 1993.	3.9–6.0	0.167	N	Also MS2.
		Herbold *et al.*,1989	4–6	0.22	N	T = 10°C.
		Vaughn *et al*,1990	4	0.40	N	T = 4°C.
	MS2	Finch *et al.*,1992	2.7–7	7.2	N	T = 22°C.
		Finch *et al.*,1992	4	.013	N	T = 22°C.
RO	<0.5 nm	Jacangelo *et al.*,1995.	[2] 100% removal	50–70% recovery	N	MWCO<0.5 nm.
	MS2	Adham *et al.*,1998	1.4–7.4	N/A	N	
NF	~0.5–13 nm	US EPA, 1993	[2] 100% removal	60–80% recovery	N	MWCO 200–400 Daltons.
UV[3] [4]	MS2	Snicer *et al.*,1996	4	87.4–93	N	Ground water.
		Roessler & Severin, 1996.	4	~63	N	
	HAV	Wiedenmann *et al.*,1993.	4	~20	N	
		Battigelli *et al.*,1993	4	16	N	
		Wilson *et al.*,1992	4	39.4	N	Also Rota SA11, Poliovirus 1.
[3] [4] UV continued	Rotavirus	Roessler & Severin, 1996.	4	~25	N	
	Poliovirus	Harris *et al.*,1987	4	120	N	Safety factor = 3.
		Chang *et al.*,1985	3–4	~30	N	
	Rotavirus SA11	Battigelli *et al.*,1993	4	42	N	Approximately 4-log.
		Chang *et al.*,1985	3–4	~30	N	
	Coxsackie B5	Battigelli *et al.*,1993	4	29	N	Approximately 4-log.

[1] CT values are values for 15 °C and a pH of 6–9, unless otherwise noted.
[2] Removal based on pore size.
[3] Inactivation measured by IT, rather than CT. IT is the UV irradiance multiplied by the contact time.
[4] Table adapted from Technologies and Costs for Ground Water Disinfection (USEPA, 1993)

When systems use anodic oxidation the primary disinfectant generated is free chlorine. Therefore, the CT value for anodic oxidation is the same as free chlorine (Table III–8). However, when using anodic oxidation other disinfectants are also generated, and data suggests that the combined effects of these disinfectants are stronger than that of free chlorine alone; however, this effect has not been substantiated.

Removal as a ground water treatment technique provides public health protection through physical filtering of water using membrane processes. The effectiveness of a particular membrane technology depends on the size of the target organism and the size of the membrane's pores (Table III–9). Membrane filters achieve removals when the MWCO of the filter is significantly smaller than the diameter of the target organism. Viruses range in diameter from approximately 20–900 nm and may be effectively removed using reverse osmosis (RO) and nanofiltration (NF), having MWCOs of approximately 5 nm and 30 nm, respectively. Those technologies which provide removal of microbial contamination cannot provide a disinfectant residual, and must be applied prior to the distribution of the water.

vi. Free Chlorine in the Distribution System

Chlorine disinfection is the most commonly practiced disinfection technology for microbial contamination of ground water. Many ground water systems which practice chlorine disinfection do so by providing a free chlorine residual at the entry point to the distribution system. In general, the level of inactivation achieved using disinfectants such as chlorine increases the longer the disinfectant is in contact with the water (*i.e.,* contact time). This is true only when there is an available supply of chlorine. When the chlorine dissipates there is no further increase in the inactivation level. Therefore, when systems use a chlorine residual at the entry point to the distribution system, microbes (including viruses) are inactivated at varying levels through the length of the distribution system, and the risk of illness from pathogens originating in the source water decreases with increased travel time through a well-maintained distribution system if there is sufficient residual. For example, if customers at the first service connection in the water main receive water disinfected to 4-log virus inactivation, those customers farther along the distribution main would receive water disinfected to levels greater than 4-logs as long as disinfectant remains, and no additional contamination has entered the distribution system.

EPA conducted analyses to evaluate the potential effectiveness of a free chlorine distribution system residual to provide 4-log inactivation of viruses originating in the source water. It was assumed that the customer at the first service connection received water disinfected to 4-log virus inactivation. Preliminary analysis indicates that a number of ground water systems can achieve at least 4-log virus inactivation throughout the distribution system. Some systems can provide this log inactivation by maintaining a 0.2 mg/l free chlorine residual at the entry point to the distribution system (as required by the SWTR) and a contact time of 20 minutes prior to the first customer. Data suggests that as many as 77% of small community ground water systems (*i.e.,* serving less than 10,000 customers) may achieve 4-log virus inactivation prior to the first customer during maximum flow conditions (AWWA, unpublished data 1998). When a ground water system uses a free chlorine distribution system residual to disinfect contaminated source water, the level of virus inactivation is likely well in excess of 4-log, especially when taking into account the time the water awaits usage in the customers' piping beyond the service connection. This extra holding time in the distribution system increases the CT value achieved and therefore increases the log inactivation level achieved. A system may also need to apply a free chlorine residual at the entry point to the distribution system that is higher than 0.2 mg/L to maintain a detectable residual throughout the distribution system, which may lead to higher levels of virus inactivation. In these instances, increased levels of protection would be provided for customers served by all service connections along the distribution main. Assuming 4-log virus inactivation at the first customer, it could also be assumed that customers at service connections at later points in the distribution system would receive water disinfected to higher levels of inactivation, in many cases much higher.

For some systems application of a 0.2 mg/L free chlorine residual at the entry point to the distribution system and a detectable free chlorine residual throughout the distribution system will not achieve 4-log virus inactivation. In some cases this will be because the system does not achieve adequate contact time, and these systems may have to increase the contact time by installing extra distribution system storage, increasing the free chlorine residual concentration, adding supplemental disinfection (such as disinfection in a contact basin) or reconfiguring the system. However, based on 1998 AWWA data, EPA believes that most ground water CWSs will have sufficient contact time.

EPA considered requiring systems to apply a disinfectant residual at the entry point to the distribution system and maintain a detectable disinfectant residual throughout the distribution system. However, EPA decided against including it in the proposed GWR since a disinfectant residual is more accepted as a distribution system tool than for controlling source water contamination. EPA will address the issue of maintaining a residual in future rulemaking efforts (*e.g.* long term 2 ESWTR) as part of a broad discussion on distribution system issues for all PWSs.

2. Proposed Requirements

EPA proposes the following requirements for ground water systems with an uncorrected significant deficiency or fecally contaminated source water. The requirements for treatment techniques, disinfection monitoring, and notification to ensure public health protection are addressed.

EPA proposes treatment technique requirements as one barrier in the multiple barrier approach. Treatment techniques contribute to public health protection by eliminating public exposure to the source of pathogens, through eliminating the source of contamination, requiring the system to provide an alternative source as the State deems appropriate, correcting significant deficiencies that can act as a potential pathway for contamination, or disinfection to remove, or inactivate the microbial contaminants. Information related to the effectiveness of these treatment techniques can be found in the ASDWA BMP study Results and Analysis of ASDWA Survey of BMPs in Community Ground Water Systems (ASDWA, 1998), as well as the SWTR.

a. Treatment Technique Requirements for Systems With Uncorrected Significant Deficiencies or Source Water Contamination

EPA proposes requiring ground water systems with an uncorrected significant deficiency or source water contamination to apply an appropriate treatment technique, as determined by the State, within 90 days of detection of the significant deficiency or source water contamination. If they cannot apply an appropriate treatment technique within that time frame, they must at a minimum have a State-

approved plan and specific schedule for doing so. Treatment techniques include: eliminate the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer. Some treatment techniques are inappropriate solutions for the nature of the problem. For example, a system with contamination entering the distribution system must not address the problem by providing treatment at the source.

Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness. If a system is unable to address the significant deficiency within 90 days, the system must develop a specific plan and schedule for providing a treatment technique, submit the plan and schedule to the State and receive State approval on the plan and schedule within the same 90 days. EPA expects the system to consult with the State on interim measures to ensure safe water is provided during the 90 day correction time frame. During this 90 day period the State and system must identify and apply a permanent treatment technique appropriate for that system, consistent with the State's general approach outlined in their primacy package. If the treatment technique is not complete within 90 days (or the deadline specified in the State-approved plan), the system is in violation of the treatment technique requirements of the GWR.

b. Disinfection Options

EPA proposes requiring systems that disinfect due to uncorrected significant deficiencies or fecally contaminated source water to provide disinfection adequate to achieve at least 4-log inactivation or removal of viruses as determined by the State. When a system provides disinfection for uncorrected significant deficiencies or fecally contaminated source water, EPA recommends that the State use EPA-published CT tables to determine what treatment technologies and what disinfection parameters are appropriate for the system. If a system is currently providing 4-log disinfection and therefore does not monitor the source water for fecal indicators, per § 140.403, then that system must meet the definition and requirements of disinfection as described in this section.

c. Monitoring the Effectiveness and Reliability of Treatment

EPA proposes requiring systems with uncorrected significant deficiencies or fecally contaminated source water under this proposal to monitor the effectiveness and reliability of disinfection as follows. This monitoring must be conducted following the last point of treatment, but prior to each point of entry to the distribution system.

Systems serving 3,300 or more people that chemically disinfect must monitor (using continuous monitoring equipment fitted with an alarm) and maintain the required residual disinfectant concentration continuously to ensure that 4-log virus inactivation is provided every day the system serves water to the public. EPA recommends that the State use EPA-developed CT tables to determine if the system meets the residual concentration and contact time requirements necessary to achieve 4-log virus inactivation. As a point of comparison, the surface water system size cutoff for systems to measure the residual disinfectant four or fewer times per day is 3,300 people served.

Systems serving 3,300 or fewer people that chemically disinfect must monitor and maintain the residual disinfectant concentration every day the system serves water to the public. The system will monitor by taking daily grab samples and measuring for the State-determined concentration of disinfectant to ensure that 4-log virus inactivation is provided. EPA recommends that the State use EPA-developed CT tables to determine if the system meets the residual concentration and contact time requirements necessary to achieve 4-log virus inactivation. If the daily grab measurement falls below the State-determined value, the system must take follow-up samples every four hours until the required residual disinfectant concentration is restored.

Systems using UV disinfection must monitor for and maintain the State-prescribed UV irradiance level continuously to ensure that 4-log virus inactivation is provided every day the system serves water to the public. EPA recommends that the State use EPA-developed IT tables to determine if the system meets the irradiance and contact time requirements necessary to achieve 4-log virus inactivation.

Systems that use membrane filtration as a treatment technology are assumed to achieve at least 4-log removal of viruses when the membrane process is operated in accordance with State-specified compliance criteria, or as provided by EPA, and the integrity of the membrane is intact. Applicable membrane filtration technologies are RO, NF and any membrane filters developed in the future that have MWCOs that can achieve 4-log virus removal.

When monitoring on a continuous basis, the system must notify the State any time the residual disinfectant concentration or irradiance falls below the State-prescribed level and is not restored within four hours. This notification must be made as soon as possible, but in no case later than the end of the next business day.

When the system takes daily grab sample measurements, the system must notify the State any time the residual disinfectant concentration falls below the State-prescribed level and is not restored within four hours. This notification must be made as soon as possible, but in no case later than the end of the next business day.

Any time a system using membrane filtration as a treatment technology fails to operate the process in accordance with State-specified compliance criteria, or as provided by EPA, or a failure of the membrane integrity occurs, and the compliance operation or integrity is not restored within four hours, the system must notify the State. This notification must be made as soon as possible, but in no case later than the end of the next business day.

These requirements are consistent with those for surface water systems. Four hours is the cutoff time by which a surface water system must restore the free chlorine residual level at entry to the distribution system to 0.2 mg/L, if the free chlorine residual at entry to the distribution system falls below 0.2 mg/L. In addition, a surface water system must notify the State anytime the residual disinfectant entering the distribution system falls below 0.2 mg/L and is not restored within 4 hours. This notification must be made by the end of the next business day.

EPA proposes that systems which were required to provide treatment for uncorrected significant deficiencies or fecally contaminated source water may discontinue treatment if the State determines the need for treatment no longer exists and documents such a decision.

d. Eliminating the Source of Contamination

For systems eliminating the source of contamination, EPA proposes that the system and State develop a strategy using appropriate BMPs considering the characteristics of the system and the nature of the significant deficiency or contamination.

e. Reporting Outbreaks

As required in 141.32(a)(iii)(D) for undisinfected surface water systems; EPA proposes that if any ground water system has reason to believe that a disease outbreak is potentially attributable to their drinking water, it must report the outbreak to the State as soon as possible, but in no case later than the end of the next business day.

f. Treatment Technique Violations

The GWR proposes the following three treatment technique violations, requiring the ground water system to give public notification:

(a) A ground water system with a significant deficiency identified by a State, which does not correct the deficiency, provide an alternative source, or provide 4-log inactivation or removal of viruses within 90 days, or does not obtain, within the same 90 days, State approval of a plan and schedule for meeting the treatment technique requirement, is in violation of the treatment technique.

(b) A ground water system that detects fecal contamination in the source water and does not eliminate the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer within 90 days, or does not obtain within the same 90 days, State approval of a plan for meeting this treatment technique requirement, is in violation of the treatment technique unless the detected sample is invalidated by the State or the treatment technique is waived by the State. Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness.

(c) A ground water system which fails to address either a significant deficiency as provided in (a) or fecal contamination as provided in (b) according to the State-approved plan, or by the State-approved deadline, is in violation of the treatment technique. In addition, a ground water system which fails to maintain 4-log inactivation or removal of viruses, once required, is in violation of the treatment technique, if the failure is not corrected within four hours.

EPA requests comment on which (if any) of these proposed treatment technique violations should or should not be treatment technique violations. EPA also requests comment as to whether a ground water system which has a source water sample that is positive for E. coli, coliphage or enterococci should be in violation of the treatment technique.

3. Public Notification

Sections 1414(c)(1) and (c)(2) of the 1996 SDWA, as amended, require that public water systems notify persons served when violations of drinking water standards occur. EPA has recently (64 FR 25963, May 13, 1999) proposed to revise the public notification regulations to incorporate new statutory provisions enacted under the 1996 SDWA amendments. EPA recently promulgated the final Public Notification Rule (PNR), under part 141. Subsequent EPA drinking water regulations that affect public notification requirements will amend the PNR as a part of each individual rulemaking. The GWR is proposing Tier 1 (discussed next) public notification requirements for the treatment technique violations (see § 141.405). EPA requests comment on the GWR public notification requirements.

The purpose of public notification is to alert customers to 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 public water system 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 proposed 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 regulations requiring a Tier 1 notice include: Violation of the TCR, where fecal contamination is present; nitrate violations; chlorine dioxide violations; and other waterborne emergencies. The State is explicitly authorized to add other violations and situations to the Tier 1 list when necessary to protect public health from short-term exposure.

Tier 2 is for other violations and situations with potential to have serious adverse effects on human health. Notice is required within 30 days, with extension up to three months at the discretion of the State or primacy agency. Violations requiring a Tier 2 notice include all other MCL and treatment technique violations 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 the monitoring violations.

Today's regulatory action proposes to make the presence of a fecal indicator in a source water sample, failure to monitor source water and treatment technique violations as Tier 1 public notification requirements. Any GWSs with a violation or situation requiring Tier 1 public notification must notify the public within 24 hours of the violation. GWS's that must make an annual CCR report, as discussed in III.A.7.d., must include any Tier 1 violations or situations in their next CCR report and include the health effects language described later in Appendix B of subpart Q. The following violations or situations require Tier 1 notice:

(a) A ground water system which has a source water sample that is positive for *E. coli,* coliphage, or enterococci under § 141.403, unless it is invalidated under § 141.403(i);

(b) Failure to conduct required monitoring, including triggered monitoring when a system has a positive total coliform sample in the distribution system and routine monitoring when the system is identified by the State as hydrogeologically sensitive;

(c) A ground water system with a significant deficiency identified by a State which does not correct the deficiency, provide an alternative source, or provide 4-log inactivation or removal of viruses within 90 days, or does not obtain, within the same 90 days, State approval of a plan and schedule for meeting the treatment technique requirement in § 141.404;

(d) A ground water system that detects fecal contamination in the source water and does not eliminate the source of contamination, provide an alternative water source, or provide 4-log inactivation or removal of viruses within 90 days, or does not obtain within the same 90 days, State approval of a plan for meeting this treatment technique requirement (unless the detected sample is invalidated under § 141.403(i) or the treatment technique is waived under § 141.403(j)); and

(e) A ground water system which fails to address either a significant deficiency as provided in (c) or fecal contamination as provided in (d) according to the

State-approved plan, or by the State-approved deadline. (In addition, a ground water system which fails to maintain 4-log inactivation or removal of viruses, once required, is in violation of the treatment technique if the failure is not corrected within 4 hours.)

EPA believes that these violations pose an immediate and serious public health threat. Fecal contamination is an acute contaminant and therefore illnesses and even deaths can occur through small volumes or short exposure to fecally contaminated drinking water. Illnesses can be avoided by alerting the public immediately. The proposed tiering requirements under the GWR are designed to be consistent with those for the Total Coliform Rule. Failure to test for fecal coliform or *E. coli* when any repeat sample tests positive for coliform is considered a Tier 1 violation requiring a Tier 1 notice under current Public Notification Regulations. EPA believes that failure to collect source water samples as proposed under the GWR poses an equivalent public health threat to the failure to test for fecal coliform or *E. coli* under the TCR. EPA believes that an undisinfected ground water system with either a TC positive in the distribution system or with a source found to be hydrogeologically sensitive has an increased likelihood of microbial contamination that if not monitored, presents a public health threat which requires immediate notice. EPA acknowledges that in some circumstances, the hydrogeologic sensitivity assessment may not be as indicative of the presence of microbial contamination in the ground water system as is the presence of total coliform in the distribution system. Given this potential situation, the Agency requests comment upon whether the failure to perform routine source water monitoring should be considered a lower Tier violation to avoid alarming the public unnecessarily. EPA also requests comment on the other proposed public notification requirements presented in this section.

4. Request for Comments

EPA requests comments on all the information presented earlier and the potential impacts on public health and regulatory provisions of the GWR. In addition, EPA specifically requests comments on the following alternative approaches. In particular, EPA requests comment on the following public health issues associated with disinfection. Stakeholders have raised concern about the potential risk from improperly managed or applied chemical disinfectants. Some stakeholders suggest that requiring small system operators who may lack training or expertise to apply chemical disinfection could lead to collateral health and safety risks. EPA requests comment on this issue. The Agency also requests input on alternative approaches for addressing demonstrated microbial contamination and the associated acute microbial health risks.

