Economic Analysis for the Final Ground Water Rule

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List of Acronyms

ADA	American Diabetes Association
AIDS	Acquired Immune Deficiency Syndrome
ASDWA	Association of State Drinking Water Administrators
AWWA	American Water Works Association
AWWARF	American Water Works Association Research Foundation
AWWSCo	American Water Works Service Company
BLS	Bureau of Labor Statistics
BMP	Best Management Practice
BGM	Buffalo Green Monkey
CCR	Consumer Confidence Report
CDC	Centers for Disease Control and Prevention
CFR	Combined Federal Register
Cl	chlorine
ClO_2	chlorine dioxide
COI	Cost of Illness
CDBG	Community Development Block Grant
CPI	Consumer Price Index
CT	product of the residual disinfectant concentration (C) & the disinfectant contact time (T)
CWS	Community Water System
CWSS	Community Water System Survey
DBP	Disinfection Byproduct
DBPR	Disinfectants and Disinfection Byproducts Rule
DOE	Department of Energy
DWSRF	Drinking Water State Revolving Fund
E	Income Elasticity
EA	Economic Analysis
EIA	Economic Impact Analysis
EPA	United States Environmental Protection Agency
FBRR	Filter Backwash Recycling Rule
FDA	Food and Drug Administration
FSIS	Federalism summary impact statement
FR	Federal Register
FTE	Full time equivalent
GDP	Gross Domestic Product
gpd	gallons per day
gpm	gallons per minute
GWR	Ground Water Rule
GWSS	Ground Water Supply Survey
GWUDI	Ground Water Under Direct Influence of Surface Water
HAA	Haloacetic Acid
HAA5	Sum of 5 Haloacetic Acids
HAV	hepatitis A virus
HCUP	Hospital Cost and Utilization Project
HSA	Hydrogeologic Sensitivity Analysis
I	Income
ICR	Information Collection Rule
IESWTR	Interim Enhanced Surface Water Treatment Rule

IDDM	Insulin-dependent diabetes mellitus
IDSE	Initial Distribution System Evaluation
ICD	International Class of Diseases
kgal	kilogallons
kgpd	kilogallons per day
kW	kilowatt
kWh	kilowatt hour
kWh/y	kilowatt hour per year
L	liter
LRAA	locational running annual average
LT1ESWTR	Long Term 1 Enhanced Surface Water Treatment Rule
MCL	Maximum Contaminant Level
MCLGs	Maximum Contaminant Level Goal
MF	Microfiltration
mgd	million gallons per day
mg/L	milligrams per liter
μg/L	microgram per liter
MPN	Most probable number
MPNIU	Most probable number of infectious units
MRDL	Maximum residual disinfectant level
MRDLG	Maximum residual disinfectant level goal
NCHS	National Center for Health Statistics
NHLBI	National Health, Lung and Blood Institute
NCWS	Noncommunity Water System
NDWAC	National Drinking Water Advisory Committee
NFID	National Foundation for Infectious Diseases
NRC	National Research Council
NWRI	National Water Research Institute
NF	Nanofiltration
nm	nanometers
NPDES	National Pollutant Discharge Elimination System
NPDWR	National Primary Drinking Water Regulations
NRC	National Research Council
NTNCWS	Nontransient Noncommunity Water System
O&M	Operation and Maintenance
OGWDW	Office of Ground Water and Drinking Water
OMB	Office of Management and Budget
POE	Point-of-Entry
PCR	Polymerase Chain Reaction
POTW	Publicly Owned Treatment Works
POU	Point-of-Use
PPI	Producer Price Index
ppm	parts per million
PWS	Public Water System
PWSS	Public Water Systems Supervision
PV	Present Value
RAA	Running Annual Average
RFA	Regulatory Flexibility Act
RNA	Ribonucleic acid

RO	Reverse Osmosis
RTI	Research Triangle Institute
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RUS	Rural Utility Service
SAB	Science Advisory Board
SBA	Small Business Administration
SBAR	Small Business Advocacy Review
SBREFA	Small Business Regulatory Enforcement Fairness Act
SDWA	Safe Drinking Water Act
SDWIS	Safe Drinking Water Information System
SER	Small entity representative
SIC	Standard Industrial Classification
SOC	Standard Occupational Classification
SRSV	Small round, structured viruses
SRMD	Standards and Risk Management Division
SWAPP	Source Water Assessment and Protection Program
SWTR	Surface Water Treatment Rule
T&C	Technology and Cost
TC	Total Coliform
TCR	Total Coliform Rule
TMF	Technical, managerial, and financial
THM	Trihalomethane
TNCWS	Transient Noncommunity Water System
TTHM	Total Trihalomethanes
UIC	Underground Injection Control
UF	Ultrafiltration
UMRA	Unfunded Mandates Reform Act
USDA	United States Department of Agriculture
UV	Ultraviolet
VSL	Value of a Statistical Life
WTP	Willingness to Pay

Health Risk Reduction and Cost Analysis

Under the Safe Drinking Water Act (SDWA) Amendments of 1996, when proposing a national primary drinking water regulation that includes an maximum contaminant level (MCL), the U.S. Environmental Protection Agency (EPA or the Agency) must conduct a health risk reduction and cost analysis (HRRCA). A HRRCA addresses seven requirements, all of which are addressed in this Economic Analysis (EA) for the Ground Water Rule (GWR).

HRRCA Crosswalk Summary

HRRCA Requirement	Addressed in Economic Analysis
Quantifiable and nonquantifiable health risk reduction benefits	Chapter 5 (All sections and exhibits) Chapter 7 (Section 7.7.1; Exhibit 7.4) Chapter 8 (Sections 8.1; Exhibits 8.1–8.3, 8.5)
Quantifiable and nonquantifiable health risk reduction benefits from co-occurring contaminants	Chapter 5 (Section 5.4)
Quantifiable and nonquantifiable costs	Chapter 6 (All sections and exhibits) Chapter 7 (Sections 7.2–7.8; Exhibits 7.1–7.7) Chapter 8 (Sections 8.1, 8.3; Exhibit 8.4, 8.6)
Incremental costs and benefits associated with regulatory alternatives	Chapter 5 (Section 5.7; Exhibit 5.31) Chapter 6 (Sections 6.9; Exhibit 6.35) Chapter 8 (Section 8.4; Exhibits 8.7 - 8.13)
Effects of the contaminants on the general population and sensitive subpopulations	Chapter 5 (Sections 5.2.2.2, 5.2.5.3, and 5.3.3) Chapter 7 (Section 7.9)
Increased health risk that may occur as a result of compliance	Chapter 5 (Section 5.2.5.9)
Other relevant factors (quality and uncertainty of information)	Chapter 4 (Section 4.6; Exhibit 4.32) Chapter 5 (Section 5.6; Exhibit 5.28) Chapter 6 (Sections 6.2 - 6.4, Section 6.7; Exhibit 6.32) Chapter 8 (Section 8.2)

Executive Summary

This Economic Analysis (EA) presents the evaluation of the benefits and costs of the Ground Water Rule (GWR). The analysis is performed in compliance with Executive Order 12866, *Regulatory Planning and Review* (58 FR 51735, September 1993), which requires the United States Environmental Protection Agency (EPA or Agency) to estimate the economic impact of rules that have an annual effect on the economy of over $100 million and make that analysis available to the public in conjunction with publication of the final rule. Although EPA's analysis of the GWR has determined that its annual costs are most likely below this threshold, EPA has chosen to publish a complete EA for this rule. Earlier, EPA had prepared an EA (formerly known as the Regulatory Impact Analysis) to accompany the May 2000 proposed GWR.

EPA developed the GWR in collaboration with States and other interested stakeholders. The primary goal of the GWR is to improve public health by identifying public ground water systems (GWSs) that are susceptible to fecal contamination and to ensure that they take adequate measures to remove or inactivate pathogens in drinking water they provide to the public.

ES.1 Need for the Rule

An estimated 147,330 public water systems (PWSs) in the United States, serving over 114 million people, use ground water as their primary water source. EPA is concerned about any potential adverse health risks that may be associated with ground water sources and, in particular, the risks associated with fecal contamination. Fecal contamination includes all of the bacteria and viruses—both pathogenic (disease-causing) and non-pathogenic—found in feces. Under certain circumstances, these microorganisms can make their way into ground water sources. Unlike for surface water sources, no federal regulations currently require filtration or disinfection of ground water sources to remove microbial contaminants. Currently for GWSs, there are only requirements for distribution system monitoring of total coliforms, periodic sanitary surveys of small GWSs, and a maximum contaminant level (MCL) for total coliforms.

The GWR will address the human risks of illness and death due to fecal contamination of ground water and improve upon the protection provided by existing sanitary survey requirements for GWSs. The reduction in risk will be accomplished through implementation of the GWR's risk-targeted approach. Because of the difficulties involved in monitoring for the wide range of specific pathogenic bacteria and viruses that could occur in ground water, one of the key provisions of the risk-targeted approach is monitoring for a more easily measured bacterial or viral fecal indicator microorganism. Based on source water sampling results, as well as sanitary survey results, PWSs will be required to take action to minimize the possible presence of pathogenic bacteria and viruses that pose threats to human health.

ES.2 Consideration of Regulatory Alternatives

EPA considered several regulatory alternatives when the GWR was proposed on May 10, 2000 (65 FR 30194). The proposed GWR and accompanying EA evaluated four regulatory alternatives, the multi-barrier approach (Alternative 3) was the preferred alternative.

After the proposal, EPA considered comments and revised the occurrence analysis underlying the cost-benefit analysis for the rule (as discussed in Chapter 4 of this EA) and made modifications to Alternatives 2 and 3. This resulted in the choice of a different rule alternative, Alternative 2, termed the risk-targeted approach, for the final GWR. .[1] The four alternatives considered for the final GWR and analyzed in this EA are as follows:

Alternative 1 - Sanitary surveys and corrective action.

Alternative 2 - Risk-targeted approach: sanitary surveys, triggered monitoring, optional assessment monitoring, corrective action, and compliance monitoring.

Alternative 3 - Multi-barrier approach: sanitary surveys, triggered monitoring, optional hydrogeologic sensitivity assessment (HSA), assessment monitoring (a derivation of the proposed routine monitoring), corrective action, and compliance monitoring.

Alternative 4 - Across-the-board disinfection.

As shown in Chapter 8, the risk-targeted approach is cost-effective (using either the Enhanced or the Traditional cost-of-illness approach) and, considering the nonquantified benefits, the benefits justify the costs. The final rule provides public health benefits while apportioning costs in a more flexible targeted manner.

ES.3 Summary of the Final GWR Requirements

The GWR applies to all community and noncommunity PWSs that use ground water as a water source. The final GWR targets GWSs that are susceptible to fecal contamination. A flowchart that illustrates the compliance steps for systems is illustrated in Exhibit ES.1. The components of the risk-targeted strategy are used to identify source contamination and significant deficiencies that may lead to source contamination. Each component is described below. Exhibit ES.2 presents the schedule for these activities.

Sanitary Surveys

The final GWR requires regular (every three years for CWSs and every five years for NCWSs) comprehensive sanitary surveys of 8 critical components: (1) source; (2) treatment; (3) distribution system; (4) finished water storage; (5) pumps, pump facilities, and controls; (6) monitoring and reporting, and data verification; (7) system management and operation; and (8) operator compliance with State requirements. The State may reduce the frequency of sanitary surveys for CWSs to at least once every five years if the water system has an outstanding performance record as determined by the State (e.g., no significant deficiencies documented in previous assessments and no history of total coliform MCL or

[1] Modifications to Alternatives 2 and 3 since proposal are described in further detail in Chapter 3.

monitoring violations under the TCR or the system maintains 4-log treatment of viruses using inactivation, removal, or State-approved combination of virus inactivation and removal). If a significant deficiency is identified, corrective action is required or a treatment technique violation is incurred.

Source Water Monitoring

In the final GWR, systems not achieving 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of these technologies) must conduct triggered source water monitoring for the presence of at least one of the following State-specified fecal indicators: *E. coli*, enterococci, or somatic coliphage. The triggered monitoring requirements apply to systems that are notified that a Total Coliform Rule (TCR) routine sample is total coliform-positive. Within 24 hours of receiving the total coliform-positive notice, GWSs must collect a source water sample and test it for the presence of the State-specified fecal indicator.

If the State does not require corrective action (see Corrective Action section below) for the initial fecal indicator-positive source water sample immediately, the system must collect five additional source water samples within 24 hours of being notified of the initial fecal indicator-positive source water sample.

The GWR provides States with the option to require systems to conduct assessment source water monitoring as needed and require systems to take corrective action. The purpose of this optional assessment source water monitoring requirement is to target source water monitoring to systems that the State determines are at higher risk for fecal contamination.

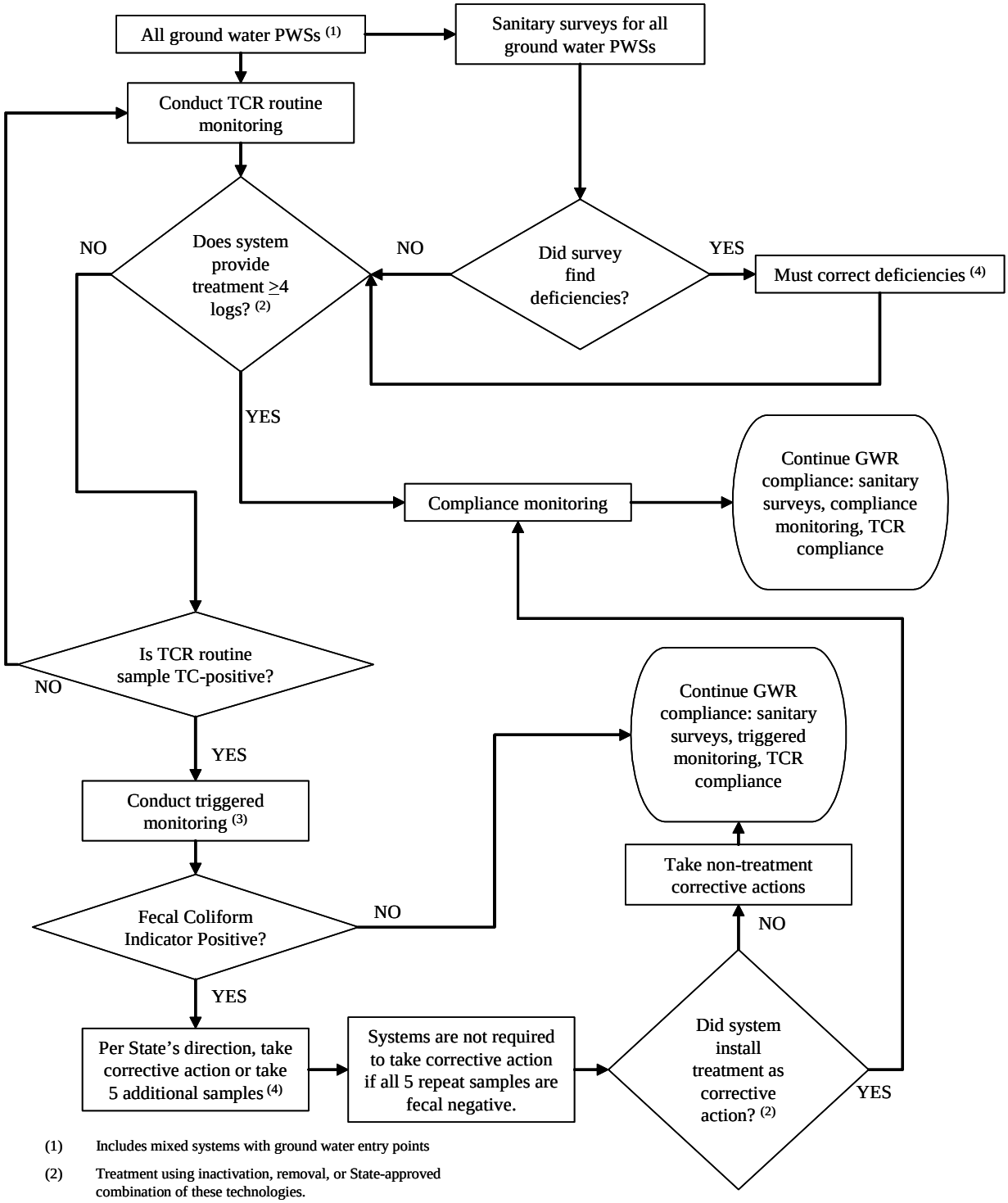
Corrective Action

The GWR requires a system with a significant deficiency or source water fecal contamination to fix the problem by implementing a corrective action. The system must implement at least one of the following corrective actions: correct all significant deficiencies; provide an alternate source of water; eliminate the source of contamination; or provide treatment that reliably achieves at least 4-log treatment of viruses. Furthermore, the system is required to notify the public served by the water system of any uncorrected significant deficiencies and/or source water contamination. (The State may also require notification of corrected significant deficiencies).

Compliance Monitoring

Compliance monitoring requirements are the final defense against microbial contaminants provided by the final GWR. All GWSs that provide at least 4-log treatment of viruses using chemical disinfection, membrane filtration, or a State-approved alternative treatment technology must conduct compliance monitoring to demonstrate continual treatment effectiveness.

Exhibit ES.1 Flowchart of Compliance with GWR Requirements for Systems



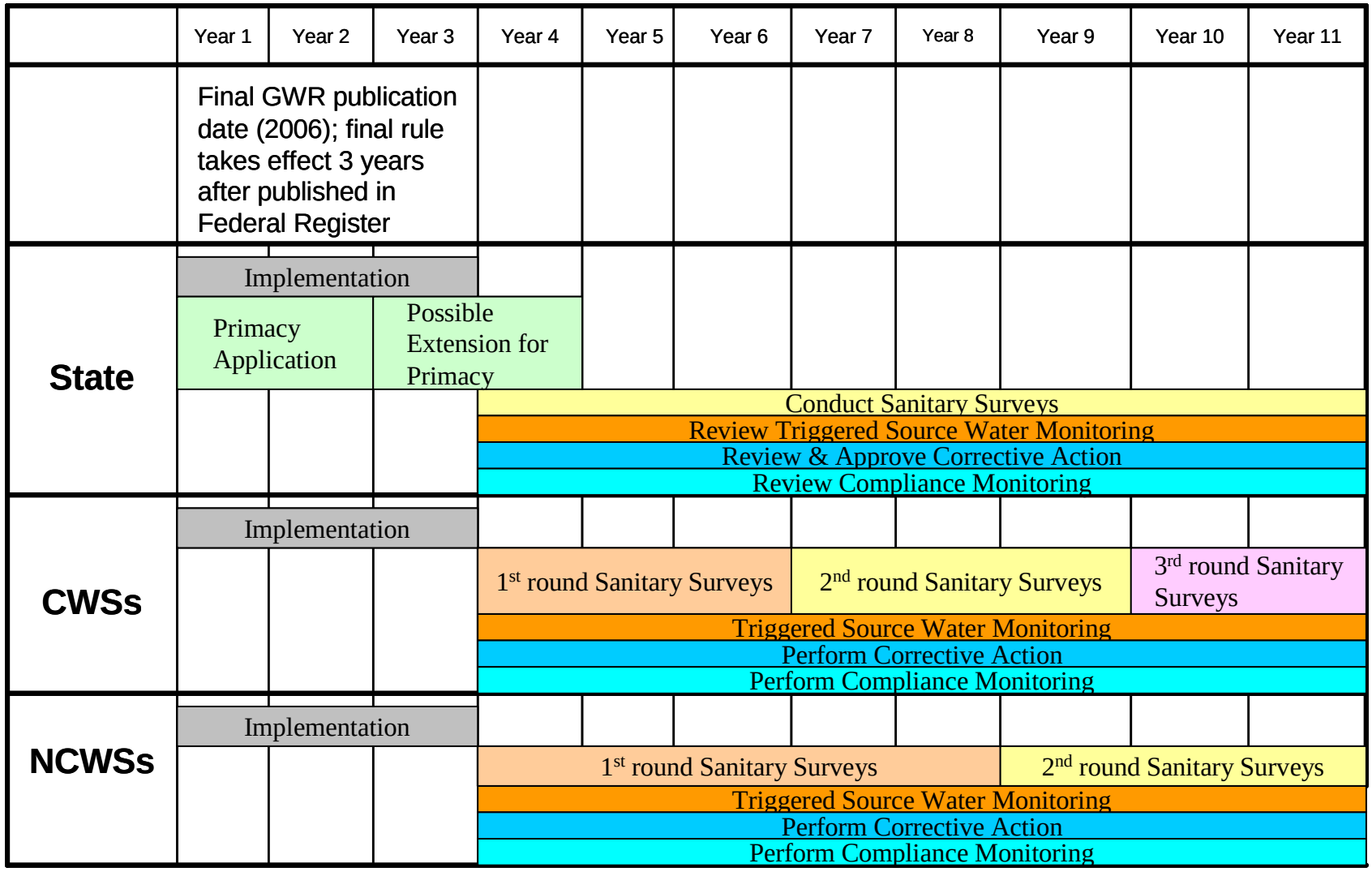
(1) Includes mixed systems with ground water entry points

(2) Treatment using inactivation, removal, or State-approved combination of these technologies.

(3) For those systems that do not receive a triggered monitoring waiver from the State

(4) The State may determine that the source of contamination has been eliminated..

Exhibit ES.2 Implementation Timeline for the GWR



ES.4 Systems Subject to the GWR

Exhibit ES.3 shows the baseline number of systems and entry points subject to the rule and the estimated number that will perform or undergo various rule activities (implementation, sanitary surveys, triggered monitoring, corrective actions, and compliance monitoring). This baseline is derived from EPA's Safe Drinking Water Information System (SDWIS) inventory, 4th quarter 2003 data.[2] The systems are subdivided by type [community water systems (CWS), nontransient noncommunity water systems (NTNCWS), and transient noncommunity water systems (TNCWS)], and size (nine size categories).

All GWSs will undergo sanitary surveys (column A). EPA estimates that all GWSs will also have to perform implementation activities (reading and understanding the rule, training, etc.) which is also represented by column A. Column B presents the number of systems estimated to find and be required to correct a significant deficiency based on conducting a sanitary survey. The remaining activities are evaluated at the entry point into the distribution system. Column C indicates that all entry points that do not achieve 4-log treatment of viruses will perform triggered source water monitoring for the GWR. Corrective actions predicted as a result of triggered monitoring are presented in column D, with estimates (cumulative) of the different levels of disinfection (i.e., increased disinfection or installation of new disinfection) resulting from those corrective actions presented in columns E and F. Finally, column G shows the number of entry points incurring costs for additional compliance monitoring to ensure the effectiveness and reliability of treatment.[3]

[2] SDWIS-Federal Version (SDWIS/FED) is a database created by EPA containing data submitted by States and regions regarding compliance with SDWA.

[3] The column G figures pertain only to entry points with newly installed treatment to achieve 4-log viral inactivation or removal. The number of entry points performing non-treatment corrective actions can be calculated by subtracting Column G figures from those presented in column F.

Exhibit ES.3 Summary of Rule Implications

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

Sources: Exhibit 6.5b

Notes:

(G) indicates number of entry points with treatment corrective actions.

(F) - (G) indicates non treatment corrective actions.

ES.5 National Benefits and Costs of the GWR

EPA has determined from its analysis of the available human exposure and epidemiological studies that the GWR will result in benefits in terms of reduced incidence of illnesses and deaths associated with fecal contamination of ground water. There are substantial benefits attributable to the GWR that are not quantified within this EA as part of the main analyses because of data limitations. Beneficial aspects of the rule not quantified are characterized as either health benefits or non-health benefits. Nonquantified health-related benefits include reducing other acute viral illness (other than those caused by rotavirus and enterovirus), endemic acute bacterial illnesses and deaths, epidemic bacterial and viral acute illness and death (associated with outbreaks, disinfection failures, and distribution system contamination). Chronic illnesses, both bacterial and viral, are also not quantified. The rule will also result in many non-health benefits such as reduced costs for responding to outbreaks, costs for averting behavior, and reduced uncertainly regarding drinking water safety. Chapter 5, Section 5.4.3.2 presents a discussion of nonquantified benefits and estimates a portion of their value, based only on bacterial illnesses avoided, at four times the primary analysis benefits (resulting in total benefits that are five times the primary benefits). This includes consideration of the value of deaths and hospitalization costs avoided for waterborne cases of bacterial illness prevented by the rule. This does not include indirect (non-medical) costs associated with waterborne bacterial illness or the value of avoiding other chronic or viral illnesses.

Sections ES.5.1 and ES.5.2 summarize the methods used to derive the benefits and costs of the rule. These sections describe the analyses of the total number of illnesses and deaths avoided, the monetized benefits resulting from those cases and deaths avoided, a summary of nonquantified benefits, and the total national costs (both one-time and annualized) for the GWR. The cases and monetized benefits are based on reductions in microbial contamination that result from corrective actions. EPA's national cost estimate includes rule implementation, sanitary surveys, triggered monitoring, corrective actions (which account for more than half of the national costs), and compliance monitoring. Note that two estimates for national costs and monetized benefits are presented depending upon the discount rate used for present value calculations and annualizing costs.[4] Benefits are also further divided into two additional estimates based on different methodologies for estimating cost of illness (COI) attributed to illnesses avoided. Chapters 4 through 6 and the appendices provide a more complete discussion of all the analyses discussed in the sections below.

The GWR EA does not include estimates of costs and benefits of assessment source water monitoring because it is an optional requirement. EPA does not know the extent to which States will use the option or the manner in which they will implement it. This provision could potentially increase both benefits and costs.

[4] There is much discussion among economists of the proper social discount rate to use for policy analysis. For GWR cost analyses, calculations are made using two social discount rates (3 and 7 percent) thought to best represent current policy evaluation methodologies. Historically, the use of 3 percent is based on rates of return on relatively risk-free investments, as described in the *Guidelines for Preparing Economic Analyses* (USEPA, 2000j). The rate of 7 percent is a recommendation of the Office of Management and Budget (OMB) as an estimate of "before-tax rate of return to incremental private investment" (USEPA, 1996b).

ES.5.1 Derivation of Benefits

The GWR is expected to reduce the current incidence of acute and chronic illness caused by a wide variety of viral and bacterial pathogens that are associated with fecal contamination of ground water. Determining the economic value of the health benefits involves a sequential two-step process. First, a risk assessment is prepared to quantify a health endpoint. Following this is the valuation of benefits. Chapter 5 of this EA presents a complete discussion of these steps. Additional benefits accrue but are not quantified.

EPA developed a risk assessment model to quantify a subset of the total number of predicted illnesses and deaths avoided. Medical research has not isolated all waterborne pathogens, nor has it thoroughly characterized the ability of these organisms to infect humans and cause illness and death. Risk from bacterial pathogens was not characterized in the risk model because occurrence data for bacterial pathogens in drinking water are limited (however, the discussion of nonquantified benefits assesses the potential impact). For the risk assessment, EPA has selected two well-characterized viral pathogens having different infectivity, morbidity, and mortality rates to represent a wide range of waterborne viral pathogens to estimate the number of acute illnesses and deaths avoided by implementing the GWR. The selected representative viruses are rotavirus and enteric viruses represented by echovirus data.

Rotavirus is a highly infectious virus, but generally does not result in life-threatening illness. It is similar to a large group of viruses that cause widespread, but usually not very serious, cases of gastroenteritis. This large group includes noroviruses (i.e., Norwalk-like viruses), sapoviruses, adenovirus, astrovirus and others. Echovirus is an enterovirus that is not highly infectious, but can cause severe health effects if illness occurs (e.g., encephalitis or myocarditis). This economic analysis identifies these two representative types as Type A and Type B viruses, respectively. EPA used these two viruses to represent the range of possible acute illness risk that could result from all viruses.

The Agency, having identified representative viruses for modeling purposes, used probability of virus occurrence in wells and samples along with estimated concentrations of enteric viruses to estimate the population's exposure to Type A and Type B viruses. Combining these occurrence and concentration data with daily drinking water intake data from the *1994–1996 USDA, Continuing Survey of Food Intakes by Individuals* (USEPA, 2000) yields estimates of risk of pathogen exposure. EPA combines these data with viral dose-response functions and health effects data to estimate infections, morbidity, and mortality to derive the baseline number of viral illnesses and deaths.

The baseline viral illnesses (185,186) and deaths (3.2) reflect conditions prior to the implementation of the GWR. To determine the number of viral illnesses and deaths avoided by the final GWR, EPA estimates the percentage reduction in viral occurrence as a result of systems implementing changes to meet all rule requirements. The estimated numbers of avoided viral illnesses and deaths are shown in Exhibit ES.4, and include the confidence bounds, reflecting uncertainty in those estimates.

Exhibit ES.4 Summary of Annual Avoided Viral Illnesses and Deaths by System Type

	Annual Illnesses Avoided			Annual Deaths Avoided		
		90% Confidence Bounds			90%Confidence Bounds	
	Mean	5th	95th	Mean	5th	95th
CWSs	32,031	8,704	68,994	0.62	0.07	1.81
NTNCWSs	2,094	533	4,308	0.03	0.00	0.09
TNCWSs	7,743	1,037	14,738	0.09	0.01	0.21
Total	41,868	10,274	88,039	0.74	0.08	2.11

Note: Detail may not add due to independent forecasting. Values presented are average annual illnesses and deaths avoided over the 25 year period of analysis following rule promulgation.

Source: Exhibit 8.1

The final step in the benefit calculation is to monetize the estimated reduction in cases by applying economic values for avoided viral illness and deaths. The value of avoiding cases of viral illness is based on estimates of the direct and indirect costs of becoming ill. Due to lack of adequate data on the willingness-to-pay (WTP) to avoid becoming ill, EPA uses a COI estimate. EPA has chosen to present two different estimates of COI, referred to in this EA as Enhanced and Traditional. Both approaches include the value of the direct medical costs and of lost work time, but differ in the assessment of value of lost nonmarket work time. The Enhanced COI values nonmarket work time based on opportunity costs. The other approach, the Traditional COI, includes nonmarket (unpaid) work time based on replacement costs. In addition, the Enhanced COI also includes the value of lost leisure time and lost productivity—the reduced utility (or sense of well-being) associated with decreased enjoyment of time spent in both market and nonmarket activities. For deaths due to viral infection, the Value of a Statistical Life (VSL) is used to capture the value of benefits. The VSL represents an estimate of the monetary value of reducing risks of premature death. The VSL, therefore, is not an estimate of the value of saving a particular individual's life. Rather, the value of a "statistical" life represents the sum of the values placed on small individual risk reductions across an exposed population. Other economic factors are taken into consideration when calculating benefits over time, such as income growth, income elasticity of demand, and social discount rates.

EPA estimates the quantified benefits of avoided illnesses and deaths from the GWR to be $8.6 million to $19.7 million depending on the discount rate and COI value used. These figures are presented by system type in Exhibit ES.5.

Exhibit ES.5 Summary of Annualized Present Value Quantified Benefits ($Millions, 2003$)

System Type	Annualized Benefits at 3% Discount Rate			Annualized Benefits at 7% Discount Rate		
	Mean	90% Confidence Bounds		Mean	90%Confidence Bounds	
		5th	95th		5th	95th
Enhanced COI						
CWSs	$ 16.0	$ 5.4	$ 37.0	$ 13.7	$ 4.6	$ 31.6
NTNCWSs	$ 0.9	$ 0.3	$ 2.2	$ 0.8	$ 0.2	$ 1.8
TNCWSs	$ 2.7	$ 0.8	$ 6.2	$ 2.3	$ 0.7	$ 5.1
Total	$ 19.7	$ 6.5	$ 45.4	$ 16.8	$ 5.5	$ 38.6
Traditional COI						
CWSs	$ 8.2	$ 1.9	$ 22.3	$ 7.1	$ 1.6	$ 19.1
NTNCWSs	$ 0.5	$ 0.1	$ 1.3	$ 0.4	$ 0.1	$ 1.0
TNCWSs	$ 1.3	$ 0.3	$ 3.4	$ 1.1	$ 0.2	$ 2.8
Total	$ 10.0	$ 2.2	$ 27.0	$ 8.6	$ 1.9	$ 22.9

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

The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to comprise a significant portion of the overall benefits of the Rule and are presented in Section 5.4 of Ch. 5 of the EA.

Source: Exhibit 5.23a, 5.23b

As mentioned above, there are substantial benefits attributable to the GWR that are not quantified within this EA as part of the main analyses. These nonquantified benefits are shown in relation to quantified benefits as part of the total benefits of the GWR in Exhibit ES.6. The nonquantified benefits result from multiple factors. First, the quantified benefits are based on limited, well-defined data and key assumptions that restrict the input parameters in the quantified benefit calculation. Typically, these assumptions resulted in low mean values and narrow uncertainty ranges in the benefit analysis. This EA, where applicable, discusses alternative assumptions. For example, the enterovirus morbidity fractions are, by assumption, not determined using coxsackievirus (an enterovirus) data although the enterovirus severity data use all enterovirus data. If coxsackievirus data were available, the mean morbidity values would be greater. Choosing alternative values and ranges and differing key assumptions, which might also be deemed reasonable, would increase the quantified benefits in this EA.

Second, the quantified benefits are based on data and assumptions that pertain to only partial representation of Type A and Type B viruses potentially found in PWS wells with fecal contamination. Due to limited available data, only rotavirus and some enterovirus data were used to calculate the quantified benefits. As is more completely discussed in Section 5.4. other viruses as well as pathogenic bacteria may contribute to the disease burden, both acute and chronic, associated with PWS wells with fecal contamination. Most importantly, bacterial illnesses can result in more frequent and lengthier hospitalization and more frequently have fatal outcomes. If bacterial diseases were considered in the quantified benefits, the monetized benefits could be substantially greater because bacterial disease can be more severe and can result in higher mortality rates.

Third, the quantified benefits are based on data and assumptions that limit the characterization of acute disease. For rotavirus, only acute gastroenteritis illness and fatal dehydration associated with that illness are monetized. Norovirus disease is not considered. For the enteroviruses, all acute disease endpoints are considered, but the prevalence of severe endemic cases may be substantially diluted by the large number of hand, foot, and mouth disease cases that are not likely to be waterborne. Thus, the proportion of severe cases in the quantitative benefits is likely to be underestimated. As is discussed more completely in Section 5.4, in neither instance, either for rotavirus or the enteroviruses, are chronic diseases identified or monetized in the quantitative benefits calculation.

Fourth, the quantified benefits are based explicitly on what has been directly measured in PWS wells, yet there is great difficulty in identifying and counting all infectious viral pathogens in dilute drinking water samples. Indeed, some viral pathogens like infectious norovirus can never be identified in any sample. Section 4.3.2 discusses these difficulties in more detail. Standard fecal indicator data such as total coliforms and *E. coli*, commonly used to identify water treatment deficiencies and potential human health hazards, are explicitly not used to determine human exposure for the purposes of quantifying the benefits in this EA.

Fifth, the quantified benefits are assumed to be based only on one contamination scenario, fecal contamination of source water. Other contamination scenarios are thoroughly documented in the ground water contamination and outbreak scientific literature. However, these scenarios, such as inadequate disinfection, are not explicitly considered in calculating the quantified benefits in this EA.

Sixth, the quantified benefits are assumed to be based only on avoidance of endemic disease. The GWR will likely also decrease the incidence of epidemic disease (outbreaks). If epidemic illnesses and the avoided non-health-related costs of ground waterborne disease outbreaks were included, the quantified benefits would increase.

In summary, this EA quantifies a subset of the total health and non-health related benefits. In a sample calculation, discussed in Section 5.4.3.2, EPA estimated that the total benefits could increase by a factor of five by only accounting for additional deaths and hospitalizations caused by bacterial illness being avoided. While EPA recognizes that this estimate includes substantial uncertainty, given all the other nonquantified factors described above, EPA believes that the total benefits from the GWR are likely to be more than five times those which have been quantified.

Exhibit ES.6 Summary of Benefits of the GWR

Benefit Category	Total Benefits	GWR EA Quantified Benefits
Health Benefits		
Reduction in endemic illness incidence	• viral exposure risk reduction (morbidity and mortality) • bacterial exposure risk reduction (morbidity and mortality) • chronic sequelae reduction • reduction in secondary transmission of viral or bacterial illness from symptomatic and asymptomatic individuals	• acute rotavirus (Type A) illnesses and deaths avoided • acute enterovirus (Type B) illnesses and deaths avoided • reduction in secondary transmission of viral illness from symptomatic individuals
Reduction in epi-demic (outbreak) illness incidence	• viral exposure risk reduction (morbidity and mortality) • bacterial exposure risk reduction (morbidity and mortality) • chronic sequelae reduction • reduction in secondary transmission of viral or bacterial illness to susceptible populations	Not quantified
Reduction in treatment failures	• Decreased illness through minimizing treatment failures or fewer episodes with inadequate treatment	Not quantified
Non-Health Benefits		
Outbreak responses avoided	• Avoided costs to affected water systems, local governments (provision of alternate water, issuing warnings and alerts), and community (decreased tourism due to bad press).	Not quantified
Avoided costs of averting behavior	• reduced need or perceived need to use bottled water, point-of-use devices, etc. (includes time and material costs) • less time spent on averting behavior: hauling/boiling water, etc.	Not quantified
Increased confidence	• Perceived reduction in risk associated with perceived improvement in drinking water quality	Not quantified

ES.5.2 Derivation of Costs

To estimate the total national costs of the GWR, EPA calculated the costs to be incurred by PWSs and States for the rule activities. Cost analyses for PWSs include estimating the costs to implement the rule, assist with sanitary surveys, perform triggered source water monitoring, undergo corrective actions, and perform compliance monitoring. State cost analyses include estimates of the labor burdens that States would face for implementation and other annual administrative tasks (e.g., recordkeeping), conducting sanitary surveys, responding to PWS reports for source water and compliance monitoring, and reviewing corrective action plans. The methodology for estimating corrective action and noncorrective action-related costs for systems is discussed in the next several paragraphs, followed by a discussion of uncertainties. A complete discussion of the cost analysis is provided in Chapter 6.

Noncorrective action costs for implementation, sanitary surveys, triggered monitoring, and compliance monitoring are based on estimates of labor hours for performing these activities and on additional laboratory costs. Some systems also incur capital costs for compliance monitoring. For all noncorrective action cost calculations, EPA used the appropriate baseline (for systems or entry points) shown in Exhibit ES.3.

Corrective action costs are based on unit cost estimates for a number of treatment technologies. Technology unit cost estimates are in the form of "dollars per entry point" for initial capital and yearly operations and maintenance (O&M) activities. Derivation of unit costs for a wide range of plant sizes, represented by different design and average daily flow rates, is described in detail in the document, *Technology and Cost Document for the Final Ground Water Rule* (USEPA, 2006b). EPA uses mean population per system for each of the nine system size categories (derived from SDWIS) combined with regression equations and entry point per system estimates to estimate mean design and average daily flows per entry point. Technology unit costs per entry point are calculated using these mean flow values for each of the nine system size categories. The technology unit costs are then combined with the predicted number of entry points assumed to select each technology to produce national treatment cost estimates.

EPA recognizes that systems vary with respect to many of the input parameters to the GWR Cost Model (e.g., entry points per system, population served, flow per population, and labor rates). In many cases, there is insufficient information to characterize fully the variability on a national scale. EPA believes that the mean values for the various input parameters are adequate to generate EPA's best estimate of national costs for the rule while still recognizing that impacts on specific systems may differ substantially from these averages.

EPA also recognizes that there is uncertainty in the national cost estimates related to the national average unit capital and O&M costs for the various technologies expected to be implemented in response to the GWR. This uncertainty has been incorporated into the cost model using a Monte Carlo simulation. The national costs of the GWR summarized below in Exhibits ES.7 and ES.8 show both the expected values and the 90 percent confidence bounds on the national cost estimates obtained from the cost model reflecting this uncertainty. Further discussion of uncertainty analysis is presented in Section 6.7.

Although EPA has quantified the significant costs of the GWR, there are some costs that the Agency did not quantify. Overall, EPA believes that these nonquantified costs are much smaller than the nonquantified benefits. These nonquantified costs result from uncertainties surrounding rule assumptions and from modeling assumptions. Detailed discussion of nonquantified costs is presented in Section 6.6.

Exhibit ES.7 Total Initial Capital and One-Time Costs ($Millions, 2003$)

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

Notes: Detail may not add to totals due to independent rounding.
Source: Exhibit 6.30

Exhibit ES.8 Total Annualized Present Value Costs of the GWR ($Millions, 2003$)

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

Notes: Detail may not add to totals due to independent rounding.
Source: Exhibit 6.33

ES.6 Projected Impacts on Household Costs

The household cost analysis assumes that systems may pass some or all costs of a new regulation on to their consumers in the form of rate increases. Exhibit ES.9 presents estimated annual household cost increases. Only CWSs are included in this analysis because they are the only systems that serve households directly. The top half of the exhibit shows summary statistics for all households affected by the rule, including households that will incur minimal costs (e.g., those served by systems incurring only implementation costs). The bottom half shows statistics only for households served by entry points adding treatment technologies to comply with the rule (see Exhibit ES.3 for estimates of entry points subject to corrective actions). Because treatment changes represent the majority of rule costs, this provides insight into how the rule will affect the segment of the population most impacted by the rule.

As shown in Exhibit ES.9, mean annual household costs based on all GWSs (including those that do not add treatment) range from $0.21 to $16.54, depending on system size. Mean household costs reflecting the subset of GWSs that undertake corrective actions range from $0.45 to $52.38, depending on system size. EPA estimates that, as a whole, households subject to the GWR face minimal increases in their annual costs. Approximately 66 percent of the households potentially subject to the rule are served by systems serving at least 10,000 people; these systems experience the lowest increases in costs due to

significant economies of scale. Households served by small systems that undertake corrective actions will face the greatest increases in annual costs.

Exhibit ES.9 Summary of Annual Per-Household Costs for the GWR (2003$Year)

Systems Size (Population Served)	Households	Mean	Median	90th Percentile
All Community Water Systems (CWSs)				
<100	289,222	$ 16.54	$ 2.81	$ 9.31
101-500	1,303,890	$ 3.51	$ 0.64	$ 6.11
501-1,000	1,278,081	$ 0.97	$ 0.16	$ 1.70
1,001-3,300	4,196,105	$ 0.37	$ 0.04	$ 0.61
3,301-10K	6,271,380	$ 0.27	$ 0.03	$ 0.43
10,001-50K	11,468,813	$ 0.21	$ 0.04	$ 0.49
50,001-100K	4,204,584	$ 0.34	$ 0.10	$ 1.02
>100,000	9,755,817	$ 0.21	$ 0.04	$ 0.62
Total	38,767,890	$ 0.51	$ 0.09	$ 0.88
Corrective Action Community Water Systems (CWSs)				
<100	70,563	$ 52.38	$ 18.99	$ 82.21
101-500	312,484	$ 12.00	$ 4.52	$ 25.76
501-1,000	302,557	$ 3.23	$ 1.33	$ 6.56
1,001-3,300	919,133	$ 1.33	$ 0.47	$ 2.59
3,301-10K	1,487,159	$ 0.80	$ 0.25	$ 2.18
10,001-50K	2,871,250	$ 0.45	$ 0.18	$ 1.18
50,001-100K	1,215,544	$ 0.53	$ 0.26	$ 1.36
>100,000	2,283,144	$ 0.68	$ 0.39	$ 1.65
Total	9,461,833	$ 1.51	$ 0.60	$ 3.20

Source: GWR model output.

ES.7 Comparison of Benefits and Costs, and of Regulatory Alternatives of the GWR

Exhibit ES.10 compares estimated quantified benefits with estimated costs. Based on the comparison of these values, the estimated quantified benefits of the rule range from approximately 14% to 32% of the costs, depending on the discount rate and COI approach. The estimated quantified benefits for the Enhanced COI approach are greater than the corresponding estimated benefits for the Traditional COI approach. The quantified estimate of the benefits significantly understates the true benefit of the rule. As discussed in Section ES.5.1 and Exhibit ES.6, the nonquantified health and non-health benefits far exceed those that EPA was able to quantify.

Exhibit ES.10 Estimated Annualized National Benefits and Costs for the GWR ($Millions, 2003$)

System Type	3% Discount Rate			7% Discount Rate		
	Mean	90% Confidence Bounds		Mean	90%Confidence Bounds	
		5th	95th		5th	95th
Enhanced COI						
Benefits	$ 19.7	$ 6.5	$ 45.4	$ 16.8	$ 5.5	$ 38.6
Costs	$ 61.8	$ 45.2	$ 81.4	$ 62.3	$ 46.1	$ 81.6
Net Benefits	$ (42.1)	Note 1	Note 1	$ (45.5)	Note 1	Note 1
Traditional COI						
Benefits	$ 10.0	$ 2.2	$ 27.0	$ 8.6	$ 1.9	$ 22.9
Costs	$ 61.8	$ 45.2	$ 81.4	$ 62.3	$ 46.1	$ 81.6
Net Benefits	$ (51.8)	Note 1	Note 1	$ (53.7)	Note 1	Note 1
Nonquantified Benefits	Decreased incidence of other acute viral disease endpoints Decreased incidence of bacterial illness and death Decreased incidence of chronic bacterial and viral illness sequelae Decreased incidence of waterborne disease outbreaks and epidemic illness Decreased illness through minimizing treatment failures or fewer episodes with inadequate treatment Decreased use of bottle water and point-of-use devices (material costs) Decreased time spent on averting behavior Avoided costs associated with outbreak response Perceived improvement in drinking water quality and reduction in risk associated with ingestion Benefits from optional Assessment Monitoring Benefits from correction of sanitary survey deficiencies identified in the distribution systems and treatment plant					
Nonquantified Costs	Costs for optional Assessment Monitoring Costs from correction of sanitary survey deficiencies identified in the distribution systems and treatment plant Costs for compliance monitoring for some systems that already disinfect Some land costs depending on the treatment technology Cost for five repeat samples but this is small compared to the overestimate of cost for the initial fecal-indicator sample that systems would take.					

Note 1: Because benefits and costs are calculated using different model modules, bounds are not calculated on net benefits.
Notes: Detail may not add due to independent rounding. The Traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The Enhanced COI also factors in valuations for lost personal time (non-work time) such as childcare and homemaking (to the extent not covered by the Traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway.
Source: Exhibit 8.5a

The Agency also performed a number of other analyses related to the final rule. This process included an analysis of net benefits, as well as cost effectiveness and efficiency analyses. In addition, the Agency performed a number of comparisons among the four regulatory alternatives that are described in more detail in Chapter 8. The following is a summary of these analyses.

The GWR likely passes economic threshold criteria:

- The GWR has positive net benefits when both quantified and nonquantified benefits are considered. For the Enhanced COI approach, the quantified benefits alone are approximately 27 to 32 percent of the costs of the GWR depending on the discount rate. For the Traditional COI approach, the quantified benefits are approximately 14 to 16 percent of the costs of the GWR. Considering that nonquantified benefits are expected to be significantly larger than the quantified benefits, it appears likely that the final GWR would have positive net benefits regardless of the discount rate or cost of illness approach used. Section 5.4.3.2 presents a discussion of nonquantified benefits and estimates a portion of their value, based only on bacterial illnesses avoided, at four times the primary analysis benefits (resulting in total benefits that are five times the primary benefits). This includes consideration of the value of deaths and hospitalization costs avoided for ground water borne cases of bacterial illness prevented by the rule. Including only these estimated bacterial illness and death benefits, the total net benefits of the GWR would be positive using the Enhanced COI approach. Total net benefits would still be slightly negative using the Traditional COI approach, however, other nonquantified benefits such as indirect (non-medical) costs associated with waterborne bacterial illness or the value of avoiding other chronic (either bacterial or viral) or other viral illnesses (not accounted for in this analysis) would most likely make this value positive.

- The number of illnesses that must be avoided to break even with costs is well above the estimated number of viral cases avoided, but is most likely within the bounds of cases avoided once nonquantified cases (both bacterial and viral) are considered. The number of deaths that must be avoided to break even, while outside the bounds of the quantitative analysis, is small in absolute terms. Consideration of all nonquantified benefits is predicted to result in favorable break even results.

- The GWR is cost-effective (using either the Enhanced or the Traditional COI approach): no other alternative achieves greater benefits at the same cost or the same benefits at lower cost.

Final GWR determinations:

- The economic analysis for this rule, considering quantified and nonquantified benefits, supports the basis for selecting the final GWR over other alternatives. However, the distinction between Alternative 2 and 3 on an economic basis, is not great.

- EPA chose the final GWR because EPA believes it is more flexible, targeted, and cost-effectively protective than Alternative 3. Optional assessment monitoring allows States to most effectively target those systems at greatest risk and minimize unnecessary monitoring. EPA took the following considerations into account in making this judgment:

    1) Under Alternative 3, some States may not be able to conduct HSAs and thereby require systems in nonsensitive aquifers to conduct assessment monitoring unnecessarily. For systems not at risk this additional monitoring would provide no benefit.

    2) Systems with frequent TC positives in the distributions system (and subsequent frequent triggered monitoring) would benefit little from assessment monitoring regardless if they were located in sensitive aquifers or not because the source water would already be thoroughly evaluated. Under Alternative 3, such systems in sensitive (or undetermined) aquifers would be required to do assessment monitoring.

3) Systems identified as having significant risk factors pertaining to potential fecal contamination at their source (e.g., aquifer condition, well characteristics, proximity to sewage or septic), but infrequent triggered monitoring source water samples, would benefit from assessment monitoring. States will be able to identify such systems on an ongoing basis through a variety of tools and information readily available to them.

- The EPA believes that the final rule is a logical outgrowth of the proposed rule, that it is supported by comments, and that it provides public health benefits while apportioning costs in a more flexible targeted manner.

ES.8 Conclusions

Pursuing its mandate to protect public health, EPA has promulgated the GWR to reduce the risk that microbial contamination of ground water poses to consumers of drinking water. Over 114 million people in the United States use ground water as a source of drinking water. It is, however, a largely unprotected source, with considerable risk of fecal contamination. This contamination includes both viral and bacterial pathogens causing illnesses of varying severity. EPA has determined that the final GWR will provide important protection against illnesses and deaths attributable to ground water contamination. EPA also believes that the GWR will provide this desired protection from ground water pathogen contamination at a justifiable cost.

1. Introduction

This Economic Analysis (EA) presents the evaluation of the benefits and costs of the Ground Water Rule (GWR). The analysis is performed in compliance with Executive Order 12866, *Regulatory Planning and Review* (58 FR 51735), which requires the United States Environmental Protection Agency (EPA or Agency) to estimate the economic impact of rules that have an annual effect on the economy of over $100 million and make that analysis available to the public in conjunction with publication of the final rule. Although EPA's analysis of the GWR has determined that its annual costs are most likely below this threshold, EPA has chosen to publish a complete EA for this rule. EPA also prepared an EA (formerly known as the Regulatory Impact Analysis) that accompanied the May 2000 proposed GWR.

EPA developed the GWR in collaboration with States and other interested stakeholders. The primary goal of the GWR is to improve public health by identifying public ground water systems (GWSs) that are susceptible to fecal contamination and to ensure that they take adequate measures to remove or inactivate pathogens in drinking water they provide to the public.

This chapter provides a summary of the GWR in section 1.1. Section 1.2 outlines the organization of this EA, and section 1.3 provides information regarding supporting calculations and citations.

1.1 Summary of the Ground Water Rule

The GWR applies to all community and noncommunity public water systems (PWSs) that serve ground water (referred to as GWSs in this document) as a water source, including mixed systems with any ground water entry points to distribution systems. The GWR does not apply to ground water determined by the State to be under the direct influence of surface water, nor does the rule apply to public water systems that combine all of their ground water with surface water prior to treatment. These systems are already regulated under surface water treatment rules.

The Risk-Targeted Approach of the final GWR targets ground water systems that are susceptible to fecal contamination and requires corrective action. Key components of the strategy are:

1. Sanitary surveys and corrective action,

2. Triggered source water monitoring,

3. Corrective actions, and

4. Compliance monitoring.

In addition to the mandatory rule components listed above, the GWR provides a mechanism for States to adopt an optional assessment source water monitoring provision, hereafter referred to as assessment monitoring. See Chapter 3 (section 3.4.2) of this EA for details.

1.2 Document Organization

The remainder of this EA is organized into the following chapters:

- Chapter 2 summarizes the technical, regulatory, and public health issues addressed by the rule and provides an overview of National Primary Drinking Water Regulations (NPDWRs) relevant to the GWR. It also explains the statutory authority for the GWR and the economic rationale for the regulatory approach.

- Chapter 3 reviews alternative approaches EPA considered during the development of the rule and presents the rationale for selecting the final rule requirements.

- Chapter 4 characterizes conditions that exist (including system inventory, treatment, and water quality data) before systems make changes to meet the GWR requirements.

- Chapter 5 presents a summary of the risk assessment performed to estimate the public health benefits of the GWR. The economic benefits of the rule are also presented. The benefits of other regulatory alternatives considered are compared.

- Chapter 6 presents an estimate of the costs of implementing the rule to industry, households, and States. The costs of other regulatory alternatives considered are compared.

- Chapter 7 discusses distributional analyses performed to evaluate the effects of the rule on different segments of the population, and considers various executive orders and requirements, including the Regulatory Flexibility Act (RFA) and Unfunded Mandates Reform Act (UMRA).

- Chapter 8 compares the rule's benefits and costs to evaluate the potential net benefits and cost-effectiveness of the rule. The results are discussed and compared to other regulatory alternatives considered.

1.3 Calculations and Citations

This EA presents results from detailed and complex analyses. To help the reader track the various calculations and analyses, the following are provided:

- A reference section.

- Appendices.
  - Appendix A provides additional discussion of the derivation of the cost of illness values used in the benefits model.
  - Appendix B presents detailed cost of illness and value of statistical life estimates by illness and year as used in the benefits model.
  - Appendix C presents detailed benefits estimates by illness and system type.
  - Appendix D presents detailed cost estimates by systems size and type.

  - Appendix E discusses the potential implications of using a population dynamic modeling to estimate secondary spread in the benefits model.
  - Appendix F describes analyses conducted to select model forms and estimate model parameters for infectivity dose response relationships.
  - Appendix G provides summary flowcharts for the baseline risk and benefits models.
  - Appendix H presents the detailed cost effectiveness analysis of the rule alternatives using a quality-adjusted life years approach.
  - Appendix I provides detailed analysis of total coliform hit rates in ground water systems.
  - Appendix J discusses changes in the cost and benefits modeling approaches between the proposed and final rules.
  - Appendix K discusses costing detail for regulatory alternatives not presented in the main text.
  - Appendix L provides summary flowcharts for the cost model.

- Exhibits. Most tabular exhibits include a row that provides the formulas used to compute the contents of each column.

- Sources for information used, but not calculated within the exhibits.

- Supporting electronic file outputs (i.e., GWR cost and benefits model outputs).

- Flowcharts that illustrate methodologies of analyses as well as rule requirements.

2. Need for the Rule

2.1 Introduction

The United States Environmental Protection Agency (EPA or Agency) is promulgating the Ground Water Rule (GWR) to address microbial contamination of ground water-supplied drinking water systems in accordance with the Safe Drinking Water Act (SDWA) of 1974, as amended in 1986 and again in 1996. The 1986 SDWA Amendments directed EPA to establish National Primary Drinking Water Regulations (NPDWRs) requiring disinfection for the inactivation of microbiological contaminants for all public water systems (PWSs), including systems supplied by ground water sources. The 1996 Amendments included more specific language regarding ground water disinfection, specifying that the Administrator must publish NPDWRs requiring disinfection as a treatment technique for all ground water PWSs only "as necessary."

This chapter summarizes the technical, regulatory, and public health issues addressed by the rule and provides an overview of other NPDWRs relevant to the GWR. It also explains the statutory authority for promulgating the GWR and the economic rationale for choosing a regulatory approach for implementing the rule.

2.1.1 Description of the Issue

An estimated 147,330 PWSs in the United States, serving over 114 million people, use ground water as their primary water source. EPA is concerned about any potential adverse health risks that may be associated with ground water sources and, in particular, the risks associated with fecal contamination. Fecal contamination includes all of the bacteria and viruses—both pathogenic (disease-causing) and nonpathogenic—found in feces. Under certain circumstances, these can make their way into ground water sources. Unlike surface water sources, no federal regulations currently require filtration or disinfection of ground water sources to remove microbial contaminants. There are, however, existing requirements for distribution system monitoring and periodic inspection of ground water systems (GWSs).

Monitoring for specific pathogenic bacteria and viruses is often difficult. Many methods for monitoring pathogenic bacteria and viruses are not reliable or as sensitive as those for nonpathogenic indicators of fecal contamination. Additionally, since pathogenic bacteria and viruses are shed in low numbers by a few infected individuals and for a limited time, their numbers are low and difficult to detect through periodic sampling compared to detection of nonpathogenic fecal microorganisms. Therefore, because of their widespread presence in fecal material, nonpathogenic fecal organisms are often used as indicators of fecal contamination. These indicators include strains of *Escherichia coli (E. coli)*, coliphage, coliform, and other bacteria. Coliphage are bacteriophages (viruses that infect bacteria) that primarily infect *E. coli.* Coliforms include many bacteria that are free-living in the environment as well as fecal coliform (bacteria more commonly found in human feces). Other bacteria that are used as indicators of fecal contamination include fecal streptococci (enterococci) and *Clostridium perfringens*, a spore-forming anaerobic organism that can persist for long periods of time in the environment.

The basic public health issue the GWR addresses is that people served by ground water sources may face an increased risk of illness due to fecal contamination of those sources. EPA has evaluated data on outbreaks and the occurrence of waterborne pathogens and indicators of fecal contamination in ground water supplying PWS wells. These data indicate that there is a subset of GWSs that are susceptible to

fecal contamination where risk management strategies are needed to protect public health. Specifically, the Centers for Disease Control and Prevention (CDC) reports that between 1991, the year in which the TCR became effective, and 2000, GWSs were associated with 68 outbreaks that caused 10,926 illnesses (Lee et al., 2002). These accounted for 51 percent of all waterborne disease outbreaks in the United States. The major deficiencies identified by the CDC report were source water contamination and inadequate treatment (or treatment failures). Distribution system deficiencies were also important. Studies of pathogen and/or fecal indicator occurrence in ground waters that supply PWSs show that a subset of PWSs utilize contaminated wells. Using cell culture methods, one large national survey of 448 wells in 35 States found five percent of the wells positive for enteroviruses, 15 percent of the wells positive for bacterial indicators, and 20 percent of the wells positive for viral indicators. Using another method designed to detect viral DNA or RNA, this same study found over 30 percent of the wells positive for viruses.

Based on outbreak and occurrence data, inadequate sanitary surveys, difficulties in monitoring directly for pathogenic bacteria and viruses, and uncorrected system deficiencies, EPA has concluded that PWSs need to implement targeted risk management strategies to protect public health. Consequently, EPA is promulgating requirements that provide a flexible, risk-based approach to achieve public health protection. The final GWR builds on existing State programs – some which emphasize the importance of monitoring and treatment and others which emphasize inspections and technical assistance – to identify susceptible GWSs. PWSs will be required to take action to minimize the presence of pathogenic bacteria and viruses, as necessary, based on the results of sampling or sanitary surveys. The GWR establishes treatment technique requirements that allow multiple options to address significant deficiencies and fecal contamination. Furthermore, the final GWR establishes compliance monitoring requirements to ensure that treatment effectiveness is maintained.

2.2 Public Health Concerns to Be Addressed

EPA's primary mission is to protect human health and the environment. The GWR requirements are intended to achieve this mission with regard to fecal contamination of drinking water drawn from ground water sources. This section describes the potential adverse health effects associated with consuming fecally contaminated ground water.

2.2.1 Contaminants and Their Health Effects

Pathogenic enteric viral and bacterial microorganisms are excreted in the feces of infected humans and animals. The word enteric (relating to the intestines or, more specifically, the human gut) indicates that the natural habitat of these microorganisms is the intestinal tract of animals and humans. Enteric microorganisms, sometimes referred to as intestinal microflora, can survive in sewage and leachate derived from septic tanks (septage). When sewage and septage are released into the environment, they are sources of intestinal microflora and potential sources of viral and bacterial pathogens. Once in the environment, fecal matter from infected humans or animals may make its way into ground water sources. If an enteric pathogen is ingested, the likelihood of infection varies depending on the number and pathogenicity of the organism. The likelihood and severity of symptomatic illness also vary with the type of pathogen, the level of acquired immunity, and the general resistance of the person who is exposed.

Examples of common fecal viral pathogens include enteroviruses (e.g., echoviruses and coxsackieviruses), rotavirus, and hepatitis A virus (HAV). Viruses cannot reproduce outside of a host,

although they can survive and remain infectious. Also, with a few exceptions, viruses that can infect human cells typically cannot infect the cells of other animals, and vice versa. Viruses that infect gut cells become capable of reproducing when they infect humans. Once infected, humans shed viruses in stools, typically for a period lasting between a few weeks to a few months. Thus, regardless of whether individuals infected by the waterborne pathogen have actual symptoms of illness (such as diarrhea), they still shed the virus, which may infect other people. This is called secondary spread, and it can result from person-to-person contact or contact with contaminated surfaces. As a result, viral pathogens may infect others via a variety of routes.

Some enteric viruses may infect cells in tissues outside the gut causing mild or serious secondary effects ("sequelae") 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 (Type 2) diabetes is that the human body, responding to coxsackie B5 virus infection, attacks both pathogenic cells and healthy pancreas cells in an autoimmune reaction because of similarities between the two (Solimena and De Camilli, 1995).

Examples of illnesses caused by known or suspected waterborne fecal viral pathogens are shown in Exhibit 2.1.

Examples of common fecal bacterial pathogens include *E. coli*, *Salmonella*, *Shigella,* and *Campylobacter jejuni*. Some waterborne bacterial pathogens 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 jejuni*, *E. coli*, and *Salmonella* have a host range that includes both animals and humans; *Shigella* is associated only with humans (Geldreich 1996). Unlike viruses, bacteria are able to reproduce outside of the host.

Most of the waterborne bacterial pathogens cause gastrointestinal illness, but some can cause other severe illnesses as well. For example, *Legionella* causes Legionnaires Disease, a form of pneumonia that has a fatality rate of about 15 percent. It can also cause Pontiac Fever, which is a milder respiratory infection form of Legionnaires Disease. Several strains of *E. coli* can cause severe disease, including kidney failure.

Some bacterial pathogens are opportunistic (i.e., they are only infectious in the presence of another, preexisting condition or weakness). Opportunistic pathogens usually cause illness only in immunocompromised persons or in other sensitive subpopulations, such as the very young or the elderly. Other pathogens, such as *Salmonella*, *Shigella*, *and Campylobacter jejuni*, are not entirely opportunistic but result in certain diseases with greater frequency and severity in immunocompromised persons (Framm and Soave, 1997).

Examples of illnesses caused by major waterborne bacterial pathogens are shown in Exhibit 2.2.

Exhibit 2.1 Examples of Illnesses Caused by Known or Suspected Waterborne Fecal Viral Pathogens

Enteric Virus	Illness
Poliovirus	**Paralysis**
Coxsackievirus A	Meningitis, fever, respiratory disease
Coxsackievirus B	**Myocarditis**, **meningitis**, **pleurodynia**, **eye infections**, congenital heart disease, rash, fever, encephalitis, associated with diabetes
Echovirus	**Meningitis**, **rash**, **fever**, **gastroenteritis**, encephalitis, flaccid paralysis
Norovirus	**Gastroenteritis**
Hepatitis A virus	**Hepatitis**
Hepatitis E virus	**Hepatitis**
Rotavirus	**Gastroenteritis**
Enteric Adenovirus	**Eye infections, gastroenteritis,** respiratory disease
Astrovirus	**Gastroenteritis**

Note: **Bold** highlights indicate diseases directly caused by the enteric virus; other illnesses represent secondary effects ("sequelae").

Source: Adapted from Irving et al. 1996, Salvato 1992.

Exhibit 2.2 Examples of Illnesses Caused by Common Waterborne Bacterial Pathogens

Bacterial Pathogen	Illness
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
Vibrio cholerae	Cholera (dehydration and kidney failure)
Escherichia coli (several species, including *E. coli* O157:H7)	Gastroenteritis, hemolytic uremic syndrome (kidney failure)
Yersinia enterocolitica	Gastroenteritis, acute mesenteric lymphadenitis, joint pain
Legionella species	Legionnaires Disease, Pontiac Fever

Source: Adapted from Irving et al. 1996, Salvato 1992.

EPA and Centers for Disease Control and Prevention (CDC) data provide an indication of the types of pathogens that have caused waterborne disease outbreaks. Exhibit 2.3 identifies the etiology of bacterial and viral waterborne outbreaks in GWSs reported to the CDC from 1991 through 2000. Of the 68 outbreaks in GWSs, 14 (21 percent) were associated with specific bacterial pathogens. The fecal bacterial pathogen, *Shigella*, caused more reported outbreaks (five-seven percent) than any other single agent. Identified viral pathogens were associated with four (six percent) reported outbreaks. Etiologic agents were not identified in 39 (57 percent) outbreaks; however, EPA suspects that many of these were caused by viruses, given that it is generally more difficult to analyze for viral pathogens than bacterial pathogens.

Exhibit 2.3 Etiology of Waterborne Outbreaks in Ground Water Systems, 1991-2000

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

Note: Detail may not add to totals due to independent rounding.
Sources: Compiled from CDC 1993, Kramer et al. 1996, Levy et al. 1998, Barwick et al. 2000, and Lee et al. 2002.

2.2.2 Sources of Contaminants

As discussed in section 2.2.1, water from ground water sources can contain microbial contaminants. Fecal contamination of ground water can occur by several routes, including through the subsurface, wellhead, or the distribution system. This section discusses these potential sources of viral and bacterial fecal contamination of ground water supplies. Because pathogens are associated with human and animal waste, the following sections discuss fecal contamination in general and not necessarily the specific types of microbes associated with each source.

2.2.2.1 Ground Water Contamination through the Subsurface

Many factors control the fate and transport of viruses and bacteria in subsurface media. Because these factors are often interrelated, defining the processes involved in the survival and migration of viruses and bacteria is a complex task. Factors such as pH, hydrogeologic conditions, soil types, inorganic ion content, organic matter content, microbial activity, moisture content, and type of pathogen all affect pathogenic fate and transport. Other factors, such as climatic changes and agriculture and land use practices, influence, and may alter, the complex soil environment. For example, wetter climatic conditions may result in high water tables, thereby potentially reducing the distance and time required for contaminants to enter the now-shallower aquifers. In addition, sewage and sludge application to land may alter the physical and chemical properties of soils and affect their capacity to impact viral migration and survival (Bitton and Gerba, 1984). These factors are likely to have a direct or indirect effect on pathogen survival.[1]

Frequently, the subsurface conditions provide adequate natural attenuation of microbial contaminants to ensure protection of the source water. However, certain hydrogeologic features make aquifers more sensitive to microbial contamination. For example, karst, fractured bedrock, and gravel aquifers are considered sensitive aquifers. In these hydrogeologic settings, contaminants that are introduced into the environment are more likely to reach the drinking water production well than in localities with greater natural attenuation capabilities (e.g., sand aquifers).

Given the right conditions, fecal contamination from a variety of sources can reach an aquifer. Normal septage and sewage practices release great amounts of human waste into the subsurface. Canter and Knox (1984) estimated the volume of septic tank waste that is released into the subsurface in the United States to be one trillion gallons per year. Contaminants from failed septic systems or sewage lagoons, leaking sewer lines, and overflowing cesspools can enter ground water sources through the subsurface. Other sources of fecal contamination include improperly treated wastewater used to recharge ground water or to irrigate crop land and improper land application of raw septage or treated sewage. Solid wastes contaminated with human or animal bacteria and viruses may contaminate ground water through individual waste disposal practices, open dumping practices, and landfills (Washington State Department of Health, 1995). Improper land application of waste waters associated with food processing or animal slaughter may also contribute to the contamination of ground water sources of drinking water. Microbial pathogens found in animal wastes may enter ground water from unlined or leaky manure lagoons, spread manure, and concentrated animal feeding operations (USEPA, 1993; Washington State Department of Health, 1995). Given the right subsurface conditions, contaminated water from any of these sources may reach the aquifer and, possibly, the intake zone of a drinking water well.

2.2.2.2 Ground Water Contamination through the Wellhead

Conditions at or near wells may contribute to the occurrence of ground water contamination. Contamination may occur at the wellhead in several ways. The main causes are poor well location and/or construction, improperly abandoned wells, and the presence of test holes or exploratory wells.

[1] For a more detailed discussion of the factors affecting bacterial and viral fate and transport, see the *Occurrence and Monitoring Document for the Final Ground Water Rule* (USEPA, 2006b).

Well Location and/or Construction

Fecal contamination can enter inappropriately located or improperly constructed wells in several ways. A well located in a low-lying area or within a well pit is susceptible to flooding. A well may be particularly vulnerable to surface water contamination if it is not adequately cased and grouted. An improperly constructed water-supply well may allow surface runoff or surface waters to enter through a non-existent or broken well seal. Ground water contamination may also result from water infiltrating through a contaminated gravelpack or the fill surrounding the intake point.

Many old wells were built before the institution of strict construction guidelines, sometimes in a manner that could allow contamination. In some cases, newer wells, built after the institution of stricter well construction guidelines, do not adhere to those guidelines. Such wells, if constructed in or near potential sources of contamination, may be vulnerable to the contamination. Even wells that are built and sited correctly may be exposed to contaminants through an improperly constructed well penetrating the same aquifer as the properly constructed well.

Abandoned Wells

Historically, well abandonment and plugging have generally not been properly planned, designed, and executed (USEPA, 1990; Canter et al., 1987). In many cases, the well casing was pulled out if it was not too worn or corroded, thereby linking aquifers at different depths through the well shaft. Such wells could then serve as conduits for contaminated ground water to spread more rapidly to other zones within an aquifer or allow contaminants to enter adjacent aquifers at lower hydraulic pressures (USEPA, 1990). Other wells may not have been adequately plugged, providing a pathway for contamination from the surface. Occasionally, abandoned wells have also been used as disposal sites for a variety of wastes, resulting in the direct contamination of an aquifer.

Test Holes, Exploratory Wells, and Monitoring Wells

Many test holes and exploratory wells have been dug or drilled into the subsurface to search for oil, gas, coal, minerals, and water. Other holes have been drilled for testing, including soil boreholes and seismic shot holes. Monitoring wells are often drilled to sample ground water quality. When these holes are not backfilled, or when the wells are not properly constructed or abandoned, they provide potential conduits for contamination to enter ground water sources.

2.2.2.3 Contamination of Drinking Water in Distribution Systems

Even if the ground water source for a water system remains clean, contamination may occur within the distribution system. Numerous contamination incidents in distribution systems have been reported from systems using ground water sources. For example, if proper precautions are not taken, water in the distribution system can become contaminated following routine maintenance or emergency repairs (e.g., flushing or chlorination). Inadequately disinfected distribution systems, including storage towers, can develop microbial mats or biofilms. Initially, biofilms may function as a filter, adsorbing pathogens (Seunghyun and Corapcioglu, 1997), but the pathogens may ultimately be shed (sloughed) from the system, potentially contaminating the drinking water at the tap.

2.3 Statutory Authority for Promulgating the Rule

EPA has the primary responsibility for regulating the quality of drinking water. The SDWA establishes this responsibility and defines the mechanisms at the Agency's disposal to protect public health. EPA sets standards by identifying which contaminants should be regulated and by establishing the maximum levels of the contaminants allowed in drinking water.

The 1986 Amendments to the Safe Drinking Water Act directed EPA to promulgate regulations requiring disinfection at all public water systems using either surface water or ground water. The Surface Water Treatment Rule (40 CFR Part 141 subpart H) implemented that requirement for surface water systems (and systems using ground water under the direct influence of surface water), but when Congress amended the Safe Drinking Water Act again in 1996, EPA had not promulgated regulations requiring disinfection for systems that use ground water. In the legislative history of the 1996 Amendments to the Safe Drinking Water Act, Congress identified several reasons for the delay, including the recognition that not all GWSs are at risk of contamination and the high cost of across-the-board disinfection. In light of this recognition, Section1412(b)(8) of the Safe Drinking Water Act, as amended on August 6, 1996, requires EPA to promulgate national primary drinking water regulations (NPDWRS) requiring disinfection as a treatment technique for all ground water systems only as necessary. In addition, Section 1412(b)(8) requires EPA to promulgate criteria as part of the regulations for determining whether disinfection should be required as a treatment technique for any public water system served by ground water.

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

2.4 Regulatory History

The following sections summarize the development of NPDWRs and programs most relevant to the GWR over the past 20 years. These include rules addressing microbial contaminants, rules addressing disinfectants and disinfection byproducts (DBPs), and other rules that were considered (e.g., to determine conflict or overlap of requirements) during the evaluation of GWR regulatory requirements. Drinking water regulations that apply only to surface water systems, including the 1989 Surface Water treatment Rule (SWTR), the 1998 Interim Enhanced Surface Water Treatment Rule (IESWTR), the 2001 Filter Backwash Recycling Rule (FBRR), the 2002 Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR), and the 2006 Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR), are not summarized.

2.4.1 1979 Total Trihalomethane Rule

Under the Total Trihalomethane (TTHM) Rule (44 FR 68624, November 1979), EPA set an MCL for TTHM, the sum of the concentrations of chloroform, bromoform, bromodichloromethane, and dibromochloromethane, of 0.10 milligrams per liter (mg/L) as a running annual average (RAA) of quarterly measurements. This standard applies to community water systems (CWSs) using surface or ground water that serve at least 10,000 people and that add a disinfectant to the drinking water during any part of the treatment process. This 1979 rule has been superceded by the 1998 Stage 1 DBPR (section 2.4.4). Compliance with the Stage 1 DBPR began in January 2002.

2.4.2 1989 Total Coliform Rule

The Total Coliform Rule (TCR) (54 FR 27544, June 1989) applies to all PWSs. Because monitoring PWSs for every possible pathogenic organism is not feasible, coliform organisms are used as indicators of possible system contamination. Coliforms are easily detected in water and are used to indicate a water system's vulnerability to pathogens. In the TCR, EPA set a Maximum Contaminant Level Goal (MCLG) of zero for total coliforms. EPA also set a monthly MCL for total coliforms and required testing of total coliform-positive cultures for the presence of *E. coli* or fecal coliforms. *E. coli* and fecal coliforms indicate more immediate health risks from sewage or fecal contamination and are used as a trigger of an acute MCL violation. Coliform monitoring frequency is determined by population served, the type of system (community or noncommunity systems), and the type of source water (surface water, ground water under the direct influence of surface water (GWUDI), or ground water). In addition, the TCR required sanitary surveys every five years (ten years for noncommunity systems using disinfected ground water) for systems that collect fewer than five total coliform samples per month (those serving 4,100 people or fewer).

2.4.3 1996 Information Collection Rule

The Information Collection Rule (ICR) (61 FR 24354, May 1996) applied to PWSs serving at least 100,000 people. A more limited set of ICR requirements cover GWSs serving 50,000 to 99,999 people. The ICR authorized EPA to collect occurrence and treatment information from water treatment plants to help evaluate the possible need for changes to the current microbial requirements and existing microbial treatment practices and to help evaluate the need for future regulation of disinfectants and DBPs. The ICR provided EPA with information on the national occurrence of (1) chemical byproducts that form when disinfectants used for microbial control react with naturally occurring compounds and ions present in source water; and (2) disease-causing microorganisms including *Cryptosporidium*, *Giardia*, viruses, and coliform bacteria. The ICR also mandated the collection of treatment train data on how water systems currently control for contaminants. The ICR monthly sampling data provided 18 months of information on the quality of the influent and treated water, including pH, alkalinity, turbidity, temperature, calcium, total hardness, total organic carbon, UV_{254} absorbency, bromide, ammonia, and disinfectant residual. These data provide some indication of the "treatability" of the water, the occurrence of contaminants, and the potential for DBP formation. The data collected under the ICR are continuing to be analyzed to help develop current and future NPDWRs.

2.4.4 1998 Stage 1 Disinfectants and Disinfection Byproducts Rule

The Stage 1 DBPR (63 FR 69390, December 1998) applies to all CWSs and nontransient noncommunity water systems (NTNCWSs) that add a chemical disinfectant to their water. Certain requirements designed to provide protection against acute health effects from chlorine dioxide also apply to transient noncommunity water systems (TNCWSs). Surface water and GWUDI systems serving at least 10,000 people were required to begin compliance with the rule by January 2002. Surface water and GWUDI systems serving fewer than 10,000 people and all GWSs must comply beginning January 2004.

The Stage 1 DBPR sets Maximum Disinfectant Residual Level Goals (MRDLGs) for chlorine (4 mg/L as Cl_2), chloramines (4 mg/L as Cl_2), and chlorine dioxide (0.8 mg/L as ClO_2) and MCLGs for bromodichloromethane (0 mg/L), bromoform (0 mg/L), dibromochloromethane (0.06 mg/L), dichloroacetic acid (0 mg/L), trichloroacetic acid (0.3 mg/L), bromate (0 mg/L), and chlorite (0.8 mg/L). The rule sets Maximum Residual Disifectant Leevels (MRDLs) for chlorine (4.0 mg/L as Cl_2), chloramines (4.0 mg/L as Cl_2), and chlorine dioxide (0.8 mg/L as ClO_2) and MCLs for TTHM (0.080 mg/L), haloacetic acids [total of five] (HAA5) (0.060 mg/L), bromate (0.010 mg/L), and chlorite (1.0 mg/L). The MRDLs and MCLs, except those for chlorite and chlorine dioxide, are calculated as RAAs of quarterly measurements. For surface water and GWUDI systems using conventional filtration treatment, a treatment technique—enhanced coagulation/softening—is specified for the removal of DBP precursors.

2.4.5 2001 Arsenic Rule

The Arsenic Rule (66 FR 6976, January 2001) increases the level of public health protection against exposure to arsenic in drinking water. The rule revises the MCL for arsenic in drinking water from 0.05 mg/L to 0.010 mg/L and sets an MCLG of 0 mg/L for all CWSs and NTNCWSs. Clarification on how compliance is demonstrated for many inorganic and organic contaminants in drinking water is also given. All existing CWSs and NTNCWSs were required to comply with the Arsenic Rule by January 23, 2006.

2.4.6 2006 Stage 2 Disinfectants and Disinfection Byproducts Rule

The Stage 2 DBPR tightens certain DBP compliance standards set by the Stage 1 DBPR. The Stage 2 DBPR was promulgated concurrently with the LT2ESWTR and is designed to reduce DBP occurrence peaks in the distribution system by changing compliance monitoring provisions. The requirements in the Stage 2 DBPR apply to all CWSs and NTNCWSs that add a primary or residual disinfectant other than ultraviolet light (UV) or that deliver water that has been treated with a disinfectant other than UV.

For the Stage 2 DBPR, the MCLs will remain at the Stage 1 DBPR levels (0.080 mg/L for TTHM and 0.060 mg/L for HAA5), but compliance will be measured based on locational running annual averages (LRAAs) instead of the RAAs used in the Stage 1 DBPR. Most systems will also be required to conduct Initial Distribution System Evaluations (IDSEs) to identify monitoring locations that represent locations with the highest concentrations of TTHM and HAA5. In addition, the Stage 2 DBPR addresses systems that are in full compliance with the Stage 2 DBPR LRAA MCLs but have individual DBP measurements that exceed the MCLs. The rule provides a formula for determining averages for TTHM and HAA5. If these averages exceed certain levels, the system must conduct an operational evaluation and submit a written report or the operational evaluation to the State.

2.4.7 Underground Injection Control Program

The EPA's Underground Injection Control (UIC) program was established to protect sources of drinking water from underground injection of fluids through wells. Owners and operators of injection wells are prohibited from operating their wells in a manner that causes the movement of fluid into underground sources of drinking water if it may cause a violation of any primary drinking water regulation or otherwise adversely affect human health. To prevent such fluid movement, EPA or the appropriate State regulatory agency may require certain construction criteria, corrective action, operation, monitoring, reporting, or plugging and abandonment. These regulations are designed to recognize varying geologic, hydrological, or historical conditions among different States or areas within a State.

The regulations included in 40 CFR 144.6 define five classes of injection wells. These wells may inject fluids that are associated with hazardous waste or radioactive waste sites, natural gas or oil production, extraction of minerals, or other purposes. Class V wells are the most prevalent of the injection well types and are most often associated with ground water contamination relevant to the GWR. They include:

- Untreated sewage waste disposal wells
- Large-capacity cesspools
- Large-capacity septic systems (undifferentiated disposal method)
- Large-capacity septic systems (well disposal method)
- Large-capacity septic systems (drainfield disposal method)
- Domestic wastewater treatment plant effluent disposal wells

EPA regulates only multiple-dwelling, community, or regional septic systems, as opposed to individual or single-family residential septic systems, as Class V wells (40 CFR 144.1(g)(1)(2)).

In November 1999, EPA finalized new UIC regulations that added requirements for two categories of Class V wells (USEPA, 1999b). The regulation bans new large-capacity cesspools nationwide and phases out existing large-capacity cesspools by April 2005. It also bans new motor vehicle waste disposal wells nationwide. Operation of existing motor vehicle waste disposal wells in ground water source water areas or other sensitive ground water areas is banned but with a provision that owners and operators of such wells may seek a waiver from closing if they obtain a permit. The permit conditions include requirements for meeting MCLs and other health-based standards at the point of injection, injectate and sludge monitoring, and implementing best management practices. EPA expects to achieve substantial protection of underground sources of drinking water by focusing the requirements on these particular wells.

2.5 Economic Rationale

This section addresses the economic rationale for choosing a regulatory approach rather than non-regulatory alternatives. An economic rationale for the rule is required by Executive Order 12866, *Regulatory Planning and Review* (58 FR 51735), which states:

> "[E]ach agency shall identify the problem that it intends to address (including, where applicable, the failures of the private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." (Section 1, b(1))

In addition, Office of Management and Budget (OMB) guidance, dated January 11, 1996, states that "in order to establish the need for the proposed action, the analysis should discuss whether the problem constitutes a significant market failure" (USEPA, 1996a).

In a perfectly competitive market, prices and quantities are determined solely by the aggregated decisions of buyers and sellers. Such a market occurs when many producers of a product are selling to many buyers and where both producers and consumers have perfect information on the characteristics and prices of each firm's products. Barriers to entry in the industry cannot exist, and individual buyers and sellers must be "price takers" (i.e., their individual decisions cannot affect the price). Several properties of the public water supply do not satisfy the conditions for a perfectly competitive market and thus lead to market failures that require regulation.

Many water systems are natural monopolies. A natural monopoly exists when it is impossible for more than one firm in each area to recover the costs of production and survive. There are high fixed costs associated with reservoirs and wells, transmission and distribution systems, treatment plants, and other facilities. For other potential suppliers to enter the market, they would have to provide the same extensive infrastructure to realize similar economies of scale and be competitive. A splitting of the market with increased fixed costs (e.g., two supplier networks in a single market) usually makes this situation unprofitable. The result is a market suitable for a single supplier and hostile to alternative suppliers. In such natural monopolies, suppliers have fewer incentives for providing quality services or maintaining competitive prices. In these situations, governments often intervene to help protect the public interest.

For example, because PWSs are legal, as well as natural, monopolies, they are often subject to price controls, if not outright public ownership. While customers may demand improvements in water quality, the regulatory structure may not facilitate the transmission of that demand to the water supplier or allow the supplier to raise its price to recover the cost of the improvements. If consumers do not believe that their drinking water is safe enough, they cannot simply switch to another water utility. Other options for obtaining safe drinking water (e.g., buying bottled water or installing point of use filtration) most often represent a higher water cost to consumers than the purchase from PWSs. Therefore, the water supplier may have little incentive to improve water quality.

The public may also not understand the health and safety issues associated with poor drinking water quality. Understanding the health risks posed by trace quantities of drinking water contaminants involves analysis and synthesis of complex toxicological and health sciences data. Therefore, the public may not be aware of the risks it faces. EPA has implemented a Consumer Confidence Report (CCR) Rule (63 FR 44512, August 1998) that makes water quality information more easily available to consumers. This rule requires CWSs to publish an annual report on local drinking water quality. Consumers, however, still have to analyze this information for its health risk implications. Furthermore, even if informed consumers are able to engage water systems in a dialogue about health issues, the transaction

costs of such interaction (measured in personal time and monetary outlays) present another significant impediment to consumer expression of risk reduction preferences.

SDWA regulations are intended to provide a level of protection from exposure to drinking water contaminants. The regulations set minimum performance requirements to protect consumers from exposure to contaminants. SDWA regulations are not intended to restructure market mechanisms or to establish competition in supply; rather, they establish the level of service to be provided that best reflects public preference for safety. The federal regulations reduce the high information and transaction costs by acting on behalf of consumers in balancing risk reduction and the social costs of achieving this risk reduction.

3. Consideration of Regulatory Alternatives

3.1 Introduction

The 1996 Amendments to the Safe Drinking Water Act (SDWA) require the United States Environmental Protection Agency (EPA or Agency) to develop a national primary drinking water regulation that requires disinfection as a treatment technique for all ground water PWSs only "as necessary." To address this mandate and the public health concerns presented in Chapter 2 of this EA, EPA developed the Ground Water Rule (GWR). The Agency convened workgroups, held stakeholder meetings, published a proposed rule, and evaluated public comments to develop a final regulation. This chapter describes the process used to evaluate regulatory alternatives considered during the development of the GWR and evaluated as part of this Economic Analysis (EA).

3.2 Process for Development of Regulatory Alternatives

In 1992, EPA circulated a draft proposal for review and comment, which began the process of developing regulatory alternatives for addressing microbial contamination in ground water systems (GWSs). In 1993, EPA published a preliminary draft of the Ground Water Disinfection Rule (later renamed the Ground Water Rule). After review of the public comments, EPA recognized that additional information needed to be gathered and, in 1995, convened a GWR regulatory workgroup. EPA used the workgroup to obtain comments and additional information regarding the GWR. In 1996, EPA published a report, *Ground Water Disinfection and Protective Practices in the United States*, on ground water-related statutes, regulations, guidance, and disinfection practices gathered from 50 State drinking water programs (USEPA, 1996b). In 1997, EPA initiated another workgroup, including members from EPA, other Federal agencies, and State agencies, to cooperate in the development of a proposed GWR.

In December 1997, EPA initiated stakeholder meetings. The Agency published public meeting announcements in the *Federal Register*. EPA involved citizens, environmental groups, small businesses, and water suppliers early in the rule development process and held public meetings in different regions (Washington, DC; Portland, OR; Madison, WI; and Dallas, TX) to facilitate rule development and allow stakeholders the opportunity to comment on the regulation.

In addition to the public meetings with stakeholders, EPA, as part of the consultation process required by the Small Business Regulatory Enforcement Fairness Act (SBREFA), met with representatives of small systems (i.e., those serving fewer than 10,000 people) in March and April 1998. EPA presented possible regulatory requirements and requested comments from the representatives during these meetings.

In January 1999, EPA published a preliminary draft preamble for the GWR and solicited comment. The preliminary draft preamble described regulatory alternatives and requested public comment on a number of potential modifications. EPA received 80 comments on the preliminary draft preamble.

3.3 Regulatory Alternatives Considered

EPA proposed four regulatory alternatives. The multi-barrier approach was the preferred alternative in the proposed GWR. The primary elements of the multi-barrier approach were sanitary surveys, triggered monitoring, HSAs, routine monitoring, corrective action, and compliance monitoring. After the proposal, EPA considered comments and chose a different final rule alternative, Alternative 2, termed the risk-targeted approach. The primary elements of the risk-targeted approach include sanitary surveys, triggered monitoring, optional assessment monitoring, corrective action, and compliance monitoring.

The following discussion provides details of the four main regulatory alternatives considered. A detailed comparison of the quantified benefits and costs of each of the four regulatory alternatives for the GWR is found in Chapter 8 of this EA.

Alternative 1: Sanitary survey and corrective action

Sanitary surveys are on-site assessments of the source water, treatment facilities, distribution systems, finished water storage tanks, monitoring records, and the management and operation of a public water system (PWS). This alternative requires sanitary surveys to be conducted by the State at least once every 3 years for community water systems (CWSs) (with a provision that States may reduce frequency to every five years for CWSs with outstanding performance and no TCR violations or that provide 4-log treatment) and every 5 years for noncommunity water systems (NCWSs). Sanitary surveys must address various elements set out in the EPA/State Joint Guidance on sanitary surveys. Operators would be required to correct any significant deficiencies within 120 days of receiving the State sanitary survey report or in accordance with a State-approved plan and schedule for correcting these deficiencies. All systems that perform treatment (including those already achieving 4-log treatment of viruses before or at the first customer) must perform compliance monitoring to ensure that the treatment is effective.

Alternative 2: Risk-Targeted Approach (Final Rule Alternative)

In addition to all the sanitary survey components of the first alternative, the Risk-Targeted Approach includes a triggered source water microbial monitoring requirement for systems. Systems that do not already achieve at least 4-log (99.99 percent) treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer and that have a total coliform (TC) positive result for any routine sample taken under the Total Coliform Rule (TCR) must collect a ground water source sample. The ground water system must test the source water sample for a fecal indicator (*E. coli*, enterococci, or coliphage) determined by the State or primacy agency. Unless the State requires immediate corrective action for the initial fecal indicator-positive source water sample, the system must collect and analyze five additional ground water source samples for the presence of a fecal indicator. If any one of the five source water samples tests fecal indicator-positive, the system must take correction action. Systems that are required to take corrective action must consult with the State within 30 days and complete the action within 120 days (or be in compliance with the State or primacy agency approved plan and schedule) of receiving notice of the fecal indicator-positive sample in one of the five additional samples or when the State determines a corrective action is necessary, whichever occurs first. The final GWR provides States with the option to require systems to conduct assessment monitoring any time and require systems to take corrective actions. See section 3.4 for more details on this alternative.

Alternative 3: Multi-barrier Approach

The multi-barrier approach described in this EA includes modifications to two proposed provisions: hydrogeologic sensitivity assessment and routine monitoring provisions. The changes made to the multi-barrier approach stemmed from public comments received on the proposed GWR regulatory alternative.

The multi-barrier approach builds on the sanitary survey and triggered monitoring requirements of the first two alternatives. This alternative includes an optional HSA provision for States rather than a required HSA provision as proposed. An HSA is a tool used to identify those systems in aquifers where water can move quickly through the subsurface, thereby increasing the possibility of fecal contamination. Under this alternative, each State has the option to complete the hydrogeologic sensitivity assessment within six and eight years from the GWR publication date for CWSs and NCWSs, respectively. HSAs would be conducted for all existing and new systems that do not maintain at least a 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer. If the State did not conduct an HSA to determined aquifer sensitivity, the system would be required to conduct twelve months of assessment monitoring.

If an aquifer that a system uses as a source is identified as sensitive through an HSA or if the State chooses not to conduct an HSA, the system would have to conduct assessment monitoring (a derivation of routine monitoring in the proposed rule). The assessment monitoring provision involves the system collecting a ground water source sample and testing it for the State-specified fecal indicator each month that the system serves water to the public until a total of 12 ground water source samples is collected. The proposed rule required a system to collect a source water sample each month that the system serves water to the public, or otherwise specified by the State. Assessment monitoring is performed in addition to any triggered source water monitoring samples that may be required.

Under the multi-barrier approach, systems found to have source water contamination (either through assessment or triggered monitoring) would be required to consult with the State within 30 days and take corrective action within 120 days (or longer if the State or primacy agency approves a plan and schedule) from the date the system receives notice of the fecal indicator-positive sample.

Alternative 4: Across-the-Board Disinfection

This alternative requires all public ground water systems to install or operate disinfection treatment processes capable of achieving a 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer on a continuing basis. Systems treating to less than 4 logs would be required to upgrade their treatment. Unlike the other alternatives, the across-the-board disinfection alternative does not consider the quality of a system's source water or potential for contamination. Similar to Alternatives 2 and 3, all systems (including those already achieving 4-log treatment of viruses before or at the first customer) would have to conduct compliance monitoring to ensure the treatment is effective. Also, States would be required to perform sanitary surveys of ground water systems to ensure the treatment practices are being properly operated and to evaluate the ground water system for potential source contamination.

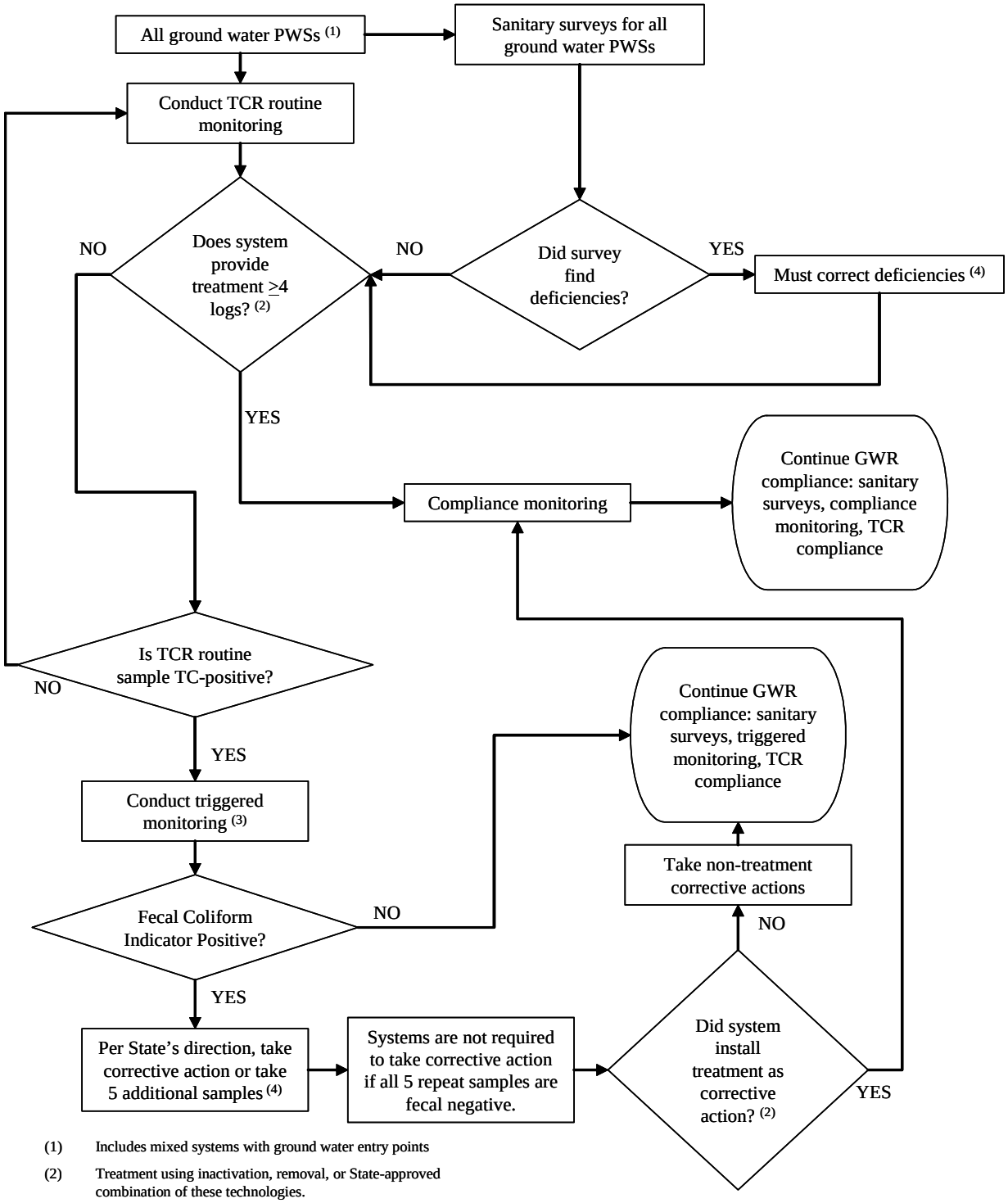
3.4 Final Rule Requirements

Following publication of the proposed GWR, EPA accepted public comments for 90 days. EPA received approximately 3,300 comments from over 250 individuals and organizations representing a wide

range of stakeholders, including public water systems, States, Tribes, other organizations, and private citizens. Each comment was read and considered as part of the process for selecting and, where appropriate, modifying the final GWR regulatory alternative. A record of every comment received on the proposal, as well as EPA's response to each, can be found in the *Public Comment and Response Document for the Final Ground Water Rule* (USEPA, 2006a). Copies of individual comments are also available as part of the public record and can be accessed through EPA's Water Docket.

Based on public comments, EPA reevaluated the regulatory alternatives, the assumptions, and data underlying the GWR proposal. As stated in section 3.3, EPA selected Alternative 2 as the final GWR alternative. Alternative 2, the risk-targeted approach, includes mandatory rule components and an optional assessment monitoring provision. Exhibit 3.1 provides a flowchart of the mandatory rule components.

Exhibit 3.1 Flowchart of Mandatory PWS Ground Water Rule Requirements



(1) Includes mixed systems with ground water entry points

(2) Treatment using inactivation, removal, or State-approved combination of these technologies.

(3) For those systems that do not receive a triggered monitoring waiver from the State

(4) The State may determine that the source of contamination has been eliminated..

3.4.1 Mandatory Rule Components

The following subsections describe the GWR regulatory requirements with which ground water systems and States must comply. Systems meeting certain criteria (i.e., 4-log disinfection or inactivation of viruses) may not be required to implement all provisions.

Sanitary Surveys

The final GWR requires States to perform sanitary surveys for all GWSs. Ground water systems must provide the State with any pertinent, existing information that will enable the State to perform the sanitary survey. The final GWR goes beyond the existing definition of sanitary survey at 40 CFR 141.2, explicitly references the use and relevance of source water assessments required under the 1996 SDWA Amendments, and specifies in more detail the scope of a sanitary survey. Specifically, the final GWR requires that States evaluate the eight components outlined in the EPA/State Joint Guidance as part of the sanitary survey to the extent that they apply to an individual system:

(1) source;
(2) treatment;
(3) distribution system;
(4) finished water storage;
(5) pumps, pump facilities, and controls;
(6) monitoring, reporting, and data verification;
(7) system management and operation; and
(8) operator compliance with State requirements.

The final GWR requires States to conduct sanitary surveys of ground water CWSs every three years (every five years for CWSs that meet performance criteria as described in the following paragraph) and of ground water NCWSs every five years. States are required to complete the initial sanitary survey cycle by December 31, 2012 for CWSs, except those that meet performance criteria (e.g., 4-log treatment or outstanding performance and no TCR violations), and December 31, 2014 for all NCWSs and CWSs that meet performance criteria. States may conduct more frequent sanitary survey cycles for any GWS as appropriate.

The final GWR allows individual components of a sanitary survey to be conducted according to a phased review process (e.g., as part of ongoing State assessment programs). While all applicable components need not be evaluated at the same time, they must be evaluated within the required three- or five-year frequency interval. Also, the final GWR allows the three-year CWS schedule to be extended to a five-year frequency if the system meets performance criteria.

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

The State must provide the GWS with written notification, which describes any significant deficiencies found, no later than 30 days after the State identifies the significant deficiency. The notice may be sent to the PWS, or it may be provided on-site either at the time the sanitary survey is conducted or the significant deficiency is identified. The State may specify appropriate follow-up corrective action steps in the notice or may notify the GWS of appropriate corrective actions during the consultation

period. After receiving the written notification, the GWS has 30 days to consult with the State regarding corrective actions. The GWS must correct the significant deficiency within 120 days or be on a State-approved corrective action plan and schedule. States must confirm that the deficiencies have been addressed within 30 days after the scheduled correction date. (See also the discussion of corrective actions below.)

Triggered Source Water Monitoring

A GWS must conduct triggered source water monitoring within 24 hours of receiving notification that a sample collected in accordance with 40 CFR 141.21(a) (TCR) is total coliform-positive. A GWS must collect at least one ground water source sample from each ground water source (e.g., a well or spring) in use at the time the total coliform-positive sample was collected. Triggered source water monitoring is required unless:

(1) the GWS provides at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for each ground water source;

(2) the GWS is notified that a positive sample collected in accordance with 40 CFR 141.21(a) (TCR) has been invalidated under 40 CFR 141.21(c); or

(3) the cause of the total coliform-positive collected under 40 CFR 141.21(a) directly relates to the distribution system according to State criteria or a State determination.

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

Systems are not required to conduct triggered source water monitoring if, according to State criteria or a State determination, the cause of the total coliform-positive sample collected under 40 CFR 141.21(a) directly relates to the distribution system. If the decision is made according to State criteria, the GWS must document the decision in writing; if the decision is made by the State, the State must document the decision in writing. In the primacy application, the State must include criteria that will be used to determine that the cause of a total coliform-positive sample collected under 40 CFR 141.21(a) is directly related to the distribution system.

If the State approves the use of E. coli as a fecal indicator for triggered source water monitoring, GWSs serving 1,000 people or fewer may use a TCR repeat sample collected from a ground water source to simultaneously meet the requirements of 40 CFR 141.21(b) and satisfy the GWR's triggered source water monitoring requirements for that ground water source only.

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

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

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

Consecutive and wholesale systems must also comply with other triggered source water monitoring requirements. A consecutive GWS that has a total coliform-positive sample collected under 40 CFR 141.21(a) (TCR) must notify the wholesale system(s) within 24 hours of being notified of the total coliform-positive sample. If a wholesale GWS receives notice from a consecutive system it serves that a sample collected under 40 CFR 141.21(a) (TCR) is total coliform-positive, the wholesale GWS must conduct triggered source water monitoring. If the sample is fecal indicator-positive, in addition to notifying its own customers, the wholesale GWS must notify all consecutive systems served by that ground water source. The consecutive system is responsible for providing any required public notice to the persons it serves.

Corrective Action

When a GWS has a significant deficiency, it must consult with the State regarding appropriate corrective action within 30 days of receiving a written notice of the significant deficiency. When a GWS receives a written notice from a laboratory indicating a fecal indicator positive result in one of the five additional triggered source water monitoring samples, the GWS must consult with the State regarding appropriate corrective action. When a GWS receives a written notice from a laboratory indicating a fecal indicator positive result and the State has determined that corrective action is necessary, the GWS must consult with the State regarding appropriate corrective action. Consultation must take place within 30 days. In any event, the State may specify corrective action without consultation. In the consultation process, the State may approve and/or modify corrective actions and completion schedules proposed by the system, or the State may specify alternatives. The State may also specify interim corrective action measures.

The final GWR rule requires that within 120 days (or earlier if directed by the State) of receiving the notification from the State or laboratory described in the preceding paragraph, the GWS must either

(i) complete appropriate corrective actions in accordance with applicable State plan review processes or other State guidance or direction, or

(ii) be in compliance with a State-approved corrective action plan and schedule.

If a GWS is unable to complete corrective action within 120 days or on the schedule specified by the State, then the GWS is in violation of the treatment technique requirement.

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

Corrective Action Alternatives

When a system has a significant deficiency or a fecal indicator-positive ground water source sample (either by the initial triggered sample, or positive additional sample, as determined by the State), the GWS must implement one or more of the following corrective action options:

(1) correct all significant deficiencies (e.g., repairs to well pads and sanitary seals, repairs to piping tanks and treatment equipment, control of cross-connections);

(2) provide an alternate source of water (e.g., new well, connection to another PWS);

(3) eliminate the source of contamination (e.g., remove point sources, relocate pipelines and waste disposal, redirect drainage or run-off, provide or fix existing fencing or housing of the wellhead); or

(4) provide treatment that reliably achieves at least 4-log treatment of viruses (using inactivation, removal, or a State-approved combination of 4-log virus inactivation and removal) before or at the first customer for each ground water source.