Alternative Approaches

a. Distribution System Residuals

EPA requests comment on requiring a 0.2 mg/L free chlorine residual at the entry points to the distribution system and a detectable free chlorine residual throughout the distribution system for all or some systems (*e.g.,* all systems serving 3,300 or more people). EPA also seeks comment on whether or not systems should be able to use a 0.2 mg/L free chlorine residual at the entry to, and detectable throughout, the distribution system to meet the disinfection requirements proposed as part of the GWR.

b. Other Log-Inactivation Levels

EPA seeks comment on the adequacy of 4-log virus inactivation or removal to protect public health from fecally contaminated ground water sources. Additionally, EPA requests comment on requiring additional levels of disinfection under certain circumstances. For example, increasing the log virus inactivation may be appropriate for contaminated systems with known sources of fecal contamination in close proximity to a well.

c. Supplemental Disinfection Strategies

EPA requests comment on whether, for certain systems with source water contamination, it may not be possible to achieve 4-log virus inactivation at the first customer either because of the distribution system size or configuration (*e.g.,* the first customer is relatively close to the point of disinfectant application). EPA requests comment on possible supplemental disinfection strategies.

d. Mandatory Disinfection for Systems in Sensitive Hydrogeology

EPA seeks comment on requiring disinfection for ground water systems which obtain their water from a sensitive aquifer regardless of microbial monitoring results (see section III.B.). This would provide proactive public health protection by disinfecting a sensitive source water before contamination becomes apparent.

e. Point-of-Entry Devices

EPA seeks comment on EPA approving the use of point-of-entry devices to disinfect contaminated source water. This would allow systems to provide protection to individual households, and may be cost-effective for some very small systems. However, the system would be responsible for maintaining the devices and this could result in significant expenditure of resources.

f. Across-the-Board Disinfection

EPA seeks comment on requiring all systems to disinfect, or requiring disinfection based on system type (*e.g.,* CWS), or size of the system (*e.g.,* greater than 3,300). The SWTR requires all systems obtaining their water from a surface water source to disinfect. EPA notes that 1996 SDWA, as amended requires that EPA should develop regulations requiring disinfection for ground water systems ''as necessary''.

g. Health and Fiscal Impacts on Small Systems (i.e., Competing Priorities)

EPA requests comment on whether or not potential health effects and fiscal impacts specific for small systems should be included in the GWR. Specifically, EPA seeks comment on what other regulatory priorities will compete with the GWR and what implementation issues this will present (*e.g.,* disinfection under the GWR versus compliance with the DBPR, difficulty in obtaining resources for simultaneous compliance with arsenic, radon, ground water and DBP regulations).

h. Differing Disinfection Strategies for Significant Deficiencies and Source Water Contamination

EPA seeks comment on whether a different disinfection strategy should be required depending on whether the system has an uncorrected significant deficiencies or fecally contaminated source water. Under this alternative, EPA could require systems with uncorrected significant deficiencies to provide only a disinfectant residual of 0.2 mg/L free chlorine at entry to the distribution system, while those systems with fecally contaminated source water would be required to provide disinfection to ensure that the system achieves 4-log virus inactivation or removal prior to entry to the distribution system.

i. Shutting Down Systems With Uncorrected Significant Deficiencies

EPA seeks comment on whether and based on what criteria systems with uncorrected significant deficiencies should not be allowed to disinfect as a

treatment technique, but instead would not be allowed to serve water to the public. Under certain circumstances this approach is used by some States. For example, disinfection is not an effective strategy for treating the significant deficiency of poor distribution system integrity.

j. Correction Time Frame

EPA requests comment on the criteria States must use to determine the adequacy of schedules which go beyond 90 days (*e.g.,* corrections which require significant capital investments or external technical expertise).

EPA also requests comment on an alternative approach for addressing correction of significant deficiencies. The alternate approach consists of: (1) A requirement that the State notify the system in writing within 30 days of conducting the sanitary survey listing the significant deficiency, (2) a requirement for the system to correct the significant deficiencies as soon as possible, but no later than 180 days of receipt of the letter from the State or in compliance with a schedule of any length agreed upon by the State, and (3) the requirement that the system notify the State in writing that the significant deficiencies have been corrected within 10 days after the date of completion. Under this alternative, a system that does not correct significant deficiencies within 180 days or within the time frames of a schedule agreed upon by the State is in violation of a treatment technique and must provide public notice. The Agency seeks comment on whether this particular alternative correction scheme would be appropriate for the purposes of this rule.

The Agency is also seeking comment on a second alternative approach for establishing deadlines to complete corrective actions of significant deficiencies. Under this approach, States, as part of their primacy requirement to identify and define the significant deficiencies, may develop and submit to EPA for approval, deadlines for the completion of corrective actions for specific types or categories of significant deficiencies. When a specific corrective action is not implemented within the State deadline, a State must take appropriate action to ensure that the system meets the corrective action requirement. Any corrective action that extends beyond 180 days to complete, must be enforceable by the State through a compliance agreement or an administrative order or judicial order. As part of primacy, the State must also provide a plan for how the State will meet the time frames established in their procedures for identifying, reporting, correcting, and certifying significant deficiencies within the 180 days. The Agency seeks comment on whether this alternative correction scheme might also be appropriate.

k. Required Disinfectant Residual Concentration

EPA requests comment on requiring systems that disinfect to maintain a specified default disinfectant residual level. This requirement would apply when the State fails to provide the system with a State-determined disinfectant concentration to meet the 4-log inactivation/removal requirement within the 90-day correction time frame. Under this approach, systems that must treat would be required to maintain a 0.2 mg/L free chlorine residual at entry to the distribution system and a detectable free chlorine residual throughout the distribution system. EPA also requests comment on other concentrations of residual free chlorine to be maintained both at entry to the distribution system and throughout the distribution system (*e.g.,* 0.5 mg/L free chlorine at entry to the distribution system and 0.2 mg/L free chlorine throughout the distribution system).

l. Record Keeping for 4-log Inactivation Requirements

EPA requests comment upon whether systems which disinfect to comply with the GWR must maintain records of the State notification of the proper residual concentrations (when using chemical disinfection), irradiance level (when using UV), or State-specified compliance criteria (when using membrane filtrations) needed to achieve 4-log inactivation or removal of virus. EPA also requests comment on systems keeping records of the level of disinfectant residuals maintained, as well as how long the system should keep the records (*e.g.,* three years). These records may be valuable in the operation of the system because they will serve as permanent records for subsequent operators and/or owners of the ground water system.

m. Differing Monitoring Requirements for Consecutive Systems

EPA requests comment on any GWR requirements that should not apply to consecutive systems. Consecutive systems are those PWSs that receive some or all of their water from other PWSs. Such systems would certainly need to undergo the proposed sanitary survey to assure that they are delivering safe water to their customers. EPA also requests comment on whether the hydrogeologic sensitivity assessment and any corresponding source water monitoring should be the responsibility of the water seller or the consecutive system. EPA requests comments on whether or not a consecutive system should be required to monitor treatment compliance in their distribution system if the seller has met 4-log inactivation or removal of viruses. In addition, EPA requests comment on the selling system being required to conduct triggered source water monitoring when the consecutive system has a total-coliform positive in the distribution system.

n. State Primacy Requirements

EPA requests comment on the scope and appropriateness of the GWR State primacy requirements. The primacy requirements include the following:

- *Sanitary surveys*: State will describe how it will implement the sanitary survey, including rationales and time frames for phasing in sanitary surveys, how it will decide that a CWS has outstanding performance, and how the State will utilize data from its SWAPP;
- *Hydrogeologic Sensitivity Assessment:* State will identify its approach to determining the adequacy of a hydrogeologic barrier, if present;
- *Source Water Monitoring:* State will describe its approach and rationale for determining which of the fecal indicators (*E. Coli, coliphage* or *enterococci*) ground water systems must use for routine and/or triggered monitoring;
- *Treatment Techniques:* State will describe treatment techniques, including how it will provide systems with the disinfectant concentration (or irradiance) and contact time required to achieve 4-log virus inactivation; the approach the State must use to determine which specific treatment option (correcting the deficiency, eliminating the source of contamination, providing an alternative source, or providing 4-log inactivation or removal of viruses) is appropriate for addressing significant deficiencies or fecally contaminated source water and under what circumstances; and how the State will consult with ground water systems regarding the treatment technique requirements.

o. State Reporting Requirements

The proposed rule contains many reporting requirements for States to submit to EPA. EPA requests comment on the scope and appropriateness of these reporting requirements. The GWR reporting requirements include the following:

- *Sanitary Survey:* State will report an annual list of ground water systems that have had a sanitary survey

completed during the previous year and an annual evaluation of the State's program for conducting sanitary surveys.

• *Hydrogeologic Sensitivity Assessment:* State will report lists of ground water systems that have had a sensitivity assessment completed during the previous year, those ground water systems which are sensitive, ground water systems which are sensitive, but for which the State has determined that a hydrogeologic barrier exists, and an annual evaluation of the State's program for conducting hydrogeologic sensitivity assessments.

• *Source Water Monitoring:* State will report an annual list of ground water systems that have had to test the source water, a list of determinations of invalid samples, and a list of waivers of source water monitoring provided by the State.

• *Treatment Techniques:* State will report lists of ground water systems that have had to meet treatment technique requirements for significant deficiencies or contaminated source water, determinations to discontinue 4-log inactivation or removal of viruses, ground water systems that violated the treatment technique requirements, and an annual list of ground water systems that have notified the State that they are currently providing 4-log inactivation or removal of viruses.

IV. Implementation

This section describes the regulations and other procedures and policies States have to adopt, and the requirements that public ground water systems would have to meet to implement today's proposal were it to be finalized as proposed. Also discussed are the compliance deadlines for these requirements. States must continue to meet all other conditions of primacy in Part 142 and ground water systems must continue to meet all other applicable requirements of Part 141.

Section 1413 of the SDWA establishes requirements that a State or eligible Indian Tribe must meet to maintain primary enforcement responsibility (primacy) for its public water systems. These include (1) adopting drinking water regulations that are no less stringent than Federal NPDWRs in effect under sections 1412(a) and 1412(b) of the Act, (2) adopting and implementing adequate procedures for enforcement, (3) keeping records and making reports available on activities that EPA requires by regulation, (4) issuing variances and exemptions (if allowed by the State) under conditions no less stringent than allowed by sections 1415 and 1416, and (5) adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the Public Water Supply Supervision (PWSS) Program, as authorized under section 1413 of the Act. In addition to adopting the basic primacy requirements, States may be required to adopt special primacy provisions pertaining to a specific regulation. These regulation-specific provisions may be necessary where implementation of the NPDWR involves activities beyond those in the generic rule. States are required by 40 CFR 142.12 to include these regulation-specific provisions in an application for approval of their program revisions. These State primacy requirements apply to today's proposed rule, along with the special primacy requirements discussed next. The proposed regulatory language under section 142 applies to the States. The proposed regulatory language in section 141 applies to the public water systems.

The 1996 SDWA amendments (see section 1412(b)(10)) provide 3 years after promulgation for compliance with new regulatory requirements. Accordingly, the GWR requirements that apply to the PWS directly, specifically requirements found under section 141 of this proposal (monitoring and corrective action), are effective three years after the promulgation date. The State may, in the case of an individual system, provide additional time of up to two years if necessary, for capital improvements in accordance with the statute.

Section 1413(a)(1) allows States two years after promulgation of the final GWR to adopt drinking water regulations that are no less stringent than the final GWR. EPA proposes to require States to submit their primacy application concerning the GWR (see section 142 of the proposed regulatory language) within two years of the promulgation of the final GWR and EPA will review and approve (if appropriate) the application within 90 days of submittal (1413(b)(2). This schedule will provide all States with approved primacy for the GWR by the three years after [DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

If the GWR is finalized as proposed today, the States will have three years from the effective date (six years from the GWR promulgation date) to complete all community water system sanitary surveys and five years from the effective date (eight years from the GWR promulgation date) to complete all non-community water system sanitary surveys. The monitoring and corrective action requirements would be effective on the effective date of the final rule (three years after the GWR promulgation date).

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

This section summarizes the Health Risk Reduction and Cost Analysis in support of the GWR as required by section 1412(b)(3)(C) of the 1996 SDWA. In addition, under Executive Order 12866, Regulatory Planning and Review, EPA must estimate the costs and benefits of the GWR in a Regulatory Impact Analysis (RIA) and submit the analysis to the Office of Management and Budget (OMB) in conjunction with publishing the proposed rule. EPA has prepared an RIA to comply with the requirements of this Order and the SDWA Health Risk Reduction and Cost Analysis (USEPA, 1999a). The RIA has been published on the Agency's web site, and can be found at http://www.epa.gov/safewater. The RIA can also be found in the docket for this rulemaking (US EPA, 1999a).

The goal of the following section is to provide an analysis of the costs, benefits, and other impacts to support decision making during the development of the GWR.

A. Overview

The analysis conducted for this rule quantifies cost and benefits for four scenarios; the proposed regulatory option (multi-barrier option), the sanitary survey option, the sanitary survey and triggered monitoring option, and the across-the-board disinfection option. All options include the sanitary survey provision. The sanitary survey option would require the primacy agent to perform surveys every three to five years, depending on the type of system. If any significant deficiency is identified, a system is required to correct it. The sanitary survey and triggered monitoring option adds a source water fecal indicator monitoring requirement triggered by a total coliform positive sample in the distribution system. The multi-barrier option adds a hydrogeologic sensitivity assessment to these elements which, if a system is found to be sensitive, results in a routine source water fecal indicator monitoring requirement. The multi-barrier option and the sanitary survey and triggered monitoring options are both a targeted regulatory approach designed to identify wells that are fecally contaminated or are at a high risk for contamination. The across-the-board disinfection option would require all systems to install treatment instead

of trying to identify only the high risk systems; therefore, it has no requirement for sensitivity assessment or microbial monitoring.

Costs for each option varied and were driven by the number of systems that would need to fix a significant deficiency or take corrective action, such as installing treatment or rehabilitating a well, in response to fecal contamination. The majority of costs for all options, with the exception of the across-the-board option, are the result of systems having to fix an actual or potential fecal contamination problem. The mean annual costs of the various options range from $73 million to $777 million using a three percent discount rate and $76 million to $866 million using a seven percent discount rate. (Note some costs have not been quantified and are not included in these totals, see section V.B.)

These total annual quantified costs can be compared to the annual monetized benefits of the GWR. The annual mean benefits of the various rule options range from $33 million to $283 million. This result is based on the quantification of the number of acute viral illnesses and deaths avoided attributable to this rule. This rule will also decrease bacterial illness and death associated with fecal contamination of ground water. EPA did not directly calculate the actual numbers of illness associated with bacterially contaminated ground water because the Agency lacked the necessary bacterial pathogen occurrence data (*e.g.,* number of wells contaminated with *Salmonella*) to include it in the risk model. However, in order to monetize the benefit from reduced bacterial illnesses and deaths from fecally contaminated ground water, the Agency used the ratio of viral and unknown etiology outbreak illnesses to bacterial outbreak illnesses reported to CDC for waterborne outbreaks in ground water systems.

Several non-health benefits from this rule were also considered by EPA but were not monetized. The non-health benefits of this rule include avoided outbreak response costs (such as the costs of providing public health warnings and boiling drinking water), and possibly the avoided costs of averting behavior and reduced uncertainty about drinking water quality. There are also non-monetized disbenefits, such as increased exposure to DBPs.

Additional analysis was conducted by EPA to look at the incremental impacts of the various rule options, impacts on households, benefits from reduction in co-occurring contaminants, and increases in risk from other contaminants. Finally, the Agency evaluated the uncertainty regarding the risk, benefits, and cost estimates.

B. Quantifiable and Non-Quantifiable Costs

In estimating the cost of each rule option, the Agency considered impacts on public water systems and on States. The GWR will result in increased costs to some PWSs for monitoring, corrective action of significant deficiencies, and installing treatment, but these vary depending on the option. With all rule options, a greater portion of the regulatory burden will be placed on those systems that do not currently disinfect to a 4-log inactivation of virus. States will incur costs for an incremental increase in sanitary survey requirements, for conducting hydrogeologic sensitivity assessments, and for follow-up inspections. Both systems and States would incur implementation costs. Some costs of today's rule options were not quantified (such as land acquisition, public notification costs and corrections to all potential significant deficiencies (See section V. B.4.)).

1. Total Annual Costs

In order 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 allowed the Agency to capture the variability in PWS configuration, current treatment in place and source water quality.

Table V–1 shows the estimated mean and range of annual costs for each rule option. At both a three and seven percent discount rate for the first three options, the costs increase as more components are added for identifying fecally contaminated wells and wells vulnerable to fecal contamination. The fourth option of across-the-board disinfection is the most costly because it would require all systems to install treatment regardless of actual fecal contamination or the potential to become fecally contaminated. Costs for the States to implement these rule options are also included in the four cost estimates. Discount rates of three and seven percent were used to calculate the annualized value for the national compliance cost estimate. The seven percent rate represents the standard discount rate required by OMB for benefit-cost analyses of government programs and regulations.

TABLE V–1.—ANNUAL COSTS OF RULE OPTIONS ($MILLION)

Option	3% Discount rate $million mean [range]	7% Discount rate $million mean [range]
Sanitary Survey	$73 [$71–$74]	$76 [$74–78]
Sanitary Survey and Triggered Monitoring	$158 [$153–$162]	$169 [$163–174]
Multi-barrier (Proposed) Option	$183 [$177–188]	$199 [$192–206]
Across-the-Board Disinfection	$777 [$744–$810]	$866 [$823–$909]

2. System Costs

In order to calculate the cost impact of each rule option on public water systems, EPA had to estimate the current baseline of systems and their current treatment practices, and then estimate how many systems would be affected by the various option requirements based on national occurrence information. The industry baseline discussion is located in section I.C. of this preamble. Estimates of the cost compliance requirements for each rule option are captured in a decision

tree analysis. The decision tree is comprised of various percentage estimates of the number of systems that will fall into each regulatory component category. Rule components include corrective action costs or costs to address significant deficiencies, monitoring costs, start-up costs, and reporting costs. Each of the rule options contains various combinations of these rule components with the sanitary survey option containing the fewest requirements.

Overall, these rule options provide a great amount of flexibility, with the exception of across-the-board disinfection, and this has complicated the cost analysis. Data were not always available to estimate the number of systems that would fall under the various rule components. EPA used data, where available but also consulted with experts and stakeholders to get the best possible estimates of the cost of this rule. More information on the GWR decision tree and how each element was estimated can be found in the Appendix to the GWR RIA (US EPA, 1999a).

As previously mentioned, the main cost component of the first three rule options results from systems having to take corrective action in response to fecal contamination or to fix significant deficiencies that could result in well contamination. In order to analyze the different rule options, the Agency had to distinguish between correction of significant deficiencies and the corrective actions that result from a confirmed source water positive sample for *E. coli,* enterococci or coliphage. In addition, it would be extremely challenging to cost out all conceivable corrective actions or significant deficiencies that a system could potentially encounter. As a result, the Agency focused on a representative estimate of potential types of corrective actions and significant deficiencies as shown in Table V–2 and Table V–3, respectively.