Compliance Monitoring for Systems Providing At Least 4-log Treatment of Viruses

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

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

- Chemical Disinfection. Inactivation, with a sufficient disinfection concentration and contact time, through disinfection with chlorine, chlorine dioxide, ozone, or through anodic oxidation. Disinfectant concentration and contact time (CT) can be based on existing CT tables (USEPA, 1991) or State-approved alternatives.

- Membrane Filtration. Removal with membrane technologies with an absolute molecular weight cut-off (MWCO), or an alternate parameter that describes the exclusion characteristics of the membrane, that can reliably achieve at least a 4-log removal of viruses.

- Alternative Treatment. Inactivation, removal or combination of inactivation and removal through alternative treatment technologies (e.g., ultraviolet radiation (UV)) approved by the State, if the alternative treatment technology, alone or in combination (e.g., UV with filtration, chlorination with filtration), can reliably provide at least 4-log treatment of viruses.

Under the final GWR, GWSs providing 4-log treatment of viruses using chemical disinfection must monitor for and must meet and maintain a State-determined residual disinfectant concentration (i.e., 4-log inactivation of viruses based on CT tables) or State-approved alternatives every day the GWS serves from the ground water source to the public. If the State has not approved compliance criteria for

the system to use to demonstrate 4-log treatment by the time that the system is required to conduct compliance monitoring, the system must comply with ground water source monitoring in '141.402 until the State approves compliance criteria for the system to use to demonstrate 4-log treatment.

Systems serving greater than 3,300 people and using chemical disinfection (e.g., chlorine) to provide 4-log inactivation must continuously monitor the residual disinfectant concentration using analytical methods specified in 40 CFR 141.74(a)(2) (Analytical and monitoring requirements) at a location approved by the State, and record the lowest residual disinfectant level each day that the GWS serves water from the ground water source to the public. The GWS must maintain the State-determined residual disinfectant concentration every day the GWS serves from the ground water source.

Systems serving 3,300 people or fewer that use chemical disinfection must monitor the residual disinfectant concentration using analytical methods specified in 40 CFR 141.74(a)(2) (Analytical and monitoring requirements) at a location approved by the State either by taking at least one grab sample every day the GWS serves water to the public or by continuously monitoring the disinfectant residual. Systems collecting grab samples must record the disinfectant residual level each day that the GWS serves water from the ground water source to the public. The GWS must take a grab sample during the hour of peak flow or at another time specified by the State. Systems serving 3,300 people or fewer that use continuous residual monitoring equipment must record the lowest residual disinfectant level each day that the GWS serves water from the ground water source to the public.

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

Ground water systems that use a membrane filtration treatment technology must maintain the integrity of the membrane and monitor and operate the membrane filtration system in accordance with State-specified monitoring and compliance requirements (e.g., membrane performance parameters and integrity testing). If a system fails to meet these requirements or maintain the integrity of the membrane, it must correct the problem within four hours or be in violation of the treatment technique requirement. Systems that use a State-approved alternative treatment technology must monitor and operate the alternative treatment in accordance with all compliance requirements that the State determines to be necessary to demonstrate that at least 4-log treatment of viruses is achieved. If the system does not comply with these requirements, fails to maintain at least 4-log treatment of viruses, and does not restore proper operation within four hours, the system is in violation of the treatment technique requirement.

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

viruses must have State approval and must comply with the triggered source water requirements of the final GWR.

3.4.2 Optional Provision

The final GWR provides States with the option to require systems to conduct assessment source water monitoring at any time and require systems to take corrective action. EPA believes that this optional provision is an important tool that should be used by States to protect public health. States may elect to require assessment source water monitoring on a case-by-case basis. EPA recommends that States require GWSs that are most susceptible to fecal contamination to conduct assessment monitoring. States may use hydrogeologic sensitivity assessments (HSAs) as a tool to identify high risk systems for assessment source water monitoring. States have other information available to them to target high risk systems, such as source water assessments, wellhead protection plans, and historical monitoring data. Data on past indications of source water fecal contamination, particularly from TCR monitoring, in combination with GWR triggered source water monitoring results, can be another important tool.

EPA recommends that States require GWSs that are conducting assessment source water monitoring to collect a total of 12 ground water source samples that represent each month the GWS provides ground water to the public. For seasonal systems, EPA recommends equally distributing 12 samples or sampling during consecutive years. EPA recommends that States require corrective action for sources that are fecally contaminated.

3.5 Other Changes Since Proposal

In addition to modifications made to Alternative 2 since proposal, updates were made based on comments to the assumptions, data, and analytical processes used to support the economic analysis of the alternatives. Wherever possible, assumptions and data were updated to reflect the latest information on the characteristics and number of entities affected, occurrence of contaminants, costs of items used as modeling inputs, and public comment. In particular, extensive consideration was given to the appropriate use of occurrence data to inform the benefits and cost analyses. EPA published a Notice of Data Availability in the March 27, 2006 *Federal Register* to present additional occurrence studies the Agency considered using in the final GWR economic analysis.

See Appendix J of this EA for a detailed discussion on changes in the GWR economic analysis since proposal.

4. Baseline Analysis

4.1 Introduction

The baseline analysis is a characterization of the industry and its operations under the conditions expected to exist before systems make changes to meet requirements of the GWR. The baseline allows a consistent comparison of public health impacts (developed in Chapter 5) and the economic and financial impacts (developed in Chapters 6 and 7) of the rule. Development of the GWR baseline consists of the following processes:

- Compiling an industry profile—identifying and collecting information on the segment(s) of the water supply industry subject to the GWR.
- Characterizing current disinfection practices of ground water systems—summarizing the status of disinfection practices currently employed to ensure public health protection from ground water contaminants.
- Characterizing current ground water quality—summarizing the relevant characteristics of ground water sources.

Section 4.2 characterizes the water industry, including the baseline estimates of systems, entry points, and population subject to the GWR. This section also includes an assessment of the current status of disinfection practices among the systems potentially affected by the rule as well as estimates of annual positive total coliform samples under the Total Coliform Rule (TCR). Source water quality is summarized in section 4.3, and the recent history of outbreaks is presented in section 4.4. Lastly, section 4.5 itemizes and estimates the effects of significant uncertainties in the baseline analysis.

This chapter presents an analysis that is at a level of detail and precision appropriate to support subsequent analyses and regulatory decisions under consideration for the GWR. Therefore, it does not give an exhaustive review of the water supply industry, source waters, or industry practices.

4.2 Industry Profile

This section provides a water industry characterization that is used to derive costs and benefits for the GWR. It is organized as follows:

Section 4.2.1 describes the data sources used to characterize the industry baseline.

Section 4.2.2 is a background section describing the various ways in which water systems can be classified and identifies distinctions that are important for regulatory analysis.

Section 4.2.3 presents the baseline numbers of systems, entry points, and population according to disinfection practices used for estimating treatment costs and subsequent benefits of the GWR.

Section 4.2.4 presents the mean plant design and average daily flow for each of the nine system size categories.

Section 4.2.5 presents the treatment practices baseline.

Section 4.2.6 estimates the total number of households in each of the nine size categories of systems subject to the GWR.

Section 4.2.7 estimates the annual number of triggered monitoring samples that systems will have to take as a result of positive total coliform samples taken under the Total Coliform Rule.

4.2.1 Data Sources

Several data sources were used to characterize the GWR baseline. Data from the Safe Drinking Water Information System-Federal Version (SDWIS/FED or SDWIS) are used to create system and population baselines (USEPA, 2003)[1]. SDWIS is the United States Environmental Protection Agency's (EPA or Agency) national regulatory compliance database for the drinking water program. It includes information on the nation's 170,000 public water systems (PWSs) and on violations of drinking water regulations. For more information on SDWIS, refer to EPA's website (http://www.epa.gov/safewater/sdwisfed/sdwis.htm). A second key source of data used to develop the industry profile is the Third Edition of the Water Industry Baseline Handbook (Baseline Handbook) (USEPA, 2001a) published in May 2001, which compiles data derived from the 1995 Community Water System Survey (CWSS) and SDWIS. For certain analyses, CWSS raw data were used to develop modeling inputs. The 1995 CWSS was a mail survey that covered ground and surface water systems of all sizes (based on population served). The survey was based on a two-phase, stratified, random sample design. Phase 1 was a telephone screening survey that provided a sampling frame for the main data collection in Phase 2. The survey sample in Phase 2 was stratified according to water system size (residential population served), ownership (public, private, or ancillary), and primary water source (ground or surface). A total of 3,681 systems covering a range of source water types and system sizes were selected to receive the main survey questionnaire. Of these, 1,980 systems responded. See the EPA Report, "Community Water System Survey, Volume 2" (USEPA, 1997a), for more information on the 1995 CWSS sample design and data evaluation.

EPA also used the December 2000 document, "Geometries and Characteristics of Water Systems Report" (Model Systems Report) (USEPA, 2000a). In this document, EPA analyzed 1995 CWSS data to create equations relating flow and population, among other things.

4.2.2 Water System Characterization

Categorization of water systems is important because system size, ownership, and consecutive/wholesale relationships affect the way in which costs and benefits are estimated. This section explains the classifications of water systems, as defined by EPA's National Primary Drinking Water Regulations (NPDWRs) and describes further subdivisions according to water source, size (population served), and ownership for regulatory analysis purposes.

[1] Data used are from the 4th quarter freeze of the 2003 database.

PWS Type

NPDWRs apply to all PWSs. A PWS is defined as a system that provides water for human consumption through pipes or other constructed conveyances if such a system has at least 15 service connections or regularly serves an average of at least 25 individuals per day for at least 60 days per year. PWSs are categorized as follows:

- ***Community Water Systems*** (CWSs) are PWSs that have at least 15 service connections used by year-round residents or that regularly serve at least 25 year-round residents.

- ***Noncommunity Water Systems*** (NCWSs) are PWSs that are not classified as CWSs.

NCWSs are subdivided into two categories:

- ***Nontransient Noncommunity Water Systems*** (NTNCWSs) are NCWSs that regularly serve at least 25 of the same people more than 6 months per year.

- ***Transient Noncommunity Water Systems*** (TNCWSs) are NCWSs that do not regularly serve at least 25 of the same people more than 6 months per year.

Source Water Type

Systems are classified by the source from which they draw water. Systems that use either surface water or ground water under the direct influence of surface water (GWUDI) are classified as surface water systems. Ground water systems are, by default, systems that draw from ground water that are not GWUDI.

Some systems may obtain water from both ground water and surface water and are referred to as "mixed systems." In SDWIS and the Baseline Handbook, a mixed system is categorized as a surface water system because it gets some portion of its flow from surface water (i.e., all mixed systems are considered surface water systems). Based on an analysis in the Geometries and Characteristics of Water Systems Report (USEPA 2000a), it is estimated that 21 percent of systems classified as surface water obtain some of their water from ground water sources. Furthermore approximately one-third of these, or 8 percent of all surface water systems in SDWIS and the Baseline Handbook, receive the majority of their flow from ground water. The 1995 CWSS data are classified by primary source (i.e., if a system receives more than 50 percent of its flow from ground water sources, it is considered a ground water system).

Population Served

Small systems are those serving fewer than 10,000 people. Systems are categorized in SDWIS and the Baseline Handbook by retail population served (i.e., not including population of wholesale customers). In the analyses that follow, nine size categories are most often used. System size is especially important because smaller systems are expected to take different approaches to meet rule provisions than large systems. Additionally, smaller systems are not able to achieve the same economies of scale as larger systems for a given treatment technology. To account for these differences, both the compliance decision tree and the unit costs for selected technologies use assumptions that are dependent on system size.

Ownership

Systems are categorized in SDWIS and in the Baseline Handbook according to three ownership types: "private," "public," and "other." Private systems are owned by private corporations or individuals. Public systems are owned by public entities such as municipalities, counties, or special districts. The "other" category contains systems where ownership is not reported in SDWIS. Ownership distinctions are important to the analysis because public systems have access to capital and other means of financing that may not be available to private systems. This distinction becomes important in calculating household costs (see Chapter 6) and in assessing the Unfunded Mandates Reform Act (UMRA) requirements (see Chapter 7).

Consecutive and Wholesale System Types

Systems are categorized according to whether they treat water themselves or purchase treated water from other systems. The GWR defines a consecutive system as a PWS that buys or otherwise receives some or all of its finished water from one or more wholesale systems for at least 60 days per year. A wholesale system is defined as a PWS that treats and then sells or otherwise delivers finished water to another PWS at least 60 days per year. Treatment modifications are generally not made by consecutive water systems, but are instead made by the associated wholesale systems. Costs of these treatment modifications are typically passed on to the consecutive systems in the form of water rate increases.

4.2.3 Baseline Number of Systems, Entry Points, and Population

The GWR applies to all PWSs, regardless of their size, that use ground water as a source. Further, because a person may need only ingest a small number of certain microbial pathogens (e.g., *Shigella*, enterovirus, rotavirus, norovirus) to become ill, this EA also considers the impact across all types of ground water systems, including those noncommunity systems that provide drinking water only part of the time or to a transient population. This section estimates the baseline number of systems, the number of entry points, and, the size of the population subject to the GWR. These will be used to estimate costs and benefits of the rule later in this EA.

Number of Systems

Estimates of the number of ground water PWSs subject to the GWR are presented in Exhibit 4.1. Most of these use ground water as their only source and reflect the SDWIS ground water system inventory. In addition to the systems served solely by ground water, PWSs served by multiple sources (i.e., those using both ground and surface water) may be subject to rule requirements. Entry points delivering only ground water are often present in PWSs that are classified as surface water systems in accordance with the SDWIS classification scheme (i.e., SDWIS classifies a system as surface water if any portion of its source water comes from a surface source). These "mixed water" systems, and associated ground water entry points and individuals served by them, would be excluded from the ground water system baseline if only the SDWIS ground water inventory were used, resulting in a potential underestimate of rule costs and benefits. To account for ground water entry points in mixed systems, EPA derived an inventory of "primarily ground water" mixed systems that is added to the ground water-only system inventory.

To derive the primarily ground water mixed system inventory, EPA identified surface water CWSs that use primarily (more than 50 percent) ground water based on CWSS data, as presented in Geometries and Characteristics of Public Water Systems (USEPA 2000a). NCWSs were not included in the mixed system analysis due to lack of data on the existence of multiple sources within such systems. Because NTNCWSs and TNCWSs are typically a single building or located in a small area, a simplifying assumption was made for this analysis that all NCWSs draw from a single source. The primarily ground water mixed CWSs identified by this calculation (862 systems, as shown in Exhibit 4.1, column P) were added to the ground water inventory to produce the baseline number of ground water systems used in this EA (Exhibit 4.1, columns Q through U).

The resulting baseline number of ground water systems are all treated as ground water-only systems throughout subsequent analyses. This methodology, treating mixed systems as ground water-only systems, may overestimate costs and benefits (i.e., some surface water entry points are now counted as ground water entry points). However, the ground water entry points in the excluded mixed surface water inventory (those mixed systems using less than 50 percent ground water) are not included in the analysis, potentially underestimating costs and benefits. The contrasting over- and under-accounting for ground water entry points are expected to offset one another in the cost and benefit analyses. Data are not available to quantify the direction or magnitude of the final effect on overall national cost estimates, but the effect is expected to be minimal.

In addition to the baseline number of systems presented in Exhibit 4.1, the national cost model requires system-by-system data. For ground water-only systems, systems and their associated attributes are taken directly from SDWIS. System identity data (e.g., PWS Identification (ID) and address) are not included in the attributes because the data are used for national level analysis and are not meant for analysis of specific systems. To derive the system-by-system data for primarily ground water mixed systems, a representative sample of systems was selected from the SDWIS surface water inventory. This was done as follows:

- For each surface water system size category, all of the SDWIS systems were placed in ascending order by population served.

- Within this ordered system list, systems were selected at equal intervals based on the overall number of primarily ground water mixed systems. For example, the SDWIS surface water inventory includes a total of 1,163 systems serving 100 or fewer people. Based on CWSS data, as presented in Geometries and Characteristics of Public Water Systems (USEPA 2000a), 3.7 percent of these systems (43 systems) are primarily ground water mixed systems. To select a representative sample of systems from the SDWIS inventory for this size category, every 27th system (1,163/43) was selected from the SDWIS surface water system list (ordered by population served) and assigned, along with its attributes (minus system identity data), to the primarily ground water mixed system data set.

Selection in this manner ensures that the systems chosen represent the full range of population served within any given size category. The resulting system data were added to the SDWIS ground water data for use in the cost model.

Exhibit 4.1 Ground Water Rule System Baseline *(continued on next page)*

System Size (population served)	Number of Ground Water Only Systems					Number of Surface Water Systems				
	Public		Private			Public		Private		
	Purchased Systems	Non-Purchased Systems	Purchased Systems	Non-Purchased Systems	Total Ground Water Only Systems	Purchased Systems	Non-Purchased Systems	Purchased Systems	Non-Purchased Systems	Total Surface Water Systems
	A	B	C	D	E	F	G	H	I	J
CWSs										
≤100	174	1,402	120	11,104	12,800	459	220	324	160	1,163
101-500	604	4,284	252	9,022	14,162	848	357	607	226	2,038
501-1,000	324	2,735	92	1,498	4,649	629	274	367	76	1,346
1,001-3,300	325	4,135	81	1,224	5,765	1,169	864	301	128	2,462
3,301-10,000	114	2,105	18	408	2,645	868	910	137	77	1,992
10,001-50,000	33	1,032	6	201	1,272	708	823	92	98	1,721
50,001-100,000	1	110	-	27	138	111	172	17	31	331
100,001-1 Million	1	52	-	12	65	58	180	9	24	271
> 1 Million	-	3	-	-	3	-	13	-	3	16
National Total	1,576	15,858	569	23,496	41,499	4,850	3,813	1,854	823	11,340
NTNCWSs										
≤100	11	1,913	13	7,519	9,456					
101-500	18	3,076	14	3,650	6,758					
501-1,000	7	1,162	3	722	1,894					
1,001-3,300	8	374	1	332	715					
3,301-10,000	4	28	1	40	73					
10,001-50,000	3	5	-	2	10					
50,001-100,000	-	1	-	-	1					
100,001-1 Million	-	-	-	1	1					
> 1 Million	-	-	-	-	-					
National Total	51	6,559	32	12,266	18,908					
TNCWSs										
≤100	71	51,730	521	12,126	64,448					
101-500	33	3,773	45	15,142	18,993					
501-1,000	18	622	9	1,291	1,940					
1,001-3,300	9	268	5	303	585					
3,301-10,000	1	41	2	30	74					
10,001-50,000	1	9	1	8	19					
50,001-100,000	1	-	-	-	1					
100,001-1 Million	-	1	-	-	1					
> 1 Million	-	-	-	-	-					
National Total	134	56,444	583	28,900	86,061					
Grand Total	1,761	78,861	1,184	64,662	146,468	4,850	3,813	1,854	823	11,340

Exhibit 4.1 Ground Water Rule System Baseline *(continued)*

System Size (population served)	Percentage of SW that is Primarily (>50%) GW	Number of Primarily Ground Water Systems					Ground Water System Baseline				
		Public		Private		Total Primarily Ground Water Systems	Public		Private		Total Number of Ground Water Systems
		Purchased Systems	Non-Purchased Systems	Purchased Systems	Non-Purchased Systems		Purchased Systems	Non-Purchased Systems	Purchased Systems	Non-Purchased Systems	
	K	L=F*K	M=G*K	N=H*K	O=I*K	P=J*K	Q=A+L	R=B+M	S=C+N	T=D+O	U=E+P
CWSs											
≤100	3.7%	17	8	12	6	43	191	1,410	132	11,110	12,843
101-500	9.6%	81	34	58	22	196	685	4,318	310	9,044	14,358
501-1,000	0.0%	-	-	-	-	-	324	2,735	92	1,498	4,649
1,001-3,300	5.9%	69	51	18	8	145	394	4,186	99	1,232	5,910
3,301-10,000	12.0%	104	109	16	9	239	218	2,214	34	417	2,884
10,001-50,000	10.0%	71	82	9	10	172	104	1,114	15	211	1,444
50,001-100,000	8.9%	10	15	2	3	29	11	125	2	30	167
100,001-1 Million	14.0%	8	25	1	3	38	9	77	1	15	103
> 1 Million	0.0%	-	-	-	-	-	-	3	-	-	3
National Total		360	325	116	60	862	1,936	16,183	685	23,556	42,361
NTNCWSs											
≤100							11	1,913	13	7,519	9,456
101-500							18	3,076	14	3,650	6,758
501-1,000							7	1,162	3	722	1,894
1,001-3,300							8	374	1	332	715
3,301-10,000							4	28	1	40	73
10,001-50,000							3	5	-	2	10
50,001-100,000							-	1	-	-	1
100,001-1 Million							-	-	-	1	1
> 1 Million							-	-	-	-	-
National Total							51	6,559	32	12,266	18,908
TNCWSs											
≤100							71	51,730	521	12,126	64,448
101-500							33	3,773	45	15,142	18,993
501-1,000							18	622	9	1,291	1,940
1,001-3,300							9	268	5	303	585
3,301-10,000							1	41	2	30	74
10,001-50,000							1	9	1	8	19
50,001-100,000							1	-	-	-	1
100,001-1 Million							-	1	-	-	1
> 1 Million							-	-	-	-	-
National Total							134	56,444	583	28,900	86,061
Grand Total	-	360	325	116	60	862	2,121	79,186	1,300	64,722	147,330

Notes: Surface water systems include mixed systems. Detail may not add to totals due to independent rounding.
Sources: (A-J) Ground water system inventories for CWSs, NTNCWSs, and TNCWSs: SDWIS (USEPA, 2003a).
(F-J) Surface water system inventory for CWSs: SDWIS (USEPA, 2003a).
(K) Percent of surface water CWSs served by more than 50% ground water from Geometries and Characteristics of Public Water Systems (USEPA 2000a), Exhibit 2.9.

Number of Disinfecting Systems

The system inventory presented in Exhibit 4.1 represents the baseline for rule activities that are applicable to PWSs on a system level (i.e., rule implementation and performance of sanitary surveys), regardless of any other factors. The applicability of other rule requirements (i.e., triggered source water monitoring and compliance monitoring) are dependent upon whether a system (or entry point) achieves 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer. Exhibit 4.2 shows the system baseline stratified according to disinfecting and nondisinfecting systems.

Exhibit 4.2 Ground Water Rule System Baseline: Disinfecting[1] and Nondisinfecting Systems

System Size (population served)	Percentage[2] of Systems Disinfecting	Number of Disinfecting Ground Water Systems					Number of Nondisinfecting Ground Water Systems				
		Public		Private			Public		Private		
		Purchased Systems	Non-Purchased Systems	Purchased Systems	Non-Purchased Systems	Total	Purchased Systems	Non-Purchased Systems	Purchased Systems	Non-Purchased Systems	Total
	A	B=Sys*A	C=Sys*A	D=Sys*A	E=Sys*A	F=Sys*A	G=Sys*(1-A)	H=Sys*(1-A)	I=Sys*(1-A)	J=Sys*(1-A)	K=Sys*(1-A)
CWSs											
≤100	52.8%	101	745	70	5,866	6,781	90	666	62	5,244	6,062
101-500	77.9%	534	3,364	242	7,045	11,185	151	954	69	1,999	3,173
501-1,000	84.0%	272	2,297	77	1,258	3,905	52	438	15	240	744
1,001-3,300	79.7%	314	3,336	79	982	4,710	80	850	20	250	1,200
3,301-10,000	86.8%	189	1,922	30	362	2,503	29	292	5	55	381
10,001-50,000	96.5%	100	1,075	15	203	1,394	4	39	1	7	51
50,001-100,000	86.3%	9	108	1	26	145	1	17	0	4	23
100,001-1 Million	96.4%	9	74	1	15	99	0	3	0	1	4
> 1 Million	100.0%	-	3	-	-	3	-	-	-	-	-
National Totals		1,529	12,925	514	15,757	30,725	408	3,258	171	7,799	11,636
NTNCWSs											
≤100	29%	3	555	4	2,181	2,742	8	1,358	9	5,338	6,714
101-500	29%	5	892	4	1,059	1,960	13	2,184	10	2,592	4,798
501-1,000	29%	2	337	1	209	549	5	825	2	513	1,345
1,001-3,300	29%	2	108	0	96	207	6	266	1	236	508
3,301-10,000	29%	1	8	0	12	21	3	20	1	28	52
10,001-50,000	29%	1	1	-	1	3	2	4	-	1	7
50,001-100,000	29%	-	0	-	-	0	-	1	-	-	1
100,001-1 Million	29%	-	-	-	0	0	-	-	-	1	1
> 1 Million	29%	-	-	-	-	-	-	-	-	-	-
National Totals		15	1,902	9	3,557	5,483	36	4,657	23	8,709	13,425
TNCWSs											
≤100	18%	13	9,311	94	2,183	11,601	58	42,419	427	9,943	52,847
101-500	18%	6	679	8	2,726	3,419	27	3,094	37	12,416	15,574
501-1,000	18%	3	112	2	232	349	15	510	7	1,059	1,591
1,001-3,300	18%	2	48	1	55	105	7	220	4	248	480
3,301-10,000	18%	0	7	0	5	13	1	34	2	25	61
10,001-50,000	18%	0	2	0	1	3	1	7	1	7	16
50,001-100,000	18%	0	-	-	-	0	1	-	-	-	1
100,001-1 Million	18%	-	0	-	-	0	-	1	-	-	1
> 1 Million	18%	-	-	-	-	-	-	-	-	-	-
National Totals		24	10,160	105	5,202	15,491	110	46,284	478	23,698	70,570
Grand Totals		1,568	24,987	629	24,516	51,699	554	54,199	672	40,206	95,631

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

Footnotes: 1) "Disinfection" refers to primary disinfection that is intended for microbial inactivation; 2) Percentages shown are weighted for item-level nonresponse, as indicated in Table 6.1 of "Geometries and Characteristics of Water Systems Report" (Model Systems Report) (USEPA, 2000a)."

Sources:(A) CWS percent disinfecting from Third Edition of the Baseline Handbook, Table B1.3.3, except for systems serving >1 million people. The three ground water systems serving >1 million people all perform disinfection. NTNCWS and TNCWS percent disinfecting derived from Ground Water Disinfection Practices in the United States (USEPA 1996b).

(B-K) Sys = System inventory from Exhibit 4.1, columns Q-U.

Number of Entry Points

The GWR benefits and cost models use entry points as a metric for exposure potential and for estimating the number of points of treatment and monitoring in response to GWR requirements. Ground water systems can consist of one entry point supplying all water to the population, or multiple entry points treating water, possibly from different sources.

As with the system baseline, the GWR requirements at the entry point level also depend on whether disinfection is applied. In order to estimate baseline disinfection rates, EPA analyzed data from a survey of disinfection practices in CWSs serving fewer than 10,000 people (AWWA, 1998). In this analysis, EPA used the data on the number of systems that apply disinfection prior to entry to the distribution system, the flow rates, the volume of the distribution system prior to the first customer, and the contact time (CT) value required for inactivation of Hepatitis A virus (HAV) at a temperature of 15 degrees C, and a pH of 6-9. EPA assumed that those systems providing insufficient information for the CT calculation in the AWWA survey are not currently achieving 4-log virus inactivation. Where additional assumptions were necessary, they were made to not overestimate the amount of 4-log treatment in place (e.g., maximum flow rate), and any treatment provided prior to distribution was not accounted for. Based on the evaluation, EPA found that 52 percent of small community ground water systems applying disinfection met 4-log inactivation of viruses prior to the first customer. The number was also applied to community ground water systems serving 10,000 or more people.

Because the AWWA survey did not have any data on NCWSs, EPA used best professional judgement to estimate the percent of NCWSs that achieved 4-log inactivation of viruses before the first customer. Because of their small size and usually simple design as well as the transient nature of the populations they serve, TNCWSs are believed to be the least likely systems to achieve 4-log inactivation. Based on this characterization, EPA estimates that only 10 percent of TNCWSs that apply disinfection (see Exhibit 4.3) achieve 4-log inactivation of viruses before the first customer. Many NTNCWSs are relatively simple systems that share many characteristics with TNCWSs. However, many also share characteristics more like CWSs (e.g., systems serving large institutions). Because of this dichotomy, EPA estimated that the percentage of NTNCWSs that apply disinfection that are achieving 4-log inactivation of viruses before the first customer falls between the percentages used for CWSs and TNCWSs, or 31 percent. Exhibit 4.3 shows the entry point baseline used for GWR analyses.

Population

System population characteristics are important to this analysis for several reasons. It is important to know the total population served by ground water systems as well as the average population served by each entry point so that the distribution of costs and benefits of the GWR can be assessed. Exhibit 4.4 presents the system-level population baseline and Exhibit 4.5 presents the entry point-level baseline.

As presented in Exhibit 4.4, ground water CWSs serve over 100 million people, while ground water NCWSs serve about 14 million people. Overlaps do occur because individuals may be served by both types of systems. For example, a person may be served by a surface water CWS at home and by a ground water NCWS at work or at a restaurant. It should be noted that there does not appear to be a consistent reporting standard for populations served by transient systems. In addition, some States may report the total population served by a system over a year, while others may report the average population served each day.

Exhibit 4.3 Ground Water Rule Entry Point Baseline (*continued on next page)*

System Size (population served)	Entry Points per System	Percentage of Entry Points Disinfecting	Percentage of Disinfecting Entry Points Achieving 4-Log	Number of Ground Water Entry Points Disinfecting to 4-Log					Number of Ground Water Entry Points Not Disinfecting or Disinfecting to <4-Log				
				Public		Private			Public		Private		
				Purchased Entry Points	Non-Purchased Entry Points	Purchased Entry Points	Non-Purchased Entry Points	Total	Purchased Entry Points	Non-Purchased Entry Points	Purchased Entry Points	Non-Purchased Entry Points	Total
	A	**B**	**C**	**D=Sys*A*B*C**	**E=Sys*A*B*C**	**F=Sys*A*B*C**	**G=Sys*A*B*C**	**H=Sys*A*B*C**	**I=Sys* A*(1-B*C)**	**J=Sys* A*(1-B*C)**	**K=Sys* A*(1-B*C)**	**L=Sys* A*(1-B*C)**	**M=Sys* A*(1-B*C)**
CWSs													
≤100	1.3	45.6%	52.0%	59	439	41	3,457	3,996	191	1,412	132	11,122	12,857
101-500	1.6	72.9%	52.0%	424	2,669	192	5,589	8,873	694	4,371	314	9,155	14,534
501-1,000	2.0	75.1%	52.0%	247	2,087	70	1,143	3,547	386	3,257	110	1,784	5,536
1,001-3,300	2.4	72.1%	52.0%	358	3,809	90	1,121	5,378	598	6,350	150	1,868	8,966
3,301-10,000	3.2	73.5%	52.0%	268	2,723	42	513	3,547	434	4,402	68	829	5,734
10,001-50,000	5.6	91.4%	52.0%	277	2,975	41	563	3,856	306	3,285	45	621	4,257
50,001-100,000	11.3	59.3%	52.0%	38	436	5	104	583	85	979	12	232	1,308
100,001-1 Million	12.4	82.2%	52.0%	48	409	7	81	545	65	548	9	109	730
> 1 Million	11.4	100.0%	100.0%	-	34	-	-	34	-	-	-	-	-
National Totals				1,720	15,581	488	12,570	30,359	2,758	24,603	840	25,721	53,921
NTNCWSs													
≤100	1.0	29%	31%	1	172	1	676	850	10	1,741	12	6,843	8,606
101-500	1.0	29%	31%	2	277	1	328	608	16	2,799	13	3,322	6,150
501-1,000	1.0	29%	31%	1	104	0	65	170	6	1,058	3	657	1,724
1,001-3,300	1.0	29%	31%	1	34	0	30	64	7	340	1	302	651
3,301-10,000	1.0	29%	31%	0	3	0	4	7	4	25	1	36	66
10,001-50,000	1.0	29%	31%	0	0	-	0	1	3	5	-	2	9
50,001-100,000	1.0	29%	31%	-	0	-	-	0	-	1	-	-	1
100,001-1 Million	1.0	29%	31%	-	-	-	0	0	-	-	-	1	1
> 1 Million	1.0	29%	31%	-	-	-	-	-	-	-	-	-	-
National Totals				5	590	3	1,103	1,700	46	5,969	29	11,163	17,208
TNCWSs													
≤100	1.0	18%	10%	1	931	9	218	1,160	70	50,799	512	11,908	63,288
101-500	1.0	18%	10%	1	68	1	273	342	32	3,705	44	14,869	18,651
501-1,000	1.0	18%	10%	0	11	0	23	35	18	611	9	1,268	1,905
1,001-3,300	1.0	18%	10%	0	5	0	5	11	9	263	5	298	574
3,301-10,000	1.0	18%	10%	0	1	0	1	1	1	40	2	29	73
10,001-50,000	1.0	18%	10%	0	0	0	0	0	1	9	1	8	19
50,001-100,000	1.0	18%	10%	0	-	-	-	0	1	-	-	-	1
100,001-1 Million	1.0	18%	10%	-	0	-	-	0	-	1	-	-	1
> 1 Million	1.0	18%	10%	-	-	-	-	-	-	-	-	-	-
National Totals				2	1,016	10	520	1,549	132	55,428	573	28,380	84,512
Grand Totals				1,727	17,186	501	14,193	33,608	2,936	86,000	1,441	65,264	155,641

Exhibit 4.3 Ground Water Rule Entry Point Baseline *(continued)*

Number of Ground Water Entry Points Not Disinfecting					Number of Ground Water Entry Points Disinfecting to <4-Log				
Public		Private			Public		Private		
Purchased Entry Points	Non-Purchased Entry Points	Purchased Entry Points	Non-Purchased Entry Points	Total	Purchased Entry Points	Non-Purchased Entry Points	Purchased Entry Points	Non-Purchased Entry Points	Total
N=Sys* A*(1-B)	**O=Sys* A*(1-B)**	**P=Sys* A*(1-B)**	**Q=Sys* A*(1-B)**	**R=Sys* A*(1-B)**	**S=I-N**	**T=J-O**	**U=K-P**	**V=L-Q**	**W=M-R**
136	1,007	94	7,931	9,168	55	405	38	3,191	3,689
303	1,908	137	3,996	6,343	391	2,463	177	5,159	8,191
158	1,331	45	729	2,262	228	1,926	65	1,055	3,274
267	2,834	67	834	4,002	331	3,516	83	1,034	4,964
186	1,888	29	356	2,459	248	2,514	39	474	3,274
50	538	7	102	698	256	2,746	37	520	3,559
50	576	7	137	770	35	403	5	96	538
20	170	3	34	227	45	377	6	75	503
-	-	-	-	-	-	-	-	-	-
1,170	10,252	389	14,117	25,929	1,588	14,351	450	11,604	27,992
8	1,358	9	5,338	6,714	2	383	3	1,505	1,892
13	2,184	10	2,592	4,798	4	616	3	730	1,352
5	825	2	513	1,345	1	233	1	144	379
6	266	1	236	508	2	75	0	66	143
3	20	1	28	52	1	6	0	8	15
2	4	-	1	7	1	1	-	0	2
-	1	-	-	1	-	0	-	-	0
-	-	-	1	1	-	-	-	0	0
-	-	-	-	-	-	-	-	-	-
36	4,657	23	8,709	13,425	10	1,312	6	2,454	3,783
58	42,419	427	9,943	52,847	12	8,380	84	1,964	10,441
27	3,094	37	12,416	15,574	5	611	7	2,453	3,077
15	510	7	1,059	1,591	3	101	1	209	314
7	220	4	248	480	1	43	1	49	95
1	34	2	25	61	0	7	0	5	12
1	7	1	7	16	0	1	0	1	3
1	-	-	-	1	0	-	-	-	0
-	1	-	-	1	-	0	-	-	0
-	-	-	-	-	-	-	-	-	-
110	46,284	478	23,698	70,570	22	9,144	94	4,682	13,942
1,316	61,193	890	46,524	109,923	1,620	24,807	551	18,740	45,718

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

Sources: (A) CWS entry points derived from Question 18 and 20 of the 1995 CWSS. NTNCWS and TNCWS entry points to system ratio assumed to be 1:1 because these systems are most often housed in a single building or small area.

(B) CWS percent disinfecting from Third Edition of the Baseline Handbook, Table B1.3.5, except for systems serving >1 million people. Ground water systems serving >1 million people (3) all perform disinfection. NTNCWS and TNCWS percent disinfecting derived from Ground Water Disinfection Practices in the United States (USEPA 1996b).

(C) Percentage of disinfecting entry points achieving 4 log derived from AWWA data (1998).

(D-R) Sys = System inventory from Exhibit 4.1, columns T-X.

Exhibit 4.4 Ground Water Rule System Population Baseline

System Size (population served)	Average Population per System	Disinfecting Systems Population					Nondisinfecting Systems Population					Total Population
		Public		Private			Public		Private			
		Purchased	Non-Purchased	Purchased	Non-Purchased	Total	Purchased	Non-Purchased	Purchased	Non-Purchased	Total	
	A	B=Sys*A	C=Sys*A	D=Sys*A	E=Sys*A	F=Sys*A	G=Sys*A	H=Sys*A	I=Sys*A	J=Sys*A	K=Sys*A	L=F+K
CWSs												
≤100	58	5,882	43,427	4,065	342,143	395,517	5,258	38,821	3,634	305,855	353,568	749,084
101-500	235	125,587	791,234	56,851	1,657,070	2,630,742	35,629	224,471	16,128	470,106	746,334	3,377,075
501-1,000	712	193,786	1,635,819	55,026	895,962	2,780,593	36,912	311,585	10,481	170,659	529,637	3,310,229
1,001-3,300	1,839	577,381	6,134,719	144,735	1,804,890	8,661,725	147,062	1,562,545	36,865	459,715	2,206,186	10,867,911
3,301-10,000	5,632	1,066,489	10,824,258	168,362	2,039,704	14,098,814	162,185	1,646,085	25,603	310,185	2,144,059	16,242,873
10,001-50,000	20,569	2,060,372	22,118,232	301,712	4,184,262	28,664,578	74,729	802,216	10,943	151,761	1,039,648	29,704,225
50,001-100,000	65,030	610,540	7,032,405	84,911	1,670,104	9,397,959	96,922	1,116,384	13,479	265,127	1,491,912	10,889,872
100,001-1 Million	207,247	1,822,052	15,423,507	251,731	3,068,718	20,566,008	68,043	575,982	9,401	114,599	768,025	21,334,033
> 1 Million	1,311,178	-	3,933,533	-	-	3,933,533	-	-	-	-	-	3,933,533
National Totals		6,462,088	67,937,134	1,067,392	15,662,854	91,129,468	626,739	6,278,088	126,535	2,248,008	9,279,369	100,408,836
NTNCWSs												
≤100	50	161	27,985	190	109,993	138,329	394	68,514	466	269,294	338,668	476,998
101-500	226	1,180	201,651	918	239,280	443,028	2,889	493,696	2,247	585,823	1,084,655	1,527,684
501-1,000	673	1,366	226,696	585	140,856	369,502	3,343	555,013	1,433	344,853	904,643	1,274,145
1,001-3,300	1,552	3,601	168,338	450	149,433	321,822	8,816	412,137	1,102	365,854	787,909	1,109,731
3,301-10,000	5,153	5,978	41,845	1,494	59,779	109,096	14,636	102,449	3,659	146,355	267,098	376,195
10,001-50,000	20,764	18,065	30,108	-	12,043	60,217	44,228	73,713	-	29,485	147,427	207,644
50,001-100,000	66,000	-	19,140	-	-	19,140	-	46,860	-	-	46,860	66,000
100,001-1 Million	110,000	-	-	-	31,900	31,900	-	-	-	78,100	78,100	110,000
> 1 Million	-	-	-	-	-	-	-	-	-	-	-	-
National Totals		30,350	715,762	3,638	743,285	1,493,035	74,306	1,752,383	8,906	1,819,766	3,655,361	5,148,396
TNCWSs												
≤100	38	488	355,608	3,582	83,358	443,036	2,223	1,619,993	16,316	379,742	2,018,274	2,461,310
101-500	177	1,051	120,171	1,433	482,276	604,932	4,788	547,445	6,529	2,197,036	2,755,799	3,360,731
501-1,000	641	2,076	71,722	1,038	148,864	223,700	9,455	326,736	4,728	678,160	1,019,079	1,242,779
1,001-3,300	1,416	2,294	68,320	1,275	77,242	149,130	10,452	311,234	5,807	351,880	679,372	828,502
3,301-10,000	5,017	903	37,029	1,806	27,094	66,832	4,114	168,687	8,229	123,429	304,459	371,291
10,001-50,000	15,770	2,839	25,547	2,839	22,709	53,933	12,931	116,382	12,931	103,451	245,696	299,629
50,001-100,000	51,850	9,333	-	-	-	9,333	42,517	-	-	-	42,517	51,850
100,001-1 Million	125,000	-	22,500	-	-	22,500	-	102,500	-	-	102,500	125,000
> 1 Million	-	-	-	-	-	-	-	-	-	-	-	-
National Totals		18,984	700,897	11,972	841,543	1,573,397	86,482	3,192,977	54,539	3,833,698	7,167,696	8,741,092
Grand Totals		6,511,422	69,353,793	1,083,002	17,247,682	94,195,899	787,526	11,223,447	189,980	7,901,471	20,102,425	114,298,324

Note: Figures are derived using unrounded source data. Detail may not add to totals due to independent rounding.

Sources: (A) Derived from SDWIS (USEPA, 2003a).
(B-K) Sys = System inventory from Exhibit 4.2, columns B-K.

Exhibit 4.5 Ground Water Rule Entry Point Population Baseline

(continued on next page)

System Size (population served)	Average Population per Entry Point	Population of Entry Points Disinfecting to 4-Log					Population of Entry Points Not Disinfecting or Disinfecting to <4-Log				
		Public		Private		Total Disinfecting to 4-log	Public		Private		Total not Disinfecting to 4-log
		Purchased	Non-Purchased	Purchased	Non-Purchased		Purchased	Non-Purchased	Purchased	Non-Purchased	
	A	**B=EP*A**	**C=EP*A**	**D=EP*A**	**E=EP*A**	**F=EP*A**	**G=EP*A**	**H=EP*A**	**I=EP*A**	**J=EP*A**	**K=EP*A**
CWSs											
≤100	44	2,641	19,503	1,825	153,653	177,623	8,498	62,745	5,873	494,345	571,461
101-500	144	61,114	385,033	27,665	806,370	1,280,182	100,102	630,671	45,314	1,320,806	2,096,894
501-1,000	364	90,092	760,500	25,582	416,537	1,292,711	140,606	1,186,903	39,925	650,084	2,017,519
1,001-3,300	758	271,608	2,885,858	68,086	849,046	4,074,597	452,834	4,811,406	113,515	1,415,559	6,793,314
3,301-10,000	1,750	469,599	4,766,165	74,134	898,128	6,208,026	759,075	7,704,178	119,832	1,451,762	10,034,847
10,001-50,000	3,662	1,014,771	10,893,630	148,598	2,060,825	14,117,824	1,120,330	12,026,817	164,056	2,275,198	15,586,401
50,001-100,000	5,758	218,153	2,512,761	30,340	596,748	3,358,001	489,309	5,636,028	68,051	1,338,483	7,531,871
100,001-1 Million	16,727	807,902	6,838,821	111,618	1,360,677	9,119,019	1,082,193	9,160,667	149,513	1,822,641	12,215,014
> 1 Million	115,450	-	3,933,533	-	-	3,933,533	-	-	-	-	-
National Totals		2,935,880	32,995,805	487,848	7,141,984	43,561,516	4,152,947	41,219,417	706,079	10,768,878	56,847,321
NTNCWSs											
≤100	50	50	8,675	59	34,098	42,882	505	87,824	597	345,190	434,116
101-500	226	366	62,512	285	74,177	137,339	3,703	632,835	2,880	750,926	1,390,345
501-1,000	673	423	70,276	181	43,665	114,546	4,286	711,433	1,837	442,044	1,159,599
1,001-3,300	1,552	1,116	52,185	140	46,324	99,765	11,300	528,290	1,413	468,963	1,009,966
3,301-10,000	5,153	1,853	12,972	463	18,531	33,820	18,760	131,322	4,690	187,603	342,375
10,001-50,000	20,764	5,600	9,334	-	3,733	18,667	56,693	94,488	-	37,795	188,976
50,001-100,000	66,000	-	5,933	-	-	5,933	-	60,067	-	-	60,067
100,001-1 Million	110,000	-	-	-	9,889	9,889	-	-	-	100,111	100,111
> 1 Million	-	-	-	-	-	-	-	-	-	-	-
National Totals		9,409	221,886	1,128	230,418	462,841	95,247	2,246,259	11,416	2,332,632	4,685,555
TNCWSs											
≤100	38	49	35,561	358	8,336	44,304	2,663	1,940,041	19,539	454,764	2,417,006
101-500	177	105	12,017	143	48,228	60,493	5,734	655,599	7,819	2,631,085	3,300,237
501-1,000	641	208	7,172	104	14,886	22,370	11,323	391,286	5,662	812,138	1,220,409
1,001-3,300	1,416	229	6,832	127	7,724	14,913	12,517	372,721	6,954	421,398	813,589
3,301-10,000	5,017	90	3,703	181	2,709	6,683	4,927	202,013	9,854	147,814	364,608
10,001-50,000	15,770	284	2,555	284	2,271	5,393	15,486	139,375	15,486	123,889	294,236
50,001-100,000	51,850	933	-	-	-	933	50,917	-	-	-	50,917
100,001-1 Million	125,000	-	2,250	-	-	2,250	-	122,750	-	-	122,750
> 1 Million	-	-	-	-	-	-	-	-	-	-	-
National Totals		1,898	70,090	1,197	84,154	157,340	103,567	3,823,784	65,314	4,591,087	8,583,753
Grand Totals		2,947,187	33,287,781	490,172	7,456,556	44,181,696	4,351,761	47,289,460	782,810	17,692,597	70,116,628

Exhibit 4.5 Ground Water Rule Entry Point Population Baseline
(continued)

Population of Entry Points Not Disinfecting					Population of Entry Points Disinfecting to <4-Log				
Public		Private			Public		Private		
Purchased	Non-Purchased	Purchased	Non-Purchased	Total Not Disinfecting	Purchased	Non-Purchased	Purchased	Non-Purchased	Total Disinfecting to <4-log
L=EP*A	**M=EP*A**	**N=EP*A**	**O=EP*A**	**P=EP*A**	**Q=EP*A**	**R=EP*A**	**S=EP*A**	**T=EP*A**	**U=EP*A**
6,060	44,743	4,188	352,511	407,502	2,438	18,002	1,685	141,834	163,960
43,689	275,256	19,777	576,465	915,187	56,413	355,415	25,537	744,341	1,181,706
57,444	484,903	16,311	265,589	824,247	83,162	702,000	23,614	384,496	1,193,271
202,119	2,147,537	50,666	631,825	3,032,147	250,715	2,663,869	62,848	783,734	3,761,167
325,599	3,304,641	51,401	622,721	4,304,361	433,476	4,399,537	68,431	829,041	5,730,486
183,619	1,971,158	26,888	372,898	2,554,563	936,711	10,055,659	137,168	1,902,300	13,031,838
287,937	3,316,557	40,045	787,639	4,432,178	201,372	2,319,471	28,006	550,844	3,099,693
336,437	2,847,909	46,481	566,631	3,797,458	745,756	6,312,758	103,032	1,256,010	8,417,556
-	-	-	-	-	-	-	-	-	-
1,442,904	14,392,704	255,758	4,176,277	20,267,644	2,710,043	26,826,712	450,321	6,592,600	36,579,676
394	68,514	466	269,294	338,668	111	19,309	131	75,896	95,447
2,889	493,696	2,247	585,823	1,084,655	814	139,139	633	165,103	305,689
3,343	555,013	1,433	344,853	904,643	942	156,420	404	97,190	254,956
8,816	412,137	1,102	365,854	787,909	2,485	116,153	311	103,109	222,057
14,636	102,449	3,659	146,355	267,098	4,125	28,873	1,031	41,247	75,277
44,228	73,713	-	29,485	147,427	12,465	20,775	-	8,310	41,549
-	46,860	-	-	46,860	-	13,207	-	-	13,207
-	-	-	78,100	78,100	-	-	-	22,011	22,011
-	-	-	-	-	-	-	-	-	-
74,306	1,752,383	8,906	1,819,766	3,655,361	20,942	493,876	2,510	512,866	1,030,194
2,223	1,619,993	16,316	379,742	2,018,274	439	320,047	3,223	75,022	398,732
4,788	547,445	6,529	2,197,036	2,755,799	946	108,154	1,290	434,049	544,438
9,455	326,736	4,728	678,160	1,019,079	1,868	64,550	934	133,978	201,330
10,452	311,234	5,807	351,880	679,372	2,065	61,488	1,147	69,518	134,217
4,114	168,687	8,229	123,429	304,459	813	33,326	1,626	24,385	60,149
12,931	116,382	12,931	103,451	245,696	2,555	22,993	2,555	20,438	48,540
42,517	-	-	-	42,517	8,400	-	-	-	8,400
-	102,500	-	-	102,500	-	20,250	-	-	20,250
-	-	-	-	-	-	-	-	-	-
86,482	3,192,977	54,539	3,833,698	7,167,696	17,085	630,808	10,775	757,389	1,416,057
1,603,691	19,338,064	319,204	9,829,741	31,090,701	2,748,070	27,951,396	463,606	7,862,856	39,025,927

Note: Figures are derived using unrounded source data. Detail may not add to totals due to independent rounding.
Sources: (A) Average population per system from Exhibit 4.4, column A divided by entry points per system from Exhibit 4.3, column A.

(B-U) EP = Entry points per system from Exhibit 4.3, columns D-Y.

Uncertainty in Baseline Input Data

Although EPA recognizes that there is uncertainty related to the various data sources used to define the system inventory for the GWR, the uncertainty in the system inventory data inputs is not quantified in this EA. However, a qualitative discussion of the identified uncertainties follows below.

As noted above, SDWIS and the 1995 CWSS are the sources of system inventory data. SDWIS is EPA's primary drinking water database, containing data for over 170,000 PWSs. SDWIS stores State-reported information on each water system, including name, ID number, population served, type of system, and source of water (ground water or surface water), along with monitoring and violation information. In 1998, EPA began a major effort to assess the quality of its drinking water data in SDWIS. The results of this effort, published in the report *Data Reliability Analysis of the EPA SDWIS/FED*, found that the data quality of the required inventory data was high (USEPA 2000b). Thus, EPA believes that uncertainty in the system inventory data from SDWIS with respect to numbers of systems, source information, and size classification is low.

The 1995 CWSS was developed to gather data on water systems in the United States. A total of 3,681 systems covering a range of source water types and system sizes were selected statistically to receive the main survey questionnaire. Of these, 1,980 systems responded. These responses were given a weighting factor to maintain statistical representation of the total universe of CWSs. This weighting factor was used in all evaluations of data. The EPA report, "Community Water System Survey" (USEPA 1997a) provides information on the 1995 CWSS survey design and data evaluation.

The 1995 CWSS was the primary data source used to estimate percentage of ground water systems that disinfect, the number of entry points per system, and average and design flow based on population served. Because the CWSS is a statistical sample, estimates based on the data will contain uncertainty because of sampling and other errors. The resulting sampling error uncertainty in some of the CWSS estimates were characterized in the published report by confidence bounds (95 percent) on the means and proportions provided. While these confidence bounds were not directly used to quantify uncertainty in the CWSS data elements used in this EA, most of the 95 percent confidence intervals for CWSS data related to those used in this EA were with within +/- 10 percent of the best estimates provided.

4.2.4 Water Treatment Plant Design and Average Daily Flows

Treatment technology costs are based on the volume of water treated per day. The cost analysis described in Chapter 6 uses two types of treatment plant flow:

Design flow—the maximum capacity at which the plant was intended to operate, expressed in millions of gallons per day (mgd).