The choice of treatment technique (in consultation with the State) is also influenced by the size of the system. This is captured in the decision tree analysis by assigning probabilities (by system size) that a certain corrective action will be chosen. These probabilities are based on the relative cost of each action, data on existing disinfection practices, and best professional judgment. Additional significant deficiencies related to improper treatment were included in the cost analysis for systems that currently disinfect. These deficiencies are also captured in the decision tree and are listed in Table V–3.

TABLE V–2.—TREATMENT TECHNIQUES TO ADDRESS POSITIVE SOURCE WATER SAMPLES

Corrective action: [1]
Rehabilitating an existing well
Drilling a new well
Purchasing water (consolidation)
Eliminating known sources of contamination
Installing disinfection (8 choices of technologies)

[1] Choice varies with systems size and corrective action feasibility.

Each treatment technique can be addressed by various low or high cost alternatives. For example, a lower cost fix for many systems would be to rehabilitate a well while a higher cost fix would be to drill a new well. It is possible that not all States, in coordination with systems, would choose the relatively lower cost alternative of well rehabilitation. It would depend on the well itself and also the problem that was being addressed. In addition, if the model predicted that a system would install treatment, the choice of treatment is contingent on system size. To capture these alternative possibilities, the Agency considered different combinations of low and high cost alternatives. For instance, when the low cost corrective action alternative was run, the model estimated a greater percentage of systems choosing the lower cost well rehabilitation option versus the higher cost option of drilling a new well. To account for the uncertainty in the types of significant deficiencies identified and in the treatment technique taken, the cost model was run for each of the following combinations of low and high costs alternatives.

- Low significant deficiency cost/low treatment technique cost
- Low significant deficiency cost/high treatment technique cost
- High significant deficiency cost/low treatment technique cost
- High significant deficiency cost/high treatment technique cost

These combinations of low and high cost are reflected in the range of cost estimates shown in Table V–1 for the multi-barrier option (proposed option), the sanitary survey and triggered monitoring option, and the across-the-board option. For the sanitary survey option, only the high and low costs associated with significant deficiencies were included in the analysis. As stated earlier, treatment technique costs are the result of source water monitoring which is not included with the sanitary survey option.

TABLE V–3.—SIGNIFICANT DEFICIENCIES

Significant deficiencies
Unsealed well or inadequate well seal
Improper well construction
Inadequate roofing on a finished water storage tank
Evidence of vandalism at finished water storage tank
Unprotected cross connection in the distribution system
Booster pump station which lacks duplicate pumps
Additional significant deficiencies for disinfecting systems:
Inadequate disinfection contact time
Inadequate application of treatment chemicals

In addition to the treatment technique costs, EPA estimated the cost to systems for monitoring. All options would have some monitoring costs. However, the monitoring costs vary depending on the rule option as indicated in Table V–4. Regardless of the option, the triggered and routine monitoring applies only to systems that do not disinfect to a 4-log inactivation of virus.

Both the triggered and routine monitoring costs are calculated based on the cost of the test and the operator's time to take and transport the sample. EPA assumed that if this source water sample is positive, all systems would take five repeat samples to confirm the positive (although this is an optional rule component). For routine monitoring, the Agency assumed that all systems would monitor their source water monthly for the first year and quarterly thereafter at the States' determination. However, in some cases the State may allow the system to discontinue monitoring after 12 monthly samples or it could also require the system to continue with monthly monitoring. The cost of disinfectant compliance monitoring varies with system size and would be required for any system that currently disinfects or installs treatment as a result of the GWR. For large systems, EPA assumed that an automated monitoring system would be installed; for smaller systems, EPA assumed that a daily grab sample would be taken. A more detailed explanation of each of these monitoring schemes is located in section III. D. and section III E.2.c.

TABLE V–4.—MONITORING REQUIREMENTS BY RULE OPTION

Option	Triggered monitoring	Routine monitoring	Disinfectant compliance monitoring
Sanitary Survey			✔
Sanitary Survey and Triggered Monitoring Option	✔		✔
Multi-barrier (Proposed) Option	✔	✔	✔
Across-the Board Disinfection Option			✔

Finally, the Agency accounted for a system's start-up costs to comply with the GWR . These costs include time to read and understand the rule, mobilization and planning, and training. EPA assumed start-up costs would remain constant across the rule options. The Agency also estimated system costs for reporting and recordkeeping of any positive source water samples.

3. State Costs

Similar to the system cost, State costs also vary by rule option. Depending on the option, States would face increased costs from the incremental difference in the sanitary survey requirements and frequency, from conducting a one-time hydrogeologic sensitivity assessments, and tracking monitoring information for those options with a monitoring requirement. States would also have start-up and annual costs for data management and training. If a system needs longer than 90 days to complete a treatment technique or repair a significant deficiency, the State would have to approve the time schedule and plan.

By including start-up costs, annual fixed costs, and incremental sanitary survey costs in the decision tree analysis for all rule options, EPA accounted for these State costs. The analysis also assumed costs for State review and approval of plans for treatment techniques. The cost for the one-time sensitivity assessments is included for the proposed rule option analysis.

4. Non-Quantifiable Costs

Although EPA has estimated the cost of all the rule's components on drinking water systems and States, there are some costs that the Agency did not quantify. These non-quantifiable costs result from uncertainties surrounding rule assumptions and from modeling assumptions. For example, EPA did not estimate a cost for systems to acquire land if they needed to build a treatment facility or drill a new well. This was not considered because many systems will be able to construct new wells or treatment facilities on land already owned by the utility. In addition, if the cost of land was prohibitive, a system may chose another lower cost alternative such as connecting to another source. A cost for systems choosing this alternative is quantified in the analysis. The cost estimates do not include costs for public notification which are proposed. These estimates have not been included because EPA has no data on which to base an estimate of the number of treatment techniques violations or the number of times systems will fail to perform source water monitoring.

In addition, the Agency did not develop costs for all conceivable significant deficiencies or corrective actions that a system may encounter. Instead, a representative sample was chosen as shown in Tables V–2 and V–3.

C. Quantifiable and Non-Quantifiable Health and Non-Health Related Benefits

The primary benefits of today's proposed rule come from reductions in the risks of microbial illness from drinking water. In particular, the GWR focuses on reducing illness and death associated with viral infection. Exposure to waterborne bacterial pathogens are also reduced by this rule and the benefits are monetized, but not by the same method used to calculate reductions in viral illness and death because of data limitations. It is likely that these monetized illness calculations which are based on a cost of illness (COI) rather than a willingness to pay (WTP) approach, underestimate the true benefit because they do not include pain and suffering associated with viral and bacterial illness.

Additional health benefits such as reduced chronic illness were investigated, but were not quantified or monetized in this analysis. Other non-health benefits will likely result from this rule but were also not quantified or monetized. These non-health related benefits are discussed in sections V.A. and V.C. 2.

1. Quantifiable Health Benefits

The benefits analysis focused on estimating reductions in viral and bacterial illness and death that would result from each of the rule options. The first part of the analysis estimates the baseline (pre-GWR) level of illness as a result of microbial contamination of ground water. A discussion about how the Agency estimated this baseline risk is located in section II. E. of today's proposal. An important component of these risk estimates is the effect that these pathogens have on children (especially infants) because they are more likely to have severe illness and die from viral infection than the general population. A detailed discussion of risks to children is located in section VI. G.

The second part of the analysis focused on the reduction in risk that results from the various rule components. These components include identifying high risk wells, fixing significant deficiencies, increased monitoring for some systems, and possibly installing treatment in the event that a problem can not be fixed or a new source found. To calculate these changes, the risk-assessment model was re-run using new assumptions based on reductions in viral exposure which results from different levels of fecal contamination identified by each rule option.

To model the reduction in source contamination that would result from implementation of the four regulatory options, EPA assumed reductions in the number of ground water systems/points of entry that are potentially contaminated with viral pathogens under baseline conditions. The reduction varies with expectations regarding the effectiveness of each option in identifying and correcting significant defects at the source. Reductions in treatment failure rate and in distribution system contamination are also addressed for each option. The estimated reductions in contamination which are expected for each rule option are summarized in Table V–4a. These estimates are based upon information from consultations by the Agency with stakeholders and the Agency's best professional judgement regarding the effectiveness of sanitary surveys and upon co-occurrence rates of fecal indicators with pathogenic viruses. See section 5.3 of the GWR RIA for a detailed discussion of the basis for the estimated reductions.

TABLE V–4A. ESTIMATED CONTAMINATION REDUCTIONS FOR GWR OPTIONS

[In Percent]

Regulatory option	Estimated reduction in viral source contamination of undisinfected ground water sources		Estimated reduction in rate of disinfection failure for GWSs with viral contamination of the source	Estimated reduction in distribution system contamination with virus of GWSs
	Properly constructed	Improperly constructed		
Option 1. Sanitary Survey Only	0	40–60	0–26 (CWS) 0–43 (NCWS)[1]	0–25 (NA for TNC)[2]
Option 2. Sanitary Survey and Triggered Monitoring	30–54	58–82	77–100	0–25 (NA for TNC)[2]
Option 3. Multi-Barrier (Proposed)	38–77	63–91	77–100	0–25 (NA for TNC)[2]
Option 4. Across-the-Board Disinfection	100	100	77–100	0–25 (NA for TNC)[2]

[1] Non-community water systems (NCWS), both transient and nontransient, have an estimated reduced risk of contamination of 0–43%; community water systems (CWS) reduced risk is 0–26%.

[2] Reduction of risk in transient non-community (TNC) systems was not considered.

After the reductions in viral illnesses and death were estimated, the Agency estimated the monetized benefit from the reduction in bacterial illnesses and death associated with each rule option. EPA could not directly calculate the actual numbers of illnesses and death associated with bacterially contaminated ground water because the Agency lacked the necessary pathogen occurrence information to include it in the risk model. In order to estimate the benefit from reducing bacterial illnesses and deaths from fecally contaminated ground water, the Agency relied on CDC's outbreak data ratio of viral outbreaks and outbreaks of unknown etiology believed to be viral to bacterial outbreaks in ground water. These data indicate that for every five viral outbreaks, there is one bacterial outbreak. It was further assumed that the cost of these bacterial illnesses would be comparable to viral illness estimates.

To assign a monetary value to the illness, EPA estimated costs-of-illness ranging from $158 to $19,711 depending upon the age of the individual and severity of illness (see Exhibits 5–9 and 5–10 in the RIA). These are considered lower-bound estimates of actual benefits because it does not include the pain and discomfort associated with the illness. This issue is discussed in greater detail in the GWR RIA (USEPA, 1999a). Mortalities were valued using a value of statistical life estimate (VSL) of $6.3 million consistent with EPA policy. The VSL estimate is based on a best-fit distribution of 26 VSL studies and this distribution has a mean of $4.8 million per life in 1990 dollars. For this analysis, EPA updated this number to 1999 dollars which results in a mean VSL value of $6.3 million. Table V–5 shows the annual monetized benefits by rule option.

TABLE V–5.—QUANTIFIED AND MONETIZED BENEFITS BY RULE OPTION ($MILLION)

Options	Morbidity $million [range]	Mortality $million [range]	Total $million [range]
Sanitary Survey	$22 [$7 to $38]	$11 [$2 to $20]	$33 [$9 to $58]
Sanitary Survey and Triggered Monitoring	$120 [$100 to $140]	$58 [$47 to $68]	$178 [$147 to $209]
Multi-Barrier Proposed (Option)	$139 [$115 to $163]	$66 [$54 to $79]	$205 [$169 to $242]
Across-the-Board Disinfection	$192 [$174 to $210]	$91 [$81 to $101]	$283 [$255 to $311]

2. Non-Quantifiable Health and Non-Health Related Benefits

Although viral and some bacterial illness have been linked to chronic diseases, insufficient data was available to forecast the number of avoided chronic cases that would result from each rule option. A review of medical and epidemiological data identified several chronic diseases linked to viral infections. The strongest evidence links Group B coxsackievirus infections with Type 1-insulin-dependent diabetes and also to heart disease. Bacterial illness can also result in longer-term complications including arthritis, recurrent colitis, and hemolytic uremic syndrome. Most of these chronic illnesses and longer term complications are extremely costly to treat.

Using cost-of-illness (COI) estimates instead of willingness-to-pay (WTP) estimates to monetize the benefit from illness reduction generally results in underestimating the actual benefits of these reductions. In general, the COI approach is considered a lower bound estimate of WTP because COI does not include pain and suffering. EPA requests comment on the use of an appropriate WTP study to calculate the reduction in illness benefits of this rule.

D. Incremental Costs and Benefits

Today's proposed rule options represent the incremental costs and benefits of this rule. Both costs and benefits increase as more fecal contamination detection measures are added to the sanitary surveys for the first three options. The proposed option has the highest cost of these three incremental options, but it also produces incrementally more benefits.

The fourth option, across-the-board disinfection, is the most costly because it would require all systems to install treatment or to upgrade to 4-log removal/inactivation. It would not provide the flexibility of the other three options and would not target specifically high risk systems. Similar to the first three options, this option also includes the sanitary survey provision. This is included to address problems in the distribution systems and with disinfection failure.

Table V–6 and Table V–6a show the monetized costs, benefits and net benefits for all four options using both a three percent and seven percent discount rate, respectively. It is important to remember that non-quantified costs and benefits are not included in these net benefit numbers.

TABLE V–6.—NET BENEFITS—3% DISCOUNT RATE ($MILLION)

Options	Mean annual costs (3%) $million	Mean annual benefits [1] $million	Net benefits of the means $million
Sanitary Survey	$73	$33	($40)
Sanitary Survey and Triggered Monitoring	158	178	20
Multi-Barrier (Proposed)	183	205	22
Across-the-board Disinfection	777	283	(494)

[1] Does not include non-quantified benefits which would increase the net benefits of these rule options.

TABLE V–6A.—NET BENEFITS—7% DISCOUNT RATE ($MILLION)

Options	Mean annual costs (7%) $million	Mean annual benefits [1] $million	Net benefits $million
Sanitary Survey	$76	$33	($43)
Sanitary Survey and Triggered Monitoring	169	178	9
Multi-Barrier (Proposed)	199	205	6
Across-the-board Disinfection	866	283	(583)

[1] Does not include non-quantified benefits which would increase the net benefits of these rule options.

E. Impacts on Households

Overall, the average annual cost per household for the first three rule options are small across most system size categories as shown in Table V–7. However, costs are greater for the smallest size category across all options. This occurs because there are fewer households per system to share the cost of any corrective action or monitoring incurred by the systems. For example, under the Multi-Barrier option household costs would increase by approximately $5 per month for those served by the smallest size systems (<100 people) while those served by the largest size systems (>100,000 people) would face only a $0.02 increase in monthly household costs. As previously mentioned, the majority of the cost from the first three rule options is the result of systems having to correct significant deficiencies in their systems or to take corrective action in response to fecal contamination. On average, household costs resulting from the first three rule options increase from $2.45 to $3.86 annually. The most expensive option, across-the-board disinfection, also has the highest average household costs at $19.37 annually.

TABLE V–7.—AVERAGE ANNUAL HOUSEHOLD COST FOR GWR OPTIONS FOR CWS TAKING CORRECTIVE ACTION OR FIXING SIGNIFICANT DEFECTS

Size categories	Sanitary survey option	Sanitary survey and triggered monitoring option	Multi-barrier option (proposed)	Across-the-board disinfection option
<100	$29.86	$67.19	$62.48	$191.87
101–500	11.23	15.02	18.95	81.38
501–1,000	5.72	6.29	6.25	38.79
1,001–3,300	2.99	2.91	3.39	23.45
3,301–10,000	1.39	1.46	2.74	16.78
10,001–50,000	0.62	0.59	0.62	4.87
50,001–100,000	0.30	0.70	1.01	10.37
100,001–1,000,000	0.32	0.20	0.27	1.66
Average	2.45	3.34	3.86	19.37

F. Cost Savings From Simultaneous Reduction of Co-Occurring Contaminants

If a system chooses to install treatment, it may choose a technology that would also address other drinking water contaminants. For example, when using packed tower aeration to treat radon, it is the accepted engineering practice, and in some States an existing requirement, to also install disinfection treatment for removal of microbial contaminants introduced in the aeration treatment process. Depending on the dosage and contact time, the routine disinfection would also address possible or actual fecal contamination in the source water. If systems had an iron or manganese problem, the addition of an oxidant and filtration can 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 is currently in the process of proposing rules to address radon and arsenic. Because of the difficulties in establishing which systems would have all three problems of fecal contamination, radon, and arsenic or any combination of the three, no estimate was made of the potential cost savings from addressing more than one contaminant simultaneously. EPA also recognizes that while there may be savings from treating several contaminants simultaneously relative to treating each of them separately, there may also be significant economic impacts to some systems (especially small systems), if they have to address several contaminants in a relatively short time frame. Because of the lack of good data on co-occurrence of contaminants, EPA has not considered these simultaneous impacts in the analysis of household and per system costs.

G. Risk Increases From Other Contaminants

The RIA for today's rule contains a detailed discussion of the increased risk from other contaminants that may result from GWR requirements. Most of the risk stems from currently untreated systems installing disinfection. When disinfection is first introduced into a previously undisinfected system, the disinfectant can react with pipe scale causing increased risk from some contaminants and water quality problems. Contaminants that may be released include lead, copper, and arsenic. It could also lead to a temporary discoloration of the water as the scale is loosened from the pipe. These risks can be reduced by gradually phasing in disinfection to the system, by routine flushing of distribution system mains and by maintaining a proper corrosion control program.

Using a chlorine-based disinfectant or ozone 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 and is currently being further considered by the Stage II M–DBP FACA. Systems could avoid this problem by choosing an alternative disinfection technology such as ultraviolet disinfection or membrane filtration, though this may increase treatment costs. The GWR cost estimate includes such additional treatment costs for a portion of systems taking corrective action.

H. Other Factors: Uncertainty in Risk, Benefits, and Cost Estimates

Today's proposal models the current baseline risk from fecal contamination in ground water as well as the reduction in risk and the cost for four rule options. There is uncertainty in the baseline number of systems, the risk calculation, the cost estimates, and the interaction of other rules currently being developed. These uncertainties are discussed further in the following section.

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. Therefore, EPA does not have a reliable estimate of how many of these mixed systems exist. To the extent that systems classified in SDWS as surface water or ground water under the influence of surface water may also have ground water wells not under the influence of surface water and thus be subject to this rule, the costs and benefits estimated here would be understated. In addition, the SDWIS data on non-community water systems does not have a consistent reporting convention for population served. Some States may report the population served over the course of a year, while others may report the population served on an average day. Also, SDWIS does not require States to provide information on current disinfection practices and, in some cases, it may overestimate the daily population served. For example, a park may report the population served yearly instead of daily. EPA is looking at new approaches to address these issues, and both are discussed in the Requests for Comment section V.I.