Average daily flow—the flow produced by a treatment plant in one day, averaged over 365 days, expressed in mgd.

Design flows are used to estimate the capital costs of the technology that will be installed to meet the requirements of the GWR. Average daily flows are used to estimate the annual cost of continuing operations and maintenance (O&M).

To derive flow information for different sized systems, EPA developed the following regression equations from the Baseline Handbook (USEPA 2001a) relating design and average daily flow (MGD) for ground water systems to population served (X), using data from the 1995 CWSS:

Design Flow (MGD) = $(0.39639*X^{0.97708})/1{,}000$

Average Daily Flow (MGD) = $(0.06428*X^{1.07652})/1{,}000$

The derivation of these equations is presented in detail in the Model Systems Report (USEPA, 2000a) and summarized in the Baseline Handbook (USEPA, 2001a). The equations are used in this EA to estimate mean flows per entry point for each size category, using the average population served per entry point. Exhibit 4.6 presents the average population per entry point and corresponding average daily and design flows.

Exhibit 4.6 Design Flows and Average Daily Flows per Plant (MGD)

System Size (population served)	Average Population Served per Entry Point	Design Flows (MGD) Per Entry Point	Average Daily Flow (MGD) Per Entry Point
	X	Y = 0.39639 X $^{0.97708}$ / 1,000	Y = 0.06428 X $^{1.07652}$ / 1,000
CWSs			
≤ 100	44	0.016	0.004
101-500	144	0.051	0.014
501-1,000	364	0.126	0.037
1,001-3,300	758	0.258	0.081
3,301-10,000	1,750	0.585	0.199
10,001-50,000	3,662	1.203	0.441
50,001-100,000	5,758	1.872	0.718
100,001-1 Million	16,727	5.306	2.263
> 1 Million	115,450	35.034	18.107
NTNCWSs			
≤ 100	50	0.02	0.00
101-500	226	0.08	0.02
501-1,000	673	0.23	0.07
1,001-3,300	1,552	0.52	0.18
3,301-10,000	5,153	1.68	0.64
10,001-50,000	20,764	6.55	2.86
50,001-100,000	66,000	20.29	9.92
100,001-1 Million	110,000	33.42	17.19
>1 Million	-	-	-
TNCWSs			
≤ 100	38	0.01	0.00
101-500	177	0.06	0.02
501-1,000	641	0.22	0.07
1,001-3,300	1,416	0.48	0.16
3,301-10,000	5,017	1.64	0.62
10,001-50,000	15,770	5.01	2.12
50,001-100,000	51,850	16.03	7.65
100,001-1 Million	125,000	37.86	19.72
>1 Million	-	-	-

Note: Flow rates are calculated from unrounded population data.

Source: Equations relating mean population to flow are from the Baseline Handbook (USEPA, 2001a).
Population per system (X) data are from Exhibit 4.5, column A.

This EA uses a single regression equation to estimate flows for both publicly and privately owned systems. There is, however, a slight difference in the flow characteristics for these two ownership types, as discussed in the Model Systems Report (USEPA, 2000a). The use of different flow equations for public and private systems would not affect total national costs, although per-household costs may be slightly affected. EPA has evaluated the equations and believes that the differences are small and would have a negligible effect on estimated household costs.

Comparable analyses relating average daily and design flow to population were not performed for the NCWSs. Other drinking water rules have evaluated flows for NCWSs according to service categories (e.g., schools, restaurants, hotels, and industry) instead of size. EPA considered using this method for evaluating NTNCWSs for the GWR, but decided against it for the following reasons:

- Service category flows are based on mean population served for all systems in that category, regardless of source water type. EPA expects that ground water sources would be less prevalent in larger NCWSs, but has no basis for developing revised population estimates for each service category by source.

- The prediction of technology selection in Chapter 6 is a function of population served and does not directly apply to service categories that may include a wide range of water system sizes and flows (e.g., schools can be very small local buildings or large metropolitan high schools).

EPA, therefore, applied the CWS regression equations to NCWSs, recognizing that this may over-estimate flows and, therefore, costs. This over-estimation is addressed as part of the uncertainties summarized in section 4.5. Mean plant flows for CWSs and NCWSs may differ from each other because of the difference in mean population per plant within each size category.

4.2.5 Treatment Practices Baseline

To properly estimate the cost of compliance with the GWR, the EA takes into account the percentage of systems presently employing certain types of disinfection. These percentages are used for determining what additional treatment technologies will be installed to comply with the rule. The GWR compliance forecast for treatment technology selection (see section 6.3.6.2) was developed based on the assumption that systems would install technologies in approximately the same proportions as the technologies that are currently employed. Exhibit 4.7 displays the percentage of systems using various treatment technologies. Because some systems perform no treatment and some may perform more than one type of treatment, percentages do not total to 100 percent of systems by system size.

4.2.6 Number of Households Served

Because CWS costs are often passed onto customers in the form of water rate increases, the GWR also conducts analyses to assess the impact of the rule provisions at a household level. The number of households served by CWSs expected to be subject to the GWR is estimated by dividing the population for each system size category by the average number of people per household (2.59, according to the 2000 U.S. Census) (U.S. Bureau of the Census, 2001a). As shown in Exhibit 4.8, CWSs serve almost 39 million households.

Exhibit 4.7 Disinfection Treatment Practices for Disinfecting Ground Water Systems

Treatment Type	Service Population Category (Population Served)							
	≤100	101-500	501-1,000	1,001-3,300	3,301-10,000	10,001-50,000	50,001-100,000	>100,000
Pre-Disinfection								
Chlorine	64.2%	69.9%	56.7%	73.2%	60.6%	57.4%	36.2%	38.1%
Chlorine dioxide	1.3%	0.0%	0.0%	0.0%	0.0%	0.0%	3.1%	0.0%
Chloramines	0.0%	0.0%	0.0%	0.0%	0.0%	0.6%	1.4%	0.7%
Ozone	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.6%
Pre-disinfection/ oxidation combinations	0.3%	0.5%	0.0%	0.7%	1.0%	2.6%	0.0%	0.0%
Filtration								
Reverse Osmosis	0.0%	0.7%	0.0%	0.6%	0.6%	0.2%	0.3%	0.0%
Post-Disinfection								
Chlorine/ Hypochlorination	23.0%	23.4%	32.5%	28.3%	42.5%	41.9%	54.5%	65.8%
Chlorine dioxide	0.0%	1.0%	0.0%	0.0%	0.0%	0.6%	0.0%	0.0%
Chloramines	0.0%	0.0%	0.0%	0.0%	0.1%	1.1%	3.9%	4.3%
Post-disinfection combinations	0.0%	0.0%	0.0%	0.0%	0.1%	0.1%	0.0%	0.0%

Notes: Represents treatment practices for plants treating water that comes entirely or partly from ground sources.
Percentages may not add to 100% because systems may perform more than one treatment.
Sources: Community Water System Survey (CWSS), 1997. Volume II, Table 1-23.

Exhibit 4.8 Ground Water Rule CWS Household Baseline

System Size (population served)	Number of Household Served by Disinfecting Systems					Number of Households Served by Non-Disinfecting Systems				
	Public		Private			Public		Private		
	Purchased	Non-Purchased	Purchased	Non-Purchased	Total	Purchased	Non-Purchased	Purchased	Non-Purchased	Total
<100	2,271	16,767	1,569	132,102	152,709	2,030	14,989	1,403	118,091	136,513
101-500	48,489	305,496	21,950	639,795	1,015,730	13,756	86,668	6,227	181,508	288,160
501-1,000	74,821	631,590	21,245	345,931	1,073,588	14,252	120,303	4,047	65,892	204,493
1,001-3,300	222,927	2,368,617	55,882	696,869	3,344,295	56,781	603,299	14,234	177,496	851,809
3,301-10,000	411,772	4,179,250	65,005	787,531	5,443,557	62,620	635,554	9,886	119,763	827,822
10,001-50,000	795,510	8,539,858	116,491	1,615,545	11,067,404	28,853	309,736	4,225	58,595	401,408
50,001-100,000	235,730	2,715,214	32,784	644,828	3,628,556	37,422	431,036	5,204	102,365	576,028
100,001-1 Million	703,495	5,955,022	97,193	1,184,833	7,940,544	26,272	222,387	3,630	44,247	296,535
> 1 Million	-	1,518,739	-	-	1,518,739	-	-	-	-	-
National Totals	2,495,015	26,230,554	412,121	6,047,434	35,185,123	241,984	2,423,972	48,855	867,957	3,582,768

Note: Detail may not add to totals due to independent rounding
Sources: System CWS population baseline (Exhibit 4.4) divided by 2.59 people per household (U.S. Bureau of the Census, 2001a).

4.2.7 Triggered Monitoring Baseline

The Ground Water Rule (GWR) requires specified systems to conduct triggered source water monitoring with every sample that tests positive for total coliform (TC) collected in accordance with the Total Coliform Rule (TCR) (40 CFR 141.21). An important variable used in the cost and benefits models is the number of a system's TCR samples that would test positive for total coliform each year. The

average varies by system type (CWS, NTNCWS, and TNCWS) and by system size (eight size categories). This is an important variable because indicator monitoring is "triggered" by positive total coliform (TC-positive) samples. Information from the Data Verification (DV) project were used as the primary inputs for modeling the occurrence of TC-positive samples, while data from other sources were used for weighting results. The following is a summary of the derivation of this baseline. More detailed discussion and calculations are presented in Appendix I.

Data Verification (DV)

The DV study involves the comparison of 1 year's worth of PWS records in SDWIS/Fed with State PWS records to identify any discrepancies between the two records. State files contain the water systems' reports on the numbers of total coliform samples taken to comply with the TCR and the numbers of TC-positive samples. Using these data, EPA derived national estimates of the percent of all TCR samples that test positive for total coliform, and the number of total coliform samples per year that test positive for all systems in the eight categories.

Description of Method

Several steps were taken to compile the data and weight them appropriately for each system type and size category.

1) Estimate the fraction of samples that are TC positive by type (CWS, NTNCWS, and TNCWS) and size of system (those serving at most 1,000 people, and those serving more than 1,000 people).

2) Estimate the number of routine TC samples taken by each system according to its type and size category. (Monitoring requirements under the TCR are related to system size.)

3) Multiply the fraction positive by the number of TC samples taken to estimate the number of TC samples that will test positive, per system and per year, for each of the three system types and eight system sizes.

Step 1: The raw annual fractions positive were computed for systems in the DV sample by dividing the total number of routine samples that tested positive for TC by the total number of TC samples that were taken for each type and size of system. The DV data includes information on systems' treatment processes, including disinfection steps. This is important, since triggered monitoring under the GWR applies only to systems that provide less than 4-log[2] virus inactivation, removal, or State-approved combination of these technologies. Thus, only systems listed as nondisinfecting in the DV database were used in this step. This is a large sample, comprising 1,252 system-years[3] of data and 18,467 TC samples

[2] X-log virus inactivation or removal means that only one of every 10^x viruses survives treatment in such a condition that it is capable of initiating infection in a human host. 10^{-x} is the fraction that is neither inactivated nor removed.

[3] System-years can be defined as the sum, across systems, of the number of years covered by their DV data. Almost every DV system produces 1 year of DV data, so system-years are approximately equal to the number of systems.

from 43 States[4] and is broadly representative of nondisinfecting ground water systems in the United States. Weights based on the number of samples taken were used to extrapolate these raw rates to the universe of nondisinfecting systems, as follows:

- The number of nondisinfecting systems was estimated by state, type, and size using two sources of data: a SDWIS inventory[5] for the number of ground water systems and a 1996 EPA study[6] for the percentages of systems by state that do not disinfect their ground water. The percentage of systems that do not disinfect was multiplied by number of systems and rounded to the nearest integer to estimate the total number of nondisinfecting systems in each state, size, and system type category.[7]

- The DV data provided values for: 1) the number of TC samples taken by each system according to state and size category and 2) the associated numbers of systems. The average number of samples taken per system was derived for each state and size category by dividing its number of TC samples by its number of systems in the DV dataset. The total national number of samples taken in a size category was then calculated by multiplying the average number of DV samples per system by the total number of systems of that size in the US.

- A weighted TC-positive rate was derived for each size category and type of system by multiplying its state-specific raw TC-positive rate by the appropriate weight (number of samples assayed by the state, within the relevant size category and type of system), summing the weighted TC-positive rates across states, and dividing by the sum of the weights.

- To improve consistency across size categories, the TC-positive data were combined into two size categories: those systems serving at most 1,000 people and those serving more than 1,000 people. The resulting approximate confidence intervals (using a 90 percent confidence level, about estimates of 0.5) were +/- 4 percent for systems serving at most 1,000 people. For systems serving more than 1,000 people, the confidence intervals were +/- 11 percent for CWS systems, +/- 29 percent for NTNCWS, and +/- 27 percent for TNCWS.

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[4] There are several reasons why states could not be included in the analysis. Four States, (Alaska, Colorado, Connecticut, and Illinois), the U.S. Territories and Regional DI programs are not included in this analysis because data on the percent of systems that do not disinfect are not available, even though DV data are available. Arkansas had no nondisinfecting systems in the DV sample. Two States, New York and North Dakota, could not be included because the data verification forms for these States could not be located. Texas requires disinfection by all ground water systems, but the DV project identified one wholesale system that took samples of source water before disinfection, and so the one Texas system was included. Data were not included from systems if the systems reported that no samples were taken, or if there was no information in SDWIS on whether disinfection was used.

[5] 2004, 4th Quarter

[6] USEPA, 1996b

[7] In a few cases, the rounding caused the estimated number of systems to drop below the number observed in the DV inventory, and so in these cases, the DV inventory number was used.

C Exhibit 4.9 shows that TC-positive rates varied by size and type of system from 0.71 percent to 6.36 percent. These values are a good representation of the TC-positive rates for systems in these size and type categories.

Exhibit 4.9 Total Coliform Positive Hit Rates

Type of System	Size of System (Population Served)	TC-positive Hit Rate (percentage of samples)
CWS	#1,000	2.72%
	>1,000	0.71%
NTNCWS	#1,000	2.98%
	>1,000	2.25%
TNCWS	#1,000	6.36%
	>1,000	3.53%

Source: Appendix I.

Step 2: This step estimates the average number of routine TC samples taken annually by each system, according to its size and type. The data set for this step was expanded to include disinfecting systems and includes 2,774 system-years of data and 94,307 TC samples from 44 states[8]. This expanded data set improves the estimate of the average number of samples taken. Systems were grouped according to their baseline monitoring requirements under the TCR, and the number of samples taken was weighted by the number of systems subject to triggered monitoring. The average number of samples per system was calculated by dividing the sum of the weighted number of samples by the number of systems subject to triggered monitoring. Exhibit 4.10 presents the results of this analysis, and Appendix I presents additional detail for the calculations used.

Step 3: EPA estimated the frequency of total coliform-positives per year per system by multiplying the number of TC samples per year (from Exhibit 4.10) by the probability of a TC-positive (from Exhibit 4.9). So, for example, the estimated number of TC-positive samples per system per year for CWSs serving less than 100 people is 0.0272 * 14 = 0.38; for TNCWs serving greater than 100,000 people it is 0.0353 * 1,496 = 52.8, Exhibit 4.11 shows these estimated frequencies for all system types and sizes.

[8] Arkansas was included because there were DV data for disinfecting systems.

Exhibit 4.10 Estimated Number of Routine Total Coliform Samples Taken Per System, Per Year, by Type and Size of System

System Type	Population Served	TCR Baseline Number of Routine Samples per System	Estimated Actual Number of Routine Samples per System
CWS	<100	12	14
	101-500	12	15
	500-1K	12	18
NTNCWS + TNCWS	<100	4	7
	101-500	4	8
	500-1K	4	9
CWS + NTNCWS + TNCWS	1011-3300	24	31
	3301-10K	84	82
	10,001-50K	360	311
	50,001-100K	960	924
	>100,001	2,520	1,496

Source: Appendix I.

Exhibit 4.11 Estimated Number of TC+ Samples Per System, Per Year, by System Size and System Type

System Type	System Size (Population Served)							
	<100	101-500	501-1K	1,001-3,300	3,301-10K	10,001-50K	50,001-100K	>100K
CWS	0.38	0.41	0.49	0.22	0.58	2.2	6.6	10.6
NTNCWS	0.22	0.23	0.28	0.70	1.8	7.0	20.8	33.7
TNCWS	0.47	0.48	0.60	1.1	2.9	11.0	32.6	52.8

Source: Derived from Exhibits 4.9 and 4.10.

The results of these analyses are used in both the benefits and cost models to estimate the number of indicator samples that systems will have to take to comply with the triggered monitoring provisions of the GWR. Further discussions of the application of these results are presented in Chapter 5 (section 5.2.5.5) for the benefits model and Chapter 6 (section 6.3.4) for the cost model.

4.3 Water Quality Baseline

This section provides an overview of baseline water quality data that are used in the GWR risk assessment model. It describes how existing historical, geological, and water quality (e.g., pathogen occurrence) data are used to characterize the baseline conditions for ground water systems. Next it describes how this information is used in a risk assessment model to estimate the baseline number of illnesses and deaths associated with ingesting pathogenic viruses (only) in public ground water systems. The standard framework is organized in accordance with EPA Policy for Risk Characterization (USEPA 1995a), EPA's Guidance for Risk Characterization (USEPA 1995b), EPA's Policy for Use of Probabilistic Analysis in Risk Assessment (USEPA 1997b), and with EPA's developing guidance for microbial risk assessment.

This standard framework requires the use of scientific data (or reasonable assumptions if data are not available) to produce estimates of the nature, extent, and degree of a risk. Where there is uncertainty in the data and assumptions used, that uncertainty is described and its impact on the risk estimates is characterized. Where feasible, variability and uncertainty are mathematically modeled. The EA accounts for different risk levels within the affected population (variability) and the confidence bounds on key parameters of the risk assessment model (uncertainty). Variability arises from true heterogeneity across people, places and time, and uncertainty represents the lack of knowledge of the true value of the factor being considered (USEPA 1997b).

According to the 1995 EPA Policy for Risk Characterization (USEPA 1995a), health risk assessments for environmental contaminants generally involve four components:

1. **Hazard Identification** addresses the nature of the potential adverse health effects associated with exposure to the contaminant.

2. **Exposure Assessment** addresses both the number of people in the population exposed to the contaminant and the distribution of levels of exposure within that population.

3. **Dose-Response Assessment** addresses information concerning the relationships, quantitatively where possible, between the magnitude of exposure to the contaminant and the extent and severity of the adverse health effects that may occur.

4. **Risk Characterization** combines the hazard identification, dose-response, and exposure assessment information to describe overall risk to the exposed population, both in terms of the distribution of risk levels in the population and the total number of cases of adverse effects anticipated.

The exposure assessment step includes evaluation of the probability of pathogen occurrence in wells and samples, pathogen concentrations in source water, disinfection treatment effectiveness, daily drinking water consumption, number of days of exposure, and size of the exposed population. Pathogen occurrence probabilities and concentration are of particular importance to the performance of the risk assessment. Pathogen occurrence probabilities include (a) the fraction of ground water sources that have some pathogen occurrence and (b) for sources with pathogens, the fraction of time that pathogens are

present and can be detected. Pathogen concentration is the amount of a given virus in that source when present. These parameters are used in conjunction to make the connection between an individual's consumption of drinking water and the possibility of contracting an illness as a result of that consumption. In terms of the risk assessment model, each contaminated well is assigned a probability that designates the fraction of time, that its source water has a detectable virus contamination. (At other times the water is assumed to be virus free.) This occurrence modeling is discussed in greater detail in the following sections. The use of the baseline data to support the GWR risk assessment benefits analysis, and a detailed description of the entire risk assessment methodology are presented in Chapter 5.

4.3.1 Background

Within the GWR risk assessment framework, two simplifying categorizations are made to simplify the analysis. The first categorization is the placement of human viral pathogens into two representative types for analysis (discussed in section 4.3.1.1). The second is the division of the universe of wells within the US into "more" and "less" vulnerable categories to best represent the available enterovirus concentration data (discussed in Section 4.3.3).

4.3.1.1 Representative Pathogens

Viruses

For purposes of conducting the GWR risk assessment, EPA has divided the universe of viruses into two groups, Type A and Type B. These two types of viruses cause illnesses of different severity and cause illness and death at different rates. A large number of viruses pathogenic to humans exist with varying levels of occurrence, infectivity, morbidity, severity, and mortality rates. However, few data are available on dose response relationship and occurrence in source water for most of these viral pathogens. EPA has based its risk estimates on two viruses for which dose response data are available. Ground water occurrence data are also available for some viral pathogens; however, only Type B occurrence data are available from multiple studies using standardized methods.

The Type A group represents viruses that have high infectivity but generally have mild symptoms. Examples of Type A viruses include but are not limited to the following: rotavirus, norovirus, hepatitis A virus, and some other common viruses such as adenovirus and astrovirus that typically cause outbreaks in schools and daycare centers. Such viruses generally do not result in life-threatening illnesses. A common illness associated with Type A viruses is gastroenteritis, sometimes accompanied by vomiting.

The Type B group represents viruses that have low to moderate infectivity but potentially more severe health effects, which may result in death. Examples of Type B viruses include but are not limited to the following: echovirus, coxsackievirus, and other enteroviruses. Illnesses associated with Type B viruses range from gastroenteritis and meningitis to more severe illnesses such as myocarditis or flaccid paralysis (due to non-polio enteroviruses).

Bacteria

Outbreak data show that bacterial pathogens occur in ground water (see Exhibit 2.3). Ideally, EPA would estimate baseline illnesses and deaths for both bacterial and viral pathogens to support this EA since the GWR will mitigate against risk from both concerns. While data (though limited) are

available to characterize viral occurrence, insufficient data are available to characterize pathogenic bacterial occurrence. Therefore, the primary analysis in this EA focuses on viral changes in viral exposure attributed to the GWR. A discussion of the unquantified benefits related to reduction in bacterial exposure is presented in Chapter 5 (section 5.5).

4.3.2 Enterovirus and *E. coli* Occurrence in PWS Well Source Ground Water

EPA evaluated all available relevant ground water occurrence studies (EPA, 2006b). This section explains the rationale for selecting the 15 studies for use in the final GWR economic analyses. The occurrence data are used to determine the probability that a well or sample will be positive for enterovirus and/or *E. coli*. *E.coli* was selected because EPA expects that most States will select *E.coli* as their monitoring target under the final rule. To assist with the analysis, EPA consulted with a group of statisticians to discuss ways to make optimal use of these limited data. The statisticians strongly recommended that EPA make use of all the available data unless there were known quality assurance problems with a data set or the well contamination scenario was outside the normal operating range of US PWS wells. Thus, EPA used all the available data on enterovirus occurrence in ground water from PWS wells in the United States except for one data set of alluvial wells from Missouri that were substantially affected by severe Mississippi River flooding (Vaughn, 1996). Data from the 15 studies selected as described in the following section were combined into one complete data set.

Study Selection

EPA has reviewed data from 24 recent studies of pathogen and fecal indicator occurrence in ground waters that supply PWSs (EPA, 2006b). Each study was conducted independently and with a unique objective and scope. The available data indicate a wide range of enterovirus occurrence in water drawn from wells across the United States. EPA selected 15 studies with results that are directly applicable to evaluating GWR benefits. These studies include the largest data sets characterizing enteroviral occurrence in the United States. One data set, Lieberman et al., 2002, targeted wells based on presence of total coliforms and other indicators of vulnerability to fecal contamination. Another data set, Abbaszadegan et al. 2003, targeted a representation of wells throughout the United States based on hydrogeological conditions, but excluded any wells that were poorly constructed or without well logs. Other studies sampled subsets of wells in particular states or in certain hydrogeologic settings within states. Because most studies were designed to capture subsets of the total PWS well population, each study description in the following is accompanied by a short discussion about the representativeness of the subset as compared with the total population. Aside from recognizing the numbers of wells surveyed, this analysis makes no attempt to weight any of the studies to compensate for any perceived over- or under-representation of the subset as compared with the total population.

General Considerations for Interpreting Viral Occurrence Data (Including Uncertainty)

When evaluating enteroviral occurrence data, it is important to realize some of the fundamental challenges in characterizing enterovirus occurrence, including detection, identification and concentration. Key issues include recognizing the limitations of enterovirus measurement and the limitations of deriving the probability of a well or sample being enterovirus-positive and the associated enterovirus concentration estimates from the measured data.

EPA relies only on the identification of enterovirus in PWS wells using cell culture methods since they allow identification of infectious pathogenic viruses. However, these measurements are underestimates of the actual occurrence because a) only a few of the viruses that can occur are detected by the method[9], b) each viral plaque that is counted as one virus originates from an infection by one or more viruses, and c) virus recovery is variable depending on the water chemistry and the viral strains present. Virus recovery can range from less than 20% to greater than 50% (Dahling, 2002; Denis-Mize et al., 2004; Sobsey and Glass, 1984).

Viruses often aggregate in water or solution. Methods that count host cell infection cannot differentiate between virus aggregates and solitary viruses and counts them all as solitary viruses (Teunis et al., 2005; Young and Sharp, 1977). Where more than one virus strain co-occur in placque assays, statistical analysis has shown that the actual concentration can be as much as 45% greater than the concentration determined by the standard method, the plaque assay count (Teunis et al., 2005). Thus, the probability that a well or sample will be positive for viruses pathogenic to humans will be an underestimate of the true probability and varies depending on the water chemistry, the type of cell culture used and the type of virus.

The standard host cell line used to recover human viruses is the Buffalo Green Monkey (BGM) continuous cell line. This cell line is less sensitive than primary cell lines derived from freshly harvested kidney cells (Ward et al., 1984). In addition, the age of the BGM cell line affects its sensitivity. BGM cell lines should not be used if they are passaged more than 250 times or if it has been longer than one week since the last passage.

Furthermore, concentration estimates derived from measured values of infectious viruses will be underestimates of the actual concentration because some viruses (such as reovirus) may be favored in the cell line used for testing and may out-compete other viruses (such as echovirus) (Carducci et al, 2002). Among the enteroviruses, slower growing enteroviruses are not favored for recovery and identification. For example, in BGM cells coxsackie B virus is a fast growing virus whereas Echo 11 grows slowly (Lieberman et al., 2002). Thus, the probability that a sample will be positive for viruses pathogenic to humans, given that such viruses are present in the sample, depends on water chemistry, the type of cell culture used, and the type of virus.

Viral occurrence can be characterized by considering the probability that a well or sample is virus-positive and the viral concentrations associated with those positive samples. However, the number of samples taken at a site and the sensitivity of measurement can significantly influence the estimated probabilities and concentrations per site for the anticipated exposure duration. Available data indicate that viral concentration at one site taken at different points in time can be highly variable, ranging from below detect to several orders of magnitude above detect (Lieberman et al., 2002). This is because some wells

[9] While each cell culture method can detect pathogens such as poliovirus, some coxsackievirus, echovirus, and reovirus (Type 3), many coxsackie A and other viruses are not detected. For example, no cell culture method exists to recover noroviruses in stool or environmental samples, yet noroviruses are responsible for the greatest proportion of water and food-borne disease outbreaks and therefore are most likely to be present in fecal contamination. Similarly, the BGM cell culture method to detect enteroviruses is inefficient for detecting rotaviruses in well water. There are few infectious rotavirus occurrence data available for making direct rotavirus health effect predictions. Rotaviruses are ubiquitous in nature, exemplified by the fact that all adults in the United States are seropositive for rotavirus, indicating previous infection. These detection method deficiencies minimize infectious virus recovery for two of the most important viruses and therefore underestimate the health effects predictions.

may never have a viral occurrence, others may have a short duration contamination, and still others may have high levels of occurrence and concentration for sustained durations. The possibility of high variation in viral occurrence at any given site makes estimates of probabilities and concentrations difficult.

In addition to the general issues regarding viral data characterization discussed above, specific issues of data representativeness, bias, uncertainty, and variability exist for any individual study. The interpretations of the data from the 15 primary studies used to support GWR analyses are presented in detail below.

4.3.2.1 Lieberman et al. 2002 Study

Study Objectives

The major objectives of the Lieberman et al. 2002 study were: 1) to obtain occurrence data for infectious human enteric viruses using the BGM cell line, 2) to assess the microbial indicators of fecal contamination, and 3) to develop and to evaluate a molecular biology monitoring method (PCR) to identify viral genomic material without consideration of the infectiousness of that material. The objectives were accomplished by sampling wells to confirm total coliform presence and to establish the presence of other fecal indicators, including somatic coliphage (Phase I) and by choosing a subset of these for monthly sampling for 1 year (Phase II). Wells were nominated for sampling in Phase I by federal, State and local drinking-water experts.

Well Selection

In Phase I, 180 wells were nominated, and 98 were selected. Each selected well was sampled once for total coliform, *E. coli*, enterococci, *Clostridium perfringens* spores, and somatic coliphage. Nominated wells were identified using historical total coliform occurrence data and any other available information about the well. In choosing which wells to nominate, other information was considered such as confirmed waterborne disease outbreaks, proximity to known sources of human fecal contamination and, in some cases, siting in a sensitive hydrogeologic setting (e.g., karst). Selected wells were located in 22 States, Puerto Rico, and the U.S.Virgin Islands. The wells from Phase I served as the well selection pool for 21 of the 30 wells chosen for Phase II sampling.

Twenty-seven of the thirty wells selected in Phase II had either a history of total or fecal coliform occurrence or had any indicator occurrence during Phase I sampling. In aggregate, the 30 wells selected for monthly sampling represent a group of wells considered to be vulnerable to fecal contamination primarily due to historical indicator occurrence, but also due to positive results for somatic coliphage, enterococci, or other indicators from a single sample during Phase I sampling. Proximity to fecal contamination sources, high nitrate concentrations, and location in a sensitive hydrogeologic setting were additional selection criteria for several additional wells. The 30 selected wells, located in 17 States and 2 U.S. territories, were sampled monthly for 1 year for total coliform, *E. coli*, enterococci, *Legionella* species, *Clostridium perfringens* spores, somatic and male-specific coliphage, *Bacteroides* bacteriophage and enteric viruses using BGM cell line.

Sample Results

For viral analyses using cell culture assays, seven of the 30 wells (23 percent) were positive for enterovirus and 20 samples (6 percent) were positive for enterovirus or reovirus. While 7 of the 30 wells sampled had a cell culture positive among the twelve samples taken, most of the measurement were below detects. One of the wells had 5 monthly viral positives, two of the wells had 4 monthly positives, one of the wells had two monthly positives, and three wells had one positive. Viral strains identified by serotyping included coxsackievirus and echovirus, as well as the enteric virus reovirus. Virus-positive samples ranged in concentration from 0.9-212 PFU or MPN/100 liters with a mean infectious virus concentration of 30.66 PFU or MPN/100 liters (PFU, or plaque forming units, and MPN, or most probable number, are estimates of concentration) among all the positive samples.

Data Representativeness

Most of the wells selected as part of Phase II of the Lieberman et al. 2002 study had a history of total coliform occurrence that was confirmed by Phase I sampling. Because most (but not all) of the wells selected for inclusion in the study had a history of fecal contamination, these data are not representative of all PWS wells in the United States because not all wells in the United States have a history of fecal contamination.

The GWR is concerned primarily with ground water sources vulnerable to contamination, especially the undisinfected sources. Most of the Lieberman et al. 2002 study wells, however, already employ disinfection, which potentially introduces a bias to the data (i.e., the use of disinfection could be considered an indication that the source is known to be contaminated). However, the use of disinfection does not necessarily correlate with known contamination. One enterovirus-contaminated well in the Lieberman et al. 2002 study was undisinfected and had the highest virus concentration for any single monthly sample of the entire study. Another factor that mitigates against this potential bias is that many States and some water systems require ground water disinfection as a matter of policy. For the Lieberman et al 2002 study, 10 of the 30 wells are located in Alabama, Florida, or Texas; States that require disinfection of all ground water sources. The existence of disinfection at a ground water system may not be directly correlated with indicator occurrence at that facility and therefore any selection bias is unknown.

4.3.2.2 Abbaszadegan et al. 2003

Study Objectives

Among the objectives of the Abbaszadegan et al. 2003 study were: 1) to determine the occurrence of virus contamination in source water of public ground water systems, 2) to investigate water quality parameters and occurrence of microbial indicators in ground water and possible correlation with human viruses, 3) to develop a statistically based screening method to identify wells at risk of fecal contamination, and 4) to develop and evaluate a molecular biology monitoring method (PCR).

Well Selection

Wells were selected for the Abbaszadegan et al. 2003 study from a pool of 750 wells. The study was initiated as a study of 150 samples from AWWSCo wells selected to test and evaluate the PCR method (Abbaszadegan et al., 1999). With additional funding, the study was expanded to 539 samples from 448 wells. The additional wells were nominated by State drinking water program or water utility staff. Study personnel requested nominations of wells not known to be vulnerable to microbial contamination. The researchers excluded 12 samples included in the first 150 AWWSCo well samples because they were believed to be under the direct influence of surface water and therefore especially vulnerable to contamination. Other nominated wells were excluded if well records were not available or if the well was improperly constructed. All nominated wells were profiled by the well operators or their designee using a questionaire that included a checklist of 11 different hydrogeologic settings. Researchers selected wells for inclusion in the study based on the reported hydrogeologic setting information. Wells were selected for inclusion if they were apparently located in a setting that was proportionately under-represented as compared with a USGS national hydrogeologic profile derived using these same 11 hydrogeologic settings.

Sample Results

Source water samples were taken from each well and analyzed using a variety of methods to detect pathogens and indicators. Samples were analyzed to determine the occurrence of viruses (using both cell culture and polymerase chain reaction (PCR) methods) and total coliform (TC), enterococci, and *C. perfringens* bacteria in ground waters of the United States. A total of 539 samples were obtained. Not all analyses were conducted on all samples, and 25 wells were sampled two or more times. Information was not available to identify which wells were sampled multiple times. Because the majority were sampled once, and having no other recourse, EPA's data were reduced to single samples as though each of these was the only one assayed for a well. PWSs performed the sampling and were given training on procedures to collect at least 400 gallons (1,512 L) of water prior to disinfection. Exhibit 4.12 presents a summary of the Abbaszadegan et al. 2003 study results.

Exhibit 4.12 Results of the Abbaszadegan et al. 2003 Study

Assay	Percent of Sites with Positive Samples (No. positive/samples analyzed)
Enterovirus (cell culture)	4.8%
Total coliform	9.9%
Enterococci	8.7%
Clostridium perfringens spores	1.8%
Male specific coliphage (*Salmonella* WG-49 host)	9.5%
Somatic Coliphage (E. coli C *host*)	4.1%
Somatic and Male Specific Coliphage (E. coli C-3000 *host)*	10.8%

Source: Abbaszadegan, 2002; Abbaszadegan et al., 1999, 2003

Data Representativeness

The Abbaszadegan et al. 2003 study included a large number of wells that were specifically chosen to be representative of the range and proportion of the hydrogeological settings of the United States. To further evaluate the representativeness of the wells with respect to hydrogeologic conditions, EPA subsequently compared nitrate concentrations from a national database of nitrate concentrations in ground water (Lanfear, 1992) with nitrate data measured in the Abbaszadegan et al. 2003 study wells to determine if there was any statistically significant difference between the nitrate levels in the two data sets. Nitrate was chosen for this comparison because a large, national database is available. The national nitrate data were selected randomly from a database of more than 100,000 wells. Using U.S. Census data, EPA stratified the nitrate data into rural and urban components and chose a small random subset of these, comparable in size to the sample in the Abbaszadegan et al. 2003 study data (all available Abbaszadegan et al. 2003 study data were used), for comparison. The analysis showed that the Abbaszadegan et al. 2003 study 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 further verified that, by this measure, the Abbaszadegan et al. 2003 study wells data appear to be nationally representative of hydrogeological conditions in the United States.

In the well selection process, the Abbaszadegan et al. 2003 study initially relied on wells that were owned by AWWSCo and subsequently used wells that were volunteered for the study. Choosing from among a restricted pool or using a volunteer process introduces a potential bias to the study. The AWWSCo wells typically serve larger populations, have greater revenues and are more professionally managed than most wells, and the volunteered wells were selected precisely because they appeared to be at low risk. Thus, there may be a downward bias in the contamination levels found during the study. As applied to the GWR risk analysis, this would result in an underestimate of benefits derived from the rule. In addition, most wells were only sampled once, which also may underestimate the risks associated with these wells.

A potential bias of the Abbaszadegan et al. 2003 study, as with the Lieberman et al. 2002 study, is that the majority of the study wells already employ disinfection (see discussion above for implications of this bias). A mitigating factor is that many States and some water system companies require ground water disinfection as a matter of policy. Fifty-two wells from the Abbaszadegan et al. 2003 study are located in Alabama, Florida, or Texas; States that require disinfection of all ground water sources. In addition, a large number of wells in the study are operated by AWWSCo, which also disinfects as a matter of policy. Therefore, the existence of disinfection at a ground water system may not be directly correlated to issues of contamination at that facility.

Because the description of the hydrogeologic setting was selected by the well operator or designee from a checklist, there are potential uncertainties associated with the hydrogeologic setting data. It is possible that the operator had insufficient data to determine the hydrogeologic setting and was unable to easily consult with a hydrogeologist. No analysis was conducted to determine whether the reported hydrogeologic setting data were correct. It would be expected that viruses would more likely be found in sensitive hydrogeologic settings, as was the case with the Lieberman et al. 2002 data, because the ground water flow within those aquifers is faster and more direct, and there are fewer opportunities for virus concentrations to become attenuated due to interaction with the aquifer solid materials.

The Lieberman et al. 2002 study found higher virus concentrations and a greater range of concentrations than those measured in the Abbaszadegan et al. 2003 study[10]. The Abbaszadegan et al. 2003 concentrations were uniformly low. Because of variations in well water matrix, source density, proximity and the concentrations in each source, virus filtration and recovery and virus analyses, it is impossible to assess the significance of the differing virus concentrations.

Overall, the magnitude and direction of the biases and uncertainties inherent to the Abbaszadegan et al. 2003 study cannot be definitively quantified.

4.3.2.3 Pennsylvania Noncommunity Wells (Lindsey et al., 2002)

Study Objectives

The purpose of this study was to measure pathogen and indicator occurrence in a random stratified sample of non-community water systems (NCWS) wells in primarily carbonate aquifers and crystalline aquifers, which are hydrogeologically sensitive settings. The United States Geological Survey (USGS) (Lindsey et al., 2002) analyzed samples from 60 NCWS wells from September to January 2001 to assess the occurrence and distribution of pathogens in ground water used for non-community water supplies and indicator organisms (evaluated as surrogates for those pathogens).

[10] In using the cell culture method for enterovirus detection, the Abbaszadegan et al. 2003 study identified only poliovirus from wells (Abbaszadegan et al., 1999) as compared with the Lieberman et al. 2002 study which identified no poliovirus.

Well Selection

USGS personnel, in collaboration with the Pennsylvania Department of Environmental Protection (PaDEP), selected random wells from a targeted population of primarily carbonate and crystalline aquifers. Ten wells were chosen in areas underlain by either siliciclastic bedrock or unconsolidated surficial aquifers. An unconsolidated aquifer is non-sensitive but the siliclastic aquifer can be either sensitive or non-sensitive depending on whether it is considered to be a sandstone or a quartzite. Aquifer sensitivity is best determined by the State, and EPA cannot make that determination based on the available data.

The vast majority of the sites were TNC PWS wells. Only two wells were NTNC PWS wells. Surrounding land use was included as a criterion for selection; a site was more likely to be selected if potential fecal point sources were located nearby. However, water suppliers with known bacterial contamination problems declined to participate while suppliers with no contamination history were much more willing to participate.

Sample Results

Of 60 wells initially selected, 59 samples were analyzed for culturable viruses, *Helicobacter pylori* (*H. pylori*), total coliform, *Escherichia coli* (*E. coli*), *Clostridium perfringens* (*C. perfringens*), somatic coliphage, male-specific coliphage, and enterococcus.

Culturable viruses were detected in 5 wells, *H. pylori* in 4 wells, *E. coli* in 7 wells, total coliform in 27 wells, *C. perfringens* in 9 wells, somatic coliphage in 5 wells, male-specific coliphage in 2 wells, and enterococci in 8 wells.

Of the 5 wells with detectable culturable viruses, two were near 0.21 PFU per 100 L, while the remaining three ranged from 18 to 56 PFU per 100 L.

Data Representativeness

This data set represents the only randomly sampled human pathogenic virus data from TNC wells among the 24 studies considered. As such, it is an important data set for representing the large number of untreated TNC wells in the United States.

4.3.2.4 Southeast Michigan (Francy et al., 2004)

Study Objectives

The purpose of this study of small (serving fewer than 3,000 people) public ground water supply wells was to assess the presence of both viral contamination and microbiological indicators of fecal contamination, relate the co-existence of indicators and enteric viruses, and consider the factors that affect the presence of enteric viruses.

Well Selection

Initially, 160 wells from a previously studied USGS National Water-Quality Assessment Program site were proposed based on nominations from local State and county experts. Wells were nominated if they produced from shallow sand and gravel aquifers, were undisinfected and did not have well construction flaws. The 38 selected wells were randomly selected from the 160 nominated wells. Well screens are typically shallow ranging from 50 to 150 feet below ground surface. In some places the aquifer is unconfined but more often the aquifer is semiconfined or confined by glacial till. Where semiconfined or confined aquifer conditions exist, these wells are protected from surficial fecal contamination sources. From July 1999 through July 2001, researchers collected a total of 169 regular samples and 32 replicate pairs in southeastern Michigan from 38 wells in discontinuous sand and gravel aquifers. Not all 38 wells were sampled for all parameters. Only 34 wells (93 samples) were analyzed for enteric virus by cell culture.

Sample Results

Two wells (two samples) were positive for enteric virus by cell culture. Four wells (four samples were positive for *E. coli*. Six wells (7 samples) were positive for enterococci. Two wells (two samples) were positive for male-specific coliphage and one well (one sample) was positive for somatic coliphage, based on 1 liter samples. All wells sampled are undisinfected so the semi-confining or confining layers are not sufficient protection against fecal contamination.

Data Representativeness

This study is unique among the 24 studies considered in that it sampled only undisinfected wells. Other studies were typically not able to sample undisinfected wells because well operators did not allow sampling. Thus, this study is representative of the large number of small, undisinfected PWS wells in the United States. Despite the apparent random well selection process, seven wells were not further considered for sampling at the request of the well owner or because they were found be unsuitable.

4.3.2.5 New Jersey (Atherholt et al., 2003)

Study Objectives

This study was designed to sample wells in New Jersey for fecal indicator organisms. No samples were analysed for enteroviruses or other viruses pathogenic to humans. Thus, data from this study was used only to determine the probability that a sample was fecally contaminated by *E. coli*.

Well Selection

Twenty-six public water supply wells were sampled for a variety of fecal indicator organisms. Twelve wells were identified as GWUDI and so data from these wells are not used in this analysis. Eighty-one samples were collected from the 13 ground water wells (128 from all wells) between June 1999 and February 2002. One well with one sample was not reported as ground water or GWUDI so this value was not included. All of the wells were located in unconfined aquifers. Although GWUDI wells were selected to increase the likelihood that fecal indicator organisms were present, no information is given for the selection of the other wells.

Sample Results

All 13 wells (81 samples) were negative for *E. coli*.

Data Representativeness

These data represent a subset of community ground water wells in New Jersey that produces water from unconfined aquifers.

4.3.2.6 Missouri Ozark Plateau #1 (Davis and Witt, 2000)

Study Objectives

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.

Well Selection

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, 2000). In order to eliminate poorly constructed wells from the study, wells that had been constructed within the last 15 years were selected primarily. Wells were also selected to obtain good coverage of the aquifer and to reflect the variability in land use. All wells were sampled twice, once in summer and once in winter.

Sample Results

One sample was reported as enteric-virus positive but this virus-positive well was not used in the data analysis for Today's Rule because this sample (and others) had some quality assurance problems due to cross contamination of samples with the poliovirus control. All wells from this study are counted as negative for enteroviruses when evaluated for the probability of well (and sample) being positive for enterovirus.

Data Representativeness

These data are representative of wells in the Ozark Plateau aquifer of Missouri. These data potentially underestimate the probability of wells and samples being positive for enteroviruses because one positive well was not included in the data set for Today's Rule.

4.3.2.7 Missouri Ozark Plateau #2 (Femmer, 2000)

Study Objectives

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.

Well Selection

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).

Sample Results

No wells were enterovirus-positive by cell culture.

Data Representativeness

These data are representative of PWS wells in the Ozark Plateau aquifer of Missouri.

4.3.2.8 Wisconsin Migrant Worker Camp (USEPA, 1998b)

Study Objectives

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 (USEPA, 1998b). 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 detection of coliforms occurred, the specific type of coliform was further identified (speciated). One total coliform positive sample was identified to contain *Klebsiella pneumoniae*, which can be due to fecal or non-fecal origins. 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.

Well Selection

These transient, non-community water systems are located in three geographic locations across the State.

Sample Results

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. No wells were analyzed for enteric virus by cell culture.

Data Representativeness

The data from this study are intended to be representative only of TNC wells in migrant labor camps.

4.3.2.9 New England (Doherty et al., 1998)

Study Objectives

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

Well Selection

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.

Sample Results

No wells were positive for enteric virus by cell culture. No wells were positive for *E. coli*.

Data Representativeness

These wells are intended to be representative of New England PWS wells. Two wells were provisionally identified as cell culture positive (and reported as positive in EPA, 2000) but were found to be laboratory contamination when the samples and lab controls were sequenced by CDC.

4.3.2.10 Three-State Study: (Wisconsin-Battigelli, 1999)

Study Objectives

The Wisconsin study sampled 25 wells quarterly for 2 years

Well Selection

No explanation is available on the method used in selecting the wells.

Sample Results

One well in Wisconsin was positive for enteric viruses by cell culture.

Data Representativeness

No information is available to evaluate the representativeness of these data.

4.3.2.11 Three-State Study: (Maryland-Banks et al, 2001)

Study Objectives

The purpose of this study was to sample shallow wells in Worcester and Wicomico Counties on Maryland's Eastern shore for enteric viruses. Twenty-seven wells were each sampled once. Three other samples (two from two deep confined wells) were sampled for use as negative control samples. Each well was sampled for enteric viruses by Buffalo Green Monkey (BGM) and RD (human embryonal rhabdomyosarcoma) cell culture, *Bacteroides fragilis* bacteriophage, somatic and male-specific coliphage, *E. coli*, *Clostridium perfringens*, and TC. Serological testing on virus-positive RD cell cultures confirmed the presence of rotavirus.

Well Selection

The 27 wells were located in two counties that are underlain entirely by sandy coastal plain aquifers. The selected wells were chosen from 278 small PWS wells by a vulnerability score that included factors such as historical fecal coliform occurrence, land use, well depth and age, and other factors.

Sample Results

One well was positive for enteric viruses by cell culture. This sample was identified as rotavirus by a non-standard test using an assay method normally used to detect rotavirus in stool. Because the assay method works primarily for rotavirus at high concentrations, this well was considered to be enteric-virus positive but not necessarily rotavrirus-positive. None of the wells was positive for *E. coli*.

Data Representativeness

These data are representative of deep wells in non-sensitive aquifers that are unlikely to be fecally contaminated.

4.3.2.12 Three-State Study: (Maryland-Banks and Battigelli, 2002)

Study Objectives

The purpose of this study was to sample shallow wells in the Maryland Piedmont physiographic province. Each well was sampled for enteric viruses by BGM cell culture, *Bacteroides fragilis* bacteriophage, somatic and male-specific coliphage, *E. coli*, *Clostridium perfringens* and TC. One-hundred-one samples were collected from April 10, 2000 to November 13, 2000. This total included ten replicate samples for QA purposes.

Well Selection

For this study, 91 small PWS wells were selected for sampling from 263 wells in the fractured bedrock aquifer of two Maryland Piedmont Physiographic Province counties. Wells were selected to distribute the sample sites evenly over the population and spatial extent of the study area. One well was selected randomly.

Sample Results

None of the wells was positive for enteroviruses by cell culture. One well was positive for *E. coli*.

Data Representativeness

These data are representative of shallow wells in fractured bedrock (sensitive) aquifers with thick soil and weathered rock (saprolite) cover that acts to protect against fecal contamination. This same aquifer setting would be more likely to be contaminated if located further north where glacial advances during the Ice Age removed much of the weathered soil and rock.

4.3.2.13 Three-State Study: (Minnesota-Banks and Battigelli, 2002)

Study Objectives

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). The Minnesota study (Minnesota Department of Health 2000) sampled 76 wells. Seventy-four wells were sampled for at least four consecutive calendar quarters. The remaining two wells were sampled for two consecutive quarters each. In addition to microbial indicator data, one sample from each well was also analyzed for tritium and tritium/3helium.

Well Selection

Sampled wells were more likely to be selected if they were small, transient PWSs, and/or were located in a aquifer that was perceived to be vulnerable. Of the 76 Minnesota wells sampled, six (8 percent) served community systems, 19 (25 percent) served non-community non-transient systems and 51 (67 percent) served transient systems. The aquifer types that are utilized by these wells include dolomite (six wells), dolomite and sandstone (three wells), fractured crystalline bedrock (nine wells), sandstone (28 wells), sand and gravel (29 wells) and regolith (surficial materials) (one well).

Sample Results

No wells in Minnesota were enteric virus-positive by cell culture.

Data Representativeness

These wells were selected to be representative of wells in Minnesota.

4.3.2.14 EPA Vulnerability Study (USEPA, 1998c)

Study Objectives

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 (USEPA 1998c). The vulnerability assessment assigned low or high vulnerability to wells according to their hydrogeologic settings, well construction and age, and distances from contaminant sources.

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.

Well Selection

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.

Sample Results

No wells were positive for enteric virus by cell culture. No *E.coli* data were collected.

Data Representativeness

Wells were selected to be representative of a variety of hydrogeologic settings in the United States. However, the small number of wells in the study and the large number of hydrogeologic settings makes such a comparison difficult.

4.3.2.15 Montana Study

Study Objectives

Miller and Meek (2006) sampled source water for *E. coli*, enterococci, male-specific and somatic coliphage from wells representing primary aquifer types, bedrock and valley-fill aquifers.

Well Selection

18 small PWS wells (and 20 residential wells) near Helena, Montana were sampled.

Sample Results

No *E. coli*, male-specific or somatic coliphage were detected in any well. Enterococci were detected in two wells but it is not known if these wells were PWS or residential wells

Data Representativeness

Wells were selected for sampling to represent both primary aquifer types, bedrock and valley-fill aquifers. Each well was sampled from one to three times.

4.3.2.16 Summary of New Data

Exhibit 4.13a identifies the new data available since the proposed GWR was published in 2000. Although all new data were evaluated, not all new data were used in the economic analysis for the GWR.

Of the seven new studies described in Exhibit 4.13a, four studies were included in the occurrence data compilation described in Section 4.3.2 and used to determine exposure in this EA. These four new studies are the Pennsylvania study (Lindsey et al, 2002), the Michigan study (Francy et al, 2004), the New Jersey study (Atheroholt et al, 2003), and the Montana study (Miller and Meek 2006). Other studies not included were not used for the reasons described in the following.

Karim et al (2003, 2004) - This study selected 20 wells (15 because of enterovirus or indicator occurrence) from the Abbaszadegan et al. 2003 study for additional (monthly) sampling. However, with the available data provided by the researchers (raw spreadsheet data and summary reports), it is impossible to combine the two data sets because the well site identifying characters differ in the two studies. Thus, there is no alternative other than treating the two studies as if they are separate, independent data sets. If treated as two data sets, significant bias is introduced. First, the same well is counted twice. Second, well data are treated as if they are unbiased, independent data when they actually were selected with based on prior sampling which identified either infectious enterovirus, enteric virus RNA, one or more fecal indicator bacteria or no contamination. (five wells from each group).