The risk calculations concerning the baseline number of illnesses and the reduction of illnesses that results from the various rule options contains uncertainty. For example, a nationally representative study of baseline microbial occurrence in ground water does not exist. EPA chose the AWWARF study (described in section II.C.1) to represent properly constructed wells because, of the thirteen available studies, it is the most representative of national geology. EPA also relied on data from the EPA/AWWARF study to represent improperly constructed wells because this study targeted wells vulnerable to contamination and tested wells monthly for a year. However, EPA recognizes the variable nature of these studies, as discussed in detail in section II.C. Additionally, EPA had to rely on CDC outbreak data to characterize the causes of endemic ground water disease. As discussed in section II. B., the U.S. National Research Council suggests that CDC numbers only represent a small percentage of actual waterborne disease outbreaks. The Agency also 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 ground water systems or if other rules, such as the TMDL, CAFO, and Class V UIC Well Rules result in decreased fecal contamination.

EPA did not have dose-response data for all viruses and bacteria associated with previous ground water disease outbreaks. For viral illness, the Agency used echo and rota viruses 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 low-to-medium infectivity viruses that cause severe illness and high infectivity viruses that cause more mild illness. Further, there is considerable uncertainty in the dose-response functions used, even for these two viruses. Dose-response 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. There is likely to be variability in both of these parameters across populations and based on case specific circumstances, and only limited data are available. Another uncertainty

concerns the number of baseline bacterial illness caused by ground water contamination. The bacterial risk could not be modeled because of lack of occurrence and dose-response data. Estimates of bacterial illness were made based on a ratio of bacterial to viral outbreak as documented by CDC and applied to the viral risk estimate discussed previously. There is also considerable uncertainty in quantifying the effectiveness of various regulatory options in reducing risk. There is little data currently on which to base quantitative estimates of the effectiveness of sanitary surveys or routine monitoring in reducing microbial risk, though there is some qualitative research suggesting that these can be effective strategies. To model risk reduction quantitatively, EPA relied primarily on best professional judgment. The quantitative estimates of risk reduction used in the analysis are summarized in Table V–4a.

There is also uncertainty in the valuation of risk reduction benefits. For this analysis EPA used a 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. In general, however, COI estimates understate benefits because they do not account for the value people place on reduced pain and suffering.

Some costs of today's proposed rule are also uncertain because of the diverse nature of possible significant deficiencies systems would need to address. Also, the rule's flexibility leads to some uncertainty in estimates of who will be affected by each rule component and how States and systems will respond to significant deficiencies. These uncertainties could either under or overestimate the costs of the rule.

EPA is in the process of proposing regulations for radon and arsenic in drinking water, which can impact some ground water systems. EPA also intends to finalize the Stage II Disinfection Byproducts Rule by the statutory deadline of May 2002. It is extremely difficult to estimate the combined effects of these future regulations on ground water systems because of various combinations of contaminants that some systems may need to address. However, it is possible for a system to choose treatment technologies that would deal with multiple problems. Therefore, the total cost impact of these drinking water rules is uncertain; however, it may be less than the estimated total cost of all individual rules combined. Conversely, the impacts on households and individual systems of multiple rules is cumulative, and in some cases maybe greater than the impacts estimated in the RIA of each rule separately.

I. Benefit Cost Determination

The Agency has determined that the benefits of the proposed GWR justify the costs. The mean quantified benefits exceed the mean quantified costs by $22 million using a three percent discount rate and $6 million using a seven percent discount rate. EPA made this determination based on provisions of the multi-barrier option that include improved sanitary surveys, hydrogeologic sensitivity assessments triggered and routine monitoring provisions corrective actions, and compliance monitoring. Overall, these elements will reduce the risk of microbial contamination reaching the consumer. The quantified cost of these provisions were compared to the monetized benefits that result from the reduction in viral and bacterial illness and death. In addition, other non-monetized benefits further justify the costs of this rule.

J. Request for Comment

The Agency requests comment on all aspects of the GWR RIA. Specifically, EPA seeks input into the following two issues.

1. NTNC and TNC Flow Estimates

In the GWR RIA, EPA estimates the cost of the GWR on NTNC and TNC water systems by using flow models. However, these flow models were developed to estimate flows only for CWS and they may not accurately represent the much smaller flows generally found in NTNC and TNC systems. The effect of the overestimate in flow would be to inflate the cost of the rule for these systems. The Agency requests comment on an alternative flow analysis for NTNC and TNC water systems described next.

Instead of using the population served data to determine the average flow for use in the rule's cost calculations, this alternative approach would re-categorize NTNC and TNC water systems based on service type (*e.g.,* restaurants or parks). Service type would be obtained from SDWIS data. However, service type data is not always available because it is a voluntary SDWIS data field. Where unavailable, the service type would be assigned based on statistical analysis. Estimates of service type design flows would be obtained from engineering design manuals and best professional judgment if no design manual specifications exist.

In addition, each service type category would also have corresponding rates for average population served and average water consumption. These would be used to determine contaminant exposure which is used in the benefit determination. Note that the current approach of assuming that the entire population served drinks an average of 1.2 liters per day for 250 days (from NTNCWSs) and 15 days (from TNCWs) may lead to an overestimation of benefits. For example, schools and churches would be two separate service type categories. They each would have their own corresponding average design flow, average population served (rather than the population as reported in SDWIS), and average water consumption rates. These elements could be used to estimate a rule's benefits and costs for the average church and the average school.

2. Mixed Systems

Current regulations require that all systems that use any amount of surface water as a source be categorized as surface water systems. This classification applies even if the majority of water in a system is from a ground water source. Therefore, SDWIS does not provide the Agency with information to identify how many mixed systems exist. This information would help the Agency to better understand regulatory impacts. Further, to the extent that mixed systems are classified as surface water, the costs and benefits of this proposed rule are underestimated.

EPA is investigating ways to identify how many mixed systems exist and how many mix their ground and surface water sources at the same entry point or at separate entry points within the same distribution systems. For example, a system may have several plants/entry points that feed the same distribution system. One of these entry points may mix and treat surface water with ground water prior to its entry into the distribution system. Another entry point might use ground water exclusively for its source while a different entry point would exclusively use surface water. However, all three entry points would supply the same system classified in SDWIS as surface water.

One method EPA could use to address this issue would be to analyze CWSS data then extrapolate this information to SDWIS to obtain a national estimate of mixed systems. CWSS data, from approximately 1,900 systems, details sources of supply at the level of the entry point to the distribution system and further subdivides flow by source type. The Agency is considering this

national estimate of mixed systems to regroup surface water systems for certain impact analyses when regulations only impact one type of source. For example, surface water systems that get more than 50 percent of their flow from ground water would be counted as a ground water system in the regulatory impact analysis for this rule. The Agency requests comment on this methodology and its applicability for use in regulatory impact analysis.

VI. Other Requirements

A. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

1. Background

The 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.

2. Use of Alternative Definition

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, ''which are appropriate to the activities of the agency'' after proposing the alternative definition(s) in the **Federal Register** and taking comment (5 U.S.C. secs. 601(3)—(5)). In addition, agencies must consult with SBA's Chief Counsel for Advocacy to establish an alternative small business definition.

EPA is proposing the GWR which contains provisions which apply to small PWSs serving fewer than 10,000 persons. This is the cut-off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. Because this definition does not correspond to the definitions of ''small'' for small businesses, governments, and non-profit organizations, EPA requested comment on an alternative definition of ''small entity'' in the preamble to the proposed Consumer Confidence Report (CCR) regulation (63 FR 7620, February 13, 1998). Comments showed that stakeholders support the proposed alternative definition. EPA also consulted with the SBA Office of Advocacy on the definition as it relates to small business analysis. In the preamble to the final CCR regulation (63 FR 4511, August 19, 1998). EPA stated its intent to establish this alternative definition for regulatory flexibility assessments under the RFA for all drinking water regulations and has thus used it in this proposed rulemaking. The SBA Office of Advocacy agrees with the use of this definition in this rulemaking.

3. Initial Regulatory Flexibility Analysis

In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) that examined the impact of the proposed rule on small entities along with regulatory alternatives that could reduce that impact. The IRFA addresses the following issues:

- The reasons the Agency is considering this action;
- The objectives of, and legal basis for the proposed rule;
- The number and types of small entities to which the rule will apply;
- Projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the reports and records;
- The other relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and,
- Any significant alternatives to the components under consideration which accomplish the stated objectives of applicable statutes and which may minimize any significant economic impact of the proposed rule on small entities.

a. The Reasons the Agency Is Considering This Action

EPA believes that there is a substantial likelihood that fecal contamination of ground water supplies is occurring at frequencies and levels which 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 which consume them.

Fecal contamination is introduced to ground water from a number of sources including, septic systems, leaking sewer pipes, landfills, sewage lagoons, cesspools, and storm water runoff. Microorganisms can be transported with the ground water as it moves through an aquifer. In addition, the transport of microorganisms to wells or other ground water system sources can also be affected by poor well construction (*e.g.,* improper well seals) which can result in large, open conduits for fecal contamination to pass unimpeded into the water supply.

Waterborne pathogens contained in fecally contaminated water can result in a variety of illnesses which range in the severity of their outcomes from mild diarrhea to kidney failure or heart disease. The populations which are particularly sensitive to waterborne and other pathogens include, infants, young children, pregnant and lactating women, the elderly and the chronically ill. These individuals may be more likely to become ill as a result of exposure to the pathogens, and are likely to have a more severe illness. A complete discussion of the public health concerns addressed by the GWR can be found in section II of the preamble.

b. The Objectives of, and the Legal Basis for, the Proposed Rule

EPA is proposing the GWR pursuant to section 1412(b)(8) of the SDWA, as amended in 1996, 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 1996 amendments establish a statutory deadline of May 2002. EPA, however, intends to finalize the GWR in the year 2000 to coincide with implementation of other drinking water regulations and programs, such as the Disinfection Byproducts Rule, the Arsenic Rule, the Radon Rule and the Source Water Assessment and Protection Program (SWAPP). EPA believes systems and States will better plan for changes in operation and capital improvements if they presented them with future regulatory requirements at one time.

c. Number of Small Entities Affected

According to the December 1997 data from EPA's Safe Drinking Water Information System (SDWIS), there are 156,846 community water systems and non-community water supplies providing potable ground water to the public, of which 155,254 (99 percent) are classified by EPA as small entities. EPA estimates that these small ground water systems serve a population of more than 48 million. Roughly one-quarter of these systems are estimated to be community water systems serving fixed populations on a year-round basis.

Under the proposed option, all community and non-community water systems are affected by at least one requirement; the sanitary survey provision. The other GWR components are estimated to affect different numbers

of small systems. For example, over 4,300 small systems are expected to have to fix significant deficiencies each year.

d. Small Entity Impacts

Reporting and Recordkeeping for the Proposed GWR

Under the proposed Multi-Barrier option, there are a number of recordkeeping and reporting requirements for all ground water system (including small systems). To minimize the burden with these provisions, the EPA is proposing a targeted risk-based regulatory strategy whereby the monitoring requirements are based on system characteristics and not directly related to system size. In this manner, the multi-barrier option takes a system-specific approach to regulation, although a sanitary survey is required of all community and non-transient non-community water systems. However, the implementation schedule for this requirement is staggered (*e.g.,* every three to five years for CWSs and every five years for NCWSs), which should provide some relief for small systems because there are proportionately more NCWSs.

To address concerns over the potential cost of additional monitoring for small systems, the proposed GWR 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). In this proposal, only systems that do not reliably treat to 4-log inactivation or removal of viruses are required to test for the presence of *E. coli,* coliphage, or enterococci in the source water within 24 hours of a total coliform positive sample in the distribution system.

Only systems determined to be hydrogeologically sensitive and do not already treat to 4-log inactivation or removal of viruses are required to conduct the additional routine monitoring. If no fecal indicators are found after 12 months of monitoring, the State may reduce the monitoring frequency for that system. Similarly, if a non-sensitive system does not have a distribution system, any sample taken for TCR compliance is effectively a source water sample, so an additional triggered source water sample would not be required. In both cases, however, if the system has a positive sample for *E. coli,* coliphage, or fecal coliform, the system is required to conduct the necessary follow-up actions.

Small Entity Compliance Costs for the Proposed GWR

Estimates of the cost of complying with each component of the multi-barrier approach are presented next. The estimated impacts for this proposed option are based on the national mean compliance cost across the four compliance scenarios. System-level impacts are investigated using various corrective action and significant defects scenarios. The high correction action/low significant defect scenario is considered a typical cost estimate. For more information on these scenarios and cost assumptions, consult the Regulatory Impact Analysis for the Proposed Ground Water Rule (USEPA, 1999a) which is available for review in the water docket.

In determining the costs and benefits of this proposed rule, EPA considered the full range of both potential costs and benefits for the rule. The flexibility of the risk-based targeted approach of the rule aims to reduce the cost of compliance with the rule. Small systems will benefit from the flexibility provided in this design. For example, a small system with fecal contamination will, in consultation with the State, be able to select the least costly corrective action. Also, small systems serving less than 3,300 people which disinfect will only be required to monitor their treatment effectiveness one time per day as opposed to the continuous monitoring required for larger systems which disinfect. Estimates of annual CWS compliance costs for the multi-barrier approach are presented in Table VI–1.

TABLE VI–1.—ANNUAL COMPLIANCE COSTS FOR THE PROPOSED GWR BY CWS SYSTEM SIZE AND TYPE

CWS system type	System size/population served				
	<100	101–500	501–1,000	1,001–3,300	3,301–10K
Publicly-Owned	$825	$934	$1,238$	$1,950	$4,480
Privately-Owned	799	933	1,449	1,730	5,358
All Systems	805	933	1,328	1,893	4,652

e. Coordination With Other Federal Rules

To avoid duplication of effort, the proposed GWR encourages States to use their source water assessments when the assessment provides data relevant to the sensitivity assessment of a system. Although not a regulatory program, source water assessments are currently being performed by States. The schedule for the sensitivity assessment (within six years for CWS and eight years for NCWS) should allow States to complete the assessment and the first round of sanitary surveys concurrently if they choose to do so.

EPA has structured this GWR proposal as a targeted, risk-based approach to reducing fecal contamination. The only regulatory requirement that applies to all ground water systems is the sanitary survey. The Agency has also considered other drinking water contaminants that may be of concern when a system install disinfection. Specifically, adding disinfection may result in an increase in other contaminants of concern, depending on the characteristics of the source water and the distribution system. These contaminants include disinfection byproducts, lead, copper, and arsenic. EPA believes that these issues, when they occur will be very localized and may be addressed through selection of the appropriate corrective action. EPA has provided States and systems with the flexibility to select among a variety of corrective actions. These include options such as UV disinfection, or purchasing water from another source, which would avoid these types of problems.

f. Minimization of Economic Burden

Description of Regulatory Options

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. These options are described in more detail in section III of this preamble.

On an annual basis, the cost of the proposed alternative ranges from $182.7 million to $198.6 million, using a three and seven percent discount rate. System costs make up 89 percent of the total

rule costs. In developing this proposal, however, EPA considered the recommendations to minimize the cost impact to small systems. The proposed multi-barrier, risk-based approach was designed to achieve maximum public health protection while avoiding excessive compliance costs associated with Across-the-Board Disinfection regulatory compliance requirements.

To mitigate the associated compliance cost increases across water systems, the proposed GWR also provides States with considerable flexibility when implementing the rule. This flexibility will allow States to work within their existing program. Similarly, the rule allows States to consider the characteristics of individual systems when determining an appropriate corrective action. For example, States have the flexibility to allow systems to obtain a new source, or use any disinfection treatment technology, provided it achieves 4-log inactivation or removal of pathogens.

4. Small Entity Outreach and Small Business Advocacy Review Panel

As required by section 609(b) of the RFA, as amended by SBREFA, EPA also conducted outreach to small entities and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the small entities that potentially would be subject to the rule's requirements. The SBAR Panel members for the GWR were the Small Business Advocacy Chair of the Environmental Protection Agency, the Director of the Standards and Risk Management Division in the Office of Ground Water and Drinking Water (OGWDW) within EPA's Office of Water, the Administrator for the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB), and the Chief Counsel for Advocacy of the Small Business Administration (SBA). The Panel convened on April 10, 1998, and met seven times before the end of the 60-day Panel period on June 8, 1998. The SBAR Panel's report Final Report of the SBREFA Small Business Advocacy Review Panel on EPA's Planned Proposed Rule for National Primary Drinking Water Regulations: Ground Water, the small entity representatives (SERs) comments on components of the GWR, and the background information provided to the SBAR Panel and the SERs are available for review in the Office of Water docket. This information and the Panel's recommendations are summarized in section VI.A.4.a.

Prior to convening the SBAR Panel, EPA consulted with a group of 22 SERs likely to be impacted by a GWR. The SERs included small system operators, local government officials (including elected officials), small business owners (*e.g.,* a bed and breakfast with its own water supply), and small nonprofit organizations (*e.g.,* a church with its own water supply for the congregation). The SERs were provided with background information on the GWR, on the need for the rule and the potential requirements. The SERs were asked to provide input on the potential impacts of the rule from their perspective. All 22 SERs commented on the information provided. These comments were provided to the SBAR Panel when the Panel convened. After a teleconference between the SERs and the Panel, the SERs were invited to provide additional comments on the information provided. Three SERs provided additional comments on the rule components after the teleconference. In general, the SERs consulted on the GWR were concerned about the impact of the rule on small water systems (because of their small staff and limited budgets), the additional monitoring that might be required, and the data and resources necessary to conduct a hydrogeologic sensitivity assessment or sanitary survey. There was also considerable discussion about how nationally representative the source data was. SER suggested providing flexibility to the States implementing these provisions and opposed mandatory disinfection across-the-board. SERs expressed support for existing monitoring requirements as a means of determining compliance, and some supported increased requirements for total coliform monitoring.

Consistent with the RFA/SBREFA requirements, the Panel evaluated the assembled materials and small-entity comments related to the elements of the IRFA. A copy of the Panel report is in the Office of Water docket for this proposed rule.

a. Number of Small Entities to Which the Rule Will Apply

When the IRFA was prepared, EPA estimated that there were over 157,000 small ground water systems that could be affected by the GWR, serving a population of more than 48 million. Roughly one-third of these systems are community water systems (CWS). The remainder are non-community water systems (NCWS) (*i.e.* non-transient non-community such as schools and transient non-community such as restaurants). A more detailed and current discussion of the impact of the proposed rule on small entities can be found in section V of this preamble.

The SBAR Panel recommended that, given the number of systems that could be affected by the rule, EPA should consider focusing compliance requirements on those systems most at risk of fecal contamination. The GWR addresses this issue and is designed to target the systems at highest risk. Risk characterization is based on system characteristics, *i.e.,* significant deficiencies in operation or maintenance and hydrogeologic sensitivity to contamination. A system is not required to perform an action such as source water microbial monitoring until the State has cause to believe the system is at risk.

The Panel also recommended that the rule requirements be based on system size. Because the GWR is a targeted risk-based rule, the regulatory strategy is based on system-specific risk indicators that are not directly related to system size. However, the monitoring required for treatment effectiveness (compliance monitoring) varies based on system size. Ninety-seven percent of all ground water systems serve less than 3,300 people. Under the proposed GWR, disinfecting ground water systems serving less than 3,300 people must monitor treatment by taking daily grab samples. Disinfecting ground water systems serving 3,300 or more people must monitor treatment continuously.

The SBAR Panel advocated that States be provided with flexibility when implementing the rule. The GWR also addresses this issue. As discussed earlier in sections III.A.1. and 2. of this proposal, States have considerable flexibility in addressing potential problems in small systems. In particular, States have the flexibility to define and identify significant system deficiencies and to describe their approaches to identifying the presence of hydrogeologic barriers to contamination. States also have the flexibility to require correction of fecal contamination or use any disinfection treatment technology, provided it achieves 4-log (99.99%) inactivation or removal of viruses. Similarly, the rule allows States to consider the characteristics of individual systems when determining an appropriate corrective action.

b. Record Keeping and Reporting and Other Compliance Requirements

Because small systems frequently have minimal staff and resources, including data on the underlying hydrogeology of the system, the SBAR Panel recommended that EPA focus the record keeping, reporting, and compliance requirements on those systems at greatest risk of fecal

contamination. The Panel also recommended that EPA consider tailoring the requirements based on system size (*e.g.,* the smaller systems would not have to monitor as frequently or perform sanitary surveys on the same schedule.)

The GWR proposed today is a targeted risk-based regulatory strategy. The regulatory strategy is based on system characteristics (*i.e.,* hydrogeologic sensitivity; TCR positive in the distribution system) and is not directly related to system size. However, the monitoring required for treatment effectiveness (compliance monitoring) varies based on system size. Ninety-seven percent of all ground water systems serve less than 3,300 people. Under the proposed GWR, disinfecting ground water systems serving less than 3,300 people must monitor treatment by taking daily grab samples. Disinfecting ground water systems serving 3,300 or more people must monitor treatment continuously. In addition, the only across-the-board requirement is for sanitary surveys, but the implementation schedule is staggered (*e.g.,* every 3 years for CWS and every 5 years for NCWS) which should provide some relief for small systems because there are proportionately more that are NCWS. EPA is also requesting comment on several options that would reduce the required frequency of sanitary surveys. Because many small systems may not have easy access to the records that would ideally be available for a hydrogeologic sensitivity assessment or a sanitary survey, EPA, after consulting with stakeholders and the SBAR Panel, has determined that it will not use the lack of adequate well records, the lack of a cross connection program, or intermittent pressure fluctuations as automatic triggers to indicate risk of potential contamination. These factors may be considered along with others that more definitively demonstrate risk. This strategy will enable States to focus their resources on the systems which need the most surveillance or follow-up action and will avoid penalizing systems with limited resources.

With respect to the potential cost of additional monitoring for small systems, particularly if the rule required viral monitoring, the SBAR Panel offered several recommendations. First, the Panel suggested that, to the extent possible, the GWR should build on the existing monitoring framework in the TCR. Given the low cost of the Total Coliform test, the Panel noted that an increase in the frequency and the locations for TCR monitoring or additional samples in the source water if the system has a Total Coliform positive sample would be preferable to other fecal indicator tests, given the current cost of a viral test. However, the Panel also recommended that the EPA continue to develop a lower cost, more accurate test to identify viral and bacterial contamination in drinking water.

Today's proposal does build on the existing TCR monitoring framework by using the results of the TCR monitoring to determine if source water monitoring is required. In the proposal, a system is required to test for the presence of *E. coli,* coliphage, or enterococci in the source water within 24 hours of a total coliform positive sample in the distribution system. Only systems determined to be hydrogeologically sensitive that do not already treat their water to 4-log inactivation or removal are required to conduct the additional routine monitoring. These systems must test their source water monthly. If no fecal indicators are found after 12 consecutive months of monitoring, the State may reduce the monitoring frequency for that system. Similarly, if a non-sensitive system does not have a distribution system, any sample taken for TCR compliance is effectively a source water sample so an additional triggered source water sample would not be required. In both cases, however, if the system has an *E. coli,* coliphage, or fecal coliform positive sample, the system is required to conduct the necessary follow-up actions.

The GWR also has incorporated low-cost fecal contamination indicator tests. EPA-approved methods for detecting bacterial indicators of fecal contamination, including *E. coli* and enterococci, are already widely used and are low cost (approximately $25 per sample). In addition, EPA is currently developing viral monitoring methods which will cost approximately the same as existing bacterial methods.

The SBAR Panel recommended that States be provided with flexibility when implementing the rule. For example, while States must have the authority to require the correction of significant deficiencies, States should also have the flexibility to determine which deficiencies are ''significant'' from a public health perspective. When a State determines that corrective action is necessary, it should have the flexibility to determine what actions a system should take, including but not limited to disinfection. Similarly, States should also have the flexibility to require disinfection across-the-board for all or a subset of the public water supply systems in their State. States should also be given the flexibility to choose from the full range of disinfection technologies that will meet the public health goals of the rule.

As discussed earlier in sections III.A.1. and 2. of this proposal, States have considerable flexibility in addressing potential problems in small systems particularly with respect to sanitary survey, where States define and identify significant deficiencies, and in conducting hydrogeologic sensitivity assessments. The GWR allows States flexibility to work within their existing programs and define and identify significant deficiencies. States also have the flexibility to require correction of fecal contamination or use any disinfection treatment technology, provided it achieves 4-log (99.99%) inactivation or removal of viruses. Similarly, the rule allows States to consider the characteristics of individual systems when determining an appropriate corrective action.

The Panel was also concerned about the potential cost of disinfection and recommended that EPA include a full range of variables when determining both the potential cost burden and benefits of the rule.

In determining the costs and benefits of today's proposed rule, EPA considered the full range of both potential costs and benefits for the rule. The flexibility in the rule is designed to reduce the cost of compliance with the rule, particularly for small systems. While determining the costs of the various technologies, EPA has estimated the percentage of systems in consultation with the States that will choose between the different technologies, in part based on system size. When determining the benefits of today's proposal, EPA considered a range of benefits from reduction in illness and mortality to outbreak cost avoided and possibly reduced uncertainty and averting behaviors. However, only reductions in acute viral and bacterial illness and decreases in mortality from virus are monetized. More detailed cost and benefit information is included in the GWR RIA (US EPA, 1999a) for today's proposal. Because systems are highly variable, the SBAR Panel recommended that States be given the flexibility to determine appropriate maintenance or cross connection control measures for each system and to the extent practicable maintenance measures should be performance-based.

EPA recognizes that systems' characteristics are highly variable. States have considerable flexibility when working with systems to address significant deficiencies, conduct hydrogeological sensitivity assessments,

and take corrective action. Cross connection control will be considered under a future rulemaking (*i.e.,* the Long Term 2 Enhanced Surface Water Treatment Rule).

c. Other Federal Rules

To avoid duplication of effort, the SBAR Panel recommended using the State Source Water Assessment and Protection Program (SWAPP) plans and susceptibility assessments as a component of the hydrogeologic sensitivity assessment process. To further streamline the process, especially for small systems, the Panel also recommended combining the hydrogeologic sensitivity assessment with the sanitary surveys.

In today's GWR proposal, States are encouraged to use their SWAPP assessments when the assessment provides data relevant to the hydrogeologic sensitivity assessment of a system. The schedule for sensitivity assessments (six years after the GWR is promulgated in the **Federal Register** for CWS and eight years after the GWR is promulgated in the **Federal Register** for NCWS) should allow States to complete the assessment and the first round of sanitary surveys concurrently if they choose to do so.

d. Significant Alternatives

Because the SBREFA consultation was conducted early in the regulatory development process before there was a draft proposal, few comments were received on specific regulatory alternatives. In general, the SERs supported the approach described in the outreach materials while at the same time commenting on particular aspects of the approach that might be burdensome or otherwise problematic. Their concerns echo the comments received on other parts of the IRFA.

The SBAR Panel reiterated their suggestion that compliance requirements be tailored to the system size. In particular, if the minimum monitoring frequency and the frequency for sanitary surveys for the smallest systems (*e.g.*, those serving less than 500 people) could be reduced, it would reduce both the resources necessary to comply with the rule and record keeping required by the system.

EPA has structured today's proposal as a targeted risk-based approach to reducing fecal contamination. The only requirement that affects all GWSs is the sanitary survey. The required frequency for sanitary surveys for community systems is once every three years which may be changed by the State to once every five years if the system either treats to 4-log inactivation or removal of virus or has an outstanding performance record documented in previous inspections and has no history of total coliform MCL or monitoring violations since the last sanitary survey under current ownership. The required frequency for sanitary surveys is once every five years for noncommunity systems. The majority of the small systems are noncommunity systems so the majority of systems will only have a sanitary survey once every five years. At this frequency, EPA believes that the requirements will not be burdensome for even the smallest systems, however EPA is also requesting comment on less frequent sanitary survey requirements.

Similarly, the only additional monitoring requirements in today's proposal are for undisinfected systems that are either located in sensitive hydrogeologic settings or have a total coliform positive sample in the distribution system. The monitoring required for a total coliform positive sample under the TCR would be a one-time event while the monitoring for sensitive systems would be on a routine monthly basis for at least 12 samples.

Finally, the SBAR Panel noted that disinfection of public water supplies may result in an increase in other contaminants of concern, depending on the characteristics of the source water and the distribution system. Of particular concern were disinfection byproducts, lead, copper, and arsenic.

EPA has discussed these issues previously in section V.G. of the GWR preamble. EPA believes that these issues, when they occur, will typically be localized and transitory. These risk/risk tradeoffs are considered qualitatively in the RIA and EPA will provide guidance on how to address these issues when the rule is finalized.

e. Other Comments

The panel members could not reach consensus regarding the use of occurrence data to support the rule. Some panel members expressed the concern that the occurrence estimates discussed by EPA with the SERs overestimated the actual occurrence of fecal contamination and the studies used did not provide a true picture of national occurrence. EPA recognizes and understands the concerns about the available data expressed by these panel members. However, the Agency believes, after consulting with experts in the field, that the available data may underestimate the extent of ground water contamination because of limitations with sampling methods and frequency. EPA believes that a central issue for all participants and stakeholders in this rulemaking is how to interpret the available data. EPA agrees that the GWR must be based on the best available data, good science and sound analysis. The studies described in the materials presented to the SERs and SBAR Panel during the SBREFA process were conducted at different times and for different reasons; each requires careful analysis to ensure its proper use and to avoid misuse. A more detailed discussion of the occurrence studies and request for comment on their interpretation is provided in section II.C. of today's proposal.

EPA invites comments on all aspects of the proposal and its impacts on small entities.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1934.01) and a copy may be obtained from Sandy Farmer by mail at Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460, by email at farmer.sandy@epamail.epa.gov, or by calling (202) 260–2740. A copy may also be downloaded from the Internet at http://www.epa.gov/icr. For technical information about the collection contact Jini Mohanty by calling (202) 260–6415.

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 in Part 141, for systems, and Part 142, for States are mandatory. The information collected is not confidential.

EPA estimates that the annual burden on PWSs and States for reporting and record keeping will be 326,215 hours. This is based on an estimate that 56 States and territories will each need to provide 3 responses each year with an average of 524 hours per response, and that 52,331 systems will each provide 2.3 responses each year with an average of less than 2 hours per response. The labor burden is estimated for the following activities: Reading and understanding the rule, planning, training, and meeting primacy requirements. The recordkeeping and reporting burden also includes capital costs of $1,376,302 for capital

improvements by PWSs (installation of disinfection monitoring equipment).

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 are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. Send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave, N.W.; Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., N.W., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after May 10, 2000, a comment to OMB is best assured of having its full effect if OMB receives it by June 9, 2000. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Unfunded Mandates Reform Act

1. Summary of UMRA Requirements

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under UMRA section 202, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in State, local and tribal government expenditures, in the aggregate, or private sector expenditures, 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 notification to potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates; and informing, educating, and advising small governments on compliance with the regulatory requirements.

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

EPA has determined that this rule contains a Federal mandate that may result in expenditures of $100 million or more for the private sector in any one year.

Table VI–2 presents a breakdown of the estimated $182.7 to$198.6 million annual cost for today's proposed rule (the proposed Multi-Barrier Option). Public ground water systems owned by State, local and tribal governments will incur $51.2 to $56.5 million of these costs and States will incur an additional $20.1 to $22.1 million for a total public sector cost of $71.3 to $78.7 million dollars per year. Public ground water systems which are owned by private entities will incur a total cost of $111.5 to $ 119.9 million per year, $5.5 to $7 million of which is incurred by entities that operate a public water system as a means of supporting their primary business (*e.g.,* a mobile home park operator).

TABLE VI–2.—PUBLIC AND PRIVATE COSTS FOR OF THE PROPOSED GWR

System type	Annual mean cost range* (millions $)	Percent of total cost
Public PWS Cost	$51.2 to $56.5	28
State Cost	20.1 to 22.1	11
Total Public Cost	71.3 to 78.7	40
Private PWS Cost	106.0 to 113.0	57
Ancillary PWS Cost.	5.5 to 7.0	4
Total Private Cost.	111.5 to 119.9	60
Total Cost	182.7 to 198.6	100

Note: Cost range based upon a 3% and 7% discount rate.

Thus, today's rule is subject to the requirements of sections 202 and 205 of the UMRA, and EPA has prepared a written statement which is summarized next. A more detailed description of this analysis is presented in EPA's Regulatory Impact Analysis of the GWR (US EPA, 1999a) which is included in the Office of Water docket for this rule.

a. Authorizing Legislation

Today's proposed rule is promulgated pursuant to section 1412(b)(8) of the SDWA, as amended in 1996, 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.''

Section 1412 (b)(8) also establishes a statutory deadline for promulgation of the GWR of no later than the date on which the Administrator promulgates a Stage II rulemaking for disinfectants and disinfection byproducts. EPA intends to finalize the GWR in the year 2000 to allow systems to consider the combined impact of this rule, the radon rule, the arsenic rule and the Stage 1 DBP rule on their design and treatment modification as well as their capital investment decisions. EPA believes States and systems will better plan for changes in operation and capital improvements, if they are presented with future requirements at one time.

b. Cost Benefit Analysis

Section V of this preamble discusses the cost and benefits associated with the GWR . Also, EPA's Regulatory Impact Analysis of the GWR (US EPA, 1999a) contains a detailed cost benefit analysis. The analysis quantifies cost and benefits for four scenarios: the proposed regulatory option, the sanitary survey

option, the sanitary survey and triggered monitoring option, and the across-the-board disinfection option. Table VI–3 summarizes the range of annual costs and benefits for each rule option.

TABLE VI–3.—ANNUAL BENEFITS AND COSTS OF RULE OPTIONS ($MILLION)

Option	Annual benefits [1] mean [range] $million	Annual costs (3%) mean [range] $million	Annual costs [2] (7%) mean [range] $million
Sanitary Survey	$33 [$9 to $58]	$73 [$71 to $74]	$76 [$74 to $78]
Sanitary Survey and Triggered Monitoring	$178 [$147 to $209]	$158 [$152 to $19]	$169 [$163 to $174]
Multi-barrier (Proposed) Option	$205 [$169 to $242]	$183 [$177 to $188]	$199 [$192 to $206]
Across-the-Board Disinfection	$283 [$255 to $311]	$777 [$744 to $810]	$866 [$823 to $909]

[1] does not include benefits from reduction in chronic illness, reduced pain and suffering, or non-health benefits.
[2] does not include non-quantified costs such as land acquisition or increases in other contaminants (*e.g.,* DBPs).

Costs varied with each option and were driven by the number of systems that would need to fix a significant deficiency, take corrective action in response to fecal contamination, or install treatment. The annual mean cost of the four rule options ranges from $73 million to $866 million using a three percent and seven percent discount rate. For the first three options, the costs increase as more components are added for identifying fecally contaminated wells and wells sensitive to fecal contamination. However, the cost of these components (*e.g.,* hydrogeologic sensitivity assessment, routine and triggered monitoring) are minor compared to the costs of correcting fecal contamination. The fourth option of across-the-board disinfection is the most costly because it would require all systems to have treatment regardless of actual or potential fecal contamination. Costs for the States to implement this rule are also included in the four cost estimates. Some costs, such as land acquisition where necessary to install treatment, were not included because of the difficulty of estimating them.

These total annual monetized costs can be compared to the annual monetized benefits of the GWR. The annual monetized mean benefits of today's rule range from $33 million to $283 million as shown in Table VI–2. This result is based on the quantification of the number of acute viral illnesses and deaths avoided attributable to each option as well as the reduction in acute bacterial illness attributable to each option. For illness, EPA used a cost-of-illness number to estimate the benefits from the reduction in viral illness that result from this rule. This is considered a lower-bound estimate of actual benefits because it does not include the pain and discomfort associated with the illness. Mortalities were valued using a value of statistical life estimate consistent with EPA policy.

This rule will also decrease bacterial illness associated with fecal contamination of ground water. EPA did not directly calculate the actual numbers of illness associated with bacterially contaminated ground water because the Agency lacked the necessary pathogen occurrence data to include it in the risk model. However, in order to get an estimate of the number of bacterial illness from fecally contaminated ground water, the Agency used the ratio of viral and unknown etiology outbreak illness to bacterial outbreak illnesses reported to CDC's for waterborne outbreaks in ground water. It was further assumed that the cost of these bacterial illnesses would be comparable to viral illness estimates. This rule also considered but did not monetize the health benefit from the reduction in chronic illness associated with some viral and bacterial infections (see section II.D.).

Various Federal programs exist to provide financial assistance to State, local, and tribal governments in complying with this rule. The Federal government provides funding to States that have primary enforcement responsibility for their drinking water programs through the Public Water Systems Supervision Grants Program. Additional funding is available from other programs administered either by EPA or other Federal agencies. These include EPA's Drinking Water State Revolving Fund (DWSRF), U.S. Department of Agriculture's Rural Utilities' Loan and Grant Program, and Housing and Urban Development's Community Development Block Grant Program.

For example, SDWA authorizes the Administrator of the EPA to award capitalization grants to States, which in turn can provide low cost loans and other types of assistance to eligible public water systems. The DWSRF assists public water systems with financing the costs of infrastructure needed to achieve or maintain compliance with SDWA requirements. Each State has considerable flexibility in determining the design of its DWSRF Program and to direct funding toward its most pressing compliance and public health protection needs. States may also, on a matching basis, use up to 10 percent of their DWSRF allotments for each fiscal year to assist in running the State drinking water program. In addition, States have the flexibility to transfer a portion of funds to the Drinking Water State Revolving Fund from the Clean Water State Revolving Fund.