USEPA (2006b) - This study was designed to field test new coliphage assay methods. Because the objective was to better identify and count fecal indicators, where present, PWS wells with fecal contamination were more likely to be selected. Most of the wells sampled in this study were not PWS wells but rather were domestic water wells (not regulated by the GWR). The raw data were not proved by the investigators so counting and analysis of the PWS wells is subject to error. Because the wells were mostly not PWS wells and likely represented a biased set of PWS wells, these data are not included in the exposure compilation in this EA.

Borchardt et al (2004) - This study was designed to use detailed hydrogeologic data and microbial assays to evaluate wells in one community that are not designated by the State as GWUDI wells. Four wells were intensively sampled (two additional wells were sampled in one month as substitutes). The study concluded that two of the four wells had substantial surface water contribution. Because this study is small, all from the same community and half the wells are likely GWUDI, these data are not included in the exposure compilation in this EA.

DeBorde et al (1995) - This study sampled two wells from the same community. Because this study was small and both wells are located in the same community, these data are not included in the exposure compilation in this EA.

Exhibit 4.13b presents a summary of the virus-positive results obtained from the 1,253 virus assays performed in the studies described in this section. Exhibit 4.13c presents a similar summary of the *E.coli* (indicator) positive results obtained from the 687 assays performed in these studies. Exhibit 4.13d presents the number virus and *E.coli* assays used to evaluate wells in each of the 15 studies. These data were used by EPA for the hit rate analysis discussed later in this chapter.

Exhibit 4.13a New Data Available since publication of the Proposed GWR

Study	# PWS Wells Sampled & Location	Sampling frequency/volume	Indicators Monitored (# Pos. Wells/# Wells Total, Unless Otherwise Indicated	Pathogenic Viruses, *Legionella,* (#Pos. Wells/ # Wells Total, Unless Otherwise Indicated)
Pennsylvania Noncommunity Wells (Lindsey et al., 2002)	60 wells	59 samples. Virus sample volume (200-1000L) Bacterial sample volume (100mL) No detection limit Measured values are 0.21, 0.21, 18.3, 33.4, and 52.0 MPN/100L.	Male-specific coliphage (3/59) Somatic coliphage (5/59) Total coliform (27/59) *E.coli* (7/59) Enterococci (8/59) *C.perfringens* (9/59) *H.pylori* (by PCR) (4/59)	Cell culture: enteric virus (5/59)
Microbial Indicators for Assessing the Vulnerability of ground water to fecal contamination (Karim et al., 2003, 2004)	20 wells (California-2, Illinois-2, Indiana-3, Massachusetts-2, Missouri-2, New Hampshire-2, New Jersey-2, New Mexico-1, Ohio-1, Pennsylvania-3)	Each well was sampled monthly for a year. All indicators sampled using 100 mL and 1L samples (except coliphage Method 1602, which used only 100mL samples) Coliphage analyzed using Method 1601 and 1602	Method 1601: Male-specific coliphage (1/20 for 100mL sample, 4/20 for 1L sample) Somatic coliphage (0/20) Method 1602: Male-specific coliphage (12/20) Somatic coliphage (2/20) Total coliform (13/20 for 100 mL sample, 16/20 for 1L sample) *E.coli* (5/20 for 100 mL sample, 7/20 for 1L sample) Enterococci (1/20 for 100 mL sample, 7/20 for 1L sample) *C.perfringens* (1/20 for 100 mL sample, 3/20 for 1 L sample).	Cell culture: enterovirus (2/20), Rotavirus (7/20), RT-PCR: enterovirus (5/20), rotavirus (9/20), norovirus (8/20), adenovirus (1/20)

Environmental Factors and Chemical and Microbiological Water-Quality Constituents Related to the Presence of Enteric Viruses in Ground Water (SE Michigan) (Francy et al. 2004)	38 wells	169 regular samples. 32 replicate pairs. Mostly 5 samples per site. Method 1601 & 1602.	Total coliforms (13/38) (34.2%) (15/152 samples) *E.coli* (4/38) (10.5%) (4/163 samples) enterococci (6/38) (15.8%) (7/158 samples) Male-specific coliphage (2/34) (5.9%) (2/117 samples) (1 L. Sample) Somatic coliphage (1/34) (2.9%) (1/118 samples) (1 L. sample)	Cell culture: enterovirus (2/34) (2/93 samples) RT-PRCR: enterovirus (4/38) HAV (5/38) Rotavirus (0/34) Reovirus (0/34) Norovirus (0/34)
Validation of methods to detect coliphages in ground water (USEPA, 2006b) Phase II Not Published Note: This study included private and public wells.	SE region (13 in NC and 4 in FL) - 27 wells SW region (TX, NM) - 11 wells Upper Midwest (MN) - 25 wells NE region (12 in NH, 4 in ME, 3 in VT, 6 in MA) - 25 wells	Two phases.	Somatic Coliphage SAL (19/116) (16.4%) F+ Coliphage SAL (13/116) (11.2%) Total Coliphage SAL (14/116)(12%) Somatic Coliphage enrichment (8/116) (6.9%) F+ Coliphage enrichment (4/116) (3.4%) Total Coliphage enrichment (6/116) (5.2%) Fecal coliform (11/80) (13.8%) *E.coli* (5/116) (4.3%) Enterococci (14/116) (12.1%)	
Vulnerability of Drinking Water Wells in La Crosse, Wisconsin to Enteric-Virus Contamination from Surface Water Contributions (Borchardt et al., 2004)	6 PWS wells (not GWUDI)	Sampled monthly for one year. Two wells were shut down during one sampling period; samples from nearby wells were used for that period. 2 wells have 12 samples; 2 wells have 11 samples; and 2 wells have 1 sample.	TC (0/6) *E.coli* (0/6) Enterococci (0/6) Somatic coliphage (0/6) Male-specific coliphage (0/6)	RT-PCR: Enterovirus (5/6) Rotavirus (4/6) Hepatitis A (3/6) Norovirus G1 (3/6) Norovirus G2 (0/6) Cell culture: Enterovirus (0/6) Hepatitis A (3/6)

Mountain Water Company in Missoula, MT (DeBorde et al., 1995)	2 wells	Sampled monthly for one year.	F+Coliphage (1/2)(8%) Somatic coliphage (0/2)(0%)	Enterovirus (0/2)
New Jersey (Atherholt et al., 2003) Note: This study included wells that were ground water under the direct influence of surface water)	26 wells	128 samples. Wells were sampled from 1 to 10 times each. Bacteria sample volumes were 100 mL. Coliphage sample volumes were 100 mL, but a few samples were larger.	TC (8/26) *E.coli* (3/26) Enterococci (2/26) Somatic coliphage (CN 13 host) (5/26) Male-specific coliphage (Famp host) (5/26)	
Montana Study (Miller and Meek, 2006)	18 wells (near Helena, Montana)	Wells sampled 1-3 times	*E.coli* (0/18) Enterococci (2/38) [uncertain if the positive wells were PWS wells] Male specific coliphage (0/18) Somatic coliphage (0/18)	

Exhibit 4.13b Virus Assays and Positives for 1,253 Wells Assayed for Viruses

	Number of Virus Positives					
Virus Assays	0	1	2	3	4	Total
1	837	28				865
2	122	1				123
3	39	1				40
4	170	2				172
5	1			1		2
6	2					2
8	25		1			26
12	18	3			1	22
14	1					1
Total	1215	35	1	1	1	1253

Exhibit 4.13c *E.coli* Assays and Positives for 687 Wells Assayed for *E.coli*

	Number of *E. Coli* Positives					
E. Coli Assays	0	1	3	5	6	Total
1	282	16				298
2	128	1				129
3	30					30
4	120	1				121
5	28	2				30
6	26		1			27
8	24	2				26
12	12	3	2	2	3	22
11	3					3
14			1			1
Total	653	25	4	2	3	687

Exhibit 4.13d Number of Virus and *E.coli* Assays

Study ID	Number of Assays	
	Virus	E.coli
Abbas	539	0
Lieb	298	298
MD - 3 State, 2002	91	90
MD - 3 State, 2001	30	30
SE Michigan	95	167
MN - 3 State	299	92
MO - 1	218	218
MO - 2	109	109
New England	458	462
PA Noncommunity	60	60
WI Migrant Worker Camp	0	126
WI - 3 State	200	200
EPA Vuln	30	0
NJ Atherholt	0	71
Montana	0	38
Total	2427	1961

4.3.3 Well Vulnerability

4.3.3.1 Background

In the EA for the proposed rule EPA estimated that 17 percent of the wells in the United States were improperly constructed and that 83 percent of the wells were properly constructed (ASDWA, 1997). EPA used the Lieberman et al. 2002 data set to represent viral occurrence in improperly constructed wells and the AwwaRF/AWWSC data set to represent properly constructed wells. It was implied that well construction corresponded with vulnerability (i.e., poorly constructed wells would be vulnerable to contamination). EPA received public comments that questioned the basis for using Lieberman et al. 2002 data to represent improperly constructed wells because the Lieberman et al. 2002 study sites were chosen based on the presence of total coliforms and indicators of fecal contamination. To clarify this issue, EPA is categorizing ground water systems into two groups: those that are more vulnerable and those that are less vulnerable.[11] Neither of the studies discussed above provide data regarding the percentage of ground water sources that might be more or less vulnerable, and EPA needed to derive such estimates to support

[11] EPA believes this terminology is more appropriate than that used in the proposal ("improperly constructed" and "properly constructed") since the Lieberman et al (2002) study did not target poorly constructed wells, but rather used criteria believed to favor the selection of vulnerable wells.

this EA. EPA has used national TCR violation data from SDWIS to estimate the percent range of wells that are more or less vulnerable. The proportion of wells in each of the well vulnerability categories is necessary to properly apportion the virus concentration data. Viral concentration data from wells with a history of TC contamination (i.e. the Lieberman et al. 2002 data) are used for the wells that are identified as belonging within the more vulnerable group. Following is a description of these estimates and their basis.

4.3.3.2 Estimating percent wells in vulnerability categories

EPA categorized systems into two groups: those that are more vulnerable and less vulnerable.

More vulnerable systems: These are systems that may be more vulnerable to source water contamination, reflected by having MCL violations under the Total Coliform Rule (TCR) during a calendar year (from SDWIS, USEPA 2003a).

Less vulnerable systems: These are systems that are expected to be less vulnerable to source water contamination, reflected by having ***not*** had an MCL violation under the Total Coliform Rule during the same year.

The percentage of systems in the "more vulnerable" category (and also the percentage in the "less vulnerable" category) varies by system type (i.e., community, nontransient community, and transient noncommunity) and system size, and ranges from zero to 6.83 percent. These proportions of wells in the more vulnerable category are identified in Exhibit 4.14. For each element in the exhibit (system size and type) the proportion of less vulnerable wells is 100% minus the value identified in the exhibit. Detail on the derivation of these percentages is presented in Exhibit B.18. MCL violations are of two types. Acute violations indicate that the system tested positive for fecal coliform or *E. coli* in repeat samples following samples that are total coliform positive. Non-Acute MCL violations for systems collecting at least 40 samples per month (i.e., those serving more than 33,001 customers) occur when more than 5 percent of samples test positive for total coliforms during a sample period. For smaller systems, an MCL violation occurs when more than one sample tests positive for total coliforms during a sample period (violations are for a reporting period, which for most noncommunity systems is one sample per quarter; thus for these systems, an MCL violation occurs when a repeat sample is positive for total coliforms). Either of these two conditions indicates a potential problem with the integrity of the system and may indicate problems with source water quality or other conditions that may make the system and its wells more vulnerable to contamination.

Exhibit 4.14 Mean Percent of Systems with Acute or Monthly MCL Violations by System Type and System Size

System Size (Population Served)	CWS	NTNCWS	TNCWS
<100	2.87%	2.84%	2.33%
101-500	2.66%	2.25%	2.40%
501-1,000	1.85%	1.86%	2.30%
1,001-3,300	2.23%	2.34%	3.59%
3,301-10,000	3.48%	2.21%	2.82%
10,001-50,000	3.41%	0.00%	2.94%
50,001-100K	1.82%	0.00%	0.00%
100,001- 1 Million	3.13%	0.00%	0.00%
> 1 Million	0.00%	0.00%	0.00%

Source: Exhibit B.18, derived from SDWIS (2003a)

For ground water systems, the violation of MCLs under the TCR is an indicator of vulnerability, especially when systems do not disinfect and distribution systems are small or do not exist. There is some uncertainty associated with the data in Exhibit 4.14 because they include systems that disinfect as well as those that do not disinfect. Exhibit 4.15 summarizes the available data on disinfecting systems. For example, 64 percent of ground water systems provide no disinfection, and thus for such systems, TC sampling under the TCR should reflect contamination in their source water. In transient noncommunity systems, which essentially have no distribution systems, 82 percent of systems provide no additional disinfection. In these systems, the influence of non-source water-related contamination is likely to be very low relative to that of source water. In summary, it is assumed that disinfection has only a small influence on the identification of more vulnerable wells using TCR violation data.

Exhibit 4.15 Number and Percent of Systems Disinfecting, By Type of System

	Total	CWS	NTNCWS	TNCWS
Number of Systems	147,330	42,361	18,908	86,061
Approximate Percent of Systems Disinfecting	36%	75%	29%	18%

Source: Derived from Exhibit 4.2

4.3.4 Occurrence Analyses

To assess potential costs and benefits of the GWR, it is necessary to estimate several occurrence parameters. Estimates are made for both viral[12] and indicator[13] hit rates, viral concentrations, and co-occurrence of viruses and indicators. Cost and benefit analyses performed for the EA accompanying the GWR proposal drew data from two of the occurrence studies to inform the analyses - the Lieberman et al. 2002 and Abbaszadegan et al. 2003 studies. At the time, these two studies were considered to be the best suited for representing viral and indicator hit rates as well as viral concentration. Specific co-occurrence parameters derived from the studies were not used in the proposal EA analysis. Instead, a correlation between indicator and viral occurrence was assumed. In response to comments received on the proposal analyses, EPA performed further detailed review and analysis of all available occurrence data.

To improve the estimates of viral and indicator hit rates and concentrations using the data available, EPA convened a 2-day statistical workshop in May 2005. The core workgroup included expert participants form several government agencies and private consulting firms. A summary of the workgroup proceedings, including a list of all participants, is included in the final docket for this rulemaking. The charge to the workgroup was to consider how to obtain improved modeling of:

a) national viral occurrence in wells,
b) indicator efficiencies for identifying fecally contaminated wells,
c) indicator efficiencies for identifying virally contaminated wells, and
d) virus concentrations in virus-positive well water.

By the end of the workshop, approaches for modeling viral and indicator prevalence and viral concentrations (items a, b, and d) were discussed, but methods for linking indicator occurrence and virus occurrence (item c) were not. Following the workshop, EPA acted on the workgroup's recommendations, provided feedback to participants, and generated model-based national estimates for both viral and indicator occurrence. The results of this effort led naturally to a combined analysis, which also modeled co-occurrence of viruses and indicators. This combined model serves as the basis of EPA's quantitative occurrence estimates. The sections below describe in detail how these new data are used to model the occurrence of virus and indicators in ground water sources.

The workgroup also considered the question of data selection with regard to the available occurrence studies. Individually, the studies are not nationally representative, but represent select portions of the ground water universe. Collectively, the studies describe a full range of geographic, geologic, and other characteristics (e.g., variety of system sizes and system types). Workshop participants recommended against discarding any study's data without cause but did not feel they had the expertise to make any final calls regarding specific studies. Because the final selection of data was beyond the scope of their expertise, the issue was remanded for further consideration by EPA's subject matter experts. The discussion of each occurrence study is presented in Section 4.3.2, with a summary of the final use(s) of each presented in Exhibit 4.12.

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[12] Although the GWR is aimed at preventing exposure to all viral pathogens, enterovirus data are used as a proxy for all viral pathogens in both the viral hit rate and viral concentration analyses.

[13] Although the GWR allows different indicators to be used for compliance purposes, *E. coli* is used as a proxy for all indicators in the hit rate analyses.

4.3.4.1 Viral and Fecal Indicator Hit Rates

This section discusses the estimation of the hit rates for viruses and fecal indicators in the source waters of ground water wells. The rates are derived from pooled analyses of the data presented in Section 4.3.2, above. Hit rate information is a critical input for both the model of baseline risk of viral infections, illnesses, and deaths and for modeling the reduction of viral risks from components of the GWR dependent upon source water monitoring of fecal indicators. Indicator hit rate information is also a critical input for cost modeling. The application of the hit rates for determining the baseline risk and risk reductions from the rule options is described in detail in Chapter 5. The application of indicator hit rates for determining the costs of some of the rule options is described in Chapter 6.

The term hit rate refers to the probability that a virus or fecal indicator, or both, will ever be present in the source water of a well and, if so, how frequently each is expected to be present. Hit rates, therefore, have two components which are referred to here as P_{well} and P_{sample}.

P_{well} refers to the probability that a randomly selected well will ever have a virus (or indicator) present in its source water. Applying this probability to all wells provides an estimate of the number of wells that ever have virus (or indicator) present in their source water.

P_{sample} refers to the probability that a random sample from a contaminated well will be positive and will vary from well-to-well.

So, for example, a virus P_{well} value of 0.10 implies that 1 out of every 10 wells will have detectable virus present in its source water at some time. Conversely, it also implies that 9 out 10 wells will not ever have detectable virus.

A well with a virus P_{sample} value of 0.25 would be expected to have detectable virus in 1 of every 4 samples assayed.

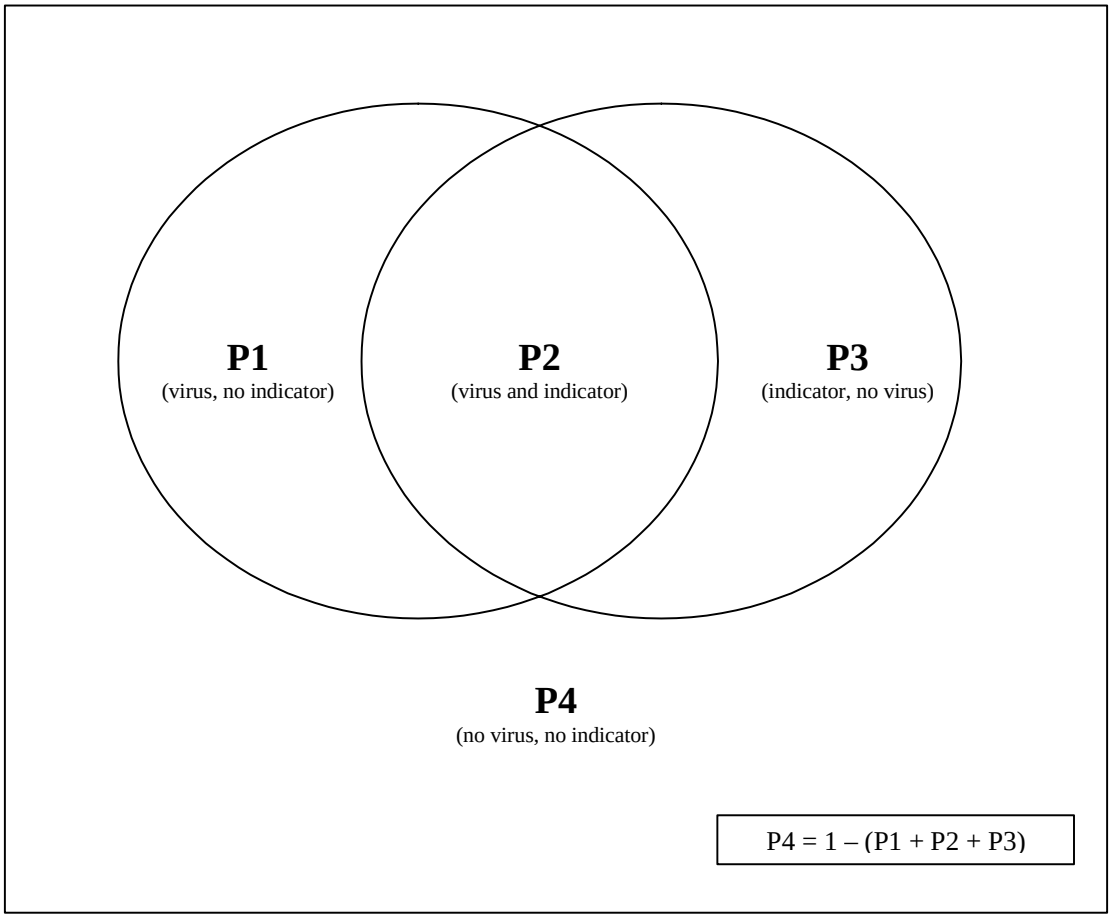
There are a number of factors that influence the estimation, as well as the interpretation, of P_{sample}. Microorganisms in water are dispersed spatially at low average concentrations relative to the volumes of water typically collected in assays. As a result, a randomly taken sample of some volume V may not have the microorganism present even when it is known to be in the source water. Often the recovery rate for these pathogens is less than 100%, and viruses that are present in samples are not always detected. In addition, the actual presence of microorganisms in the source water is recognized as being intermittent in nature due to changes in the actual sources of the contamination as well as hydrogeological and other physical factors affecting transport from the sources to the water used at that well.

It is important to recognize that while the same P_{well} value applies to all wells, each individual contaminated well is expected to have its own P_{sample} value. That is, the underlying data suggest that among those wells that have a virus or fecal indicator present at some time, the probability of observing it in a given sample (that is, of it being present in that sample volume on that particular day) will vary from well to well. Consequently, a distribution of P_{sample} values was derived to reflect P_{sample} variability from well to well. Specifically, a beta distribution of P_{sample} was derived from the underlying occurrence data. The beta distribution is often used for this purpose, that is, to describe distributions of probabilities or other variables that range between zero and one. (The probit and logit distributions are sometimes used for this purpose, and generally produce estimates similar to those produced using the beta distribution.)

The beta distribution is a two-parameter distribution; the parameters are usually designated α and β. The estimation of those parameters for the beta distribution of P_{sample} is described further below.

The Venn diagram shown in Exhibit 4.16 describes the basic co-occurrence model. This diagram shows that some fraction of wells (P1) has some virus contamination, but no indicator, while another fraction of wells (P2) has both virus and indicator, and a third fraction of wells (P3) has indicator, but no viral occurrence. A fourth fraction of wells (P4), having neither viral nor indicator occurrence is the remainder: P4 = 1 - (P1+P2+P3).

Exhibit 4.16 Categories of Indicator and Viral Classification Among PWS Wells in U.S.



To fully characterize both P_{well} and P_{sample} for viral pathogens and fecal indicators, and to characterize their co-occurrence, the model requires the estimation of seven parameters: P1, P2, P3, α_{virus}, β_{virus}, $\alpha_{indicator}$, and $\beta_{indicator}$ from the available occurrence data. P_{well} for virus is equal to P1+P2, and P_{well} for indicators is equal to P2+P3. P_{sample} for viruses (referred to hereafter as Pv_{sample}) at different wells is

described by a beta distribution with the parameters α_{virus} and β_{virus}. Similarly, P_{sample} for indicators (referred to hereafter as Pi_{sample}) at different wells is described by a beta distribution with the parameters $\alpha_{indicator}$ and $\beta_{indicator}$.

It is important to note that the occurrence model developed by EPA relates virus and indicator co-occurrence only in terms of P_{well} (the fraction of wells having one, the other, or both). It does not provide for different levels of Pv_{sample} or Pi_{sample} in wells having both or only one of the two contaminants. Wells having both virus and indicator presence may well have them greater fractions of the time than wells having only virus or wells having only indicator. A model that would include this feature would require four parameters to explain variable Pv_{sample} and Pi_{sample} in wells having both virus and indicator. However, the limited amount of occurrence data is not sufficient for a model with that degree of complexity.

Another important point to note is that, while the preceding overview of the occurrence model refers to the P1, P2 and P3 parameters for P_{well} and the α and β parameters for P_{sample} as though only single "best values" are estimated, the occurrence model is actually designed to capture the uncertainty in those values and produces a very large number (10,000) of sets of those seven parameters that are subsequently sampled in the Monte Carlo simulations that are performed for both the risk/benefits model and the cost model used to evaluate the impact of the ground water rule options.

Parameter Estimation Methods

Markov Chain Monte Carlo (MCMC) methods were used in a Bayesian framework to produce samples from the joint posterior parameter distribution (the sample of 10,000 discussed in the paragraph above). This posterior density function is a product of a prior density function and a likelihood function. WinBUGS software (Gilks and Spiegelhalter, 1994) was used to produce the large MCMC sample, which, in turn was used to inform the Rule's risk and cost analyses. This section describes the prior and likelihood functions of the seven-parameter model.

Non-Informative Priors

Parameters P1, P2, and P3 [together with P4, where P4 = 1 – (P1 + P2 + P3)] are the fractions of all ground water wells falling into the four possible subsets as shown in Exhibit 4.11. A relatively non-informative prior on these is Dirichlet with parameters (1, 1, 1, 1). This is the multivariate extension of the Beta (1, 1) distribution, which is often used for the one-parameter case. Beta (1, 1) is a uniform distribution for one unknown over the range [0, 1] and likewise, Dirichlet(1, 1, 1, 1) is uniform over the three-dimensional space where the sum of P1, P2, and P3 is in the range [0, 1].

Pv_{sample} and Pi_{sample} are both assumed to be beta-distributed across wells having virus presence and wells having indicator presence, respectively. The Beta density function is usually expressed in terms of its parameters α and β as:

$$\text{dbeta}(p, \alpha, \beta) = p^{\alpha-1} \cdot (1-p)^{\beta-1} \cdot \frac{\Gamma(\alpha+\beta)}{\Gamma(\alpha) \cdot \Gamma(\beta)}$$

where p in this expression is one of the P_{sample} variables. Assigning priors with this form of the density is difficult. First, it is difficult because one cannot think about α (or β) without understanding β (or α). Second, a non-informative prior leads to an improper posterior density, with increasing mass as the sum ($\alpha + \beta$) becomes large. In our case, a uniform prior on (α, β) suggests strong knowledge that the variability of P_{sample} is small about some mean value. Gelman, et al. (1995), discuss this problem in their book "Bayesian Data Analysis" and suggest reparameterization in terms of the mean, $a = \alpha / (\alpha + \beta)$ and the inverse square root of the "sample size," $b = 1/(\alpha + \beta)^{0.5}$. EPA adopted this parameterization and utilized disperse uniform priors for the two new parameters (a and b). The conventional beta distribution parameters can be derived from new parameters a and b as follows:

$$\alpha = a / b^2$$
$$\beta = (1 - a) / b^2$$

Therefore, for parameterization of the occurrence model, a_{virus}, b_{virus}, $a_{inidicator}$, and $b_{indicator}$ are estimated, and the corresponding α and β values for the beta distributions are computed from them as shown above.

The Likelihood Function

The virus and indicator data for an individual well used as input to EPA's occurrence model can be reduced to four integers. The four integers for a well are:

N_v = the total number of virus assays for the well
K_v = the number of virus positives for the well
N_i = the total number of indicator assays for the well
K_i = the total number of indicator positives for the well

Up to three of these may be zeros; at least one of the values N_v or N_i must be ≥ 1 for it to be valid input to the model.

The likelihood of a well's data, given parameter values (P1, P2, P3, α_{virus}, β_{virus}, $\alpha_{indicator}$, and $\beta_{indicator}$, and the category of a well), is a function of the parameter values and the well's data (the well's N_v, K_v, N_i, and K_i values), where α_{virus} and β_{virus} are parameters for beta-distributed Pv_{sample} for viruses and $\alpha_{indicator}$ and $\beta_{indicator}$ are parameters for beta-distributed Pi_{sample} for indicators. The total likelihood (for the entire data set) is simply the product of these individual well likelihoods.

In general, the likelihood for a well has three parts, the probability of what was observed for virus, given the number of virus assays, the probability of what was observed for *E. coli*, given the number of *E. coli* assays, and the probability of the well's membership in its category (P1, P2, P3, or P4). Below, these two factors are defined for wells of the four different categories (virus only, virus and *E. coli*, *E. coli* only, and no contamination):

1. Well has some virus occurrence, but no *E. coli* occurrence (in area P1 of Exhibit 4.16):

$$L1\left(K_v, N_v\right) = P1 \cdot \int_0^1 dbeta\left(Psample_v, \alpha_v, \beta_v\right) \cdot dbinom\left(K_v, N_v, Psample_v\right) dPsample_v$$

where dbeta is the beta probability density function and dbinom is the binomial probability mass function. A well of this type must have had no *E. coli* detections, so the probability of observing $K_i = 0$ positives is 1 and its product with $L1(K_v, N_v)$ is simply $L1(K_v, N_v)$.

2. Well has both virus and *E. coli* occurrence (in area P2 of Exhibit 4.16):

$$L2\left(K_V, N_V, K_i, N_i\right) = P2 \cdot L1\left(K_v, N_v\right) \cdot \int_0^1 dbeta\left(Psample_i, \alpha_i, \beta_i\right) \cdot dbinom\left(K_i, N_i, Psample_i\right) dPsample_i$$

Note that, to be in this category, it is not necessary that a well actually have observed virus and *E. coli* positives. Having no positive, based on a small number of assays, is only weak evidence that a well belongs to another category. At each uncertainty iteration, wells are assigned to categories according to the likelihood, conditional on the well's data plus all other parameter values at that time. In this fashion, parameters P1, P2, P3, and P4 also enter the likelihood. The only wells that are assigned to this category with certainty are those which were observed to be positive for both viruses and *E. coli*. At every iteration, they are placed in this category. All other wells are randomly assigned to different categories from iteration-to-iteration, according to their likelihoods.

3. Well has *E. coli*, but no virus occurrence:

$$L3\left(K_i, N_i\right) = P3 \cdot \int_0^1 dbeta\left(Psample_i, \alpha_i, \beta_i\right) \cdot dbinom\left(K_i, N_i, Psample_i\right) dPsample_i$$

4. Well has neither virus nor *E. coli* occurrence:

Wells having no observed contamination can belong to any category. Wells assigned to this category must always have negative assays. The likelihood of observing no positives is certain, so the only contribution to the likelihood is the probability of membership, P4.

Estimates for Combined Model

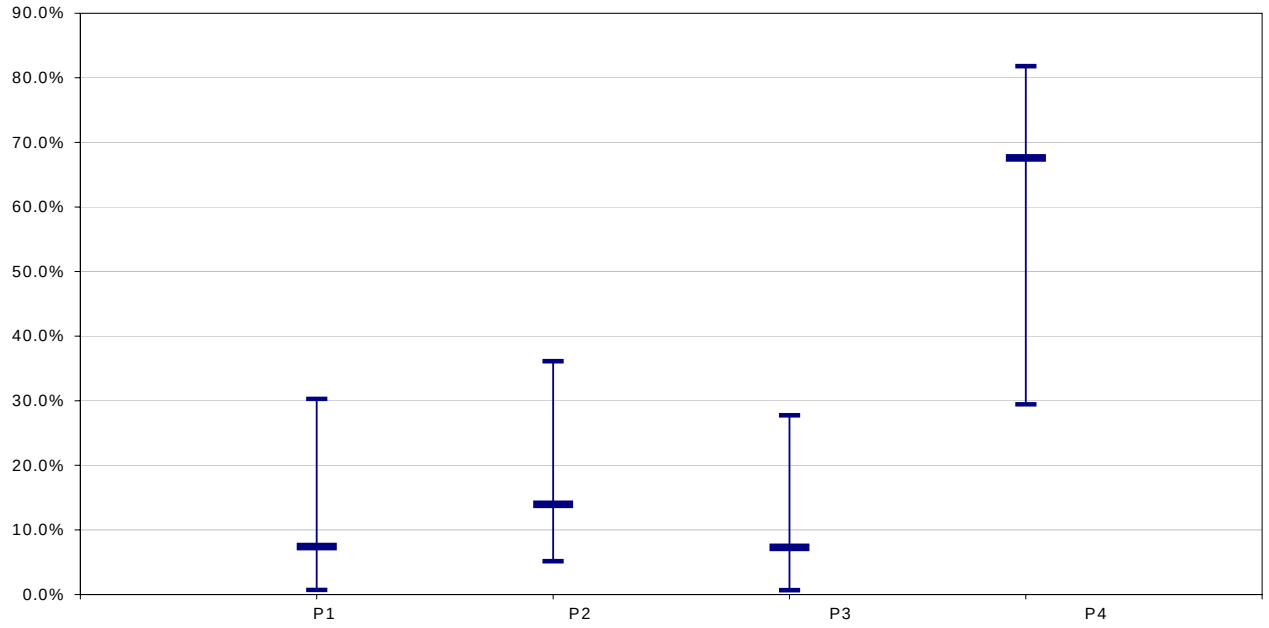
Estimates were produced by Markov Chain Monte Carlo methods using WinBUGS software (Gilks and Spiegelhalter, 1994). An important feature of this MCMC analysis is that it produces a large, well-mixed sample of outputs wherein each individual output contains a plausible value for each of the seven parameters in combination with one another. In this modeling, EPA captured 10,000 sets of results

for the seven parameters to characterize uncertainty about the parameter values. The MCMC modeling captures the uncertainty in the parameter estimates through this large number of sets of results with appropriate correlation structure.

The actual data used to estimate the seven parameters was the enteroviruses cell culture data for viruses and the *E. coli* for the indicators data from the 15 occurrence studies described in Section 4.3.2. Of those 15 studies, 12 have enterovirus cell culture data and 12 have *E. coli* data.

The following exhibits provide summaries of the P_{well} and P_{sample} results obtained from the modeling for viruses and indicators. Exhibit 4.17 shows the median values for P1, P2, P3 and P4. The "error bars" included on the graphs reflect the 5th and 95th percentiles of the 10,000 values estimated. As indicated earlier (refer to Exhibit 4.11), P1 refers to the fraction of wells having virus at some time (but no indicator), P2 refers to those wells having virus and an indicator at some time, and P3 refers to those having an indicator at some time (but no virus). P4 are those wells having neither virus nor indicator occurrence. Estimates were produced by Markov Chain Monte Carlo methods using WinBUGS software (Gilks and Spiegelhalter, 1994).

Exhibit 4.17 Median of 10,000 Estimates of P1, P2, P3, and P4 (with error bars showing the 5th and 95th percentiles)



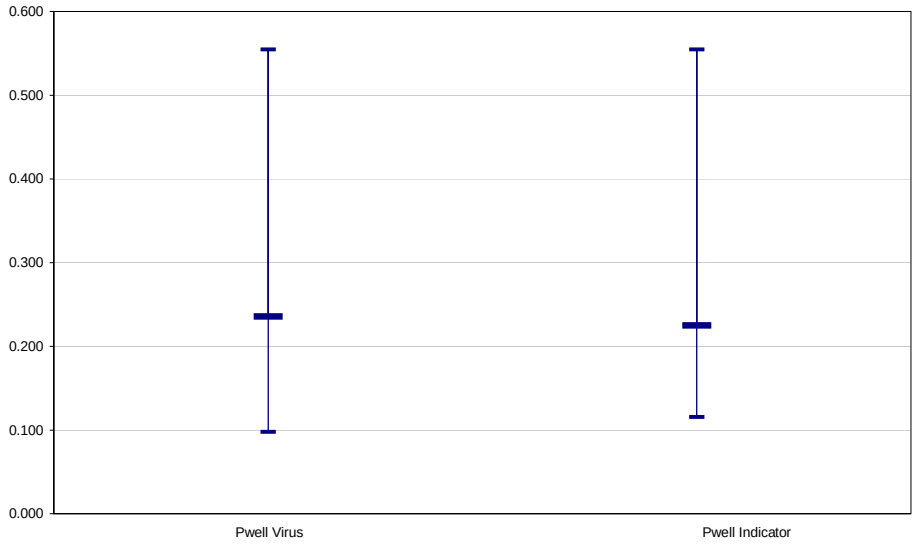
The median values obtained in the model for P1, P2 and P3 are 7.4%, 14.0% and 7.3%, respectively. The median value for the sum P1+P2+P3 (wells with sometime presence of virus and/or indicator) is 32.4%. The 5th and 95th percentiles on the sum of P1, P2 and P3 were found to be 18.2% and 70.6%. P4, the remaining wells that have neither virus nor indictor present at anytime is derived from the model estimates for the other three as 1 minus (P1+P2+ P3). The median P4 value is 67.6%, with 5th and

95th percentiles on P4 of 29.4% and 81.8%. Thus, approximately 90% of the 10,000 estimates of wells having either virus or fecal indicator occurrence fall between about 20% and 70%, with a central estimate of about 32%.

If *E. coli* was a perfect indicator of virus occurrence, there would be no wells with only virus or only *E. coli*. P1 and P3 would both be zero. Clearly, *E. coli* is not a perfect indicator of viral occurrence. Exhibit 4.17 shows that most wells with virus occurrence tend to also have *E. coli* occurrence (P2 is greater than P1) and that most wells with *E. coli* occurrence tend to also have virus occurrence (P2 is greater than P3). Given that approximately 24% of wells have virus occurrence while 23% of wells have *E. coli* occurrence, if viruses and *E. coli* were completely independent, then the fraction of wells having both (P2) would equal the product 0.24 * 0.23, or 5.5%. The large median value of P2 (14.0%) demonstrates that, though imperfect, *E. coli* is a positive indicator of viral occurrence.

As noted previously, two of the important hit rate values are P_{well} for viruses and P_{well} for indicators. These are composed of P1+P2 for viruses and P2+P3 for indicators. Exhibit 4.18 provides the median (and the 5th and 95th percentile values) for P_{well} for viruses and for indicators.

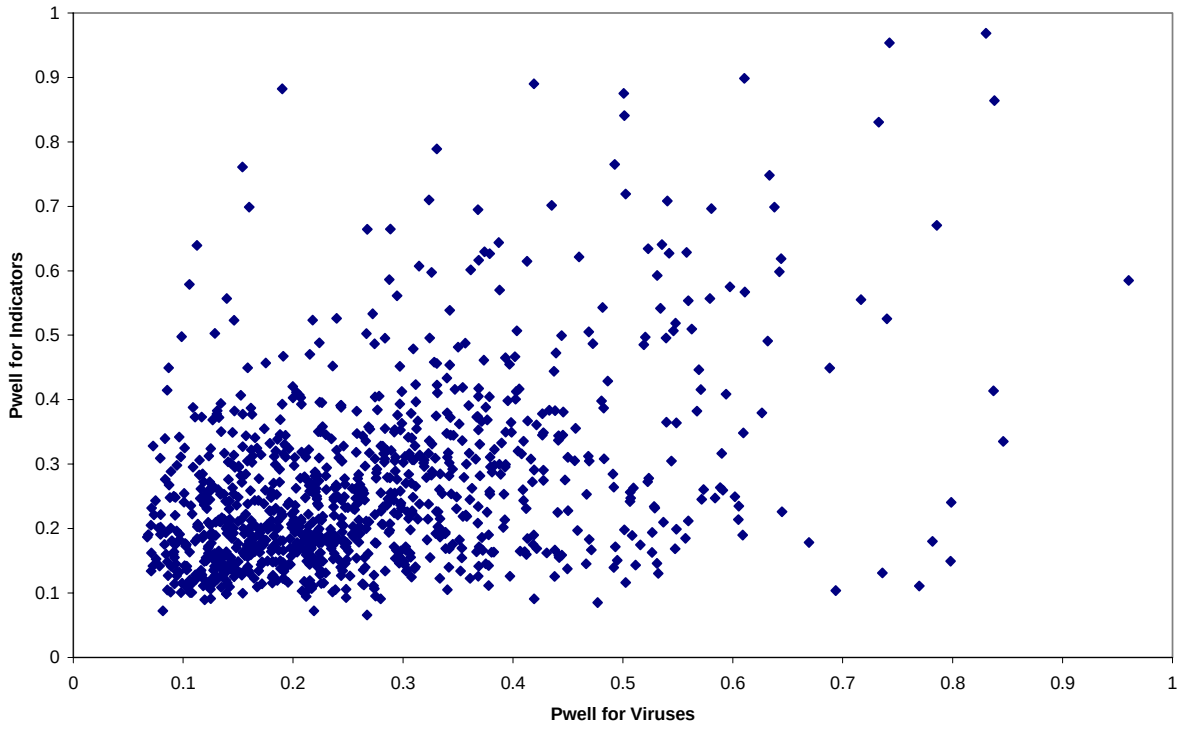
Exhibit 4.18 Median of 10,000 Estimates of P_{well} for Virus and Indicator (with error bars showing the 5th and 95th percentiles)



The median value of P_{well} for viruses was found to be 23.6% with 5th and 95th percentiles of 9.8% and 55.5%. The median of P_{well} for indicators was 22.5% with 5th and 95th percentiles of 11.6% and 55.5%. As shown in Exhibit 4.18, median values and overall ranges of P_{well} for viruses and indicators are quite similar. However, the distribution of paired values for these covers a very wide range of combinations. The scatter plot shown in Exhibit 4.19 shows the paired combinations of a sample of 1,000 of the 10,000 values. While most of the pairs tend to fall in the 10% to 20% range for both viruses and

indicators, there are a substantial number that fall above this range including many where one value for the pair is high and the other relatively low.

Exhibit 4.19 Scatter Plot of P_{well} Pairs for Indicators and Viruses



As described above, the Pv_{sample} for viruses and Pi_{sample} for indicators are not single value estimates but are, rather, distributions of values reflecting the variability in P_{sample} from well to well. As a result, the occurrence model generates 10,000 of these distributions for both Pv_{sample} and Pi_{sample}. It is difficult to provide a summary of all 10,000 of those distributions, particularly because the beta distribution used in this analysis can take on a wide range of shapes.

The beta distributions obtained for P_{sample} have three different shapes: exponential, U-shaped, and bell-shaped (right-skewed). Representative examples of these three shapes for P_{sample} for viruses are presented in Exhibit 4-20 as the density functions and in Exhibit 4-21 as the cumulative probability distributions. (Note that these particular examples were selected because they present values that are close to the central tendencies for the three distribution shapes of P_{sample} for viruses.)

For P_{sample} for viruses, about 73% of the distributions have the exponential shape, 23% have the U-shape and 4% have the right-skewed bell shape. For P_{sample} for indicators, about 79% of the distributions have the exponential shape, 2% have the U-shape and 19% have the right-skewed bell shape.

Exhibit 4.20 Density Function Shapes of P_{sample} for Viruses

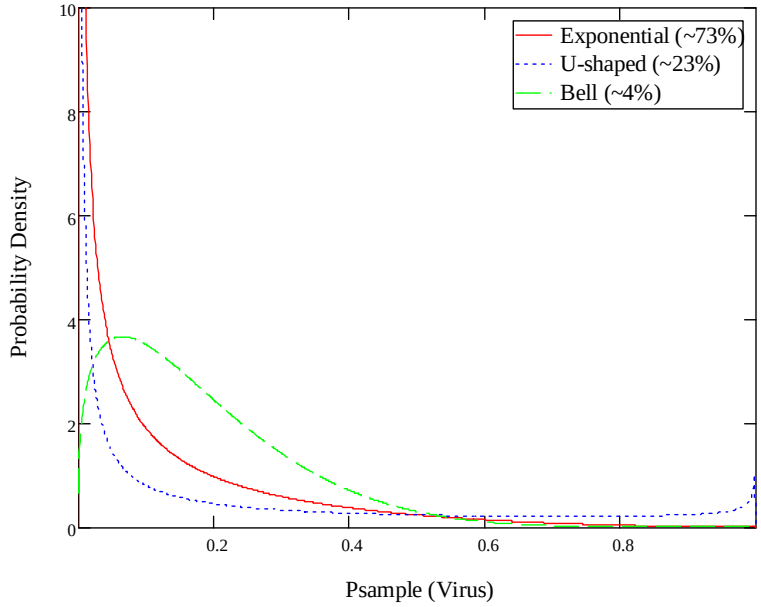
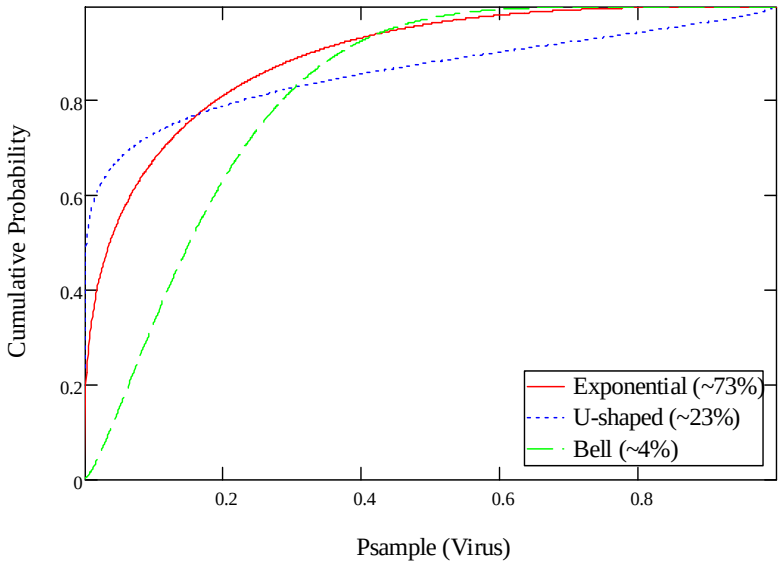
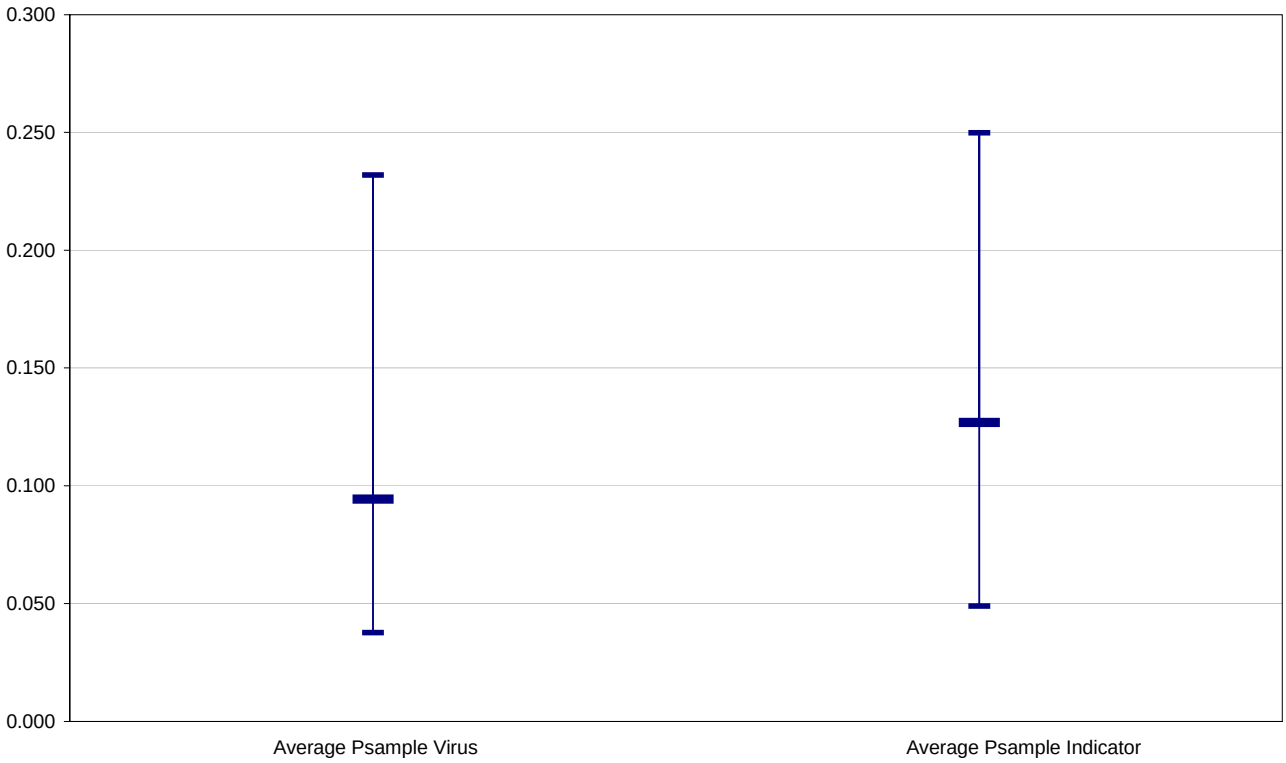


Exhibit 4.21 Cumulative Distributions of P_{sample} for Viruses



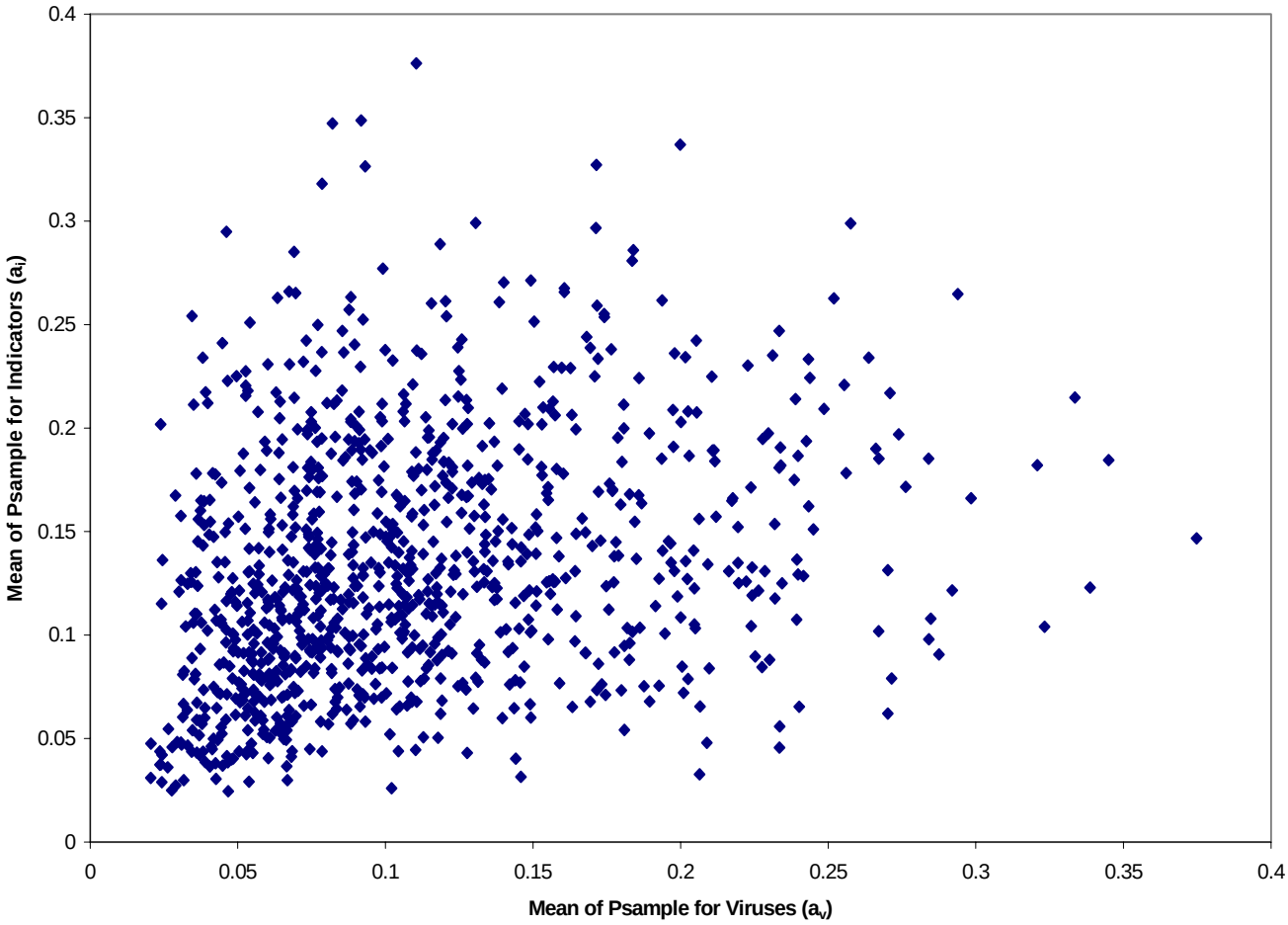
One way to summarize the full set of 10,000 P_{sample} distributions generated by the occurrence model is in terms of the range and central tendency of their expected values. For Pv_{sample}, the median of the expected values is 9.4%, with 5th and 95th percentile values are 3.8% and 23.2%, respectively. For Pi_{sample}, the median of the expected values is 12.7%, with 5th and 95th percentile values are 4.9% and 25.0%, respectively. These values are also shown graphically in Exhibit 4.22.

Exhibit 4.22 Median of 10,000 Estimates of P_{sample} for Virus and Indicator (with error bars showing the 5th and 95th percentiles)



The range and central tendency of the expected values for Pv_{sample} and Pi_{sample} are similar. The distribution of expected values for Pv_{sample} and Pi_{sample} pairs produced by the model, shown in Exhibit 4.23 for a sample of 1,000 pairs, shows a substantial number of pairs where both have values in the 5% to 15% range. However, there are a number where one of the pair is substantially higher (or lower) than the other member of the pair.

Exhibit 4.23 Scatter Plot of Means of P_{sample} Pairs for Indicators and Viruses



An important relationship that can be seen from the results of the occurrence modeling is between paired P_{sample} means and P_{well} values. For both viruses and indicators, it was found that there is, generally, an inverse relationship between them. The product of P_{well} and the average of P_{sample} is approximately equal to the overall fraction of samples found to be virus-positive, therefore the inverse relationship is expected. If either P_{well} or the average P_{sample} were increased without increasing the other, then significantly more virus-positive results should have been observed across the survey data sets. Similarly, a decrease in one, but not the other, would predict fewer positives than were observed. That is, a characteristic of the uncertainty revealed by the 10,000 sets of results from the occurrence modeling is that if the 'true' value of P_{well} (the fraction of wells that have virus or indicator present at some time) is high, the chance of finding the organism in a given sample at those wells tends to be low. Conversely, if the 'true' value of P_{well} is low, the chance of finding the organism in a given sample at those wells tends to be higher. These relationships are shown in Exhibits 4.24 and 4.25 for viruses and indicators, respectively, for a sample of 1,000 from the 10,000 sets of results produced by the occurrence model.

Exhibit 4.24 Mean of P_{sample} Versus P_{well} for Viruses (1,000 Pairs from Occurrence Model)

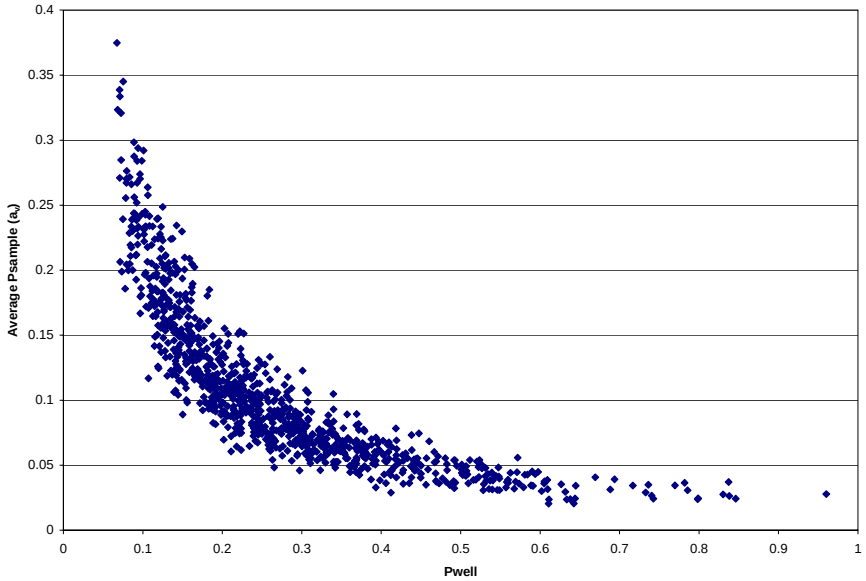
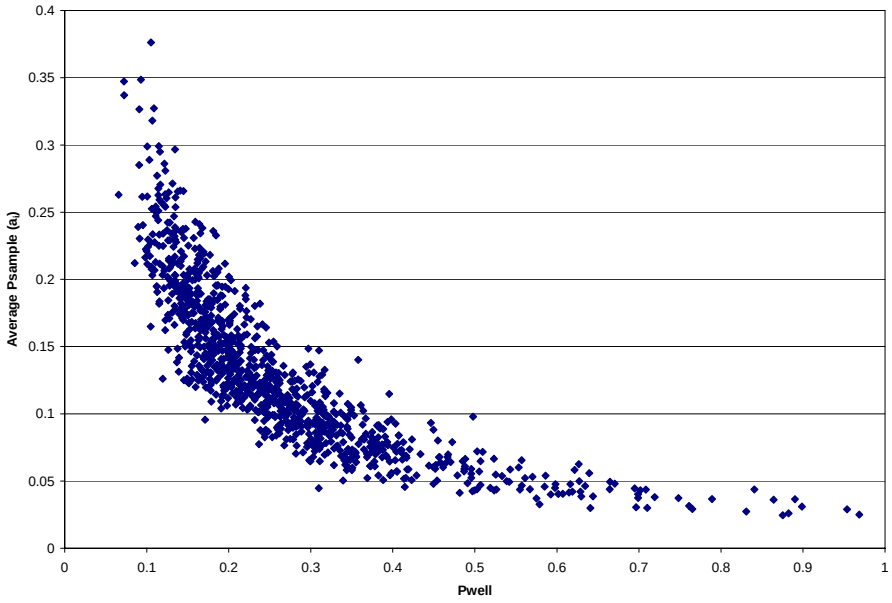


Exhibit 4.25 Mean of P_{sample} Versus P_{well} for Indicators (1,000 Pairs from Occurrence Model)



Use of Indicator Occurrence for Triggered Monitoring[14]

This section describes how the occurrence modeling described above, specifically that for the indicator hit rates, is used to predict the number of wells "captured" by triggered source water monitoring. The fraction of wells producing an indicator positive upon their first assay can be estimated as a function of the following:

Pi_{well} = fraction of wells with some indicator occurrence
αi = first parameter of beta-distributed Pi_{sample}
βi = second parameter of beta-distributed Pi_{sample}

As discussed in the section above, in each uncertainty iteration of the occurrence model, a set of parameter values describing indicator occurrence is selected from the MCMC sample (as well as parameters for Pv_{well} and Pv_{sample} that describe virus occurrence). The probability that an indicator positive will be observed by the time of the i^{th} assay can be obtained from $F_{n,i}$:

The probability that the i^{th} assay will be the very first positive for the site is the difference $F_{n,i}$ -

$$F_{n,i} = Piwell_n \cdot \int_0^1 dbeta\left(Ps, \alpha_n, \beta_n\right) \cdot \left[1 - (1 - Ps)^{i+1}\right] dPs ,$$

which simplifies to:

$$F_{n,i} = Piwell_n - Piwell_n \cdot \frac{\Gamma\left(\alpha_n + \beta_n\right) \cdot \Gamma\left(\beta_n + i\right)}{\Gamma\left(\alpha_n + \beta_n + i\right) \cdot \Gamma\left(\beta_n\right)} .$$

$F_{n,i-1}$. This is, then, the fraction of all wells expected to return an indicator positive upon the i^{th} assay.

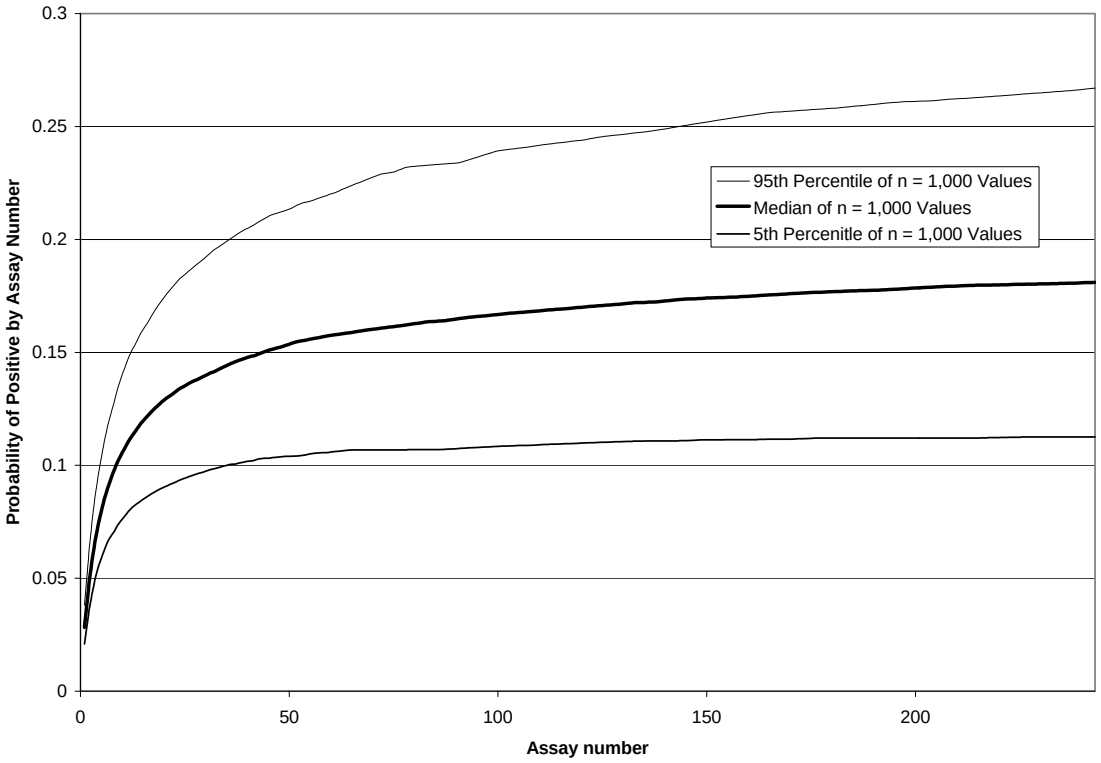
These probabilities (the F_n values) were derived for assays i = 1 through 200 for n = 10,000 uncertainty iterations. These probabilities are specifically associated with each set of the seven occurrence parameters generated by the model as described previously.

Exhibit 4.26 shows the cumulative probability of having an indicator on or before the indicator assay number. A sample of 1,000 sets was generated from the occurrence model, and three of the 1,000 curves are shown in the graph corresponding to the 5th percentile, median, and 95th percentile of all values for that assay number. These data are used in the cost model simulation, discussed further in Chapter 6, to determine whether, and if so when, a given well conducting triggered source water monitoring will

[14] The discussion below can also be applied to estimate the impact of assessment monitoring as an optional activity under the final rule, as well as under Alternative 3. The difference in the application of the analysis described below is driven solely by the number of samples taken, which will be more under assessment monitoring scenarios.

have its first indicator positive and as a result initiate corrective action. These data suggest that of all wells taking source water indicator samples, just under 20% would be expected to have a positive result on or before the 200th assay, as a central tendency estimate, with an uncertainty range from approximately 10% to over 25%.

Exhibit 4.26 Cumulative Probability of an Indicator Positive as a Function of Assay Number -- All Wells (used for cost analysis)



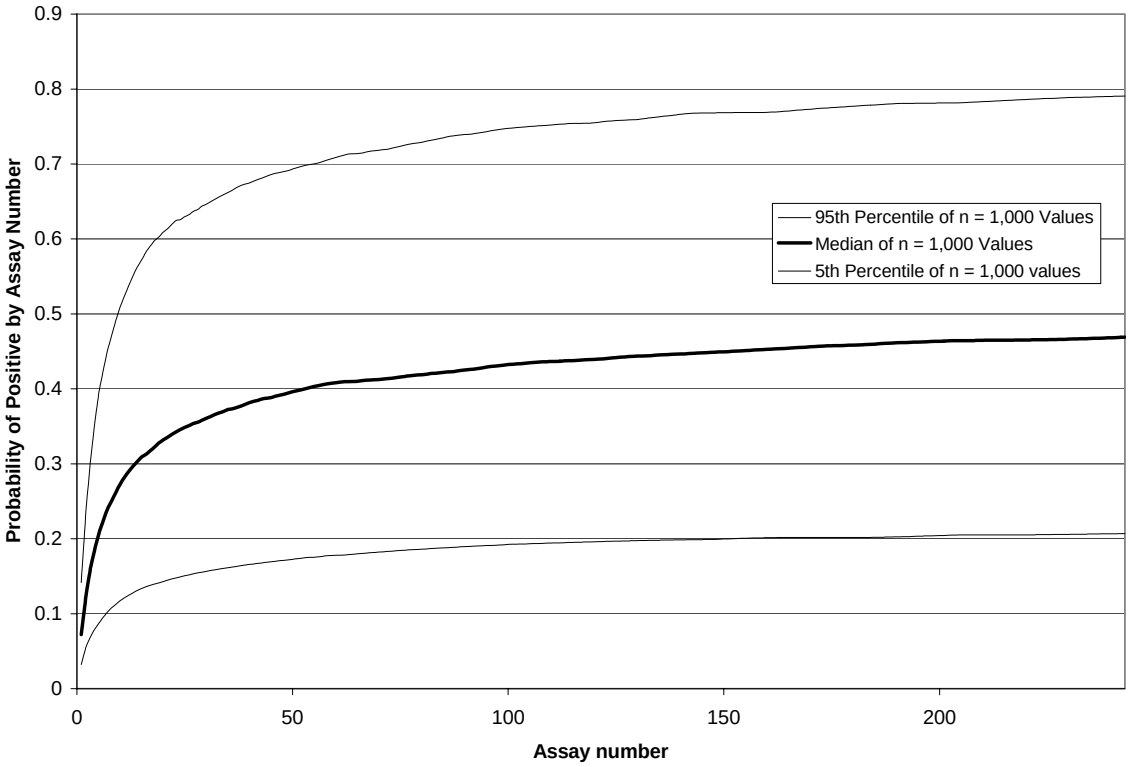
Similar data on the occurrence of the first indicator positive as a function of assay number are used in the risk reduction model, as discussed further in Chapter 5, to determine the effectiveness of indicator monitoring in source water to "capture" wells that are known to have virus present at some time (that is, areas P1 + P2 in the Venn diagram shown earlier in this chapter). For this part of the analysis, the $F_{n,i}$ values are adjusted to account for assays performed on those wells that are in the P1 + P2 "space". The adjustment made to the value of each assay probability result obtained as shown above is to multiply it by:

$$\frac{P2}{(P1+P2)\cdot(P2+P3)}$$

Exhibit 4.27 shows the three corresponding distributions for these adjusted values used for the risk reduction modeling. These data suggest that of those wells that have sometime presence of a virus and take source water indicator samples, just under 50% would be expected to have a positive on or

before the 200th assay, as a central tendency estimate, with an uncertainty range from approximately 20% to 80%. The higher values shown here relative to the "all wells" data shown above reflect the outcome that a much higher proportion of wells having some time virus presence also have some time indicator presence [i.e., P2/(P1+P2) than do all wells [i.e., (P2+P3)/(P1+P2+P3+P4)].

Exhibit 4.27 Cumulative Probability of an Indicator Positive as a Function of Assay Number -- Virus-positive Wells (used for risk reduction analysis)



It is important to note also that both of these sets of results indicate that observing an indicator positive in an early assay is more likely than on a later assay. This is because the structure of the model accounts for the higher likelihood of observing positives among those wells where the frequency of occurrence (that is, P_{sample}) is greatest.

4.3.4.2 Pathogen Concentration Analysis

The preceding section addressed hit rates, which comprise the first aspect of characterizing virus occurrence in source water used by public ground water wells. This section addresses virus concentrations which comprise the second aspect of occurrence.

Hit rates primarily address the consideration of "presence / absence" of virus in the water. The two components of hit rates are P_{well}, which characterizes the fraction of wells where viruses are either present at some time or are never present, and P_{sample}, which characterizes the fraction of samples or duration of time that the organisms occur in those wells that have viruses at some time.

If a well is one in which the virus is never detected (which is expected to be the case the majority of the time), the virus concentration is assumed to be zero. For those wells at which viruses are present at detectable levels however, it is necessary to characterize the expected concentrations of viruses so that the baseline risk and the risk reductions from regulatory alternatives can be estimated[15].

The available information on virus concentrations in wells is limited. Although the analysis performed here considers two categories of pathogenic viruses (Type A and Type B), useful information on virus concentrations are only available from cell culture results for Type B viruses (enteroviruses). For the purposes of this analysis, it has been assumed that the concentrations of Type A viruses are similar to those for Type B.

Just as there is variability in virus occurrence with respect to prevalence (some wells have viruses while others do not, and for those that do, the frequency of occurrence varies among contaminated wells), so too, there is variability in expected concentrations of viruses from well to well among those wells where viruses occur. As will be evident from the information presented, this variability encompasses both large scale differences between those wells considered to be less vulnerable and those considered to be more vulnerable, as well as differences from one location to another within each of these two categories of wells.

As noted previously, participants in the May 2005 statistics workshop were asked to consider how to model virus concentrations in virus-positive well water. Several options were considered both for stratifying the wells into different categories to reflect different ranges of expected concentrations and for fitting the concentration data to specific distributional forms to use in the baseline risk and risk reduction modeling. However, no specific recommendations were made.

Following the workshop, EPA decided to stratify wells into two categories according to overall vulnerability characteristics (more and less vulnerable wells). Unlike the hit rate analyses which draw on data from 15 different studies, EPA relied upon only three key studies for viral concentration data. The data from the Lieberman et al. 2002 study are used to represent virus concentrations in more vulnerable wells and the combined data from the Abbaszadegan et al. 2003 study and the Pennsylvania study are used to represent concentrations from less vulnerable wells. The Lieberman et al. 2002 concentration data comes from wells that were included in the study because they had a history of TC contamination or other evidence of vulnerability. As such, they are most like wells with TCR violations and therefore are assumed to be representative of this group of more vulnerable wells. The Abbaszadegan et al. 2003 study and the Pennsylvania study include wells selected for reasons other than a TC occurrence history. As such, they are assumed to represent the less vulnerable wells group. Furthermore, the Pennsylvania wells are exclusively noncommunity wells and therefore the measured concentrations in these wells represent the group of less vulnerable noncommunity wells.

[15] Although hit rates were developed for both viruses and indicators, virus concentration modeling is necessary for the risk and benefits analysis, but *E.coli* concentration modeling is not. For the indicators, the hit rate information is needed to estimate risk reduction for the regulatory alternatives.

Virus Concentration Data Used

Concentrations for More Vulnerable Wells

EPA identified the Lieberman et al. 2002 study as providing the most complete set of virus concentration information for wells considered to be more vulnerable. These data are from cell culture assays for Type B viruses. As described in section 4.3.2, seven of the 30 wells in this study were found to have virus present by the cell culture method. A total of 20 positive values were observed. The concentrations of the positive values are presented in Exhibit 4.28 below.

Exhibit 4.28 Summary of Virus Concentrations Observed in the Lieberman et al. 2002 Study

Study Well Number	Concentration (PFU or MPN per 100 L)
29	6.55
29	12.32
29	27.01
29	0.86
29	3.72
29	2.01
29	10.59
31	19.63
31	15.37
31	10.76
31	9.61
47	45.33
47	3.17
47	43.99
47	47.72
61	53.37
61	25.17
91	12.78
97	9.52
99	212.51

Note: Shaded rows indicate State determined GWUDI wells.

Concentrations for Less Vulnerable Wells

EPA identified the Abbaszadegan et al. 2003 and the Pennsylvania Noncommunity Well studies as providing the most complete set of virus concentration information for wells considered to be less vulnerable. These data are from cell culture assays for Type B viruses.

In the Abbaszadegan et al. 2003 data, there were a total of 22 samples taken from 21 different wells with cell culture concentration data, as summarized in Exhibit 4.29 below.

Exhibit 4.29 Summary of Virus Concentrations Observed in the Abbaszadegan et al. 2003 Study

Study Well Number	Concentration (viruses per 100 L)
AZ-0001 / 3	1.89
AZ-0001 / 3	0.18
ID-0002	0.09
MO-0001	0.36
NH-1	0.19
IL-5	1.56
CA-1	0.45
PA-7	0.15
PA-21	0.17
NJ-13	0.17
CA-12	0.45
NJ-12	0.18
IL-10	0.18
IN-32	0.64
O-NY-15	0.18
O-WI-10	0.46
O-CA-22	0.92
O-CA-21	0.18
O-OH-6	0.19
OH-1	0.92
OH-3	0.15
IN-31	0.18

In the Pennsylvania Noncommunity Well study, there were a total of 5 samples taken from 5 different wells with cell culture concentration data, as summarized in Exhibit 4.30 below.

Exhibit 4.30 Summary of Virus Concentrations Observed in the Pennsylvania Noncommunity Study

Study Well Number	Concentration (viruses per 100 L)
HU 425	0.21
JU 372	51.99
CE396	18.30
CH 5994	0.21
BR852	33.4

Application of Virus Concentration Data for Baseline Risk and Risk Reduction Models

As noted above, the participants in the May 2005 statistics workshop discussed alternative distributional forms to fit to the concentration data for use in the risk and risk reduction models. Following the workshop, EPA explored several options for fitting the data but determined that because of the limited number of data points and the considerable variability in the data even within the two vulnerability strata, that rather than fitting the data to a specific distributional form it was preferable to use the data directly and draw from them randomly, with replacement, in the simulation model.

Therefore, for the baseline risk and risk reduction simulation models as described in Chapter 5, each well that is identified as having virus present at some time has a concentration value drawn from one of the 20 values shown above from the Lieberman et al. 2002 study if that well is in the more vulnerable stratum, and from one of the 27 values shown above from the Abbaszadegan et al. 2003 and Pennsylvania studies if that well is in the less vulnerable stratum.

The concentration thus selected is assumed to be the average concentration in those samples or on those days when the virus is present. The use of these concentrations along with the P_{sample} value for the wells identified as having virus present is described in more detail in Chapter 5.

4.4 Outbreak Baseline and Causes of Contamination

CDC, EPA, and the Council of State and Territorial Epidemiologists have maintained a collaborative surveillance program for collection and periodic reporting of data on waterborne disease outbreaks since 1971. The CDC database and biennial CDC–EPA surveillance summaries include data reported voluntarily by the States on the incidence and prevalence of waterborne illnesses. According to the CDC–EPA database for ground water systems, between 1991 and 2000, a total of 68 outbreaks and 10,926 cases of illnesses were reported for GWSs (see Exhibit 4.32). Although CDC has data dating back to 1971, the 1991 to 2000 data represent the best available data since the implementation of the current

drinking water regulations (e.g., Total Coliform Rule). The reported outbreaks resulted from virus contamination, bacterial contamination, and unknown factors. Exhibit 4.31 shows a summary of waterborne disease outbreaks for ground water systems. Causes reported as miscellaneous are outbreaks where insufficient data exist to accurately categorize the source of the contamination.

Exhibit 4.31 Summary of Waterborne Disease Outbreaks Attributable to PWSs Served by Wells using Ground Water: 1991-2000*

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

*Excludes disease caused by pathogenic protozoa in PWS since such systems are deemed as ground water under the direct influence (and are subject to surface water treatment rule requiements) .
Sources: CDC, 1993; Kramer et al., 1996; Levy et al., 1998; Barwick et al., 2000; Lee et al., 2002

The number of outbreaks reported to the CDC are believed to be an underestimate of the total number of waterborne outbreaks that actually occur (National Research Council 1997a, Frost et al., 1996). Some of the reasons for the lack of recognition and reporting of outbreaks include the following.

- 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.

- Health officials may not recognize the occurrence of small outbreaks, even in States with effective disease surveillance systems. In cities, large outbreaks are more likely to be recognized than sporadic cases or small outbreaks in which ill persons may consult different physicians.

- Some States do not always report identified waterborne disease outbreaks to the CDC. Reporting outbreaks is voluntary.

- Most cases of waterborne disease are characterized by general symptoms (diarrhea, vomiting, etc.) that cannot be distinguished from other illnesses.

- 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.

- Even if a clinical test is ordered, the patient must comply, a laboratory must be available and be 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 one-time contamination events.

- The vast majority of ground water systems are NCWSs. Outbreaks associated with many types of NCWSs may be less likely to be recognized than those in CWSs because NCWSs generally serve nonresidential areas and transient populations.

Although they may be under-reported, documented outbreaks demonstrate that ground water sources are not free of pathogenic contaminants and thus support the need for the GWR. The true incidence of waterborne outbreaks and associated illness is unknown. In addition, persistent low to moderate levels of endemic waterborne illness often go undetected by routine disease surveillance programs. This lack of knowledge stems from inadequate surveillance of disease outbreaks, insufficient outbreak detection methods, lack of epidemiologic investigation, and lack of microbial monitoring.

4.5 Summary of Uncertainties in Development of GWR Baselines

Uncertainty in this baseline analysis is due to limitations of the available information. These uncertainties contribute to uncertainties in the cost and/or benefit estimates presented in Chapters 5 and 6. Exhibit 4.32 presents a summary of these uncertainties and indicates their potential impacts on the cost and benefits estimates.

Exhibit 4.32 Summary of Uncertainties Affecting GWR Baseline Estimates

Uncertainty	Section with Full Discussion of Uncertainty	Effect on Benefit Estimate			Effect on Cost Estimates		
		Under-estimate	Over-estimate	Unknown Impact	Under-estimate	Over-estimate	Unknown Impact
Uncertainty in baseline data inputs (SDWIS and 1995 CWSS data)	4.2.3			X			X
Mixed systems in baseline	4.2.3			X			X
CWS flow equations used for NCWSs	4.2.4		X			X	
Percent of wells in vulnerable category	4.3.3			X			X
Percent of sensitive wells	below			X			X
Viral hit rates	4.3.2, 4.5.4.1, and below	X					
Viral concentrations	4.4.2 and below	X					
Indicator hit rates	4.3.2			X			X
Wells with viruses have them at same levels regardless of indicator presence	below	X			X		
Wells with viruses have them the same fractions of time regardless of indicator presence	below	X			X		
Wells with indicator have it same fractions of time regardless of virus presence	below	X			X		
Indicator and virus occurrence not related to well's hydrogeologic sensitivity	below			X			X

About half of the impacts are "unknown," meaning that they could lead to either over- or under-estimates. Of those whose effect is under- or over-estimation, the two that seem most significant are those for hit rate and concentration. Viral hit rates tend to be understated because virus recovery is highly dependent upon the matrix and virus types and because the measurement methods fail to detect many pathogenic viruses. Assuming zero viruses when none is detected leads to systematic underestimation of average concentrations. Perhaps more important than these is the fact that the occurrence model assumed no relationship between indicator occurrence and either a) the fraction of time that virus is present in virally-contaminanted wells or b) the virus concentration levels that are realized whenever virus is present. The only relationship modeled between indicator and virus is the fraction of wells having both (P2) as compared to wells having only virus (P1) or only indicator (P3). It is likely that wells containing *E. coli* and virus will have virus more often and at higher concentrations than in wells containing only virus. Not modeling this relationship between *E. coli* and virus results in a significant underestimate of benefits derived from the Rule's indicator-based corrective action.

The occurrence models do not distinguish between sensitive and nonsensitive wells. The benefits analysis assumes no difference between these with respect to virus and indicator hit rates. The effects of this assumption on the cost and benefits estimates are unknown. If occurrence (hit rates and/or concentration) in sensitive wells is greater, or if the virus-indicator relationship is stronger, then the benefits of monitoring are probably underestimated.

5. Benefits Analysis

5.1 Introduction

The Ground Water Rule (GWR) reduces the public health risks of illness and death (morbidity and mortality), by reducing public exposure to viral and bacterial pathogens present in ground water wells due to intrusion of fecal matter. The health-related benefits of the GWR are due to reductions in both endemic and outbreak risks and reductions in both acute and chronic illnesses. These health benefits and non-health benefits are presented in Exhibit 5.1.

Exhibit 5.1 also presents a comparison of the subset of quantified benefits quantified in this EA with the total (both quantified and nonquantified) GWR benefits. The quantified benefits are a small subset of the total benefits because 1) of the many ground waterborne viruses avoided, only illnesses and deaths from subsets of two types of viruses are quantified, 2) no quantified benefits accrue from avoided acute and chronic bacterial illnesses and deaths, 3) only endemic illnesses and deaths avoided are included in the analysis (epidemic illnesses and deaths are specifically excluded), 4) of these endemic illnesses, only avoided acute illnesses and resulting deaths–from two types of viral illnesses ! are quantified, and 5) non-health related benefits are excluded.

Exhibit 5.1 Overview of Quantified and Nonquantified GWR Benefits

(continued on next page)

Benefit Category	Total Benefits	GWR EA Quantified Benefits
Health Benefits		
Reduction in endemic illness incidence	• viral exposure risk reduction (morbidity and mortality) • bacterial exposure risk reduction (morbidity and mortality) • chronic sequelae reduction • reduction in secondary transmission of viral or bacterial illness from symptomatic and asymptomatic individuals	• acute rotavirus (Type A) illnesses and deaths avoided • acute enterovirus (Type B) illnesses and deaths avoided • subsets of viruses within Type A and Type B categories and bacterial illness and death not quantified • reduction in secondary transmission of viral illness from symptomatic individuals
Reduction in epi-demic (outbreak) illness incidence	• viral exposure risk reduction (morbidity and mortality) • bacterial exposure risk reduction (morbidity and mortality) • chronic sequelae reduction • reduction in secondary transmission of viral or bacterial illness from symptomatic and asymptomatic individuals	Not quantified

Benefit Category	Total Benefits	GWR EA Quantified Benefits
Reduction in treatment failures	• Decreased illness through minimizing treatment failures or fewer episodes with inadequate treatment	Not quantified
Non-health Benefits		
Outbreak responses avoided	• Avoided costs to affected water systems, local governments (provision of alternate water, issuing warnings and alerts), and community (decreased tourism due to bad press).	Not quantified
Avoided costs of averting behavior	• reduced need or perceived need to use bottled water, point-of-use devices, etc. (includes time and material costs) • less time spent on averting behavior: hauling/boiling water, etc.	Not quantified
Increased confidence	• Perceived reduction in risk associated with perceived improvement in drinking water quality	Not quantified

This chapter presents estimates of the GWR health-based benefits, including a discussion of nonquantified benefits and provides estimates of the monetized value of the quantified avoided illnesses and deaths. It describes the methodology of the risk assessment and benefits valuation that is outlined in Exhibit 5.2. In addition, this chapter discusses health and nonhealth benefits of the GWR uncertainties and sensitivities and presents a comparison of other regulatory alternatives considered. More detail on the risk assessment for the GWR is presented in Appendices F and G.

5.1.1 Quantified Benefits

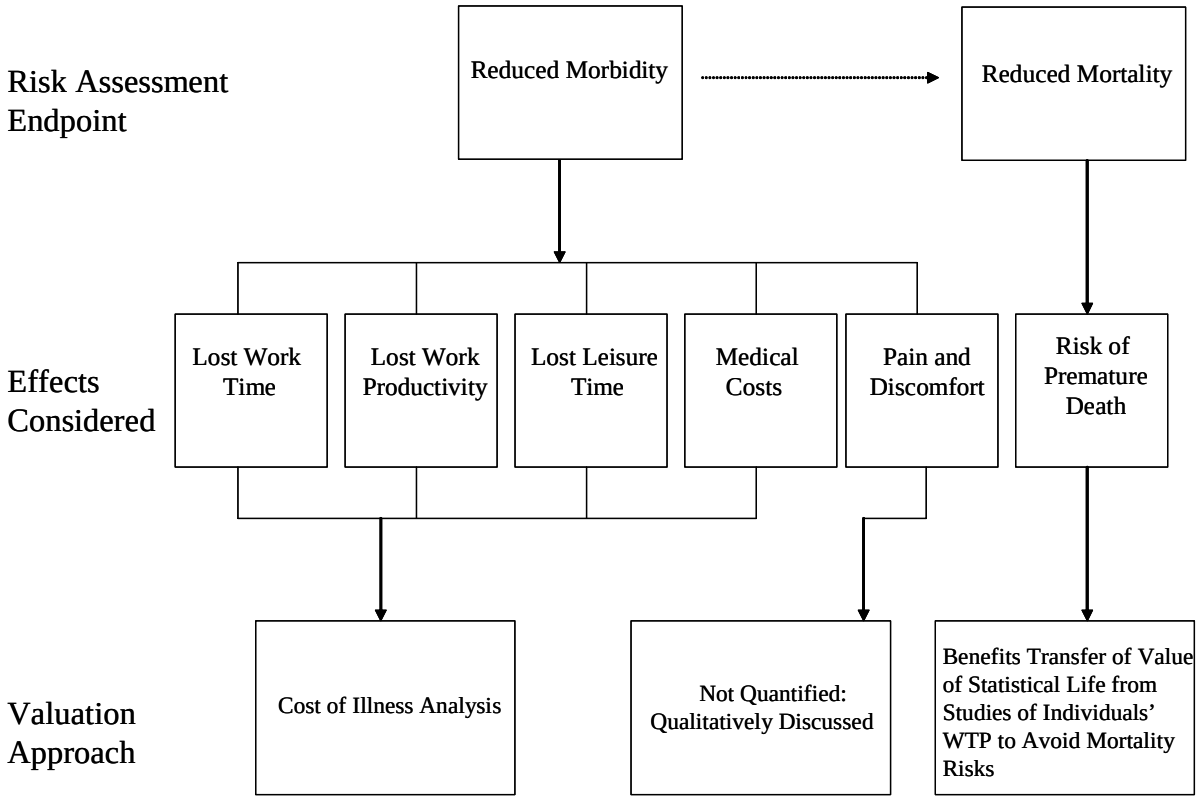
The quantified benefits include the avoided endemic acute illnesses (morbidity) and associated deaths (mortality) each year from a subset of pathogenic viruses. The risk assessment is used to quantify the number of baseline viral illnesses and deaths (i.e. those under current exposure conditions) and those remaining after implementation of the GWR for the various regulatory alternatives. The differences between the baseline estimates and those following implementation of the GWR are the avoided cases of morbidity or mortality. EPA uses the estimates of avoided illness and deaths to establish the quantified benefits of the GWR. Section 5.4 of this EA discusses the nonquantified benefits (both endemic and epidemic), including chronic sequelae, for viruses and bacteria. The GWR total benefits include both the quantified and nonquantified benefits, which are illustrated in Exhibit 5.1 above.

The risk assessment modeling requires a number of assumptions to be made regarding exposures to viral pathogens in drinking water. An overview of the risk assessment methodology is presented in

section 5.2.1. The hazard identification process is presented in section 5.2.2. The assumptions that are required to assess pathogen exposures are presented in section 5.2.3. The dose response assessment is presented in section 5.2.4. Baseline risk and the results of the risk reduction analysis (i.e., in terms of illnesses and deaths avoided) are presented in section 5.2.5.

The benefits valuation process applies monetary values to the results of the risk reduction analysis to estimate the value of the illnesses and deaths avoided in exposed populations. The assumptions and inputs used to determine the unit values of avoided illness and death are discussed in section 5.3.1 and Appendix A of this EA. The results of this analysis, the monetized benefits of avoided morbidity and mortality for the GWR, are presented in section 5.3.2 and the results for all regulatory alternatives considered are compared in section 5.7. The monetized benefits are compared to the rule costs for the GWR and all regulatory alternatives in Chapter 8 of this EA.

Exhibit 5.2 Overview of Viral Pathogen Risk Assessment and Benefits Valuation Procedure for Quantified Benefits (Main Analysis)[1]



[1]This schematic presents an overview of only the quantifiable benefits of the GWR. The nonquantified benefits are expected to comprise a significant portion of the overall benefits of the Rule and are presented in Section 5.4.

5.1.2 Nonquantified Benefits

There are substantial benefits attributable to the GWR that are not quantified within this EA as part of the main analyses because of data limitations. Nonquantified benefits due to etiological agents, disease endpoints and exposure scenarios not considered in the main analysis are discussed in the nonquantified benefits section (Section 5.4).

The monetized benefits from avoided acute illness due to many viral pathogens and all waterborne bacterial pathogens are not quantified as a part of the main analysis. Chronic health effects associated with viral and bacterial contamination are also not quantified. As discussed in section 5.4.2, the benefit of avoiding these chronic cases may be significant, as affected individuals incur significant costs in medical care and losses in productivity and quality of life in such instances. EPA considers these nonquantified factors to be significant and a qualitative discussion of these nonquantified benefits is included in Section 5.4.

The natural history of infectious disease suggests that symptomatic and asymptomatic carriers can infect other individuals by secondary transmission, either directly by physical contact and respiratory droplets or indirectly via aerosols and contaminated surfaces. EPA estimates the number of secondary cases arising from each primary case in the main analysis. Additionally, the nonquantified benefits section (5.4) and Appendix E address this issue in a qualitative discussion supported by simulations of the infectious disease process in large, susceptible (capable of being infected) populations.

In addition to the health-based benefits identified above, there are a number of nonhealth benefits that also arise from promulgation of the rule. Other nonquantified benefits may result from overall system improvements (e.g., upgrades to distribution systems, increased water treatment plant operational efficiency and reliability, increased frequency/intensity of system surveillance), from improved risk perception of drinking water quality, or from avoided outbreak response costs. While the value of these nonhealth benefits are not quantified for this EA, these potential benefits are discussed qualitatively in Section 5.4.

5.2 Quantified Health Benefits from Reduction in Exposure to Viruses

This section describes the risk assessment methods and assumptions used to quantify the baseline health risks and the expected health benefits of the GWR. Quantified health benefits for a subset of reduced pathogen exposure from the final GWR are derived from the risk assessment estimates of the pre- and post-GWR annual endemic acute illnesses and deaths attributable to ground water source contamination. Annual endemic acute illnesses are those that occur as a result of drinking water contaminated with waterborne pathogens occurring under normal operating conditions. The main analysis addresses only viral acute illnesses and, specifically, those caused by rotavirus and enteroviruses. Other illnesses resulting from other etiologic agents, disease endpoints, and exposure scenarios are addressed in the nonquantified benefits section (Section 5.4).

The two viruses quantified in the main analysis (Type A virus represented by rotavirus data and Type B virus represented by enterovirus data) were selected because human challenge study data are available for both viruses and because they are suitable representatives of two broad classes of pathogenic viruses (Ward et al., 1986 and Schiff et al., 1984).

5.2.1 Overview of Risk Assessment Methodology[1]

Risk assessment is an analytical tool that can be used to characterize the expected incidence of adverse health effects associated with exposure to an environmental hazard. For the GWR, the EPA has developed a risk assessment model to estimate the baseline number of endemic acute illnesses and deaths associated with ingesting a subset of pathogenic viruses present in public ground water systems (GWSs). The risk assessment uses a standard framework that is organized in accordance with EPA Policy for Risk Characterization (USEPA 1995a), EPA's Guidance for Risk Characterization (USEPA 1995b), and EPA's Policy for Use of Probabilistic Analysis in Risk Assessment (USEPA 1997b).

This standard framework requires the use of scientific data (or reasonable assumptions if data are not available) to produce estimates of the nature, extent, and degree of a risk. Where there is uncertainty in the data and assumptions used, that uncertainty is described and its impact on the risk estimates is characterized. The risk assessment used in the GWR incorporates information on variability and uncertainty associated with the data that characterize both the distribution of risk levels within the affected population (variability) and the confidence bounds on key parameters of the risk assessment model (uncertainty). Variability arises from true heterogenicity across people, places and time, and uncertainty represents the lack of knowledge of the true value of the factor being considered (EPA 1997b).

According to the 1995 EPA Policy for Risk Characterization (USEPA 1995a), health risk assessments for environmental contaminants generally involve four components:

- Hazard Identification addresses the nature of the potential adverse health effects associated with exposure to the contaminant.

- Exposure Assessment addresses both the number of people in the population exposed to the contaminant and the distribution of levels of exposure within that population.

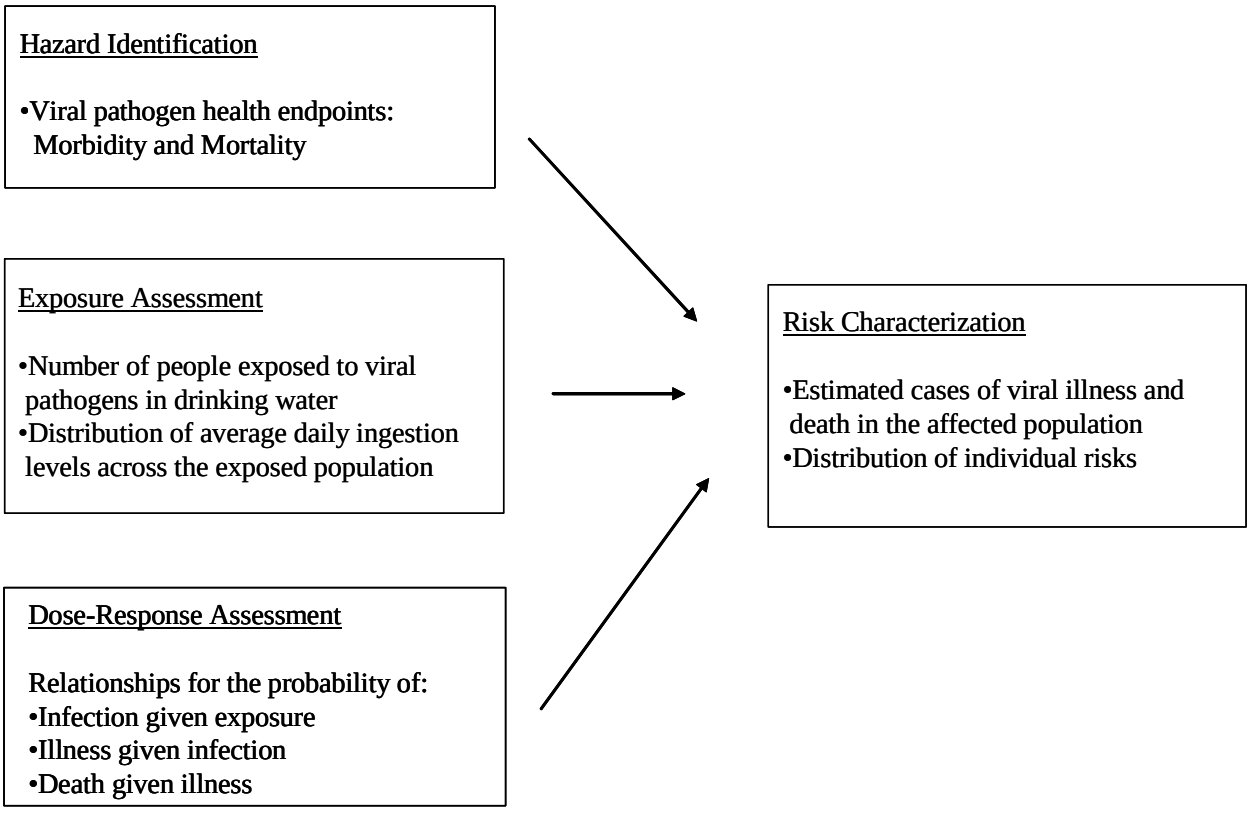
- Dose Response Assessment addresses information concerning the relationships, quantitatively where possible, between the magnitude of exposure to the contaminant and the extent and severity of the adverse health effects that may occur.

- Risk Characterization combines the hazard identification, dose response, and exposure assessment information to describe overall risk to the exposed population, both in terms of the distribution of individual risk levels in the population and the total number of cases of adverse effects anticipated.

Exhibit 5.3 depicts these major elements of the risk assessment for characterizing the risk of illness (morbidity) and death (mortality) from exposure to viral pathogens in drinking water systems covered by the GWR. Each of these four components is addressed specifically for the GWR risk assessment in sections 5.2.2 through 5.2.5.

[1] For a more detailed description of the risk assessment process, see Appendix F.

Exhibit 5.3 Health Risk Assessment Framework



The GWR is expected to reduce the current incidence (baseline) of acute and chronic illness caused by a wide variety of viral and bacterial pathogens associated with fecal contamination of ground water. Although the quantified benefits risk assessment accounts for only some viral pathogens and only some acute illnesses and deaths associated with these viral pathogens, different pathogens can cause different types of illnesses, and pathogens differ in their virulence, the degree or ability to cause illness or death. Medical research has not isolated all waterborne pathogens, nor has it thoroughly characterized the virulence of all of the waterborne pathogens that have been identified. As detailed in Chapter 4, there are two types of viruses found in water with data judged to be adequate for a risk assessment: Type A (rotavirus) and Type B (enteroviruses). EPA has chosen to quantify these two types of viruses to represent the range of waterborne viral pathogens for the GWR risk assessment. A more comprehensive range of bacterial and viral pathogens addressed by the GWR is discussed in Section 5.4.

The GWR risk assessment is based on routine exposure to two representative virus types (Type A represented by data on rotavirus and Type B represented by data on echovirus or enterovirus). As discussed in Chapter 4, Section 4.3.2, the virus assay method used in all viral occurrence studies was developed and optimized for recovery of poliovirus in water. Poliovirus is a member of the enterovirus group and so the virus assay is also relatively efficient at recovering the enteroviruses other than poliovirus with the prominent exception of some coxsackie A viruses, which are not recoverable. Other viruses, including Type A and similar viruses such as rotavirus and hepatitis A virus are substantially less

efficiently recovered. Thus, the viral occurrence data used in the risk assessment are based primarily on enterovirus recovery. Based on EPA's analyses of the occurrence data, enteric viruses such as Type B viruses are intermittently present in a virus positive well each year for only short durations (generally from a few days to a few weeks). EPA assumes that equal concentrations of Type A viruses are also present when enteric viruses such as Type B are measured in wells during those short intervals of virus contamination.

The first step of the risk assessment framework is to estimate the baseline (pre-GWR) number of acute illnesses and deaths occurring from rotavirus (Type A viruses) and enteroviruses (Type B viruses). An analysis is then conducted for conditions reflecting changes resulting from the final GWR regulatory requirements (as well as several other regulatory alternatives) to produce an estimate of the number of illnesses and deaths remaining after implementation. The quantified health benefits of the GWR are then obtained from the difference between the baseline and the results under the regulation (the estimated cases of illness and deaths avoided as a result of the regulation).

5.2.2 Hazard Identification

This section presents summary information on the adverse health effects associated with ingesting waterborne viral pathogens, including a discussion of the effects on sensitive subpopulations. The acute and chronic health effects associated with bacterial pathogens are included in the nonquantified benefits discussion (Section 5.4).

5.2.2.1 Health Effects of Viral Infections

A review of the medical and epidemiological literature reveals that the extent of acute viral health effects varies by severity and by population subgroup for each virus. As described previously in Chapter 4, the viruses of concern were categorized as Type A (represented by rotavirus) and Type B (represented by enterovirus). The subsections below summarize the typical health effects of each virus type. Additional descriptions of the health effects of viral illnesses are presented in Chapter 2 and Section 5.4 of the GWR EA.

Type A Viruses (rotavirus)

Generally, Type A viruses are highly infectious viruses that cause acute gastroenteritis, resulting in symptoms that include watery diarrhea, fever, abdominal pain, and vomiting. Although they are highly infectious, Type A viruses generally lead to mild, non-life-threatening acute illnesses. Common strain rotaviruses typically affect young children, particularly those less than 3 years old, but other strains (G1, G2 and G9) have been found to be common in adults and the elderly in nursing homes, and found to be responsible for more severe illness in children (Griffin et al., 2000). As discussed further in Section 5.4, most ground water-borne gasteroenteritis associated with viral exposure in the U.S. is believed to be the result of norovirus, although rotavirus outbreaks are known (e.g. Gallay et al, 2006). Norovirus causes gastroenteritis with vomiting in both adults and children. Due to data limitations, this EA only addresses the disease burden related to a few strains of rotavirus, which rarely causes illness with debilitating symptoms in adults and is not often accompanied by vomiting in either adults or children. Therefore, the EA quantifies only one part of the total Type A virus risk.

Type B Viruses (enteroviruses)

People of all ages may experience various adverse health conditions as a result of ingesting Type B viruses. Type B viruses are less infectious than Type A but result in more severe illnesses than Type A viruses. For this type of virus, acute illnesses are classified into three levels of severity:

- Illness that does not require medical attention (mild symptoms)
- Illness that requires a doctor visit
- Illness that requires hospitalization

Mild enteroviral illness include nonspecific febrile illness, respiratory illness, photophobia or sensitivity, stiff neck, and gastrointestinal illness. Aseptic meningitis may or may not require a doctor's visit, but more severe illnesses such as viral encephalitis, myocarditis, and non-polio flaccid paralysis are likely to require hospitalization. Most likely to be hospitalized are young infants (<3 months old) with non-specific febrile illnesses that require treatment to rule out and expectantly treat serious bacterial illness. Chronic illnesses such as diabetes and dilated cardiomyopathy more likely result from Type B infection as compared with Type A (chronic illnesses are not quantified in this EA but are discussed in Section 5.4).

5.2.2.2 Sensitive Subgroups

Although it is generally believed that most people are vulnerable to repeated infection by viruses and other microorganisms during their lifetime, factors such as being very young, elderly, or immunocompromised can affect the probability of illness given exposure, the severity of illness, and the likelihood of a fatal outcome. Virus morbidity and mortality (see section 5.2.4 for further description of these factors) incorporated in the GWR model include higher rates for some age groups, typically for neonates (Type B viruses) and children (both Type A and Type B viruses). Some of these sensitive populations are presented with their percentages of the United States population in Exhibit 5.4.

Exhibit 5.4 Sensitive Populations in the United States

Sensitive Population	Individuals	% of US population[1]	Citation/Notes
Pregnant women and neonates			
Pregnant Women	6,240,000	2.2	Vital and Health Statistics, CDC (Ventura, 2000)
Neonates (< 1 month) [2]	317,137	0.1	US Bureau of the Census (2000)
Age-based sensitive populations			
Children (< 5 years)	19,175,798	6.8	US Bureau of the Census (2000)
Elderly (> 64 years)	34,991,753	12.4	US Bureau of the Census (2000)
Compromised Immune Status			
Bone marrow transplant recipients	20,000	0.01	National Marrow Donor Program http://www.marrow.org/MEDIA/facts_figures.pdf
AIDS patients	816,149	0.3	HIV/AIDS Surveillance Report, cases through 2001 (CDC, 2002)
Organ Transplant Recipients	23,143	0.01	US Bureau of the Census, Stat Abs of US, based on 1998 data 2001b)

[1]U.S. Census estimtate July 2000.
[2] Reflects the estimated number of newborns age <1 month (1/12 of the 2000 census population for age < 1 year).

The Very Young

The very young [e.g., infants (neonates) less than one month old] are considered to be more likely to develop severe illness and death from gastroenteritis and other waterborne viral and bacterial infections than the general population. Most vertical transmission between mother and infant occurs during and after childbirth. Viral gastroenteritis, caused mainly by Type A viruses, is prevalent among U.S. children. The Agency's document, "Health Risks of Enteric Viral Infections in Children" provides a comprehensive review of viruses that pose adverse health implications for children (USEPA, 2000g). Primary food or waterborne exposure followed by secondary transmission via the fecal-oral route contributes to high rates of illness in group settings where care is provided for children that wear diapers such as day-care centers. The Centers for Disease Control and Prevention (CDC) has determined that the incidence of rotavirus diarrhea can reach 0.30 episodes/child/year by age two, with a cumulative incidence approaching 0.80 episodes/child by age five (Glass et al., 1996). Hospitalizations for rotavirus diarrhea are most common in children 6 months to 3 years of age (Parashar et al., 1998), while self-limiting norovirus infections are prevalent in school-age children (LeBaron et al., 1990). Although deaths from infectious diarrhea have generally declined among U.S. children since 1965 because of re-hydration therapy, newborn children, especially infants born prematurely, remain at risk of death from severe diarrheal illness (Kilgore et al., 1995).