Furthermore, a State can use the financial resources of the DWSRF to assist small systems, the majority of which are ground water systems. In fact, a minimum of 15% of a State's DWSRF grant must be used to provide infrastructure loans to small systems. Two percent of the State's grant may be used to provide technical assistance to small systems. For small systems that are disadvantaged, up to 30% of a State's DWSRF may be used for increased loan subsidies. Under the DWSRF, Tribes have a separate set-aside which they can use.

In addition to the DWSRF, money is available from the Department of Agriculture's Rural Utility Service (RUS) and Housing and Urban Development's Community

Development Block Grant (CDBG) program. RUS provides loans, guaranteed loans, and grants to improve, repair, or construct water supply and distribution systems in rural areas and towns up to 10,000 people. In Fiscal Year 1997, the RUS had over $1.3 billion in available funds. Also, three sources of funding exist under the CDBG program to finance building and improvements of public facilities such as water systems. The three sources of funding include: (1) direct grants to communities with populations over 200,000; (2) direct grants to States, which they in turn award to smaller communities, rural areas, and colonias in Arizona, California, New Mexico, and Texas; and (3) direct grants to US. Territories and Trusts. The CDBG budget for Fiscal Year 1997 totaled over $4 billion dollars.

c. Estimates of Future Compliance Costs and Disproportionate Budgetary Effects

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

In analyzing disproportionate impacts, the Agency considered three measures: reviewing the impacts on small systems versus large systems; reviewing the costs to public versus private water systems; and reviewing the household costs for each proposed rule option. It is also possible that some States or EPA Regions may face greater challenges from the GWR because they have comparatively more ground water systems. However, States that have a larger percentage of systems also receive a greater share of the Public Water Systems Supervision Grants Program and the DWSRF. A detailed analysis of these impacts is presented in the Regulatory Impact Analysis of the GWR (US EPA, 1999a).

The first measure of disproportionate impact considers the cost incurred by small and large systems. As a group, small systems will experience a greater impact than large systems under the GWR. The higher cost to the small ground water systems is mostly attributable to the large number of these types of systems (*i.e.,* 99% of ground water systems serve <10,000). Other reasons for the disparity include: (1) Large systems are more likely to already disinfect their ground water (disinfection exempts a system from triggered and routine monitoring), (2) large systems typically have greater technical and operational expertise, and (3) they are more likely to engage in source water protection programs. The potential economic impact among the small systems will be the greatest for systems serving less than 100 persons, as shown in Table VI–4.

TABLE VI–4.—AVERAGE ANNUAL HOUSEHOLD COSTS FOR GWR OPTIONS FOR CWS TAKING CORRECTIVE ACTION OR FIXING SIGNIFICANT DEFECTS

Size categories	Sanitary survey option	Sanitary survey and triggered monitoring option	Multi-barrier option (proposed)	Across-the-board disinfection option
100	29.86	67.19	62.48	191.87
101–500	11.23	15.02	18.95	81.38
501–1,000	5.72	6.29	6.25	38.79
1,001–3,300	2.99	2.91	3.39	23.45
3,301–10,000	1.39	1.46	2.74	16.78
10,001–50,000	0.62	0.59	0.62	4.87
50,001–100,000	0.30	0.70	1.01	10.37
100,001–1,000,000	0.32	0.20	0.27	1.66
Average	2.45	3.34	3.86	19.37

The second measure of impact is the relative total cost to privately owned water systems compared to that incurred by publicly owned water systems. The majority of the small systems are privately-owned (61% of the total). As a result, privately-owned systems as a group will have a slightly larger share of the total costs of the rule. However, EPA has no basis for expecting cost per-system to differ systematically with ownership.

The third measure, household costs, can also be used to gauge the impact of a regulation and to determine whether there are disproportionately high impacts in particular segments of the population. Table VI–4 shows household costs by system size for each rule component. On average, annual household costs increases attributable to the first three rule options range from $2.45 to $3.86 (Table VI–4). For these three options, 90 percent of households will face less than a $5 increase in annual household costs. The most expensive option, Across-the-Board Disinfection, results in the highest average annual household costs of $19.37. However, household costs increase across all options for those households served by the smallest sized systems. This occurs because they serve fewer households, and as a result, there are fewer households to share the system's compliance costs.

d. Macro-economic Effects

Under UMRA section 202, EPA is required to estimate the potential macro-economic effects of the regulation. These types of effects include those on productivity, economic growth, full employment, creation of productive jobs, and international competitiveness. Macro-economic effects tend to be measurable in nationwide econometric models only if the economic impact of the regulation reaches 0.25 percent to 0.5 percent of Gross Domestic Product (GDP). In 1998, real GDP was $7,552 billion, so a rule would have to cost at least $18 billion to have a measurable effect. A regulation with a smaller aggregate effect is unlikely to have any measurable impact unless it is highly focused on a particular geographic region or economic sector. The macro-economic effects on the national economy from the GWR should not have a measurable effect because the total annual costs for the proposed option range from $183 million to $199 million per year using a three and seven percent discount rate. Even the most expensive option, Across-the-Board Disinfection falls below the measurable threshold. The costs are not expected to be highly focused on a particular geographic region or sector.

e. Summary of EPA's Consultation With State, Local, and Tribal Governments and Their Concerns

Consistent with the intergovernmental consultation provisions of section 204 of UMRA, EPA has initiated consultations with the governmental entities affected by this rule. EPA held four public meetings for all stakeholders and three Association of State Drinking Water Administrators early involvement meetings. 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. A more detailed description of the SBREFA process can be found in section VI.A. of this preamble. 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. Twelve State drinking water representatives also participated in the Agency's GWR workgroup.

In addition to these consultations, EPA circulated a draft of this proposed rule and requested comment from the public through an informal process. Specifically, on February 3, 1999, EPA posted on the EPA's Internet web page and mailed out over 300 copies of the draft to people who had attended the 1997 and 1998 public stakeholder meetings as well as people on the EPA workgroup. EPA received 80 letters or electronic responses to this draft: 34 from State government (representing 30 different States), 26 from local governments, ten from trade associations, six from Federal government agencies, and four from other people/organizations. No comments were received from tribal governments. EPA reviewed the comments carefully and considered their merit. Today's proposal reflects many of the commenters' points and suggestions. For example, numerous commenters felt that proposing a requirement to monitor source water using coliphage at this time was premature based on currently available data. EPA has recently completed round robin testing of coliphage methods and is requesting comment on the use of these methods.

To inform and involve tribal governments in the rulemaking process, EPA presented the GWR at the 16th Annual Consumer Conference of the National Indian Health Board, at the annual conference of the National Tribal Environmental Council, and at an EPA Office of Ground Water and Drinking Water (OGWDW)/Inter Tribal Council of Arizona, Inc. tribal consultation meeting. Over 900 attendees representing Tribes from across the country attended the National Indian Health Board's Consumer Conference and over 100 Tribes were represented at the annual conference of the National Tribal Environmental Council. At both conferences, an EPA representative conducted two workshops on EPA's drinking water program and upcoming regulations, including the GWR.

Comments received from tribal governments regarding the GWR focused on concerns and some opposition to mandatory disinfection for ground water systems. They also suggested that any waiver process be adequately characterized by guidance and simple to implement. EPA agrees with concerns of Tribes and has designed the proposed GWR so that disinfection is not mandatory. Systems will have the opportunity to correct significant deficiencies, eliminate the source of contamination, obtain a new source of water, or install disinfection to achieve 4-log inactivation or removal of virus. However, some systems in coordination with the primacy agent or State, might choose disinfection over these other options because it may be the least costly alternative.

At the OGWDW/Inter Tribal Council of Arizona meeting, representatives from 15 Tribes participated. In addition, over 500 Tribes and tribal organizations were sent the presentation materials and meeting summary. Because many Tribes have ground water systems, participants expressed concerns over some elements of the rule. Specifically, they had concerns about how the primacy agent would determine significant deficiencies identified in a sanitary survey and how the sensitivity assessment would be conducted. Because no Tribes currently have primacy, EPA is the primacy agent and will identify significant deficiencies as part of sanitary surveys and conduct the hydrogeologic sensitivity assessment as outlined in section III. A. and III.B. of this preamble.

The Agency believes the proposed option in the GWR will provide public health benefits to individuals by reducing their exposure to fecal contamination through targeted expenditures to address significant deficiencies or fecal contamination. As discussed earlier in paragraph IV.C.1.c, over 90 percent of households will incur additional costs of less than $3.00 per month based on EPA's proposed regulatory approach. EPA will consider other options for the final rule as outlined in this proposal and discussed next.

f. Regulatory Alternatives Considered

As required under section 205 of the UMRA, EPA considered several regulatory alternatives and numerous methods to identify ground water systems most at risk to microbial contamination. A detailed discussion of these alternatives can be found in section V of the preamble and also in the RIA for the GWR(US EPA, 1999a). Today's proposal also seeks comment on many regulatory options that EPA will consider for the final rule.

g. Selection of the Least Costly, Most Cost-Effective or Least Burdensome Alternative That Achieves the Objectives of the Rule

As discussed earlier, EPA has considered various regulatory options that would reduce microbial contamination in ground water systems. EPA believes that the proposed option as described in today's rule, is the most cost effective option that achieves the rule's objective to reduce the risk of illness and death from microbial contamination in PWS relying on ground water. This option is a targeted approach where costs are driven by the number of systems having to fix fecal contamination problems and correct significant deficiencies that could lead to fecal contamination. EPA requests comment on how possible modifications to the proposed option, as outlined in section III of the preamble, may affect not only the cost but also the objectives of this rule.

3. Impacts on Small Governments

In developing this rule, EPA consulted with small governments to address impacts of regulatory requirements in the rule that might significantly or uniquely affect small governments. In preparation for the proposed GWR, EPA conducted an analysis on small government impacts and included small government officials or their designated representatives in the rulemaking process. As discussed previously, a variety of stakeholders, including small governments, had the opportunity for timely and meaningful participation in the regulatory

development process through the SBREFA process, public stakeholder meetings, and tribal meetings. Representatives of small governments took part in the SBREFA process for this rulemaking and they also attended public stakeholder meetings. Through such participation and exchange, EPA notified some potentially affected small governments of requirements under consideration and provided officials of affected small governments with an opportunity to have meaningful and timely input into the development of regulatory proposals. A more detailed discussion of the SBREFA process and stakeholder meetings can be found in section VI.A. and section VI.C.2.e, respectively.

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

D. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Pub L. No. 104–113, § 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards.

EPA also notes that the Agency plans to implement in the future a performance-based measurement system (PBMS) that would allow the option of using either performance criteria or reference methods in its drinking water regulatory programs. The Agency is determining the specific steps necessary to implement PBMS in its programs. Final decisions have not yet been made concerning the implementation of PBMS in water programs. However, EPA is evaluating what relevant performance characteristics should be specified for monitoring methods used in the water programs under a PBMS approach to ensure adequate data quality. EPA would then specify performance requirements in its regulations to ensure that any method used for determination of a regulated analyte is at least equivalent to the performance achieved by other currently approved methods.

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

1. Microbial Monitoring Methods

The proposed rulemaking involves technical standards. Ground water systems that are identified by the State as having hydrogeologically sensitive wells as described in §§ 142.16(k)(3) and 141.403(a), and ground water systems that have a TCR positive sample as described in § 141.403(b) of today's proposed rule must sample and test their source water. GWSs must test for at least one of the following fecal indicators: *E. coli,* enterococci and coliphage using one of the methods in § 141.403(d) and discussed in greater detail in III.D.4. Table VI–5 lists the microbial methods which must be used for source water monitoring.

EPA proposes to use several approved methods. For testing *E. coli* and enterococci, the methods in § 141.403(d) are either consensus methods or new methods that EPA has recently approved for drinking water monitoring with the exception of Enterolert (a method for enterococci) for which EPA is proposing approval through this rulemaking. EPA is also proposing testing source waters for the presence for coliphage. EPA proposes to use EPA Method 1601: Two-Step Enrichment Presence-Absence Procedure and EPA Method 1602: Single Agar layer Procedure.

While the Agency identified Standards Methods, Method 9211D Coliphage Detection (20th edition of Standard Methods for the Examination of Water and Wastewater) as being potentially applicable, EPA does not propose to use it in this rulemaking. The use of this voluntary consensus standard would not meet the Agency's needs because the method does not detect male specific coliphage, the sample volume is inappropriately small (20 ml versus the GWR's proposed 100 ml sample requirement), and according to the method, the sensitivity may not be high enough to detect one coliphage in a 100 ml sample. EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

TABLE VI–5.—MICROBIAL METHODS

Analytical methods for source water monitoring	
Indicator	Method[1]
E. coli	Colilert Test (Method 9223B)[2 3]
	Colisure Test (Method 9223B)[2 3]
	Membrane Filter Method with MI Agar[4 5]
	m-ColiBlue24 Test[4 6]
	E*Colite Test[4 7]
	May also use the EC–MUG (Method 9212F)[2] and NA–MUG (Method 9222G)[2] *E. coli* confirmation step § 141.21(f)(6) after the EPA approved Total Coliform methods in § 141.21(f)(3)
enterococci	Multiple-Tube Tech. (Method 9230B)[1]
	Membrane Filter Tech. (Method 9230C)[1 8]
	Enterolert[3]
Coliphage	EPA Method 1601: Two-Step Enrichment Presence-Absence Procedure[9]
	EPA Method 1602: Single Agar layer Procedure[9]

[1] The time from sample collection to initiation of analysis may not exceed 30 hours. Systems are encouraged but not required to hold samples below 10 °C during transit.

[2] Methods are approved and described in Standard Methods for the Examination of Water and Wastewater (20th edition).

[3] Medium available through IDEXX Laboratories, Inc., One IDEXX Drive, Westbrook, Maine 04092.

[4] EPA approved drinking water methods.

[5] Brenner, K.P., C.C. Rankin, Y.R. Roybal, G.N. Stelma, P.V. Scarpino, and A.P. Dufour. 1993. New medium for the simultaneous detection of total coliforms and *Escherichia coli* in water. Appl. Environ. Microbiol. 59:3534–3544.

[6] Hach Company, 100 Dayton Ave., Ames, IA 50010.

[7] Charm Sciences, Inc., 36 Franklin St., Malden, MA 02148–4120.

[8] Proposed for EPA approval, EPA Method 1600: MF Test Method for enterococci in Water (EPA–821–R–97–004 (May 1997)) is an approved variation of Standard Method 9230C.

[9] Proposed for EPA approval are EPA Methods 1601 and 1602, which are available from the EPA's Water Resources Center, Mail code: RC–4100, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

E. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51,735,October 4,1993) the Agency must determine whether the regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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

F. Executive Order 12898: Environmental Justice

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

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. There are two aspects of today's proposed rule that relate specifically to this policy: the overall nature of the rule, and the convening of a stakeholder meeting specifically to address environmental justice issues. The GWR applies to all public water systems: community water systems, nontransient noncommunity water systems, and transient noncommunity water systems that use ground water as their source water. Consequently, the health protection benefits provided by this proposal are equal across all income and minority groups served by these systems. Existing regulations such as the SWTR and IESWTR provide similar health benefit protection to communities that use surface water or ground water under the direct influence of surface water.

As part of EPA's responsibilities to comply with Executive Order 12898, the Agency held a stakeholder meeting on March 12, 1998 to address various components of pending drinking water regulations; and how they may impact sensitive sub-populations, minority populations, and low-income populations. Topics discussed included treatment techniques, costs and benefits, data quality, health effects, and the regulatory process. Participants included national, State, tribal, municipal, and individual stakeholders. EPA conducted the meetings by video conference call with participants in eleven cities. This meeting was a continuation of stakeholder meetings that started in 1995 to obtain input on the Agency's drinking water programs. The major objectives for the March 12, 1998 meeting were: solicit ideas from environmental justice (EJ) stakeholders on known issues concerning current drinking water regulatory efforts; identify key issues of concern to EJ stakeholders; and receive suggestions from EJ stakeholders concerning ways to increase representation of EJ communities in EPA's Office of Water regulatory efforts. In addition, EPA developed a plain-English guide specifically for this meeting to assist stakeholders in understanding the multiple and sometimes complex drinking water issues.

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 ''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.

This proposed rule is subject to this Executive Order because it is an economically significant regulatory action as defined by Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Accordingly, EPA has evaluated the environmental health or safety effects of viruses on children. The results of this evaluation are contained in section II.E. of the preamble and in the RIA for today's rule (US EPA, 1999a). A copy of RIA and its supporting documents have been placed in the Office of Water docket for this proposal.

1. Risk of Viral Illness to Children and Pregnant Women

The risk of illness and death due to viral contamination of drinking water depends on several factors, including the age and the immune status of the exposed individual. Two groups that are at increased risk of illness and mortality due to waterborne pathogens are children and pregnant women (Gerba *et al.,* 1996). For example, rotavirus infections can occur in people of all ages, however they primarily affect young children (US EPA, 1999b). Infants and young children have higher rates of infection and disease from enteroviruses than other age groups (US EPA, 1999b). Several viruses 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 paralytic polio, heart disease, encephalitis, hemorrhagic conjunctivitis, hand-foot-and-mouth disease and diabetes mellitis (CDC, 1997; Modlin, 1997; Melnick, 1996; Cherry, 1995; Berlin and Rorabaugh, 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 (US EPA, 1999c). Coxsackievirus and echovirus may be transmitted from the mother to the child *in utero* (Gerba *et al.,* 1996).

To comply with Executive Order 13045, EPA calculated the baseline risk (*e.g.,* risk without this rule) and with-rule reduction of risk from waterborne illness and mortality for children. To address the disproportionate risk of waterborne illness and mortality to children under this rulemaking, EPA applied age-specific parameters regarding morbidity to the risk assessment. The risk assessment first

extracted the proportion of the population that falls into several age categories that may be more or less susceptible to waterborne viral illness than the general population. The extraction was done separately for two model viruses. Bacterial illnesses are not addressed in this analysis, however, EPA estimates that bacterial illnesses account for an additional 20% of viral illnesses.

When assessing the risk of illness due to viruses of low-to-medium infectivity (using echovirus as a surrogate), the age categories used were less than one month of age, one month to five years of age, five to sixteen years of age and greater than sixteen years of age. It was assumed that 50% of children less than five years old would become ill once infected with low-to-medium infectivity viruses; while 57% of children five years to sixteen years of age and 33% of people over sixteen would become ill once infected. This estimate was based on a community-wide echovirus type 30 epidemic (Hall, 1970). See Appendix A of the RIA.

When assessing the risk of illness due to viruses of high infectivity (using rotavirus as a surrogate) the age categories used were less than two years of age, two to five years of age, five to sixteen years old and greater than sixteen years old. It was assumed that 88% of children less than two years old would become ill once infected with high infectivity viruses; while 40% was assumed for everyone else. The morbidity rates for high infectivity viruses were based on data from Kapikian and Chanock (1996) for children less than two. For other age categories, EPA has conservatively estimated a morbidity of 10 based upon studies of rotavirus illness in households with newborn children (Wenman *et al.,* 1979) and of an outbreak in an isolated community (Foster *et. al.,* 1980). See Appendix A of the RIA.