In addition, some viral pathogens such as coxsackie B virus (a Type B enterovirus) can be transmitted transplacentally from an infected mother to her child *in utero*, during birth, or shortly thereafter. This type of transmission places the infected newborn infant at risk of severe symptomatic illness from meningitis or myocarditis, for which the case fatality rates are high (Gerba et al., 1996a).

The Elderly

The elderly (individuals over 65 years of age) are also at greater risk than the general population of experiencing severe health effects from rotavirus diarrhea, hepatitis, and other viral infections. Sensitivity among individuals in this age group is due to declining immunity and poorer general health (Gerba et al., 1996a and Lew et al., 1991). Conditions such as cardiovascular disease make the elderly more susceptible to complications of diarrhea such as electrolyte imbalance, dehydration, and shock (Maasdam and Anuras 1981). More than half of the diarrheal deaths that occur in the United States are among persons older than 74 years of age, and the risk of death from diarrhea is generally higher among elderly persons confined to nursing homes and other care facilities (Lew et al., 1991; Gerba et al., 1996b).

In this EA, due to limited data the morbidity and mortality factors assigned to the elderly for Type A and B virus infections are the same as those used for the general population. These factors underestimate the risks for elderly individuals. The EPA believes there are insufficient data available to assign higher morbidity or mortality rates from waterborne viral infections.

The Immunocompromised

Immunocompromised and immunosuppressed persons comprise a population subgroup who are more susceptible to viral and bacterial infections and are more sensitive to serious health effects from them. More specifically, Acquired Immunodeficiency Syndrome (AIDS) patients (e.g. Morpeth and Thielman, 2006), organ transplant patients, and persons undergoing bone marrow transplantation are considered sensitive to viruses based on compromised immune status. These immunocompromised groups constitute approximately 0.3 percent of the general population. This estimate is based on best available data and assumptions as summarized in Exhibit 5.4. The estimate does not include other groups of immunocompromised people, including those with chronic illness or those cancer patients who are undergoing chemotherapy and radiation (Morris and Potter, 1997). The population estimate also does not account for the estimated 25,000 to 50,000 persons in the U.S. with primary immunodeficiency diseases that primarily affect B-lymphocyte cell function. The most common and serious primary immune diseases are X-linked Agammaglobulinemia (NICHD, 1999; Gerwurz et al., 1985; McKinney et al., 1987; Hertal et al., 1989). In addition, the population estimate does not include persons with potentially autoimmune diseases (e.g. type 1 diabetes, myocarditis, multiple sclerosis and rheumatoid arthritis) who may also experience more serious adverse health effects brought on by viral and other infections (Fujinami, 2006).

A limited number of available studies suggest that viral infections can contribute to deaths in immunocompromised persons. Chronic diarrhea is a serious complication of AIDS, and rotavirus and adenovirus are commonly isolated from stool samples from AIDS patients with diarrhea (Gerba et al., 1996a). Enteric rotavirus and coxsackievirus infections were reported as the cause of death among bone-marrow transplant patients (Yolken et al., 1982).

In this EA, the morbidity and mortality factors assigned to immunocompromised subgroups for Type A and B virus infections are the same as those used for the general population. These factors underestimate risks for these subgroups, but the EPA believes that there are insufficient data available to assign higher morbidity or mortality rates from waterborne infections based on immune status. However, because there is a higher cost-of-illness among severely immunocompromised persons having lengthy viral illnesses, the reductions in numbers of illnesses and deaths attributable to the GWR in this subgroup are calculated separately by the risk model and valued separately in the monetary benefits calculations.

5.2.3 Exposure Assessment

This section discusses the key elements for characterizing human exposure to viral pathogens in drinking water. The primary exposure pathway is ingestion of drinking water from public ground water supplies that are contaminated with viruses from fecal pollution.[2] EPA believes that there are three key exposure scenarios or events whereby virus-contaminated drinking water is delivered to consumers in public GWSs.

1) Source water contamination under normal operating conditions

2) Source water contamination due to treatment failures

3) Contamination due to distribution system deficiencies

The remainder of this discussion of the main exposure assessment for the GWR addresses only the first contamination scenario due to data availability. EPA's modeling of this first scenario includes exposure from both systems that serve untreated ground water and systems with low levels of viral inactivation.

With regard to the other scenarios, there is insufficient information on the frequency and severity of drinking water treatment failures and distribution system deficiencies in ground water public water systems (PWSs) to directly model these events. However, the proportions of reported outbreaks caused by the three contamination scenarios listed above serve as an indicator of the relative frequency of GWS contamination events that cause disease in exposed populations (see Section 5.4.7 and 5.4.8 for further discussion).

The assessment of exposures to pathogens from ground water sources requires that the following factors be quantified:

- Occurrence (presence/absence) of pathogens in source water (including duration of time that it is present)
- Concentration of pathogens in source water when it is contaminated
- Level of pathogen inactivation in the system and resulting pathogen concentration in tap water
- Size of the exposed population, including sensitive subgroups
- Volume of water ingested daily and how many days per year it is ingested

EPA evaluated available occurrence and exposure data and developed assumptions where needed regarding these exposure factors, each of which is discussed briefly below.

[2] The risk assessment also considers exposure via secondary spread from those who become ill through drinking water. This is addressed in section 5.2.4.

5.2.3.1 Source Water Viral Occurrence and Concentration

Virus occurrence values for this exposure assessment are based on occurrence data from 12 studies of U.S. ground water source quality. Presence/absence of enteroviruses were directly measured in 12 studies using methods optimal for recovering enteroviruses but not other viruses.[3] Viral concentrations are based on three of the 12 studies that included concentration data (Lieberman et al, 2002; Abbaszadegan et al, 2003; Lindsey et al., 2003). EPA's risk model applies a randomly chosen concentration from the data in these three studies. However, concentration data from the Lieberman data set is only applied to a small subset (2.5% on average) of wells with predicted viral presence, whereas the concentration data from the Abbaszadegan and Lindsey data sets are applied to all other wells (97.5% on average) with predicted viral presence (see section 4.3.4.2 for further discussion). More detailed descriptions of each study are presented in section 4.3.2 and in the Ground Water Rule Occurrence and Monitoring Document (USEPA, 2006b).

Modeling of the available virus occurrence data predicts that enteric viruses such as Type B viruses are intermittently present in a virus positive well each year for only short durations (generally from a few days to a few weeks). EPA assumes that equal concentrations of Type A viruses are also present when enteric viruses such as Type B are measured in wells during those short intervals of virus contamination. The probability that a well or sample is virus contaminated is unchanged by this assumption.

EPA recognizes that Type A virus concentration assumed present in wells could be either an underestimate or an overestimate. The assumption could be an underestimate if Type A viruses are present at higher concentrations or if they contaminate wells for longer intervals than assumed because they may be more prevalent in the human population and may be shed at much higher concentrations than Type B viruses. The assumption could be an overestimate if the prevalence of Type A viruses in human populations is less than the Type B viruses.

EPA considered using other assumptions about Type A occurrence but identified problems with each. EPA considered randomly assigning Type A or Type B to the randomly chosen viruses concentrations or assigning a fixed percentage to the number wells that are assumed to exhibit Type A virus concentrations. However, these assumptions would contradict available data by assigning Type A virus character to samples that are measured using methods that are favorable for recovering Type B viruses.

5.2.3.2 Finished Water Concentrations in Disinfecting Ground Water Systems

For the purposes of this exposure assessment, EPA assumed that the pathogen concentration in tap water from GWSs that serve untreated ground water is the same as the pathogen concentration in source

[3] The infectious viruses counted in the occurrence studies represent a group of enteric viruses that are favored for recovery because they are most efficient at infecting the host cell line used in the concentration measurements. Poliovirus is most favored but other closely-related Type B enteroviruses (including echovirus) are also likely to be recovered. Rotaviruses are also likely to be present because they are shed in fecal material at concentrations several orders of magnitude greater than the enteroviruses. However, rotavirus is not efficiently recovered in that commonly used host cell line and other Type A viruses, such as norovirus, are not recoverable.

water. In contrast, properly operating disinfecting systems are assumed to inactivate 99 percent (2-log), or 99.99 percent (4-log) of viral pathogens depending on the disinfection practices employed. Therefore, the concentration of pathogens in tap water from properly operating disinfecting (4-log inactivation) systems is assumed to be 0.01 percent of the concentration in source water. For 2-log inactivation, the concentration is assumed to be 1.0 percent of the concentration in source water. These finished water viral concentration estimates do not take into account the effects of elevated concentrations from any upsets or treatment failures that might occur.

5.2.3.3 Size of Exposed Population

As presented in section 4.2.3 and in Exhibit 4.4, ground water CWSs serve over 100 million people, while ground water NCWSs serve about 14 million people. This population has the potential to be exposed to pathogens via drinking water from GWSs.

5.2.3.4 Drinking Water Consumption Factors

The amount of drinking water consumed daily by individuals is a key input to the exposure assessment component of the risk analyses. The higher the average daily consumption of water by an individual, the higher the risk of infection for a given level of pathogen occurrence. EPA bases its estimates of per-capita water ingestion on data collected by the U.S. Department of Agriculture's (USDA) 1994-96 Continuing Survey of Food Intakes by Individuals (CSFII). Data derived from this survey are presented in the report, "Estimated Per Capita Water Ingestion in the United States" (USEPA 2000c). For noncommunity water systems, which represent a significant number of the systems potentially impacted by the GWR and where individuals consume water for shorter periods, EPA further adjusted the USDA estimates to better reflect drinking water patterns at those systems. These adjustments were based on the classifications of noncommunity water systems from the EPA report, Geometries and Characteristics of Public Water Systems (USEPA, 2000a) and EPA estimates of daily ingestion in these systems.

The EPA water ingestion study used to estimate water consumption reports information for two different aggregations of the population: all respondents (which is used in this exposure assessment) and the subset who report consuming water directly ("consumers"). The category of all respondents is more appropriate to this exposure assessment as EPA assumes that all people consume or are exposed to tap water, even if they reported no tap water consumption during the three day diary period of the CSFII survey. This is because even people who report no direct consumption may consume some public water at other times during the year. Furthermore, they still do ingest water indirectly (for example, through washing vegetables and other foods, and consuming foods prepared in restaurants) or are otherwise exposed to potential waterborne viruses in tap water (during showers and brushing teeth, for example). Exhibit 5.5 summarizes the CSFII data for consumption of water from all sources.

Exhibit 5.5 Distribution of Individual Daily Drinking Water Consumption by Age Group (L/person/day)

Age (years)	Mean	Percentiles								
		p1	p5	p10	p25	p50	p75	p90	p95	p99
<0.5	0.409	-	-	-	0.002	0.394	0.696	0.903	0.969	1.307
0.5-0.9	0.569	-	0.03	0.86	0.248	0.548	0.771	1.126	1.272	1.671
1-3	0.417	0.001	0.046	0.09	0.196	0.346	0.580	0.805	0.993	1.393
4-6	0.544	0.004	0.087	0.147	0.276	0.462	0.719	1.017	1.267	2.026
7-10	0.604	0.006	0.115	0.174	0.305	0.512	0.808	1.130	1.422	2.170
11-14	0.811	0.01	0.119	0.209	0.382	0.643	1.066	1.623	1.960	3.025
15-19	0.990	-	0.108	0.231	0.407	0.768	1.276	1.891	2.387	4.020
20-24	1.271	0.001	0.117	0.237	0.554	1.000	1.577	2.506	3.608	5.796
25-54	1.480	0.041	0.301	0.473	0.798	1.272	1.893	2.631	3.333	5.244
55-64	1.529	0.118	0.473	0.652	0.946	1.378	1.952	2.557	2.997	4.393
65+	1.451	0.245	0.531	0.651	0.935	1.344	1.832	2.323	2.708	3.747
All ages	1.232	0.009	0.163	0.283	0.573	1.037	1.633	2.341	2.908	4.805

Source: "All Sources" from USEPA 2000c. Includes bottled water and tap water; see text describing the adjustment made to account for bottled water consumption.

The survey also reports information by type of source water (community water, bottled water, other sources, and non-reported source). The survey questions categorized respondents based on their reported "main" source of direct water and indirect water. Thus, many respondents who reported that their main source of drinking water was bottled water or another source, may still consume water from community sources at least some of the time. Likewise, respondents who categorize their drinking water as being mainly from a community source may also consume bottled water and water from other sources.

More importantly, those who are not now served by community water systems would report "other sources" or bottled water as their main source of water. These groups are presented as components of the national average and cannot be subtracted from the total without affecting the value of the national average. Thus, the consumption of those who reported no source or "other sources" as their main source of drinking water are included in the national average, because subtracting these categories would lead to an underestimate of average consumption levels. Their consumption patterns are assumed to be similar to those served only by community systems (or at least, cannot be adjusted using the available data).

Therefore, there were no adjustments for those who reported no source or other sources as their main source of water.

The consumption of bottled water, however, is thought to reflect a replacement of tap water, and thus an adjustment for this is more appropriate. Further, there is evidence that consumption of bottled water is significant. In the CSFII study, 13.4 percent of all water was consumed by those who categorized bottled water as their "main" source of water for direct or indirect ingestion. The implicit assumption is that the distribution of consumption for bottled water drinkers is proportionally about the same as for all individuals. EPA believes the closest approximation of the distribution of consumption for the GWR is the distribution for "All Sources Less Bottled Water" (13.4 percent). Because the survey did not attempt to determine for each individual the proportion of water from each source, the approach used in the exposure assessment (i.e., applying the 13.4 percent reduction to all mean values) may understate or overstate actual consumption from public water systems, depending on the extent and direction of overlap in drinking water sources. EPA believes however, that making this adjustment produces an estimate of drinking water consumption closer to actual practices. In the EA model, EPA used the mean values for each size category in Exhibit 5.5, adjusted downward by 13.4 percent. EPA used this approach rather than considering the percentile distribution because this gives similar estimates and reduces modeling complexity.

To better estimate the daily drinking water consumption patterns for the populations served by noncommunity GWSs, which reflect a significant number of systems potentially impacted by the GWR, EPA further adjusted its estimates of daily consumption. Adjustments were made based on the system classification (non-transient or transient) and the area served (i.e. campgrounds, restaurants, etc).

Nontransient noncommunity water systems, by definition, serve the same population each day and many of these system are businesses where employees spend their work day. Based on this definition, EPA assumes that populations are served by these systems for 8 eight hours of each day and then return home to be served by a CWS. For the purposes of estimating exposure, EPA assumes that populations served by NTNCWs consume 50 percent of the mean daily consumption levels (first reduced by 13.4 percent) from Exhibit 5.5 for each population category.

For transient noncommunity GWSs, EPA estimated daily consumption for the 25 types of transient noncommunity GWSs, that serve the largest transient populations. EPA used Best Professional Judgement to estimate daily consumption in each of these 25 system types and weighted these consumption levels by the populations served by these systems. This weighting captures the influence of the significant differences in populations served by different types of systems. To estimate exposure in all transient non community GWSs, EPA used the average of all 25 weighted daily consumption estimates. As with the NTNCWS adjustment described above, the average TNCWS consumption factor of 0.4 is applied to the mean daily consumption levels (first reduced by 13.4 percent) from Exhibit 5.5. Details of this analysis are presented in Exhibit 5.6 below.

Exhibit 5.6 Derivation of Transient Noncommunity Water System Consumption Factor

TNCWS Type	% Daily Consumption Relative to CWS	Total Population Among All TNCWSs Within Type	Daily Consumption * Total Poulation	Weighted Daily Consumption
	A	B	C = A * B	C / Total Population
Restaurants	0.3	2,255,959	676,788	0.0669
Churches	0.25	1,301,552	325,388	0.0322
State Parks	0.5	842,518	421,259	0.0416
Wholesalers	0.5	791,429	395,715	0.0391
Summer Camps	1	765,742	765,742	0.0757
Campgrounds	0.5	639,160	319,580	0.0316
Hotels/Motels	0.5	558,443	279,222	0.0276
Highway Rest Areas	0.25	516,369	129,092	0.0128
Misc. Recreational Services	0.5	337,152	168,576	0.0167
Service Stations	0.25	326,644	81,661	0.0081
Golf & Country Clubs	1	254,016	254,016	0.0251
Mixed Service Areas	0.5	214,345	107,173	0.0106
Medical Facilities	0.25	208,623	52,156	0.0052
Office Parks	0.5	197,600	98,800	0.0098
Retailers - Non-Food Related	0.25	184,128	46,032	0.0045
Manufacturing: Food	0.5	158,301	79,151	0.0078
Schools	0.5	150,365	75,183	0.0074
Retailers - Food Related	0.25	142,988	35,747	0.0035
Federal Parks	0.5	93,665	46,833	0.0046
Amusement Parks	1	88,038	88,038	0.0087
Mobile Home Parks	1	66,797	66,797	0.0066
Day Care Centers	0.5	10,213	5,107	0.0005
Manufacturing: Misc.	0.5	8,991	4,496	0.0004
Non-water utilities	0.5	6,025	3,013	0.0003
Total	N/A	10,119,063	4,525,560	**0.4**

Sources: [A] Geometries and Characteristics of Public Water Systems (USEPA, 2000a).
[B] EPA Estimate.

In addition to daily consumption, EPA estimated the number of days per year tap water is consumed by users of different types of water systems. EPA's estimates for exposure days are presented in Exhibit 5.7. For the TNCWSs, it is assumed that the average number of days of exposure per year for each individual consuming water at one of these systems is 10. To account for all of the individuals who are expected to be consume water at a TNCWS over the course of a year, an adjustment was made to the population reported in SDWIS for these systems. The population for TNCWS reported in SDWIS is intended to reflect the population served during the peak month of operation. Assuming 30 days in the peak month, and an average of 10 days of exposure for each individual at a TNCWS, the total number of different individuals exposed per month at each TNCWS is assumed to be 3 times the reported SDWIS population number (that is, the peak month serves 3 cohorts of 10 days each). Further, it is assumed that TNCWSs are open on average of 6 months per year, with an uncertainty range of 3 months to 9 months. (This number of months of operation for TNCWS is included in the risk model as a triangular distribution with minimum = 3, mode = 6 and maximum = 9 months.) Therefore, for TNCWSs, the risk model assumes 10 days of exposure for each individual and a total population exposed ranging from 9 to 27 times

the peak month population served reported in SDWIS (i.e., 3 cohorts / month * 3 months (=9) to 3 cohorts/ month * 9 months (=27). Since the SDWIS population values reflect the peak month of operation, the total population served by TNCWS for their duration of operation as determined here should be considered a likely overestimate.

Exhibit 5.7 Estimated Exposure Days by System Type[1]

Type of System	Exposure Days Per Year
CWS	350
NTNCWS	250
TNCWS	10

[1] Number of days in which tap water is consumed per individual in each system type. See text for additional discussion pertaining to the TNCWS exposure.

5.2.4 Probability of Infection, Illness, and Mortality

This section presents information on the relationship between ingestion of viruses and the probability of infection, illness, and mortality. Specific elements of the dose response relationships addressed in this section include the following:

- Infectivity (the ability of a microorganism to colonize in the body of the host, expressed as probability of infection, a function of dose)
- Morbidity (the probability of illness given infection)
- Secondary Spread (the expected additional illnesses due to contact with those affected directly by ground water consumption)
- Mortality (the probability of death given illness)

5.2.4.1 Infectivity from Dose response Modeling of Human Challenge Study Data

All of the elements listed above depend on high quality infectivity data and an appropriate dose-response model. Two key publications report high quality human challenge study data suitable for dose-response modeling. One, by Ward et al (1986), reports dose-response data for rotavirus, which represents Type A viruses. The other, by Schiff et al (1984), reports dose-response data for echovirus type 12, which represents Type B viruses. The summary data from the two studies, shown in Exhibits 5.8 and 5.9, are simple, but their use in dose-response modeling involves a number of key decisions or assumptions that are discussed below.

Microbial risk assessment requires an estimate of the dose required to cause infection in humans. These data can be prospectively determined directly by dosing volunteers, indirectly by dosing animals, or can be retrospectively estimated using outbreak data. The highest quality data are acquired from dosing human volunteers. However, human volunteer data are necessarily biased for ethical reasons. All studies

with human participants must be approved by an ethical review board. Limitations in pathogen human feeding studies include using only low virulence pathogens (not necessarily representative of the virulence encountered in nature) and studying only healthy populations (whose response to the experiment is not indicative of that of sensitive subpopulations). For example, the echovirus type 12 strain used in the human challenge study by Schiff (1984) was a benign strain not associated with serious human illness. In fact the strain was originally recovered from a child with a clinical diagnosis of erythema infectiosum (fifth disease), a mild facial rash.

Human challenge study data are also available for poliovirus (and for aerosol exposure to coxsackievirus [Couch, 1970]), which together with echovirus, comprises the enteroviruses which are one of the target viruses for determining GWR benefits. Three poliovirus challenges studies were conducted, all using infants. Two studies used poliovirus I (Minor et al., 1981; Lepow et al., 1962) and one study used poliovirus III (Katz and Plotkin, 1967).

EPA considered using data from all four enterovirus human challenge studies to represent the Type B enterovirus dose response. (EPA did not think it appropriate to use the coxsackievirus dose response data because of the route of exposure.) All the poliovirus challenge study data are from infants who, unlike adults exposed to Echovirus type 12, exhibit lifetime immunity after infection. Even among identical strains, there are potential virulence differences between laboratory-maintained isolates and isolates recovered in human or environmental samples. Because poliovirus is no longer a health issue in the U.S. and because of differences among the challenge studies, EPA decided to use only the echovirus 12 data. However, EPA believes that a meta-analysis of all the enterovirus human challenge study data would document that the enteroviruses are more infectious than is predicted by the echovirus 12 human challenge study data. EPA believes that the echovirus 12 data substantially underestimates the infectivity of the enteroviruses. The GWR EA would predict more enteroviral infections, illnesses and deaths if other enterovirus human challenge study data were considered.

The rotavirus human challenge study by Ward et al (1986) is the only published Type A human challenge study data. The rotavirus challenge study was conducted using the CJN strain which was recovered from an infected infant. The CJN strain is now classified as a Group A rotavirus and is among the most common strains currently identified in the United States. The proportion of adult volunteers infected by the CJN rotavirus strain at a dose of 1000 FFU in Ward et al (1986) was confirmed in a later challenge study (13 of 14 adults infected in Ward et al, 1991). Thus, unlike the echovirus data, EPA believes that the rotavirus human challenge study data are representative of the rotaviruses. However, the infectivities of other Type A viruses, such as norovirus, are not necessarily represented by the rotavirus human challenge study data. Funded under an EPA cooperative agreement, Moe et al. (2001) reported on human challenge studies using Norwalk virus (now known as norovirus). They conclude that norovirus "is one of the most infectious agents that has ever been described." Infection was observed at doses below one PCR dectectable unit (which represents as few as one physical virus particle) (Moe et al, 2001).

Although the norovirus human challenge study data are not yet published, EPA believes that the noroviruses are at least as infectious as the rotavirus, and likely more infectious. If the norovirus data were made available to EPA, EPA would use the norovirus rather than rotavirus human challenge study data to characterize Type A viruses, because norovirus disease affects all populations equally. Epidemiological data suggests that other Type A viruses such as hepatitis A virus, adenovirus and astrovirus are also highly infectious and could be more infectious than the rotaviruses. Thus, EPA believes that the rotavirus human challenge study data, while representative of the rotaviruses, may underestimate the infectivity of the Type A viruses. If so, then the GWR EA under-predicts Type A infections, illnesses and deaths.

Exhibit 5.8 Rotavirus Dose-Response Data

Dose (Poisson), focus-forming units (ffu)	Subjects receiving Dose	Subjects Infected
0.009	7	0
0.09	7	0
0.9	7	1
9	11	8
90	7	6
900	8	7
9,000	7	5
90,000	3	3

Exhibit 5.9 Echovirus Dose-Response Data

Dose (Poisson), plaque-forming units (pfu)	Subjects receiving Dose	Subjects Infected
330	50	15
1000	20	9
3300	26	19
10000	12	12
33000	4	2
330000	3	2

Rotavirus Dose-Response Modeling

The human feeding study data shown in Exhibit 5.8 cover a wide dose range (0.009 to 90,000 units). Ground water concentrations are expected to be similar to those found for echovirus, that is, generally less than 2 per 100 liters. If contamination is intermittent, such that it is present about 1% of the time, then the average concentration would be 0.02 per 100 liters or 0.0002 per liter. A person ingesting one liter per day would receive a dose of 0.0002 infectious units, which is considerably smaller than the smallest dose used in the human feeding study. Predicting risks for such low doses requires extrapolation, using a biologically-plausible dose-response model.

The World Health Organization (WHO, 2003) has considered the issue of low-dose modeling / extrapolation, and recommends using models that have the following characteristics: absence of a threshold and independent action among infectious units, i.e., absence of synergistic action. Based on these factors, WHO (2003) identified a family of acceptable models and these included the Beta-Poisson and exponential models, while excluding the Probit model.

Ward, et al. used data collected at the dose range 0.009 to 90,000 ffu to estimate parameters of a probit model. Other authors, notably Teunis and Havelaar, use these same data, but with a beta-Poisson model (Teunis et al. 1996). These two models (probit and beta-Poisson) predict similar infection probabilities across the range of doses employed in the study. As discussed above, EPA does not believe that the probit model's predictions outside of the dose range of the study are biologically plausible. For this reason, EPA has selected the beta-Poisson model for rotavirus dose-response modeling. In the main analysis (reported in this section), all of the data shown in Exhibit 5.8 are used to inform the beta-Poisson model.

Arguably, the most significant dose in terms of environmental exposure is that nearest 1 ffu: 0.9. One of seven subjects was infected at that dose. Given the beta-Poisson model, and data at all of the higher doses, this outcome at dose 0.9 ffu is not surprising, i.e. at order of magnitude or greater doses most subjects were infected and at order of magnitude or lower doses no subjects were infected. However, since most exposures to populations receiving contaminated ground water occur near one viral infectious unit, there is a question as to the usefulness of other dose response data being used well outside this range for estimating infection probability at this dose level. The smallest dose, 0.009 ffu, is smaller than 0.9 ffu by a factor of 100. The greatest dose, 90,000 ffu, is greater by a factor of 100,000. To address this concern about the influence of extreme dose data, EPA has estimated the parameter of an exponential model using only the fact that one of seven subjects was infected at dose 0.9. This alternative or sensitivity analysis is described in Appendix F.

EPA recognizes that there is significant uncertainty associated with measuring viruses in environmental samples and has summarized that uncertainty in Chapter 4, Section 4.3.2. Virus aggregation in routine environmental exposure is especially difficult to quantify, so there is considerable uncertainty associated with the assumption above that most ground water consumers are getting a virus dose of about one ffu. Virus occurrence and concentration is measured in the laboratory after the sample is manipulated to disaggregate virus clusters by changing the ground water ionic strength. After disaggregation, the highest measured virus concentration in any ground water sample (Exhibit 4.28) is 2.12 PFU (or MPN) per liter. Clusters may exist in routine ground water exposure (in aquifers where ionic strength is relatively stable) and ground water consumers may get doses higher than one FFU on occasion as a result.

Echovirus Dose-Response Modeling

The echovirus data shown in Exhibit 5.9 cover a narrower relative range than rotavirus (from 330 to 330,000 pfu), but all doses are significantly greater than the environmentally-relevant dose of 1 pfu. Using any dose-response models with these data to predict environmental risks involves extrapolation and the potential to over- or underestimate the low-dose risk.

Before discussing the modeling, it is important to understand how the data in Exhibit 5.9 were derived. Schiff et al. described how their data were generated in two phases. In the first, a "range-finding" phase, small numbers of subjects were dosed at each level over a wide range. Three or four subjects were dosed at each of some number of levels between 330 and 330,000 pfu. Exhibit 5.9 only shows that four subjects received dose 33,000 and three subjects received dose 330,000. In the second phase, numerous additional subjects were challenged with doses in the 330 to 10,000 pfu range (for these doses, Exhibit 5.9 includes subjects from both phases).

EPA considered two published echovirus dose-response analyses: that of the original researchers, Schiff et al. (1984), and that of Teunis and Havelaar (Teunis et al., 1996). In their dose response analysis, Schiff et al. discarded the data from doses 33,000 and 330,000 and used the remaining data to estimate parameters of a probit model. Teunis and Havelaar utilized all of the echovirus dose-response data (including 33,000 and 330,000) and fit a beta-Poisson model. After assessing the published analyses, EPA decided to use the full data set with the beta-Poisson model in the main analysis and the partial data set with the exponential model as a sensitivity analysis.

EPA based its analysis of the full data set on the analysis of Teunis and Havelaar (Teunis et al., 1996). An important feature of this model is its ability to explain variable susceptibility; the notion that human subjects may differ. Technically, this model acts as though each subject has his/her own exponential dose-response parameter (probability of infection, given exactly one infectious unit) and that these parameters are beta-distributed. EPA decided to employ the beta-Poisson model in its analysis of the full data set.

For the analysis of the low-dose echovirus data, EPA examined the Schiff analysis (Schiff et al., 1984). Although Schiff used a probit model, EPA discovered it behaves implausibly when extrapolating to estimate the risk of environmental exposures. Theoretically, risk at low doses should be approximately proportional to probability of ingesting an infectious unit, but in this application, the probit model predicts extreme sublinear behavior. In contrast, the simple exponential and beta-Poisson models (which is a derivation of the simple exponential) both feature approximate low dose linearity. When applied to the data below dose 33,000, the exponential model fits very well. The extra parameter provided in the beta-Poisson model doesn't seem to add significantly to the goodness-of-fit (or likelihood), so EPA decided to employ the exponential model in its analysis of the low-dose echovirus data.

Two reasonable options are therefore available for echovirus modeling: utilizing the partial data set with an exponential model and utilizing the full data set with the beta-Poisson model. As detailed in Appendix F, these two analyses produce considerably different predictions of low-dose risk for echovirus. Taken together, the results demonstrate considerable model uncertainty.

5.2.4.2 Morbidity and Mortality Data Sources and Uncertainty

EPA based its analysis of morbidity and mortality on epidemiologic data published in the scientific literature. The literature includes epidemic (outbreak) and endemic disease studies conducted using a variety of epidemiological methods, both prospective and retrospective. Some study cohorts represented the entire U.S. population, other cohorts represented selected sub-populations. The studies used in the EA include data based on person-to-person spread, foodborne exposures, and waterborne exposures, as well as those for which no source of viral exposure or transmission mode was identified. Due to the limited number of published studies on water as a primary route of exposure, viral morbidity and mortality rates incorporate information derived from all routes of exposure and transmission. EPA used to the extent possible, prospective, endemic data of study cohorts that represent the entire U.S. population. Prospective studies are assumed to have less reporting bias than retrospective studies (only those who got ill are likely to have a reason to report their exposure and the likelihood of reporting increases with illness severity). Where such data were not available, EPA used retrospective endemic disease studies of the entire population. At times, general population study data were not available and so EPA used prospective (and retrospective, as necessary) studies of sub-populations and applied these values to the general population, but noted the associated uncertainty or bias. This EA describes the data source, the type of study, the

population cohort studied and the assumptions and limitations associated with epidemiological data that, at times, were not optimal.

Morbidity rates are based, to the extent possible, on prospective epidemiological studies of endemic illness in the general population. Morbidity data were specifically excluded if they were based on; 1) retrospective outbreak studies, 2) retrospective or prospective sensitive sub-population studies (limited prospective age related sub-population studies were included), 3) retrospective passive disease reporting studies or 4) predictions from infectious disease simulation of illness acquisition and spread. The majority of studies cited in the EA were conducted in the U.S. or Canada. Where U.S. (and Canadian) data were identified as limited, incomplete or biased, data from other developed countries were used to inform data ranges for sub-populations.

EPA excluded the above four categories of morbidity data because of an assumption that including these data would bias the illness predictions upward. However, there are some uncertainties associated with that EPA assumption. The following text addresses these uncertainties about the estimated morbidity rates for each of the four exclusions listed.

Retrospective outbreak studies have an inherent apparent disease burden bias. That is, common source outbreaks come to the attention of public health authorities and are more likely to be reported to CDC if the outbreak is large or causes illness that is relatively severe, compared with milder disease endpoints such as rash or muscle stiffness. (Other factors, not related to disease burden, such as occurrence in a locality with more effective public health surveillance and sufficient laboratory capacity also affect outbreak reporting.) EPA excluded retrospective outbreak studies because of a concern that outbreak data may not be reflective of endemic illness rates. However, in doing so EPA may be biasing the estimated viral morbidity rates downward because the more virulent etiologic agents more likely associated with outbreaks may be excluded from the analysis.

For the more highly infectious viruses, such as rotavirus and norovirus (Type A viruses), there may be little difference between small epidemics and endemic illness. Unlike bacteria, waterborne viruses do not have known animal reservoirs so the agent is continually circulating within the human population within the U.S. (albeit supplemented by travelers coming or returning to the U.S.). A small outbreak (CDC defines an outbreak as two or more contemporaneous illnesses), such as one occurring within a family, may be counted as either endemic or epidemic disease. For especially infectious agents, epidemic rather than endemic cases might be observed. Thus, there is uncertainty as to how to separate endemic versus epidemic disease for the Type A viruses because they are highly infectious, continually circulating within the human population, cause only mild illness and may be counted as either endemic or epidemic disease, depending on the definitions used in the compilation.

EPA excluded sub-population morbidity data (with the exception of some age related data discussed later) because of a concern that it may not reflect endemic illness in the general U.S. population. Studies of sub-populations in the U.S. report differing likelihood of becoming ill or severely ill. As discussed in Section 5.2.2. sensitive subpopulations comprise a substantial proportion of U.S. population, as much as 20% in one estimate (Gerba, 1996). EPA recognizes that the EA underestimates the number of illnesses and deaths because greater morbidity and mortality rates among some sensitive sub-populations, such as pregnant women (e.g. in developing countries, twenty percent of pregnant women have a fatal outcome due to Hepatitis E viral illness) are not recognized in the main analysis. In addition, some sensitive sub-populations have greater morbidity rates than the general population. Because the EA does

not consider data on a large portion of the population that generally is more highly affected by rotavirus and enterovirus, it underestimates the morbidity and mortality rates for rotavirus and enterovirus.

With respect to age related sub-populations, EPA captured as much of the age related difference as possible but could not do so comprehensively. Age is important because sub-populations divided by age have significantly differing rates of morbidity and mortality. All waterborne viruses, and especially rotavirus, are more likely to affect children under five than other age groups. As discussed by Ramig (2004) the reason that children are more likely to become ill from rotavirus is due to several possibilites. Ramig lists three reasons that apply to children in the U.S. (a fourth reason is malnutrition); one reason is that children are less likely to be previously exposed and therefore have no pre-existing partial immunity. The other two reasons have to do with role of key enzymes with prevalence that changes with age. The GWR accounted for some age heterogeneity among the general population by, for example, using differing rotavirus morbidity rates for children under two and determining echovirus case-fatality ratios among neonates. However, EPA recognizes that some age related sub-populations, such as the elderly, that may have differing morbidity and/or mortality rates are not explicitly characterized.in the EA and that absence contributes to uncertainty.

EPA explicitly excluded enteroviral disease data reported to CDC for three reasons. First, the data are not current because passive enteroviral etiology reporting was discontinued in 1994 (Currently, hepatitis A virus is the only potentially waterborne virus reported to CDC.). Second, as recognized by CDC (Mead et al., 1999), disease reporting is designed and administered so that reporting is done voluntarily by State and local public health agencies and laboratories. Third, an enteroviral etiology comes to the attention of State and local public health authorities primarily when significant illness and/or significant frequency occurs. Because many enteroviral illnesses do not result in symptoms sufficiently grave so as to require a physician's care, the passively reported illnesses associated with an enterovirus etiology are assumed to be biased toward the more severe outcomes.

EPA explicitly excluded some rotavirus and enteroviral illnesses due to disease secondary transmission within a community. EPA identifies primary illnesses as those that are acquired by consuming rotavirus and enterovirus from a contaminated PWS well. Secondary illnesses are those cases that are acquired by individuals who do not consume the contaminated drinking water, but instead acquire illness through person-to-person exposure from a primary case. The EA does include a secondary disease transmission factor to account for the number of secondary illnesses that are estimated to arise from each primary illness. However, as is discussed in Section 5.2.4.3, this secondary disease transmission factor is not a secondary morbidity rate because it assumes that only ill individuals can make others ill by secondary transmission. As is well known from the case of Typhoid Mary, asymptomatic individuals can also serve as carriers of disease, and thus infected individuals can infect others who can also become ill or who can become carriers also. As a result of neglecting secondary cases that arise from asymptomatic carriers as opposed to symptomatic carriers, the EA underestimates the total number of secondary cases.

In addition to estimating morbidity rates, EPA has estimated illness severity. Severity is important because monetization of the rotavirus and enterovirus disease burden bestows greater benefits (avoided costs), such as hospitalization costs and physicians's office visit costs, if the disease is more severe. In this EA, fatal outcomes occur for the general population (non-neonates) ill from enterovirus only if disease is severe. Thus, to estimate mortality rates, the number of severe cases must be determined.

EPA used total disease burden estimates from CDC to account for the relative proportion of severe enterovirus (Type B) outcomes. EPA defines severe outcome as any illness resulting in hospitalization.

CDC estimates that about 10 million cases of enteroviral disease occur each year in the U.S.. EPA estimated that about 100,000 severe outcomes result from illness (myocarditis, encephalitis, and viral meningitis) potentially caused by enteroviruses. The ratio of 100,000 severe outcomes divided by 10 million cases was used in the EA to estimate that 1% of enteroviral cases are severe. There are uncertainties in using this 1% severity factor for the enteroviruses. In determining enteroviral severity, EPA believes that a large proportion of the 10 million enteroviral cases in the U.S. could be due to hand, foot and mouth disease (e.g. Pichichero et al. (1998) found in a four month study that 244 of 372 physician's office visits were due to symptomatic (stomatitis) or diagnosed hand, foot and mouth disease) which is a benign childhood disease (in the United States but not necessarily elsewhere such as Taiwan) caused by enterovirus 70 and 71.[4] Enterovirus 70 or 71 has never been found in drinking water or ground water and is not believed to be waterborne in the U.S.. Rather, it is spread almost exclusively by person to person transmission. Because enterovirus 70 and 71 illness is included in the total cases of enteroviral disease, this EA could significantly underestimate the proportion of severe outcomes due to enterovirus in the general population. However, in years or seasons for which no data are available, depending on which enterovirus strains predominate, clinical symptoms not characteristic of enterovirus 70 or 71 could be more likely observed and could account for more or most of the enteroviral illness.

As compared with the expansive definition of Type B (enteroviral) disease severity described above, Type A disease severity is restricted to consideration only of the rotaviruses. For the Type A viruses, only rotavirus is included in the estimate of the total disease burden despite the fact that norovirus disease is widespread and norovirus makes both adults and children ill at significant rates. Other Type A viruses, such as adenovirus and hepatitis A virus also disproportionately cause illness in younger adults. As a result of restricting the Type A disease burden to rotavirus only, the EA significantly underestimates the proportion of severe Type A disease in the general (adult) population.

Mortality from ground waterborne agents, especially viruses, is sufficiently infrequent that a mortality rate for the general population is difficult to determine from the scientific literature. This difficulty is compounded for Type A virus because the available data are limited to rotavirus which is highly infectious but has relatively mild severity. Mortality data are available only for sub-populations at greatest risk of a fatal outcome. For enterovirus, data are available from a study of neonates with enteroviral infection supplemented with fatal outcome case data from several other studies and applied to the neonate population. For rotavirus, a fatal outcome is based on deaths in children under five identified by CDC as part of a study to assess the costs and benefits of a rotavirus vaccine (subsequently removed

[4] Enteroviral type 71 disease was particularly virulent in Taiwan in 1998 where there was over 129,000 cases and 78 deaths, 90% among children less than 5 years old (Lin et al, 2003; Chang et al, 2004). In severe cases, hand, foot and mouth disease proceeds to encephalomyelitis and cardiopulmonary collapse. The widespread transmission is enhanced by the long period of viral shedding (as much as 5 weeks) in infected individuals. Infection rates for parents (41%) were higher than other adults (26%). These data suggest that enterovirus 71 is efficiently transmitted by asymptomatic or mildly symptomatic adults (Chang et al, 2004). It is likely that most hand, foot and mouth disease in the United States is also due to contact with other individuals. However, enterovirus 71 is copiously shed via the gut and can, along with other fecal/oral agents, be transmitted via ground water, although the available data seem to indicate that this pathway is not likely. Three possible reasons that enterovirus 71 is not likely to be transmitted via ground water are that it may not survive long at ground water temperatures, it may not be mobile in the subsurface and/or the infectious dose required to cause illness is so large that dilute environmental samples cannot transmit infection. However, as the data from Taiwan indicate, the disease can cause fatal outcomes at rates greater than the rates used in this EA for the enteroviruses, albeit perhaps not in developed countries.

from the market due to unintended intestinal obstruction effects). Thus, the available mortality data are limited to data from children. No U.S. endemic mortality data are available for fatal outcomes in the sensitive subpopulations, such as the elderly, a population also greatly susceptible to dehydration-related mortality due to gastroenteritis.

As discussed in Section 5.2.4.3, only rotavirus mortality rates in children are applied to the entire population. The neonate mortality rate for enterovirus is restricted to neonates and not used to inform mortality rates for other population sub-groups. EPA believes that, for the enteroviruses, neonate mortality rates are higher than for the general population and thus the neonate data cannot be applied more broadly. On the other hand, EPA has no data on rotavirus mortality in population subgroups other than children under 5 years in age, so EPA cannot determine if the rotavirus mortality rate in children is high or low compared to other subgroups. EPA applies the rotavirus mortality to all age groups, recognizing that this is a source of uncertainty (it could be an over or underestimate). The enterovirus mortality rates for the non-neonates is based on a simple calculation that estimates the number of severe (hospitalized) enterovirus cases together with an estimate of the number of fatal outcomes in severe cases. This mortality rate is sensitive to the proportion of severe cases as discussed above and could be an underestimate if the number of severe cases is underestimated.

Another source of uncertainty in the EA estimates of morbidity and mortality rates for rotavirus (Type A virus) is whether or to what degree these rates could change due to a rotavirus vaccine. In 2006, the U.S. Food and Drug Administration (FDA) approved a new pentavalent vaccine for rotavirus (Vesikari et al, 2006) in children. The vaccine protects against the most common rotaviruses now found in the U.S. (serotypes G1, G2, G3, G4, G9) but does not protect again all rotaviruses found in the U.S. or all rotaviruses. Most current rotavirus infections in the U.S. are G1 serotype so Vesikari et al (2006) were able to demonstrate that the vaccine was 74.9% (95% CI: 67.3-80.9) efficient in protecting against G1 gastroenteritis. Because few rotavirus cases occurred in the U.S. for the other serotypes during the study, Vesikari et al (2006) report protection efficiency with very large uncertainty [G2 - 63.4% (95% CI: 2.6-88.2); G3 - 82.7% (95% CI: <0-99.6%); G4 - 48.1 (95% CI: <0-91.6%); G9 - 65.4 (95% CI: (<0-99.3%)]. These data suggest that after a prolonged vaccination program, substantial rotavirus gastroenteritis will continue to occur in the U.S., most from G1 serotype, but some from G2, G3, G4 and G9 serotype in vaccinated children as well as from other rotavirus serotypes and additionally, in unvaccinated children and adults. The most common rotavirus strains found in the U.S. could change in the future, either naturally or as an unintended result of vaccination. EPA believes that norovirus, rather than rotavirus is the more important health concern in the U.S. as a result of Type A viral exposure from ground water. EPA believes that, successfully implemented, the rotavirus vaccine has the potential to affect the future number of health effects in children. Within the first 25 years of GWR implementation, all children that are vaccinated would have reduced likelihood of incurring illness from rotavirus. Similarly, rotavirus secondary spread, which in this EA is assume to originate only from children less than five years in age, would be significantly reduced.

Most importantly, a rotavirus vaccine will have no impact on norovirus illnesses or other Type A viral illnesses resulting from ground water exposure. Type A virus morbidity and mortality rates are estimated with data on rotavirus because only rotavirus human challenge study data are available to determine the likelihood of infection given a virus dose. No such infectivity data are currently available for other Type A viruses (see Section 5.4.1 for a discussion of other Type A data including unpublished norovirus infectivity data). EPA believes that the total Type A disease burden, especially in adults, is not captured by monetizing rotavirus illness, with or without consideration of a rotavirus vaccine.

5.2.4.3 Quantified GWR Benefits (Predictions of Illnesses and Deaths)–Model Input Values

The quantified GWR benefits are determined for rotavirus and enterovirus using dose response models fitted to human challenge study data, morbidity, mortality and secondary illness factor when ingested from ground water sources. These data are summarized in Exhibit 5.10 and described in more detail below.

Exhibit 5.10 Dose Response Assumptions of Viral Pathogens for the GWR Risk Assessment *(continued on next page)*

Pathogen Hazards	Infectivity[1]	Morbidity		Mortality (M_m)
		M_p	M_s	
Definition	Infectivity measures the probability of infection for exposure to a specified dose. "Annual infectivity risk" estimates risk for a year for exposure to a daily dose, N, for a given number of days, D, during the year (see text for details.) Dose response function for annual risk is: $P_{Annual} = 1 - (1 - P_{Daily})^D$ (see below for estimating the probability of daily infection P_{Daily})	Primary morbidity is the probability of illness given infection; it can vary from person to person and can be greater in sensitive subgroups.	Secondary morbidity is the probability of illness given exposure to an asymptomatic or symptomatic ill person.	Mortality is the probability of death as a result of illness.

Pathogen Hazards	Infectivity[1]	Morbidity		Mortality (M_m)
		M_p	M_s	
Type A viruses (Highly infective virus) Represented by data on Rotavirus	Dose response function for daily risk of infection is given by the expected value of the Beta Poisson dose response function: $P_{Daily} = N \times \left(\frac{\alpha}{\alpha + \beta} \right)$ P_{Daily} for a single exposure to one Type A infectious unit is estimated to be 22.4% with 90% confidence bounds of 8.8% and 41.4% reflecting uncertainty in the **"** and **$** parameters.	< 3 yrs [2] = 0.10-0.88, uniform distribution	< 3 yrs[2a] = 0.55 (applied to the entire exposed population)	All ages [4] = 5.7×10^{-6} - 7.3×10^{-6}, uniform distribution
		$ 3 yrs [3] = 0.10-0.50, uniform distribution	$ 3 yrs = 0 (assumed)	
Type B viruses (Moderately infective virus) Represented by data on Echovirus or Enterovirus	Dose response function for daily risk of infection is given by the Pareto approximation to the Beta Poisson dose response function: $P_{Daily} = 1 - \left(1 + \frac{N}{\beta} \right)^{-\alpha}$ P_{Daily} for a single exposure to one Type B infectious unit is estimated to be 0.44% with 90% confidence bounds of 0.06% and 1.65% reflecting uncertainty in the **"** and **$** parameters.	< 5 yrs [5] = 0.5 - 0.78, uniform distribution	Triangular distribution (all age groups) [6], from 0.11 to 0.55; mode = 0.35	< 1 month [7] = 9.2×10^{-3}
		$ 5 - 19 years [5] = 0.12 - 0.57, uniform distribution		$ 1 month [8] = .02 (applied only to illnesses that require hospitalization, which are 1% of all illnesses)
		> 19 years [5] = 0.12 - 0.33, uniform distribution		

[1] See Appendix F for details of infectivity dose response functions.
[2] Based on Rodriguez et al. (1987) for the upper range value and Perez-Schael (1984) for the lower range value.
[2a] Based on Kim et al. (1977)
[3] The range for older children and adults based on Ward et al. (1986) (upper range value), Kim et al. (1977) (lower range value), and Wenman et al. (1979)
[4] From Tucker et al. (1998) and Kapikian (2001) for children less than 5 years old and assumed to apply to all ages.
[5] Hall et al. (1970); Kogon et al. (1969)
[6] Morens et al., 1978 [citing Karzon et al (1961), Winkelstein et al (1957) and Lehan et al (1957)]
[7] From Jenista et al. (1984), Modlin (1986) and Kaplan and Klein (1983)
[8] Based on data from Melnick (1996), Modlin (1995) and Bennet et al. (1987).
Notes: Mortality rates are rates of mortality given illness.

Morbidity

In the EA, Type A viruses are represented by data on rotavirus because published data from human challenge studies to determine the probability of infection given a virus dose are available only for rotavirus (see Section 5.4.1 for a discussion on other Type A viruses, including unpublished human challenge study data for norovirus which are not used in this analysis). For rotavirus, separate morbidity factors were used for children less than 3 years old and for individuals greater than or equal to 3 years old. For children less than 3 years old, a morbidity factor was taken as a uniform distribution from 0.10 to 0.88 (Perez-Schael et al, 1984; Rodriguez et al, 1987). The lower range value was reported by Perez-Schael et al (1984) and the upper range value was reported by Rodriquez et al (1987). There are significant differences in the two study designs that may account for the great variability in the reported morbidity rate. Rodriguez studied children under 3 while Perez-Schael studied newborns. Newborns are protected against illness by maternal antibodies which fade by about 6 months in age. Older children can report a wide range of clinical symptoms (e.g. pharyngitis and otitis media) in contrast to newborns who cannot report symptoms. Thus Rodriquez used multiple disease endpoints while Perez-Schael was able to use only diarrhea as a clinical symptom of disease. The Rodrizquez study was conducted in a private pediatric medical practice in Virginia USA while the Perez-Schael study was conducted in a large maternity hospital in Caracas, Venzuela. Because of the differences in the study designs used to determine rotavirus morbidities, there is significant uncertainty in the rotavirus morbidity range.

For people aged 3 years or more, this EA uses a uniform distribution from 0.10 to 0.50. The lower bound of 0.10 is from Kim et al (1977). Kim et al. (1977) found that 3 parents of infant children hospitalized with rotavirus illness were ill (with gastroenteritis) among the 26 parents exposed to those ill children and infected with rotavirus. The upper bound of 0.50 is from Ward et al. (1986). Ward et al. (1986) found a 50% diarrhea (other ill individuals exhibited differing disease endpoints) morbidity rate in adults challenged with a rotavirus dose under experimental conditions. Wenman et al. (1979) reported that 17 parents became ill of 43 parents infected by rotavirus (40%) in a prospective study of diarrhea in households with newborn children in Canada. As discussed in Section 5.2.4.2, the G1 serotype is most common in the U.S. and most adults have had one or more exposures to this serotype. Rotaviral immunity to reinfection and illness is short (as opposed to lifetime immunity characteristic of poliovirus and hepatitis A virus) and multiple infections are possible (Anderson and Weber, 2004; Koopman and Monto, 1989).

Griffin et al. (2002) analyzed rotavirus outbreaks and identified one rotavirus serotype (G2) that is associated with outbreaks in adults. Outbreak data from nursing homes in Australia (Marshall et al, 2003) identified G1, G4 and G9 rotavirus strains as causing outbreaks among adults. Because multiple serotypes can produce rotavirus disease in adults, these data suggest that the morbidity value for adults can differ from the morbidity identified from a single strain. If the human subjects in Ward et al (1986) were challenged by G2, G4 and G9 strains, in addition to G1, then it is likely that a greater percentage would become ill. There is uncertainty in the EA estimate of rotavirus morbidity for adults because it is based primarily on infections produced by only one strain of rotavirus (G1). It is possible that other rotavirus strains, such as G2, and consideration of disease endpoints other than diarrhea, would provide higher morbidity estimates.