In addition to illness, EPA also considered child mortality attributable to waterborne microbial illness. For low-to-medium infectivity viruses, 0.92% of children less than one month of age who become ill were assumed to die based on information from Jenista *et al.*, (1984) and Modlin (1986), while .041% of people greater than one month old who become ill were assumed to die. For viruses of high infectivity, 0.00073% of infected children less than four years old were assumed to die (Tucker *et al.,* 1998). The low-to-medium infectivity viruses result in a higher mortality rate than the high infectivity viruses because the low-to-medium infectivity viruses cause more serious health effects.

The proposed GWR specifically targets systems with existing or potential fecal contamination, including viral contamination. To estimate the benefits to children from today's proposed rule, the Agency calculated the number of illnesses and deaths avoided by the rule for the children less than 5 years old and for children between the ages of 5 and 16. Table VI–6 presents a summary of these estimates. Overall, the proposed rule would result in 26,566 less illnesses caused by viruses per year occurring in children 16 years of age and less. The proposed rule is also expected to result in 2 less deaths per year due to viral illness among children aged 16 or less.

TABLE VI–6.—REDUCTIONS OF VIRAL ILLNESS AND DEATH IN CHILDREN RESULTING FROM VARIOUS REGULATORY APPROACHES

Options	Illness reduction (ages 0–5)	Death reduction (ages 0–5)	Illness reduction (5–16 years old)	Death reduction (5–16 years old)
Sanitary Survey Only	2,292	0	1,773	0
Sanitary Survey and Triggered Monitoring	13,044	1	9,974	1
Multi-barrier (Proposed)	15,058	1	11,508	1
Across-the-board Disinfection	21,125	1	16,059	2

The Agency believes the proposed multi-barrier approach will provide the most cost-effective method of reducing viral and bacterial illness in children that results from contaminated ground water. The proposed option will reduce 3,500 more cases of viral illness in children each year than the sanitary survey and triggered monitoring option. This additional reduction is obtained with only a slightly larger increase in total annual costs. Conversely, the additional reductions in illness gained with the across-the-board option comes at a much higher cost. It is estimated that the across-the-board option will cost approximately $12,000 more per case of illness avoided than the multi-barrier approach.

2. Full Analysis of the Microbial Risk Assessment

A full analysis of the microbial risk assessment is provided in the Appendix to the RIA for the proposed GWR, and a summary is provided in this preamble (see section II.E.).

The public is invited to submit or identify peer-reviewed studies and data, of which EPA may not be aware, that assessed results of early life exposure to viruses and bacteria.

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

In accordance with section 1412 (d) and (e) of the SDWA, the Agency did consult with the Science Advisory Board and will request comment from the National Drinking Water Advisory Council (NDWAC) and the Secretary of Health and Human Services on the proposed rule.

I. Executive Order on 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''. Under section 6 of Executive Order 13132, EPA may not issue a regulation that has Federalism 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 State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has Federalism implications and that preempts State

law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to the Office of Management and Budget (OMB), in a separately identified section of the preamble to the final rule, a Federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the Agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with Federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the Agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

EPA has concluded that this proposed rule may have Federalism implications since it may impose substantial direct compliance costs on local governments, and the Federal government will not provide the funds necessary to pay those cost. Accordingly, EPA provides the following FSIS as required by section 6(b) of Executive Order 13132.

As discussed in section I.A., EPA met with a variety of State and local representatives including several local elected officials, who provided meaningful and timely input in the development of the proposed rule. Summaries of the meetings have been included in the public record for this proposed rulemaking. EPA consulted extensively with State, local, and tribal governments. For example, four public stakeholder meetings were held in Washington, DC, Portland, Oregon, Madison Wisconsin and Dallas, Texas. EPA also held three early involvement meetings with the Association of State Drinking Water Administrators. Several key issues were raised by stakeholders regarding the GWR provisions, many of which were related to reducing burden and maintaining flexibility. The Office of Water was able to reduce burden and increase flexibility by creating a targeted risk based approach which builds upon existing State programs. It should be noted that this rule is important because it will reduce the incidence of fecally contaminated drinking water supplies by requiring corrective actions for fecally contaminated systems or systems with a significant risk of fecal contamination resulting in a reduced waterborne illness. Because consultation on this proposed rule occurred before the November 2, 1999, effective date of Executive Order 13132, EPA will initiate discussions with State and local elected officials regarding the implications of this rule during the public comment period.

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

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

EPA has concluded that this rule will significantly affect communities of Indian tribal governments because 92 percent of PWSs in Indian Country are ground water systems. It will also impose substantial direct compliance costs on such communities, and the Federal government will not provide the funds necessary to pay the direct costs incurred by the tribal governments in complying with the rule. In developing this rule, EPA consulted with representatives of tribal governments pursuant to Executive Order 13084. EPA's consultation, the nature of the tribal governments' concerns, and EPA's position supporting the need for this rule are discussed in section VI.C. which addresses compliance with UMRA.

As described in section VI.C.2.e. of the UMRA discussion, EPA held extensive public meetings that provided the opportunity for meaningful and timely input in the development of the proposed rule. Summaries of the meetings have been included in the Office of Water public docket for this rulemaking. In addition, the Agency presented the rule and asked for comment at three tribal conferences. Two consultations took place at national conferences; one for the National Indian Health Board and the other for the National Tribal Environmental Council. The third consultation was conducted in conjunction with the Inter-Tribal Council of Arizona, Inc. A more detailed discussion of these consultations can be found in the UMRA consultation section (section VI.C.2.c.).

K. Plain Language

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write its rules in plain language. EPA invites comments on how to make this proposed rule easier to understand. For example: Has EPA organized the material to suit commenters' needs? Are the requirements in the rule clearly stated? Does the rule contain technical language or jargon that is not clear? Would a different format (grouping and order of sections, use of headings, paragraphs) make the rule easier to understand? Would shorter sections make this rule easier to understand? Could EPA improve clarity by adding tables, lists, or diagrams? What else could EPA do to make the rule easier to understand?

VII. Public Comment Procedures

EPA invites you to provide your views on this proposal, approaches we have not considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider. Many of the sections within today's proposed rule contain ''Request for Comment'' portions which the Agency is also interested in receiving comment on.

A. Deadlines for Comment

Send your comments on or before July 10, 2000. Comments received after this date may not be considered in decision making on the proposed rule.

B. Where To Send Comment

Send an original and 3 copies of your comments and enclosures (including references) to W–98–23 Comment Clerk, Water Docket (MC4101), USEPA, 1200 Pennsylvania Ave., NW, Washington DC 20460. Hand deliveries should be delivered to the Comment Clerk, Water Docket (MC4101), USEPA 401 M , Washington, D.C. 20460. Comments may also be submitted electronically to ow-docket@epamail.epa.gov. Electronic comments must be submitted as an

ASCII, WP5.1, WP6.1 or WP8 file avoiding the use of special characters and form of encryption. Electronic comments must be identified by the docket number W–98–23. Comments and data will also be accepted on disks in WP 5.1, 6.1, 8 or ASCII file format. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Those who comment and want EPA to acknowledge receipt of their comments must enclose a self-addressed stamped envelope. No facsimiles (faxes) will be accepted. Comments may also be submitted electronically to ow-docket@epamail.epa.gov.

C. Guidelines for Commenting

To ensure that EPA can read, understand and therefore properly respond to comments, the Agency would prefer that commenters cite, where possible, the paragraph(s) or sections in the notice or supporting documents to which each comment refers. Commenters should use a separate paragraph for each issue discussed. Note that the Agency is not soliciting comment on, nor will it respond to, comments on previously published regulatory language that is included in this notice to ease the reader's understanding of proposed language. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide technical information and/or data to support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate.

5. Indicate what you support, as well as what you disagree with.

6. Provide specific examples to illustrate your concerns.

7. Make sure to submit your comments by the deadline in this proposed rule.

8. At the beginning of your comments (*e.g.,* as part of the ''Subject'' heading), be sure to properly identify the document you are commenting on. You can do this by providing the docket control number assigned to the proposed rule, along with the name, date, and *Federal Register* citation.

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List of Subjects in 40 CFR Parts 141 and 142

Environmental protection, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water.

Dated: April 17, 2000.

Carol M. Browner,

Administrator.

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

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

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

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

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

§ 141.21 Coliform sampling.

* * * * *

(d) * * *

(3) Sanitary surveys conducted by the State under § 142.16(k)(2) of this chapter, at the frequencies specified, may be used to meet the sanitary surveys requirements of this section.

* * * * *

3. Section 141.154 is amended by adding paragraph (f) to read as follows:

§ 141.154 Required additional health information.

* * * * *

(f) Ground water systems that detect *E. coli*, enterococci or coliphage in the source water as required by § 141.403 must include the health effects language prescribed by Appendix B of subpart Q of this part.

* * * * *

4. Section 141.202 as added by the final rule published on May 4, 2000 is amended by adding entry (9) in numerical order to the table in paragraph (a) 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

*	*	*	*	*
(9) Violation of the treatment technique for the Ground Water Rule (as specified in § 141.405(a) through (c) or when *E. coli,* enterococci, or coliphage are present as specified in § 141.403) or when the water system fails to test for *E. coli,* enterococci, coliphage (as specified in § 141.403).				
*	*	*	*	*

5. Appendix A of subpart Q as added by the final rule published on May 4, 2000 is amended by adding entry 8. under I.A. ''Microbiological Contaminants'' and by adding entry G. under IV. ''Other Situations Requiring Public Notification'' to read as follows:

APPENDIX A TO SUBPART Q OF PART 141.—NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE [1] (INCLUDING D/DBP AND IESWTR VIOLATIONS)

Contaminant	MCL/MRDL/TT violations [2]		Monitoring and testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
* * * * * * *				
A. Microbiological Contaminants				
* * * * * * *				
8. GWR TT violations	1	141.405	N/A	N/A
* * * * * * *				
IV. Other Situations Requiring Public Notification				
* * * * * * *				
G. Fecal indicators for GWR: *E. coli,* enterococci, coliphage	1	141.403	1	141.403

Appendix A Endnotes

[1] Violations and other situations not listed in this table (*e.g.,* reporting violations and 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.

* * * * *

6. Appendix B to subpart Q as added by the final rule published on May 4, 2000 is amended by adding a new entry 1c in numerical order un A. ''Microbiological Contaminants'' and by redisinating entries C. through H. as D. through I. and adding a new C. in alphabetical order to read as follows:

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

Contaminant	MCLG [1]	mg/L	MCL [2] mg/L	
* * * * * * *				
A. Microbiological Contaminants				
* * * * * * *				
1c. Fecal indicators (GWR):				
i. *E. coli*	Zero	None	Fecal indicators are bacteria or viruses whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term 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			
iii. coliphage	None			
* * * * * * *				
C. Ground Water Rule (GWR) TT violations.	None	TT	Inadequately treated or inadequately protected water may contain disease-causing organisms. These organisms include bacteria and viruses which can cause symptoms such as diarrhea, nausea, cramps, and associated headaches.	
* * * * * * *				

Appendix B Endnotes

1. MCLG—Maximum contaminant level goal.
2. MCL—Maximum contaminant level.

* * * * *

7. Appendix C to subpart Q as added in the final rule published on May 4, 2000 amended by adding the following abbreviation in alphabetical order to read as follow:

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

* * * * *

GWR Ground Water Rule

* * * * *

9. A new subpart S is proposed to be added to read as follows:

Subpart S—Ground Water Rule

Sec.

141.400 General requirements and applicability.
141.401 Sanitary survey information request.
141.402 Hydrogeologic sensitivity assessment information request.
141.403 Microbial monitoring of source water and analytical methods.
141.404 Treatment technique requirements.
141.405 Treatment technique violations.
141.406 Reporting and record keeping.

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.* All public water systems that are served solely by ground water. The requirements in this subpart also apply to subpart H systems that distribute ground water that is not treated to 4-log inactivation or removal of viruses before entry into the distribution system. Systems supplied by ground water under the direct influence of surface water are regulated under subparts H and P of this part, not under this subpart. For the purposes of this subpart, ''ground water system'' is defined as any public water system meeting this applicability statement.

(c) *General requirements.* These regulations in this subpart establish requirements related to sanitary surveys, hydrogeologic sensitivity assessments, and source water microbial monitoring performed at ground water systems as defined by paragraph (b) of this section. The regulations in this subpart also establish treatment technique requirements for these ground water systems which have fecally contaminated source waters, as demonstrated under § 141.403, or significant deficiencies as identified in a sanitary survey conducted by a State under either § 142.16(k)(2) of this chapter or by EPA under SDWA section 1445. Ground water systems with fecally contaminated source water or significant deficiencies must meet one or more of the following treatment technique requirements: eliminate the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer. Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness.

(d) *Compliance dates.* Ground water systems must comply with the requirements of this subpart beginning [DATE 3 YEARS AFTER PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER.

§ 141.401 Sanitary survey information request.

Ground water systems must provide the State at its request, any pertinent existing information that would allow the State to perform a sanitary survey as described in § 142.16(k)(2) of this chapter. For the purposes of this subpart, ''sanitary survey,'' as conducted by the State, includes but is not limited to an onsite review of the water source (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.

§ 141.402 Hydrogeologic sensitivity assessment information request.

Ground water systems must provide the State at its request, any pertinent existing information that would allow the State to perform a hydrogeologic sensitivity assessment as described in § 142.16(k)(3) of this chapter.

§ 141.403 Microbial monitoring of source water and analytical methods.

(a) *Routine monitoring.* Any ground water system that draws water from a hydrogeologically sensitive drinking water source, as determined under § 142.16(k)(3) of this chapter, and that does not provide 4-log inactivation or removal of viruses, must collect a source water sample each month that it provides water to the public and test the sample for the fecal indicator specified by the State under paragraph (d) of this section. Ground water systems must begin monitoring the month after being notified of the hydrogeologic sensitivity assessment.

(b) *Triggered monitoring.* Any ground water system that does not provide 4-log inactivation or removal of viruses, and is notified of a total coliform-positive sample under § 141.21, must collect, within 24 hours of notification, at least one source water sample and have the sample tested for the fecal indicator specified by the State under paragraph (d) of this section. This requirement is in addition to all monitoring and testing requirements under § 141.21.

(c) *Systems with disinfection.* Ground water systems currently providing 4-log inactivation or removal of viruses must notify the State of such and must conduct compliance monitoring in accordance with § 141.404(c). This notification must be made by the effective date of the rule. All new systems must notify the State of the level of virus inactivation they are achieving prior to serving their first customer.

(d) *Analytical methods.* Source water samples must be tested for one of the following fecal indicators: *E. coli,* coliphage, or enterococci, as specified by the State. For whichever fecal indicator is specified by the State, the ground water system must use one of the analytical methods listed in the following table:

ANALYTICAL METHODS FOR SOURCE WATER MONITORING

Indicator	Method[1]
E. coli	Colilert Test (Method 9223B)[2, 3] Colisure Test (Method 9223B)[2, 3] Membrane Filter Method with MI Agar[4, 5] m-ColiBlue24 Test[4, 6] E*Colite Test[4, 7] May also use the EC-MUG (Method 9212F)[2] and NA-MUG (Method 9222G)[2] *E. coli* confirmation step § 141.21(f)(6) after the EPA approved Total Coliform methods in § 141.21(f)(3)
enterococci	Multiple-Tube Tech. (Method 9230B)[1] Membrane Filter Tech. (Method 9230C)[1, 8] Enterolert[3]
Coliphage	EPA Method 1601: Two-Step Enrichment Presence-Absence Procedure[9] EPA Method 1602: Single Agar layer Procedure[9]

[1] The time from sample collection to initiation of analysis may not exceed 30 hours. Systems are encouraged but not required to hold samples below 10°C during transit.

[2] Methods are approved and described in Standard Methods for the Examination of Water and Wastewater (20th edition).

[3] Medium available through IDEXX Laboratories, Inc., One IDEXX Drive, Westbrook, Maine 04092.

[4] EPA approved drinking water methods.

[5] Brenner, K.P., C.C. Rankin, Y.R. Roybal, G.N. Stelma, P.V. Scarpino, and A.P. Dufour. 1993. New medium for the simultaneous detection of total coliforms and *Escherichia coli* in water. Appl. Environ. Microbiol. 59:3534–3544.

[6] Hach Company, 100 Dayton Ave., Ames, IA 50010.

[7] Charm Sciences, Inc., 36 Franklin St., Malden, MA 02148–4120.

[8] Proposed for EPA approval, EPA Method 1600: MF Test Method for enterococci in Water (EPA–821–R–97–004 (May 1997)) is an approved variation of Standard Method 9230C.

[9] Proposed for EPA approval are EPA Methods 1601 and 1602, which are available from the EPA's Water Resources Center, Mail code: RC–4100, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

(e) *Notification of State.* If any source water sample is positive for *E. coli*, coliphage, or enterococci, the ground water system shall notify the State as soon as possible after the system is notified of the test result, but in no case later than the end of the next business day, and take corrective action in accordance with § 141.404(b).

(f) *Resampling after invalidation.* Where the State invalidates a positive source water sample under paragraph (i) of this section, the ground water system must collect another source water sample and have it analyzed for the same fecal indicator within 24 hours of being notified of the invalidation.

(g) *Triggered monitoring waiver.* The State may waive triggered source water monitoring as described in § 141.403(b) due to a total coliform-positive sample, on a case-by-case basis, if the State determines that the total coliform positive sample is associated solely with a demonstrated distribution system problem. In such a case, a State official must document the decision, including the rationale for the decision, in writing, and sign the document.

(h) *Reduce frequency for routine monitoring.* The State may reduce routine source water monitoring to quarterly if a hydrogeologically sensitive ground water system detects no fecal indicator-positive samples in the most recent twelve monthly samples, during the months the ground water system is in operation. Moreover, the State may, after those twelve monthly samples, waive source water monitoring altogether for a ground water system if the State determines, and documents the determination in writing, that fecal contamination of the well(s) has not been identified and is highly unlikely based on the sampling history, land use pattern, disposal practices in the recharge area, and proximity of septic tanks and other fecal contamination sources. If the State determines that circumstances have changed, the State has the discretion to reinstate routine monthly monitoring. In any case, a State official must document the determination in writing, including the rationale for the determination, addressing each factor noted in this paragraph and sign the document.

(i) *Invalidation of samples.* A source water sample may be determined by the State to be invalid only if the laboratory establishes that improper sample analysis occurred or the State has substantial grounds to believe that a sample result is due to circumstances that do not reflect source water quality. In such a case, a State official must document the decision, including the rationale for the decision, in writing, and sign the document. The written documentation must state the specific cause of the invalid sample and what action the ground water system or laboratory has taken or will take to correct this problem. A positive sample may not be invalidated by the State solely on the grounds that repeat samples are negative.

(j) *Repeat sampling.* A ground water system may apply to the State, and the State may consider, on a one-time basis, to waive compliance with the treatment technique requirements in § 141.404(b), after a single fecal indicator-positive from a routine source water sample as required in § 141.403(a), if all the following conditions are met:

(1) The ground water system collects five repeat source water samples within 24 hours after being notified of a source water fecal indicator positive result;

(2) The ground water system has the samples analyzed for the same fecal indicator as the original sample;

(3) All the repeat samples are fecal indicator negative; and

(4) All required source water samples (routine and triggered) during the past five years were fecal indicator-negative.

§ 141.404 Treatment technique requirements.

(a) *Ground water systems with significant deficiencies.* As soon as possible, but no later than 90 days after receiving written notification from the State of a significant deficiency, a ground water system must do one or more of the following: eliminate the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer. Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness. The ground water system must consult with the State to determine which of the approaches, or combination of approaches, are appropriate for meeting the treatment technique requirement. Ground water systems unable to address the significant deficiencies in 90 days, must develop a specific plan and schedule for meeting this treatment technique requirement, submit them to the State, and receive State approval before the end of the same 90-day period. For the purposes of this paragraph, a ''significant deficiency'' includes: 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 potential for causing the introduction of contamination into the water delivered to consumers.

(b) *Ground water systems with source water contamination.* As soon as possible, but no later than 90 days after the ground water system is notified that a source water sample is positive for a fecal indicator, the ground water system must do one or more of the following: eliminate the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer. Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness. The ground water system must consult with the State to determine which of the approaches, or combination of approaches, are appropriate for meeting the treatment technique requirement. Ground water systems unable to address the contamination problem in 90 days must develop a specific plan and schedule for meeting this treatment technique requirement, submit them to the State, and receive State approval before the end of the same 90-day period specified previously. This requirement also applies to ground water systems for which States have waived source water monitoring under § 141.403(h) and have a fecal coliform-or E. coli-positive while testing under § 141.21.

(c) *Compliance monitoring.* Ground water systems that provide 4-log inactivation or removal of viruses, or begin treatment pursuant to paragraph (a) or (b) of this section, must monitor the effectiveness and reliability of treatment as follows:

(1) *Chemical disinfection.* (i) Ground water systems serving 3,300 or more people must continuously monitor and maintain the State-determined residual disinfectant concentration every day the ground water system serves water to the public.

(ii) Ground water systems serving fewer than 3,300 people must monitor and maintain the State-determined residual disinfectant concentration every day the ground water system serves water to the public. The ground water system will monitor by taking a daily grab sample during the hour of peak flow or 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.

(2) *UV disinfection.* Ground water systems using UV disinfection must continuously monitor for and maintain the State-prescribed UV irradiance level every day the ground water system serves water to the public.

(3) *Membrane filtration.* Ground water systems that use membrane filtration as a treatment technology are assumed to be achieving at least 4-log removal of viruses when the membrane process is operated in accordance with State-specified compliance criteria developed under § 142.16(k)(5)(ii) of this chapter, or as provided by EPA, and the integrity of the membrane is intact. Applicable membrane filtration technologies are reverse osmosis (RO), nanofiltration (NF), and any membrane filters developed in the future that have absolute MWCOs (molecular weight cut-offs) that can achieve 4-log virus removal.

(d) *Discontinuing treatment.* Ground water systems may discontinue 4-log inactivation or removal of viruses if the State determines based on an on-site investigation, and documents that determination in writing, that the need for 4-log inactivation or removal of viruses no longer exists. Ground water systems are subject to triggered monitoring in accordance with § 141.403(b).

§ 141.405 Treatment technique violations.

The following are treatment technique violations which require the ground water system to give public notification pursuant to Appendix A of subpart Q of this part, using the language specified in Appendix B of subpart Q of this part.

(a) A ground water system with a significant deficiency identified by a State (as defined in § 141.401) which does not correct the deficiency, provide an alternative source, or provide 4-log inactivation or removal of viruses within 90 days, or does not obtain, within the same 90 days, State approval of a plan and schedule for meeting the treatment technique requirement in § 141.404, is in violation of the treatment technique.

(b) A ground water system that detects fecal contamination in the source water and does not eliminate the source of contamination, correct the significant deficiency, provide an alternate source water, or provide a treatment which reliably achieves at least 99.99 percent (4-log) inactivation or removal of viruses before or at the first customer within 90 days, or does not obtain within the same 90 days, State approval of a plan for meeting this treatment technique requirement, is in violation of the treatment technique unless the detected sample is invalidated under § 141.403(i) or the treatment technique is waived under § 141.403(j). Ground water systems which provide 4-log inactivation or removal of viruses will be required to conduct compliance monitoring to demonstrate treatment effectiveness.

(c) A ground water system which fails to address either a significant deficiency as provided in paragraph (a) of this section or fecal contamination as provided in paragraph (b) of this section according to the State-approved plan, or by the State-approved deadline, is in violation of the treatment technique. In addition, a ground water system which fails to maintain 4-log inactivation or removal of viruses, is in violation of the treatment technique, if the failure is not corrected within four hours.

§ 141.406 Reporting and record keeping.

(a) *Reporting.* In addition to the requirements of § 141.31, ground water systems regulated under this subpart must provide the following information to the State:

(1) Ground water systems conducting continuous monitoring must notify the State any time the residual disinfectant concentration (irradiance in the case of UV) falls below the State-determined value and is not restored within 4 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) Ground water systems taking daily grab samples must notify the State any time the residual disinfectant concentration falls below the State-determined value and is not restored within 4 hours, as determined by follow-up samples. 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.

(3) Ground water systems using membrane filtration must notify the State any time the membrane is not operated in accordance with standard operation and maintenance procedures for more than 4 hours, or any failure of the membrane integrity occurs and is not restored within 4 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. These operation and maintenance procedures will be provided by EPA or developed by the State under § 142.16(k)(5)(ii) of this chapter.

(4) If any source water sample is positive for *E. coli,* coliphage, or enterococci, the ground water system shall notify the State as soon as possible, but in no case later than the end of the next business day, and take corrective action in accordance with § 141.404(b).

(5) If any ground water system has reason to believe that a disease outbreak is potentially attributable to their drinking water, it must report the outbreak to the State as soon as possible, but in no case later than the end of the next business day.

(6) After implementation of any required treatment techniques, a ground water system must provide as soon as possible, but in no case later than the end of the next business day, written confirmation to the State that the corrective action required by § 141.404(a) and (b) were met.

(7) Notification that the ground water system is currently providing 4-log inactivation or removal of viruses.

(b) *Record keeping.* In addition to the requirements of § 141.33, ground water systems regulated under this subpart must maintain the following information in their records:

(1) Documentation showing the fecal indicator the State is requiring the ground water system to use.

(2) Documentation showing consultation with the State on approaches for addressing significant deficiencies including alternative plans and schedules and State approval of such plans and schedules.

(3) Documentation showing consultation with the State on approaches for addressing source water fecal contamination including alternative plans and schedules and State approval of such plans and schedules.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. The authority citation for part 142 continues to read as follows:

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

2. Section 142.14 is amended by adding paragraph (d)(17) to read as follows:

§ 142.14 Records kept by States.

* * * * *

(d) * * *

(17) Records of the currently applicable or most recent State determinations, including all supporting information and an explanation of the technical basis for each decision, made under the following provisions of 40 CFR part 141, subpart S for the Ground Water Rule.

(i) Section 142.16(k)(3)—State determinations of source water hydrogeologic sensitivity, and determinations of the presence of hydrogeologic barriers.

(ii) Section 141.404(c) '' notification to individual ground water systems of the proper residual disinfection concentrations (when using chemical disinfection), irradiance level (when using UV), or EPA-specified or State specified compliance criteria (when using membrane filtration) needed to achieve 4-log inactivation of viruses.

(iii) Section 141.403(g)—waivers of triggered monitoring.

(iv) Section 141.403(h)—reductions of monitoring.

(v) Section 141.403(i)—invalidation of positive source water samples.

(vi) Section 141.403(j)—waiver of compliance with treatment technique requirements.

(vii) Section 141.404(a)—notifications of significant deficiencies, consultation with the ground water systems, including written confirmation of corrections of significant deficiencies by ground water systems and written records of State site visits and approved plans and schedules.

(ix) Section 141.404(d)—determinations of when a ground water system can discontinue 4-log inactivation or removal of viruses.

* * * * *

3. Section 142.15 is amended by adding paragraphs (c)(6) through (10) to read as follows:

§ 142.15 Reports by States.

* * * * *

(c) * * *

(6) Sanitary surveys. An annual list of ground water systems that have had a sanitary survey completed during the previous year and an annual evaluation of the State's program for conducting sanitary surveys under § 142.16(k)(2).

(7) Hydrogeologic sensitivity assessments. An annual list of ground water systems that have had a sensitivity assessment completed during the previous year, a list of those ground water systems which are sensitive, a list of ground water systems which are sensitive, but for which the State has determined that a hydrogeologic barrier exists at the site sufficient for protecting public health, and an annual evaluation of the State's program for conducting hydrogeologic sensitivity assessments under § 142.16 (k)(3).

(8) Source water microbial monitoring. An annual list of ground water systems that have had to test the source water as described under § 141.403 of this chapter, a list of determinations of invalid samples, and a list of waivers of source water monitoring provided by the State.

(9) Treatment technique compliance. An annual list of ground water systems that have had to meet treatment technique requirements for significant deficiencies or contaminated source water under § 141.404 of this chapter, a list of determinations to discontinue 4-log inactivation or removal of viruses, and a list of ground water systems that violated the treatment technique requirements.

(10) Ground water systems providing 4-log inactivation or removal of viruses. An annual list of ground water systems that have notified the State that they are currently providing 4-log inactivation or removal of viruses.

* * * * *

4. Section 142.16 is amended by adding and reserving paragraphs (i) and (j) and adding paragraph (k) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(i) [Reserved]

(j) [Reserved]

(k) 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 a description of how the State will accomplish the following program requirements:

(1) *Enforceable requirements.* (i) States must have the appropriate rules or other authority to ensure that ground water systems take the steps necessary to address, in accordance with § 141.404(a) of this chapter, any significant deficiencies identified in the written notification provided by the State as required under paragraph (k)(2) of this section.

(ii) States must have appropriate rules or other authority to ensure that ground water systems respond in writing in regard to the resolution of significant deficiencies identified in the written notification provided by the State following identification of the significant deficiencies.

(iii) States must have the appropriate rules or other authority to ensure that ground water systems take the steps necessary to address, in accordance with § 141.404(b) of this chapter, any fecal contamination identified during routine or triggered monitoring in accordance with § 141.403(a) and (b) of this chapter.

(2) *Sanitary survey.* In its primacy application the State must describe how it, or an authorized agent, will implement a sanitary survey program that meets the requirements of this section.

(i) For the purposes of this paragraph (k)(2), ''sanitary survey'' includes, but is not limited to, an onsite review of the water source (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.

(ii) The State, or an authorized agent, must conduct sanitary surveys for all ground water systems. The sanitary survey must address the eight sanitary survey components listed in paragraphs (k)(2)(ii)(A) through (H) of this section no less frequently than every three years for community systems and no less frequently than every five years for noncommunity systems. The first sanitary survey for community water systems must be completed by [DATE 6 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER] and for noncommunity water systems, must be completed by [DATE 8 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

(A) Source.

(B) Treatment.

(C) Distribution system.

(D) Finished water storage.

(E) Pumps, pump facilities, and controls.

(F) Monitoring and reporting and data verification.

(G) System management and operation.

(H) Operator compliance with State requirements.

(iii) After the initial sanitary survey for ground water systems in accordance with § 142.16(k)(2)(ii), the State may reduce the frequency of sanitary surveys for community water systems to no less frequently than every five years, if the ground water system either treats to 4-log inactivation or removal of viruses or has an outstanding performance record documented in previous inspections and has no history of total coliform MCL or monitoring violations under § 141.21 of this chapter as determined by the State, since the last sanitary survey under the current ownership. In its primacy application, the State must describe how it will decide whether a community water system has outstanding performance and is thus eligible for sanitary surveys at a reduced frequency.

(iv) States may complete components of a sanitary survey as part of a staged or phased State review process within the established frequency specified in paragraph (k)(2)(ii) or (iii) of this section. In its primacy application, a State which plan to complete the sanitary survey in a staged or phased State review process must indicate which approach it will take and provide the rationale for the specified time frames for sanitary surveys conducted on a staged or phased approach basis.

(v) Sanitary surveys that meet the requirements of this subpart, including the requisite eight components identified in paragraph (k)(2)(ii) of this section and conducted at the specified frequency, are considered to meet the requirements for sanitary surveys under the Total Coliform Rule (TCR) as described in § 141.21 of this chapter. Note however, compliance only with the TCR sanitary survey requirements may not be adequate to meet the revised scope and frequency sanitary survey requirement of this subpart.

(vi) States must provide ground water systems with written notification identifying and describing any significant deficiencies identified at the ground water system no later than 30 days after identifying the significant deficiencies. States will provide ground water systems with written notification by certified mail or on-site from the sanitary survey inspector. In its primacy application, the State must indicate how it will define what constitutes a significant deficiency for purposes of this subpart. For the purposes of this paragraph, a ''significant deficiency'' includes: 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 potential for causing the introduction of contamination into the water delivered to consumers.

(vii) In its primacy application, the State must describe how it will consult with the ground water system regarding the treatment technique requirements specified in § 141.404 and criteria for determining when a ground water system has met the 4-log inactivation or removal of viruses of this chapter.

(viii) States must confirm that the deficiency has been addressed, either through written confirmation from ground water systems or a site visit by the State, within 30 days after the ground water system has met the treatment technique requirements under § 141.404(a) of this chapter.

(ix) In its primacy application, the State must specify if and how it will integrate Source Water Assessment and Protection Program (SWAPP) susceptibility determinations into the sanitary survey and the definition of significant deficiency.

(3) *Hydrogeologic sensitivity assessments.* (i) For the purposes of this paragraph (k)(3), ''hydrogeologic sensitivity assessment'' means the methodology used by the State to identify whether ground water systems are obtaining water from karst, gravel, or fractured bedrock aquifers. A State may add additional hydrogeologic sensitive settings, *e.g.*, volcanic aquifers. A well obtaining water from a karst, gravel or fractured bedrock aquifer is sensitive to fecal contamination unless the well is protected by a hydrogeologic barrier. A ''hydrogeologic barrier'' consists of physical, chemical and biological factors that, singularly or in combination, prevent the movement of viable pathogens from a contaminant source to a ground water system well.

(ii) The State, or an authorized agent, must conduct a one-time hydrogeologic sensitivity assessment for all existing ground water systems not providing 4-log inactivation or removal of viruses by [DATE SIX YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER] for community water systems and by [DATE EIGHT YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER] for non-community water systems. The State, or an authorized agent, must conduct a hydrogeologic sensitivity assessment for new systems prior to their serving water to the public.

(iii) In its primacy application, a State must identify its approach to determine the adequacy of a hydrogeologic barrier, if present, as part of its effort to determine the sensitivity of a ground water system in a hydrogeologic sensitivity assessment.

(4) *Source water microbial monitoring.* (i) In its primacy application, the State must identify its approach and rationale for determining which of the fecal indicators (E. coli, coliphage, or enterococci) ground water systems must use in accordance with § 141.403(d) of this chapter.

(ii) The State may waive triggered source water monitoring as described in § 141.403(b) of this chapter due to a total coliform-positive sample, on a case-by-case basis, if the State determines that the total coliform positive sample is associated solely with a demonstrated distribution system problem. In such a case, a State official must document the decision, including the rationale for the decision, in writing, and sign the document.

(iii) The State may reduce routine source water monitoring to quarterly if a hydrogeologically sensitive ground water system detects no fecal indicator-positive samples in the most recent twelve consecutive monthly samples during the months the ground water system is in operation. Moreover, the State may, after those twelve consecutive monthly samples, waive source water monitoring altogether for a ground water system if the State determines, in writing, that fecal contamination of the well(s) has not been identified and is highly unlikely, based on the sampling history, land use pattern, disposal practices in the recharge area, and proximity of septic tanks and other fecal contamination sources. If the State determines that circumstances have changed, the State has the discretion to reinstate routine monthly monitoring. In any case, a State official must document the determination in writing, including the rationale for the determination, and sign the document.

(iv) The State may determine a source water sample to be invalid only if the laboratory establishes that improper sample analysis occurred or the State has substantial grounds to believe that a sample result is due to circumstances that do not reflect source water quality. In such a case, a State official must document the decision, including the rationale for the decision, in writing, and sign the document. The written documentation must state the specific cause of the invalid sample and what action the ground water system or laboratory has taken or must take to

correct this problem. A positive sample may not be invalidated by the State solely on the grounds that repeat samples are negative, though this could be considered along with other evidence that the original sample result does not reflect source water quality.

(v) A ground water system may apply to the State, and the State may consider, on a one-time basis, to waive compliance with the treatment technique requirements in § 141.404(a) of this chapter, after a single fecal indicator-positive from a routine source water sample as required in § 141.403(a) of this chapter, if all the following conditions are met:

(A) The ground water system collects five repeat source water samples within 24 hours after being notified of a source water fecal positive result;

(B) The ground water system has the samples analyzed for the same fecal indicator as the original sample;

(C) All the repeat samples are fecal indicator negative; and

(D) All previous source water samples (routine and triggered) during the past 5 years were fecal indicator-negative.

(5) *Treatment technique requirements.* (i) In its primacy application, the State must describe how it must provide every ground water system treating to 4-log inactivation or removal the disinfectant concentration (or irradiance) and contact time to achieve 4-log virus inactivation or removal. EPA recommends that the State use applicable EPA-developed CT tables (IT (the product of irradiance, in mW/cm^2, multiplied by exposure time, in seconds) in the case of UV disinfection) to determine the concentration (or irradiance) and contact time that it will require ground water systems to achieve 4-log virus inactivation.

(ii) If the State intends to approve membrane filtration for treatment it must, in its primacy application, describe the monitoring and compliance requirements, including membrane integrity testing, that it will require of ground water systems to demonstrate proper operation of membrane filtration technologies.

(iii) In its primacy application, a State must describe the approach it must use to determine which specific treatment technique option (correcting the deficiency, eliminating the source of contamination, providing an alternative source, or providing 4-log inactivation or removal of viruses) is appropriate for addressing significant deficiencies or fecally contaminated source water and under what circumstances. In addition, the State must describe the approach it intends to use when consulting with ground water systems on determining the treatment technique options.

(iv) States must confirm that the ground water system has addressed the source water fecal contamination identified under routine or triggered monitoring in accordance with § 141.403(a) and (b) of this chapter, either through written confirmation from ground water systems or a site visit by the State, within 30 days after the ground water system has met the treatment technique requirements under § 141.404(b) of this chapter.

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