Type B viruses are represented by data on echovirus or enterovirus. The morbidity data for Type B viruses are taken directly from two virus watch studies in Seattle (Hall et al., 1970) and New York (Kogon et al, 1969) which are prospective epidemiological investigations undertaken in a general population cohort. As such, they are high quality (and costly) data.and represent the best prospective enterovirus morbidity data available for the general population. To the extent that current molecular

methods are more sensitive in determining infection by identifying viruses shed in stool, the cell culture methods used in the virus watch studies may underestimate the number of infected individuals.

Exhibit 5.11 shows echovirus morbidity data from both the Seattle and New York Virus Watch studies. Coxsackievirus (another subgroup of the Type B enteroviruses) are also reported from the New York Virus Watch study and shown in Exhibit 5.11. However, only echovirus data were used in the EA to represent the Type B viruses.

Three age-based morbidity rates ranges for echovirus (one group of the enteroviruses) from the Seattle (Hall et al., 1970) and New York virus watch studies (Kogon et al., 1969) are used in the EA, each in the form of a uniform distribution. The morbidity rate used for children less than 5 years of age is 0.5 - 0.78; for children 5 years to 19 years is 0.12 - 0.57; and for adults greater than 19 years old is 0.12 - 0.33. For children less than five years old, the lower bound comes from the Seattle study and the upper bound comes from the New York study. For children between ages 5 and 19, the lower bound comes from the New York study and the upper bound comes from the Seattle study. For adults, the lower bound comes from the New York study and the upper bound comes from the Seattle study. The coxsackievirus morbidity data from the New York study were not used.

As shown in Exhibit 5.11, the Seattle virus watch reported data for children aged 5 to 19 years and for individuals over 19 years; the New York virus watch data reported data only for individuals under and over four years in age. Because the New York virus watch only reported data for the over four age group, these data (0.12) were used to populate both the 5 to 19 year group and the greater than 19 year group. For the Seattle virus watch study, a total of 43 individuals were infected by echovirus and 20 people became ill. For the New York virus watch study, 53 individuals were infected by echovirus and 24 people became ill. Thus, despite the high quality of the data, the total number of people used to determine morbidity is small.

There is large uncertainty associated with the Type B morbidity values currently used in the EA because they are based only on echovirus data. For other parameters in the GWR EA (e.g., disease severity) data from all enteroviruses were used. A significant uncertainty is the exclusion of the coxsackievirus morbidity data. If coxsackievirus (also an enterovirus) morbidity data were used from the New York viral watch study (Kogon et al, 1969) then the mean morbidity rates would be significantly higher because coxsackievirus is more likely to cause illness than echovirus, upon infection. Kogon et al (1969) report 10 illnesses resulting from 15 infections. Thus, the moribidity range for the 5-19 year olds would change from 0.12 - 0.57 to 0.12 - 0.67 and the morbidity range for adults would change from 0.12 - 0.12 - 0.67. For all age groups in the New York Viral Watch study, Kogon reported 53 illnesses resulting from 103 infections.

In this EA, only echovirus data were used to determine Type B virus morbidity rates (despite the availability of coxsackievirus morbidity data) to ensure consistency with the infectivity data for Type B viruses. The human challenge study data representative of Type B viruses was conducted using echovirus (type 12). By using only echovirus morbidity data, both infection and illness rates are determined using only echovirus data, thereby ensuring that the predicted number of illnesses is more closely represented by the challenge doses.

Exhibit 5.11 presents a summary of the morbidity data from the Seattle and New York Virus Watch studies discussed above.

Exhibit 5.11 Summary of Virus Watch Morbidity Data

Seattle Virus Watch Study (Hall et al, 1970)			New York Virus Watch Study (Kogon et al, 1969)		
Age Bins	**Echovirus Morbidity**	**Coxsackievirus Morbidity**	**Age Bins**	**Echovirus Morbidity**	**Coxsackievirus Morbidity**
0-5 years	12 ill/ 24 infected (**50%**)	no data	0-4 years	21 ill/ 27 infected (**78%**)	28 ill/ 54 infected (**52%**)
5-19 years	4 ill/ 7 infected (**57%**)	no data	5-9 years (Coxsackie-virus) 5+ years (Echovirus)	3 ill/ 26 infected (**12%**)	15 ill/33 infected (**45%**)
19+ years	4 ill/ 12 infected (**33%**)	no data	10+ years (Coxsackie-virus)	see above	10 ill/15 infected (**67%**)

The mean morbidity rate is based on the observed range and assumed distribution for both Type A (rotavirus) and Type B (echovirus) illnesses. This value is likely underestimated because viral pathogens other than the surrogate types will also be avoided by rule implementation and may include agents with greater capability to cause illness, as is shown in the above example for coxsackievirus, thereby increasing the upper part of the range and the corresponding mean value. The potential benefits of reducing illness from pathogens other than enterovirus are discussed in section 5.4 of this chapter. In particular, section 5.4 identifies norovirus as a common waterborne etiologic agent that, unlike rotavirus, causes illness in adults as well as in children. Thus, in choosing a differing Type A surrogate virus, the mean morbidity rate in the general population (adults and children) could increase, as compared with rotavirus that causes illness primarily in children.

Secondary Spread

Secondary spread can occur from contact with an infected or ill individual. It is likely that most secondary spread occurs from contact with asymptomatic carriers (e.g., Typhoid Mary) because, for most age groups, there are no clinical symptoms expressed to keep others away. Because data on secondary spread from asymptomatic carriers are not available, in this analysis, it is assumed that only ill persons are capable of causing secondary transmission. Thus, the secondary spread value used is the EA is not a secondary morbidity rate (which includes contact with both symptomatic and asymptomatic carriers) but rather a secondary spread factor. This assumption underestimates the secondary spread morbidity rates which ideally should be applied to the total number of infected rather than ill individuals.

Secondary spread of waterborne illnesses is a reasonable assumption because the pathogens of concern for the GWR are also commonly transmitted by respiratory or direct contact (fecal-oral) pathways. Aerosols containing fecal-oral viruses can be transmitted either by the ingestion or the inhalation route.

Some waterborne-viruses, such as coxsackievirus and adenovirus cause eye infections (conjunctivitis) and so they may be transmitted by the dermal pathway via primary or secondary exposure.

Because the enteroviruses and rotavirus do not have animal reservoirs, they circulate only within the human population. For the viral strain to avoid dying out, each individual with a viral infection must, on average, transmit at least one additional infection to maintain that virus strain within the human population. Thus, high rates of secondary transmission are necessary for virus viability.

Most available secondary morbidity data are obtained from studies of households. In these households, both parents and children become ill and secondary transmission values are based on data and/or assumptions about whether parents or children were the primary case. Few data are available to evaluate secondary transmission outside the household (within the community) or within other higher risk settings such as nursing homes. For rotavirus, a virus watch study was used to collect data from Tecumseh, Michigan (Koopman and Monto, 1989; Koopman et al, 1989) and an infectious disease simulation was conducted to determine the secondary morbidity rates (Longini and Koopman, 1982). As discussed in section 5.2.4.2, data derived from infectious disease simulations are specifically excluded from consideration in the GWR EA.

For rotavirus (Type A), the secondary spread factor was determined separately for children under 3 and all others. For all individuals over age 3, it is assumed that there is no secondary spread of rotavirus. This assumption is based on the apparent exposure of most individuals to multiple strains of rotavirus early in life. As a result, it is assumed that most individuals have acquired some temporary immunity to rotavirus by age 3 and so, while there is a likelihood of developing clinical illness from primary exposure, it is expected that there would be a lower likelihood of developing clinical illness from secondary exposure. Primary exposure morbidity data from Ward et al. (1986) and secondary morbidity data from Wenman et al. (1979) (assuming adults are secondarily exposed in Wenman) show that the higher rotavirus morbidity rates comes from primary exposure while the lower (but not zero) rates come from exposures that might be secondary. The EA underestimates the number of illnesses and deaths in adults from rotavirus by assuming no clinical illness in individuals over age three by secondary transmission.

For children under age 3, the rotaviral secondary illnesses factor is 0.55 (i.e. for every two primary rotavirus illnesses among children under age 3, there is about one secondary illness in individuals of any age that is included in the GWR EA benefits analysis). This value is based on Kim et al. (1977). Kim et al. (1977) is a study of the adult contacts of pediatric patients with gastroenteritis. It was not designed to determine secondary transmission values, either secondary morbidity rates or secondary illness factors. For example, there are no data that definitively identify whether the adults or the children were the primary case and either assumption is appropriate. EPA has identified at least two differing analyses for determining secondary illness using the Kim paper. Fortunately, the two differing analyses (either may be correct) give approximately similar results which are presented here (Exhibit 5.10).

Echovirus (Type B) secondary illness factor is a triangular distribution for individuals of all ages. The range is 0.11 - 0.55 with a mode of 0.35. These data are derived from echovirus outbreak data reported by Morens et al (1991) (Table 17-3) in a reference work on the enteroviruses. The lower value in the range comes from a study of a New York aseptic meningitis outbreak in 1956 (Karzon et al, 1961). The upper value in the range comes from a New York aseptic meningitis outbreak in 1955 (Winkelstein et al, 1957). The mode is informed by the other aseptic meningitis outbreak (in Iowa) listed in the table (Lehan et al, 1957).

In general, primary sources are used in the GWR EA to determine input values for the risk assessment. However, secondary transmission data are very difficult to acquire and evaluate because key data describing which household members are primary and which are secondary cases are typically not available. There are no data on secondary transmission of echovirus or other enteroviruses (Type B) outside the household. For these reasons, the echovirus secondary illness factor used in the EA is taken directly from a reference work where, it is presumed that the authors had adequate expertise to evaluate the original paper and make an informed judgement as to whether to use these data to inform secondary spread values.

The enterovirus secondary transmission factor is defined only by echovirus data. Because of low infectivity rates, secondary transmission data are rare for the other enteroviruses. It is likely that, if other enteroviruses, such as coxsackievirus, were considered, the secondary transmission values could differ. For example, most enterovirus 70 or 71 is acquired by secondary transmission via person to person contact. Thus, if secondary transmission data were available and used in this EA, the secondary spread factor would likely be higher.

The use of observational epidemiologic data in the quantitative benefits analysis is an appropriate and acceptable method to determine the number of secondary cases. However, it is not the only appropriate and acceptable method. In Appendix E, *Potential Implications of Population Dynamics and Secondary Transmission of Infection on the Benefits of the Ground water Rule*, another method is described and results are presented for the number of secondary cases that might accrue, after infection or illness from a primary ground water exposure. One difference between these two methods is that in the quantified benefits section of the GWR EA, EPA assumes that only ill individuals can make others ill. As is well known from the case of Typhoid Mary, asymptomatic individuals can also serve as carriers of disease, and thus infected individuals can infect others who can also become ill or who can become carriers also. The number of secondary cases is limited by the number of susceptible individuals in the population under consideration and the length of acquired immunity, if appropriate, for the agent.

Appendix E presents a different modeling approach which accommodates dynamic phenomena typical of real infectious disease transmission systems. A dynamic model is described and results are presented for the number of secondary cases that might accrue in a large community after Type A virus (e.g. rotavirus) infection and illness is introduced into a subset of travelers who acquire the infection from drinking contaminated ground water at a TNCWS well outside their home community. The travelers return to the home community and secondary cases accrue from normal interactions among infected and ill individuals who transmit the disease to others in their household or their community. The analysis considers only infection and illness from two Type A viruses, rotavirus and norovirus.

One important difference between the simple secondary spread factor multiplier used in the GWR EA and the partial differential equation methodology of Appendix E is in the assumptions about the characteristics of secondary spread of Type A virus. The GWR EA assumes that 1) only rotavirus causes Type A illness and 2) all children younger than 3 years of age can infect other individuals with rotavirus, while older (than 3 years) children and adults can not transmit rotavirus to others. Norovirus is not considered in the quantified benefits analysis of the EA. The alternative analysis in Appendix E assumes 1) Type A viruses other than rotavirus, such as norovirus are causing illness in the people that consume water from the hypothetical TNCWS well and 2) symptomatic and asymptomatic individuals of all ages infected with a Type A virus can infect others who can also become ill or can become asymptomatic carriers.

The results of the analysis, presented in Appendix E, suggest that population dynamics could substantially impact the potential benefits calculated quantitatively in this EA, depending on the suite of population dynamic elements considered. The results demonstrated that important assumptions had a strong influence on the estimated number of secondary cases. Model parameters that strongly influence the estimate include the duration of clinical disease, duration of shedding (etiological agent carrier), etiologic agent infectivity, duration of protective immunity, and person-to-person transmission characteristics of the infectious agent.

The population dynamic simulation results illustrate that the number of additional illnesses due to secondary exposure could either increase or decrease relative to the method used in the GWR EA, depending on the choice of elements. For example, using median values for the elements, it is determined that approximately 0.18 additional secondary illnesses, on average, would result from each primary infection and illness. The median value analysis also showed that the number of secondary illnesses due to asymptomatic carriers is roughly equal to the number of secondary illnesses due to contact with ill individuals. However, simulations using different model parameters (sensitivity analysis) also demonstrate that the predicted number of additional illnesses due to secondary transmission could either increase by approximately an order of magnitude or be reduced to effectively zero, depending on the assumptions about infection transmission parameters.

The model results presented in Appendix E serve to demonstrate the concept and method of dynamic transmission system analysis to predict the number of secondary cases that might accrue.

Mortality

For rotavirus (Type A), the mortality factor for all ages used in this analysis is a uniform uncertainty distribution from 5.7×10^{-6} to 7.3×10^{-6}. This range is based on data from a cost-effectiveness analysis of a rotavirus immunization program (Tucker et al. 1998). The cumulative total for rotavirus diarrhea was 2,730,000 cases (by year five in a birth cohort), and the estimate of rotaviral deaths for that same birth cohort was 20. To determine the upper value of the mortality rate range, the deaths are divided by the diarrhea events (20/2,730,000) resulting in 0.00073%. The lower value for that range is based on a differing estimate for the for the total number of rotavirus cases. Kapikian (2001) estimated 3.5 million rotavirus cases as compared with the CDC estimate of 2.73 million. Applying the CDC estimate of 20 deaths to the Kapikian value for the number of cases yields a lower bound factor of 5.7×10^{-6}. These rates are assumed to apply applied to all age categories.

For Type B viruses, the mortality factor for infants less than 1 month old is based on case fatality rates from three sources (Jenista 1984, Modlin 1986, Kaplan and Klein 1983). Jenista (1984) reported a case-fatality rate of 3% for neonates with culture-proven enterovirus infection in the Strong Memorial Hospital study. Modlin (1986) reported 7 of 206 infants in newborn nurseries who became ill during echovirus outbreaks died (3.4%). Kaplan and Klein (1983) reported that 6 of 77 patients younger than three months of age hospitalized with cultures positive for Coxsackievirus died (7.8%). The mean from these studies is 4.9%. Since this is a hospital case fatality rate, it is necessary to multiply by the proportion of infants hospitalized to arrive at the mortality rate. Jenista (1984) reported the percent of enteroviral-infected infants (re-)admitted to the hospital with suspected sepsis was 18.7%. The final mortality rate for neonates of 0.0092 was calculated as 0.187 * 4.9%. This analysis assumes that neonate enteroviral illness severity is represented by the Jenista (1984) cohort. Modlin (1986) reports differing severity depending on whether the neonate is infected by echovirus *in utero* as compared with during and after birth. The EA

mortality rate is based on hospitalization data from all neonates in a prospective study (Jenista, 1984) rather than data only from sensitive subgroups such as neonates with infection acquired *in utero*.

For Type B viruses, the mortality factor used for persons of all ages (other than neonates) is 0.02%. It is assumed that 1% of cases are severe enough to require hospitalization. Modlin (1995) finds that 0-4% (mode of 2%) of cases that require hospitalization result in death. Currently a general mortality value of 0.001% for cases that do not require hospitalization is used when specific rates are not available (Bennet et al., 1987). Therefore, the calculated mortality rate is (0.01 x 0.02) + (.00001* 0.99) = .02%.

The proportion of severe cases is determined to be 1% based on the following calculation. CDC estimates about 10 million enteroviral illnesses each year (e.g. Strikas et al, 1986). By compiling data on the annual number of severe enterovirus cases, assumed to be encephalitis (19,000 cases; Khetsuriani et al, 2002), myocarditis (60,000 cases; Kim et al, 2001), and viral meningitis and meningioencephalitis (34,000 cases; Khetsuriani et al, 2003), it is estimated that about 100,000 severe acute illnesses occur each year. The number of severe cases divided by the total number of cases yields a factor of 1% of cases. As discussed in Section 5.4, the severe chronic illnesses due to echovirus or other enterovirus, such as dilated cardiomyopathy and Type I diabetes are not included in the tally of severe cases. In addition, as discussed in Section 5.2.4.2, the total number of cases (ten million) includes a substantial number of mild hand, foot and mouth disease cases caused by enterovirus 70 and 71. Thus, the percentage of cases that are severe would likely be higher if only waterborne enterovirus were considered.

5.2.5 Risk Characterization

Risk characterization combines the hazard identification, exposure assessment, and dose-response information to describe the overall risk to the exposed population. The following sections will describe the risk assessment methodology for the baseline risk calculations, provide results of the risk calculations, and describe the methods used in estimating the reduction in risk from the regulatory alternatives.

5.2.5.1 Risk Assessment Methodology for Baseline (Pre-GWR) Risk Calculations

This section summarizes the risk assessment modeling approach used by EPA to estimate the baseline number of annual endemic infections, illnesses and deaths due to viruses in GWSs. For a more complete and detailed discussion of the risk assessment model, the reader is referred to Appendix G.

A Monte Carlo simulation model was used for this risk assessment so that the effects of those model inputs for which variability and/or uncertainty could be described quantitatively could be reflected in the estimated cases of illness and deaths.

The risk model operates on 2,376 distinct population categories. The 2,376 population categories considered in the risk model reflect differences in virus occurrence and individual exposure factors that influence individual risks of infection and resulting illnesses and deaths in both the pre-GWR baseline and following implementation of the final GWR (or the other regulatory alternatives considered). The 2,376 strata result from the 3 system types, 9 systems size categories, 8 well types, and 11 age groups that are considered (3 * 9 * 8 * 11 = 2,376). The 3 system types are CWS, NTNCWS, and TNCWS. The 9 system size categories are those described in Chapter 4 and provide information on the number of people served per entry point (well) in each size group of each system type. The 8 well types reflect the various

combinations of being more or less vulnerable to contamination, disinfecting or nondisinfecting, and construction to standards (2 * 2 * 2 = 8). The 11 age groups, as described in the preceding section, reflect differences in average daily water consumption. The risk assessment model has three major parts that are summarized below.

The first major part of the risk model generates information on the annual individual risks of infection for 2,376 population categories. There are two types of outputs from this first part of the model for each of the 2,376 population categories: (1) uncertainty distributions of average risk of infection and (2) variability distributions of individual risk of infection.

The second major part of the risk model uses the uncertainty distributions of average individual risk of infection in each population category as its inputs to calculate the expected number of annual endemic illnesses and deaths in each of the 2,376 strata, which are then aggregated to arrive at the national totals.

The third major part of the risk model uses the variability distributions of individual infectivity risks generated in the first part of the model. In this third part of the model, these 2,376 individual risk distributions are drawn from to generate an overall individual infectivity risk curves for the baseline and post-regulatory conditions.

One of the key factors considered in constructing the risk model in parts was to efficiently accommodate addressing the variability and the uncertainty in the model inputs. The computation of the range of individual risks of infection in the population groups served by GWSs involves inputs that reflect both variability and uncertainty. However, the computation of cases of illnesses and deaths, based on the individual infectivity risks, involves inputs that reflect uncertainty only. The third part of the model addresses only variability in individual risks of infection.

The first part of the risk model was therefore constructed as a two-dimensional (2D) Monte Carlo simulation to properly manage both the variability and uncertainty factors involved. For each of the 2,376 population categories, the modeling involved 250 uncertainty loops with 1,000 variability loops within each of the uncertainty loops. (The specific inputs considered as variability and uncertainty items are described later in this section.) The first output of this first part of the model (for each of the 2,376 categories) is a set of 250 average individual infection values (that is, the average of each of the 1,000 estimates of individual risk in each of the 250 uncertainty loops). The second output of this first part of the model (again for each of the 2,376 categories) is a distribution of 1,000 individual infectivity risk values averaged across the 250 uncertainty loops (where each is first sorted from lowest to highest risk values).

The second part of the risk model is a one dimensional Monte Carlo simulation model that uses the first output of part one of the model, which is an uncertainty distribution, along with other inputs that are either constants or are distributions reflecting uncertainty. Again, this second part of the risk model produces estimates of cases of illness and death, presented as uncertainty distributions from which the best estimate (taken as the mean) and the lower and upper 90% confidence bounds on the cases (taken from the 5th and 95th percentiles, respectively) are obtained.

The third part of the risk model is also a one dimensional Monte Carlo simulation model in which values are drawn from the 2,376 distributions of individual risk variability in proportion to the population that they each represent to construct overall risk distribution curves for both the baseline conditions and for post-regulatory conditions.

The following provides some further discussion of each of the three parts of the risk assessment model. Again, the reader is referred to Appendix G for details of the modeling performed. Exhibit 5.12 provides a summary description of the various factors used in the risk calculation and indicates whether they were inputs as variability distributions, uncertainty distributions, or constants.

Exhibit 5.12 Summary Table of Risk Calculation Factors, Distribution Category (Variability, Uncertainty, Constant) and Distribution Type) *(continued on next page)*

Risk Calculation Factor	Description and Use in Calculations	Variability	Uncertainty	Constant	Type
% Vulnerable Wells	Used in Step 1 to characterize whether the well is less or more vulnerable	X			Different point estimates for different system types and sizes
Occurrence Hit Rate (P_{well})	Used in Step 1 to characterize the fraction of systems (and therefore of population) having viruses present in the source water.		X		Multiple input sets from MCMC model output
Occurrence Hit Rate (P_{sample})	Used in Step 1 to determine the number of days of exposure to water with virus present	X	X		Multiple input sets of distributions from MCMC model output (uncertainty); selection of a specific value from the distributions for each well (variability)
Occurrence Concentration	Used in Step 1 to characterize the concentrations of viruses in source water.	X			sample with replacement
Fraction of Disinfecting and Non-disinfecting Systems	Used in Step 1 to separate those systems currently practicing disinfection from those that do not.	X			Different point estimates for different system types and sizes
Log Removal for Disinfecting Systems	Used in Step 1, an assumed 2 or 4-log removal of virus concentration in source water for those systems practicing disinfection.			X	point estimate

Risk Calculation Factor	Description and Use in Calculations	Variability	Uncertainty	Constant	Type
Viability	Used in Step 1 to indicate the fraction of viruses in water considered to be infectious (assumed here to be 1.0).			X	point estimate
Drinking Water Consumption	Used in Step 1 to characterize the daily water consumption by various age groups in the exposed population.	X			point estimate for each age group derived from distributions
Type A and Type B Dose response Equation Parameters	Used in Step 1, empirically derived parameters in equations used to calculate daily and annual risk of infection.		X		multiple pairs of parameters obtained by simulation
Days of Consumption	Used in Step 1 to indicate the number of days per year an exposed individual consumes water from ground water sources.		X (for TNCWSs)	X (for CWSs and NTCWSs)	triangular for TNCWS, constants for CWSs and NTCWSs
Population Exposed	Used in Step 1 to indicate the population consuming drinking water from ground water sources.			X	point estimates
Average Annual Individual Risk of Infection	Product of the Step 1 calculation used in Step 2 to calculate cases of illness and death.		X		calculated in risk model

Risk Calculation Factor	Description and Use in Calculations	Variability	Uncertainty	Constant	Type
Population Served	Used in Step 2 to scale up the annual individual infection risks to total cases of infection, and ultimately to total cases of illness and death in the exposed population.			X	point estimates
Primary Morbidity Factors	Used in Step 2 to estimate the number of illnesses per infection in the exposed population.			X	point estimate
Secondary Morbidity Factors	Used in Step 2 to estimate the number of additional illnesses resulting from contact with individuals becoming ill through primary consumption of drinking water.		X (for Type B virus)	X (for Type A virus)	point estimate (Type A) triangular (Type B)
Mortality Factors	Used in Step 2 to estimate the number of deaths in the exposed population.			X	point estimate

Part 1. Estimation of the Annual Individual Risk of Infection

The key value calculated in Part 1 of the risk assessment model is the annual individual risk of infection. The algorithm used for this calculation is:

$$P_{Annual} = 1 - (1 - P_{Daily})^{D}$$

In this algorithm, it is implied that an individual's risk of being infected at some time during the year is the result of his or her experiencing an average daily risk of infection given by P_{Daily} for D days of exposure during the year. The value for D in this algorithm is generated from the value selected for a given well from the P_{sample} distribution. The P_{sample} value, which falls between 0 and 1 and represents the duration of fraction of time that a contaminated well has virus present, is multiplied by the days of exposure for each type of well as shown in Exhibit 5.7 to give the days of exposure to water with virus present.

For reasons discussed in detail in Appendix F, there were different, though related, forms of the dose-response model for determining the average daily risk of infection for the Type A and Type B virus. Both model forms are rooted in the Beta-Poisson dose-response model described by Haas et al. (1999).

For Type A viruses, the model form used was:

$$P_{Daily} = N \times \left(\frac{\alpha}{\alpha + \beta} \right)$$

where N is the expected number of viruses ingested per day, and **"** and **$** are the parameters of a beta distribution that characterizes the variability in the survival probability of the Type A viruses that are ingested.

For Type B viruses, the model form used was:

$$P_{Daily} = 1 - \left(1 + \frac{N}{\beta} \right)^{-\alpha}$$

where N is again the expected number of viruses ingested per day, and **"** and **$** are the parameters of a Pareto Distribution used here as an approximation to the exact Beta Poisson distribution.

The expected number of viruses ingested per day, N, in this model is the product of the average concentration of the virus in the water consumed and the average daily amount of water consumption of the individual consuming that water. Also, for those categories of wells that practice disinfection, the concentration of virus was further reduced to reflect either 2-log or 4-log inactivation in proportion to the fraction of disinfecting systems in that category achieving those levels of disinfection.

As indicated earlier, this part of the risk model was structured as a 2D Monte Carlo simulation to accommodate both variability and uncertainty in various inputs.

The inputs to this part of the model that were treated as uncertainty items were:

- The hit rate, used to characterize the probability that a well would have virus present in the source water;
- The **"** and **$** parameters used in the daily risk dose-response functions; and
- The fraction of wells that are either more or less vulnerable.

The inputs to this part of the model that were treated as variability items were:

- The concentration of virus in source water when present, and
- The daily water consumption amount (varied by age group).

More details on the characterization of uncertainty in the hit rates and of variability in virus concentration for the various well types is presented in Chapter 4. More information on water consumption variability distributions is presented in section 5.2.3 of this chapter. Also, a more thorough discussion of the derivation of the " and $ parameters of the infectivity dose-response functions to reflect uncertainty in those values is provided in Appendix F.

Part 2. Estimation of the Annual Cases of Illness and Death

In the second part of the risk assessment model, the uncertainty distributions of average individual risk of infection for each of the 2,376 population categories are used together with information on the number of individuals in each of these categories, risk of illness given infection (morbidity factor), and factors describing secondary spread of illness to compute the number of cases of annual endemic illnesses. The basic algorithm for the calculation of illnesses across all 2,376 categories is:[5]

$$\sum_{i=1}^{792} Pop_i \times P_{Annual(i)} \times M_{P(i)} \times \left(1 + M_{S(i)}\right)$$

These calculations are carried out as a Monte Carlo simulation using 1,000 iterations. In addition to the uncertainty distributions for individual risk of infection that are used as inputs ($P_{Annual(i)}$), uncertainty is also reflected in the secondary spread factor used for Type B viruses. The resulting output of this step is an uncertainty distribution of estimated annual endemic cases of illnesses for each virus type from which the mean is used as the best estimate of the annual cases and the 5th and 95th percentile values are used as the lower and upper 90% confidence bounds.

The basic algorithm for the calculation of annual endemic deaths is a simple extension of the algorithm for total illnesses shown above:

$$\sum_{i=1}^{792} Pop_i \times P_{Annual(i)} \times M_{P(i)} \times \left(1 + M_{S(i)}\right) \times M_{M(i)}$$

which includes the mortality factor (MM(i)) for each category.[6] In the risk assessment model, deaths are calculated in tandem with illnesses in the simulation as noted above. Similarly, the output for this step is an uncertainty distribution of estimated annual endemic deaths for each virus type from which the mean is

[5] It is necessary to modify some of the age categories within these 2,376 groups to apply the morbidity and secondary spread factors to reflect the specific age ranges as shown in Exhibit 5.10 for which they have been developed.

[6] As with the morbidity and secondary spread factor noted above, some adjustment of the age groups is made to apply the morbidity factors to reflect the specific age ranges as shown in Exhibit 5.10.

used as the best estimate of the annual cases and the 5th and 95th percentile values are used as the lower and upper 90% confidence bounds.

Part 3. Characterization of the Distribution of Individual Risks

The outputs of the second part of the model focus on estimates of the number of cases of illnesses and deaths in the population. Those estimates are built up from consideration of the average or expected risk of infection from the consumption of virally contaminated ground water applied to the population groups to which those averages apply. It is noteworthy that these average annual risks of infection span the full range from 0 (for the vast majority of the population consuming water where there is no "hit" and therefore no virus present) to a risk of 1 (for those individuals found to be consuming water where viruses are present at levels sufficiently high to ensure an infection occurring at some point during the course of a year of exposure).

This third part of the risk assessment model is aimed at providing some insights into how the annual risks of infection are distributed in the population within this range of 0 to 1. In part 1 of the risk model, for each of the 2,376 population groups, the simulation produces 1,000 estimates of individual risk for 250 alternative sets of uncertainty inputs. In Part 3 of the model, the 1,000 individual risk estimates in each of these 250 distributions of the 2,376 population groups is sorted from lowest to highest risk value. An overall "expected individual risk" distribution for each of the 2,376 population groups is created by computing the average of the sorted 1,000 values across the 250 sorted distributions.

Then, in a separate simulation, a probability is assigned to each of these 2,376 "expected individual risk" distributions reflecting the fraction of the total population served by ground water that each represents. Then 25,000 individual values are drawn from these 2,376 distributions in proportion to these probabilities to determine which distribution to draw from on a given iteration, and then randomly from that "expected individual risk" distribution that was selected.

The result of this process is an overall distribution of individual risk that reflects the entire exposed population. The shape of this distribution for the baseline conditions can then be compared to similar distributions constructed for the post-GWR conditions to provide insights into how the rule affects not only the number of cases of illness and death, but also how it differentially affects those individuals experiencing different levels of risk prior to the rule.

5.2.5.2 Results of the Baseline Risk Calculations

Estimated annual numbers of endemic illnesses from ingestion of Type A and Type B viruses in ground water PWSs are summarized in Exhibit 5.13. These are the average of the avoided illnesses and deaths calculated for each of the 25 years following rule promulgation. This table presents the calculated mean, as well as the 5th and 95th percentile estimates of annual illness and deaths for Type A and Type B viruses from the Monte-Carlo simulation. The mean from the simulation is the expected number and the 5th and 95th percentile reflect uncertainty around that reflection.

Exhibit 5.13 Estimates of Annual Baseline Viral Illness and Death[1]

Virus Type	Illnesses per Year			Deaths per Year		
	mean	5th	95th	mean	5th	95th
Type A	175,168	32,652	435,381	1.16	0.22	2.92
Type B	10,018	501	40,718	2.01	0.04	8.10
Total	**185,186**	**33,153**	**476,099**	**3.18**	**0.26**	**11.02**

[1] Illnesses are rounded to nearest whole number and deaths to the nearest tenth. Detail may not sum due to independent statistical analyses.

It is important to recognize that the two-step procedure for calculating the number of cases of illness and death in the population from exposure to viruses in ground water was carried out separately for the Type A and Type B virus categories (reflecting different occurrence distributions and dose-response relationships), different age groups (reflecting different morbidity and mortality factors), different water system size groups (reflecting different numbers of people served), and different water system types (reflecting different exposure days of consumption per year for CWSs and NCWSs). The results of these many separate estimates of risk and cases of illness and death are then summed to obtain the overall estimates presented in Exhibit 5.13 (for Type A and Type B viruses).

In presenting the results of this two-step procedure for computing the baseline illnesses and deaths as shown in Exhibit 5.13, the best estimate is the mean of the iterations run in the second step. The uncertainty in that estimate is characterized by the 5th percentile and 95th percentile values obtained from those iterations (90 percent confidence bounds). These imply that, given the variability and uncertainty factors explicitly included in the analysis, there is a 5 percent chance that the actual number of cases falls below the 5th percentile value, and a 5 percent chance that it falls above the 95th percentile value, and therefore a 90 percent chance of falling within the specified bounds.

Summing the estimates of illness for both types of viruses gives a combined estimate of more than 180,000 illnesses each year, the majority of which are attributable to the highly infective, but less lethal, Type A viruses. The estimated combined number of deaths per year is approximately three, with slightly more of those being due to the more lethal, but less infectious, Type B viruses.

5.2.5.3 Baseline Illnesses and Deaths in Sensitive Subgroups

Exhibit 5.13 above summarizes the total estimated numbers of illnesses and deaths each year from ingestion of virally contaminated ground water under baseline exposure conditions. Of these illnesses and deaths, a portion will occur in sensitive subgroups (see Exhibit 5.4). The sensitive subgroups included in this analysis include the following:

- Immunocompromised persons in all age groups: bone marrow transplant recipients, AIDS patients, and organ transplant patients.
- Children less than 5 years old
- Elderly adults greater 64 years old

These sensitive subgroups comprise approximately 33 percent of the total exposed population (37.7 million exposed sensitive / 114.3 million total exposed = 33%) (from Exhibits 4.4 and 5.24). The baseline illnesses and deaths for these sensitive subgroups are shown in Exhibit 5.14. For Type B illnesses, the high mortality rate of enteroviruses among neonates (infants less than one month old) contributes to a higher proportion of deaths in sensitive subgroups, which account for approximately 75 percent of the echovirus deaths (1.5 / 2.0 = 75%) (Exhibits 5.13 and 5.14). For this dose response assessment, there is no specific morbidity and mortality information for the elderly or for the immunocompromised. Also, persons with autoimmune disorders were not included as part of the sensitive population. Although these persons may experience severe consequences of infection, their increased severity has not been modeled or included as part of the economic analysis.

Exhibit 5.14 Baseline Illnesses and Deaths in Sensitive Subgroups

Virus Type	Health Effect	Immunocom-promised[1] (all ages)	Infants and Young Children <5 years old[2]	Elderly Adults >65 years old[2]	Total Sensitive Subgroups
Type A	Illness	526	11,413	23,370	35,308
	Death	0.0	0.1	0.2	0.2
Type B	Illness	30	761	6,542	7,333
	Death	0.0	0.2	1.3	1.5

Footnotes: 1) The immunocompromised population is estimated to account for 0.3% of the total number of illnesses and deaths. 2) The Immunocomprised portion has been excluded from "Infants and Young Children" and "Elderly" subgroups to avoid counting them twice.
Sources: U.S. population data is from the 2000 U.S. census.

5.2.5.4 Baseline Risk to a Highly Exposed Individual

The annual risk of illness was also estimated for a highly exposed individual. For this calculation, it is assumed that a typical, highly-exposed individual would ingest drinking water from an untreated, more vulnerable well contaminated by virus. The source water from such a system is assumed to be contaminated with viral pathogens at a concentration of 40 viruses/100 L, which approximates the mean value (41.5) of the 7 virus concentration values from the Lieberman data used for the More Vulnerable wells. Because the source water is not disinfected, there is no inactivation of viral pathogens in the system. This person would be a member of the age category with the highest water ingestion rate at the 75^{th} percentile, which is 55-64 years. The 75^{th} percentile of daily intake of drinking water for this age group is 1.925 L/day. Annual exposure under this scenario is 49 days, based on 350 days/year consumption from a CWS and a P_{sample} value of 0.14, which is the 75^{th} percentile of the expected values from the P_{sample} distributions. The analysis also assumes dose response parameter inputs and morbidity factor inputs corresponding to mean values of their respective distributions.

Using these assumptions for drinking water exposure, the calculated annual probability of Type A viral illness for a person with these characteristics is 0.30. For Type B illness, the annual probability of illness is 0.035. These results reflect the higher infectivity of Type A viruses in comparison to the moderately infective Type B viruses.

5.2.5.5 Sensitivity of Baseline Estimates to Quantified Uncertainty Inputs

The Monte Carlo simulation model includes several inputs for which EPA has explicitly considered uncertainty. In some cases, these values are selected from a specific distribution describing the range and probability of particular values. In other cases, these values are selected from a set of plausible values that have been generated using Bayesian methods as described previously. In some cases, a particular uncertain input value is specifically related to one or more other uncertain input values.

This section describes an analysis performed by EPA to assess the relative influence of these inputs on the estimated annual cases of illness. The inputs fall into two general categories: occurrence inputs and dose-response morbidity inputs.

Uncertainty in Occurrence Inputs

The key occurrence inputs to the are: P_{well}, P_{sample} distribution parameters, and Percent More Vulnerable Wells.

The P_{well}, and P_{sample} distribution parameters used in the model are selected from a set of 10,000 values generated by a Bayesian analysis as described in Section 4.3.4.1 of Chapter 4 of the GWR EA. It is important to note that P_{well}, and P_{sample} are selected from the dataset for input to the model as paired values. As described previously, there is an inverse relationship between P_{well}, and the expected value of the P_{sample} distribution. As P_{well}, increases, the expected value for P_{sample} decreases and vice versa. Therefore, it is necessary to select an appropriately paired set of P_{well}, and P_{sample} values as inputs to each iteration of the model to ensure that this relationship is maintained.

The Percent More Vulnerable parameter is sampled from uniform distributions that are determined for each water system type and size based on acute and non-acute MCL violation data (see Section 4.3.4.2 in Chapter 4). In the risk model, the More Vulnerable wells typically have higher virus concentrations, which are expected to result in higher numbers of infections and illnesses. Note, however, that the range of the uniform uncertainty distributions of Percent More Vulnerable wells is relatively small (typically 0.5% to 5%), so the overall influence of this uncertainty input on the number of cases of illnesses is small (Exhibits 5.15a-b).

Uncertainty in Dose Response Inputs

The key dose-response inputs are the parameters for the infectivity dose-response equations and the morbidity factors.

The infectivity dose-response relationships for Type A and Type B virus include two parameters (alpha and beta). For the risk model input, a set of 1,000 pairs of parameters were developed for both Type A and Type B viruses from the challenge studies (see Section 5.2.4.1 in Chapter 5). In each iteration of the Monte Carlo simulation model, a parameter pair (alpha, beta) is selected for Type A and another is independently selected for Type B.

The uncertainties in the primary morbidity factors are incorporated as uniform distributions that differ for the two virus types and by certain age groups for each virus. Since these factors are applied to the number of cases of infection, higher morbidity factor values will result in higher cases of illness.

For Type B viruses there is also uncertainty in the secondary spread factor, which is included as a symmetrical triangular distribution. As with the primary morbidity factors, higher values for this factor will lead to increases in the number of illnesses estimated.

Approach to Sensitivity Analysis

A sensitivity analysis was performed to evaluate the relative influence of the selected uncertain inputs on the range of estimates of baseline cases of illness. Because of the complexity of the risk assessment simulation model and the total number (2,376) of strata of well types and population age groups, this sensitivity analysis was limited to one specific age group (20-24 year olds) served by CWSs, but it does consider all well-types and size categories. A separate model run was performed using 100 uncertainty loop iterations and 250 inner loop iterations. The output captured the number of cases of illness estimated for each virus for each of the 100 loops, as well as the 100 specific values selected for the uncertain inputs in each iteration.

For the uncertain P_{well} and P_{sample} occurrence inputs, a metric was used to combine the effect of the selected values since these inputs are linked and have an inverse relationship as described above. The metric used was the product of P_{well} and the expected value of the P_{sample} distribution for that iteration, referred to here as P_w*P_s. The reason for using this metric was that the product of these values reflects the combination of the fraction of wells that are virally contaminated and the fraction of time that contaminated wells have virus present. Higher values of P_w*P_s would be expected to result in a higher number of cases of illness.

For the uncertain inputs for the parameters for the infectivity dose-response equations, a metric was also used to reflect the combined effect of the alpha and beta parameters. For the selected parameters in a given iteration, the probability of infection from an exact dose of one viral infectious unit was computed.

For the other uncertain inputs, the actual values selected for the given iteration were used.

The Pearson Correlation Coefficient was computed based on the uncertain input values (or metric is described above) and the estimated annual cases of illness obtained. Pearson Correlation Coefficients are always values that fall between -1 and +1. Positive values indicate that increases in the uncertain input values lead to increases in the estimates of cases; negative values imply that increases in the input values lead to decreases in the estimates of cases. The larger the absolute value of the coefficient, the more pronounced is its influence on the results.

The results obtained are summarized below and shown graphically in Exhibits 5.15a and 5.15b for Type A and Type B viruses, respectively.

Virus Type A:

P_w*P_s: 0.323
Percent More Vulnerable Wells: 0.114
Infectivity Dose-Response Parameters: 0.531
Primary Morbidity Factor: 0.384

Virus Type B:

P_w*P_s: 0.054
Percent More Vulnerable Wells: -0.027
Infectivity Dose-Response Parameters: 0.033
Primary Morbidity Factor: 0.114
Secondary Spread Factor: -0.025

These results indicate that for Type A viruses, the uncertainty in the dose-response parameters is the main factor affecting the number of illnesses, while for Type B viruses it is the Primary Morbidity Factor. It should be pointed out, however, that because the values of all of these correlation coefficients are relatively low, none would be considered strong drivers of the outcome individually. Rather, it would appear that it is the random combinations of multiple uncertain input factors that lead to higher (or lower) estimates of cases of illness.

Exhibit 5.15a Summary of Pearson Correlation Coefficients for Uncertain Inputs, Virus Type A

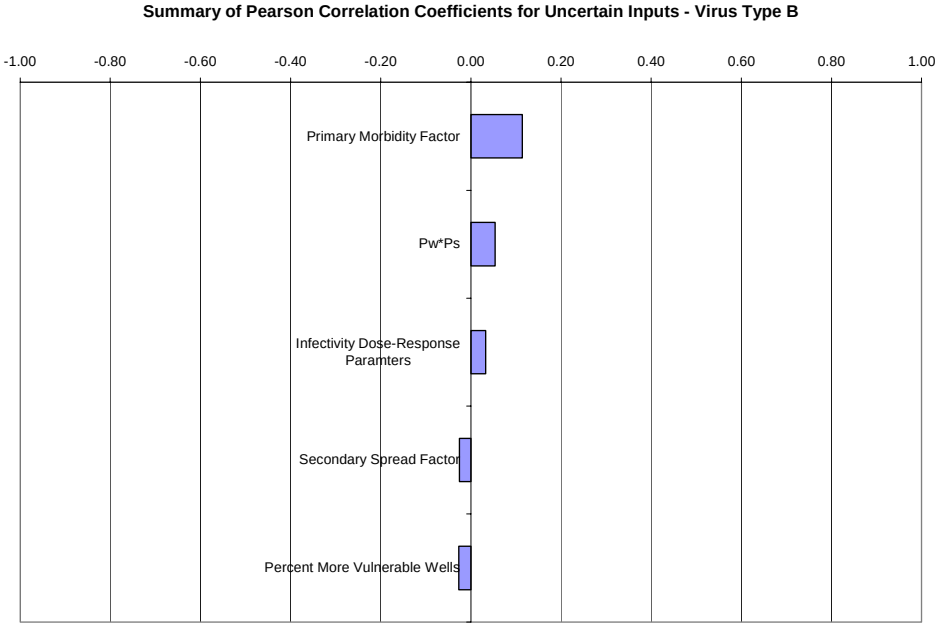
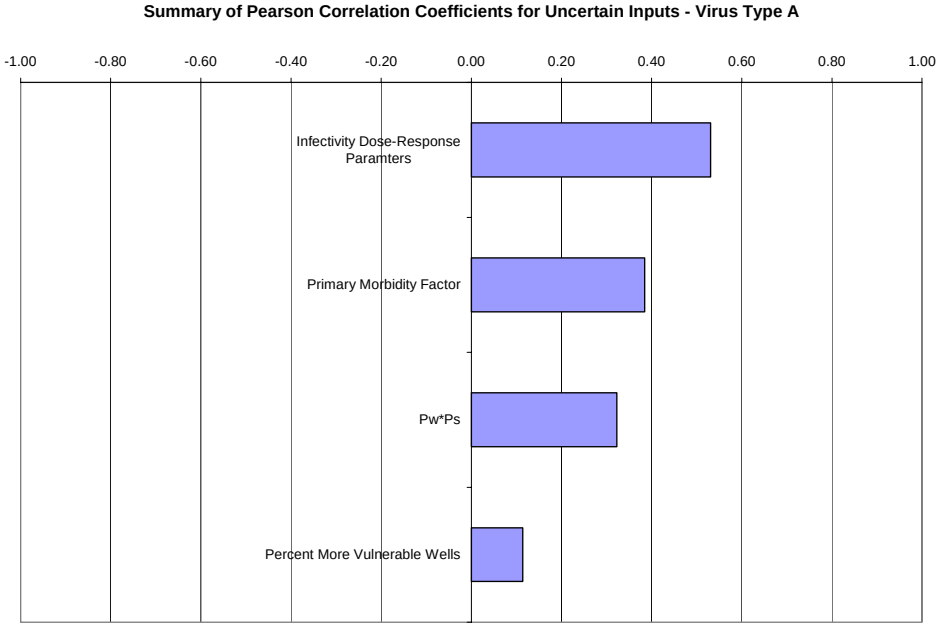


Exhibit 5.15b Summary of Pearson Correlation Coefficients for Uncertain Inputs, Virus Type B



5.2.5.6 Methodology for Estimating Risk Reductions

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

As discussed in the description of the baseline risk analysis in Section 5.2.5.1, each well in the simulation process is designated as either having a virus present at some time or never having a virus present based on the P_{well} probability. Also, for those wells having some viral occurrence, values are assigned for P_{sample} and for the virus concentration. The risk reduction part of the model uses the exact same simulated wells as those generated in the baseline risk part of the model.

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

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

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

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

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

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

In the baseline risk analysis, the primary outputs are estimates of annual cases of illness and deaths due to endemic infection from Type A and Type B viruses, and these are assumed to be the same for each of the 25 years following rule promulgation. The outputs from the risk reduction model are the same - the cases of illness and death that remain in each of the 25 years following rule promulgation. These are the remaining cases each year resulting from the virus concentrations that remain after the corrective actions are performed. The risk reductions, in terms of cases of illness and deaths avoided, are then obtained by subtracting the cases remaining after the rule from the baseline cases.

Exhibit 5.16 shows an example of what the model might predict for a particular well with a viral pathogen present. In this example, the baseline annual cases of illness resulting from the presence of a pathogen in the undisinfected source water is assumed to be 1,000. The baseline risk shows these 1,000 cases each year for the 25 year period. If 4-log disinfection is implemented as a corrective action after year 10 as a result of the rule, the remaining number of baseline cases would be 1, beginning in year 11 and continuing through year 25. The cases avoided each year for this well are, then, 0 for the first 10 years and 999 for years 11 through 25.

Exhibit 5.16 Example of Baseline Cases, Cases Remaining, and Cases Avoided at the Well Level

Year	Baseline Cases	Cases Remaining	Cases Avoided
1	1,000	1,000	0
2	1,000	1,000	0
3	1,000	1,000	0
4	1,000	1,000	0
5	1,000	1,000	0
6	1,000	1,000	0
7	1,000	1,000	0
8	1,000	1,000	0
9	1,000	1,000	0
10	1,000	1,000	0
11	1,000	1	999
12	1,000	1	999
13	1,000	1	999
14	1,000	1	999
15	1,000	1	999
16	1,000	1	999
17	1,000	1	999
18	1,000	1	999
19	1,000	1	999
20	1,000	1	999
21	1,000	1	999
22	1,000	1	999
23	1,000	1	999
24	1,000	1	999
25	1,000	1	999

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

The following sections describe in more detail the specific assumptions and inputs–including considerations of uncertainty–that are used to model risk reduction for the sanitary survey and triggered monitoring components of the GWR.

Sanitary Surveys

The Sanitary Survey component of the rule applies to all ground water wells, including those wells that are currently disinfecting and meeting 4-log reductions. As described in the baseline information in Chapter 4 and in the estimation of the baseline risk, all wells are stratified into 8 major categories that reflect the 2x2x2 (=8) combinations of the well characteristics of: Disinfecting or Nondisinfecting; More Vulnerable or Less Vulnerable; and Proper or Improper well construction.

As discussed in Chapter 4 (Section 4.3.3), the fraction of wells considered More Vulnerable varies from 0% to approximately 7% as a function of systems system size and type. The average (weighted by number of systems) is that about 2.5% are in the More Vulnerable stratum (the remaining 97.5% are, therefore, in the Less Vulnerable stratum). To estimate the benefits from correcting significant deficiencies, each of these strata must be further defined in regards to well construction.

Construction status of a well (i.e., whether a well is properly or improperly constructed) is estimated based on ASDWA survey data (ASDWA, 1997). Those wells identified as improperly constructed are likely to be identified by states during a sanitary survey. Different percentages of improper construction are estimated based on historical total or fecal coliform detections. EPA believes that a history of detection of these contaminants is indicative of wells that fall into the More Vulnerable classification within the benefits model. The percentages of properly and improperly constructed wells are estimated as follows.

Less vulnerable wells - The ASDWA survey of States found that of community GWSs with no TC or fecal coliform detections, 83.6 percent of the systems had wells that were constructed according to State standards. Thus, 16.4 percent of systems had wells identified by State officials as not being constructed to State standards and are considered to be improperly constructed.

More vulnerable wells - The same survey found that of community GWSs with TC detections, but no fecal coliform detections, 217 of 277 systems had wells constructed according to State standards. A third group consisted of systems with positive fecal coliform detections, of which 164 of 231 systems had wells constructed according to State standards. Thus, for systems with TC or fecal coliform detections, 381 of 508 systems (75.0 percent) had wells that were constructed according to State standards. Therefore, 25.0 percent of systems had wells identified by State officials as not being constructed to State standards and are considered to be improperly constructed.

The combination of the vulnerability and well construction estimates described above can be used to approximate the percent of all wells having virus present that are expected to be identified and corrected by sanitary surveys. To arrive at this estimate, the percent of all wells that are improperly constructed is first calculated as the weighted average for the More and Less Vulnerable strata as:

- More vulnerable (2.5%), Improperly constructed (25.0%):
  2.5% * 25.0% = 0.6%

- Less vulnerable (97.5%), Improperly constructed (16.4%):
  97.5% * 16.4% = 16.0%

The total fraction of all wells that are improperly constructed is the sum of these, which is 16.6%.

It is assumed that the sanitary survey provisions of the ground water rule will result in identifying some (but not all) wells that are improperly constructed. It is assumed that corrective actions will be performed on those improperly constructed wells. Specifically, EPA has estimated that for those wells that are improperly constructed and also have a virus present, 50% will be identified and the contamination eliminated by a corrective action. To recognize the uncertainty in this estimate of the effectiveness of sanitary surveys, EPA has assumed a uniform distribution of 40% to 60% (mean = 50%). Therefore, as a central value, it is expected that the sanitary survey and corrective action alternative of the rule will result in corrective actions being performed and contamination eliminated at approximately half of the 16.6% of all wells that are improperly constructed, which is 8.3% of all wells. Therefore, it can be estimated that this rule alternative will result in the reduction of 8.3% of the baseline cases of illnesses and deaths per year by the 25th year after rule promulgation.

For those wells that have virus present in the source water that are caught by a sanitary survey, the corrective action is assumed to eliminate the virus completely. Therefore, the finished water concentration as well as the source water concentration for these wells is set to zero for the risk reduction calculations for those wells. While the fraction of wells corrected by sanitary survey is the same for both the disinfecting and the nondisinfecting strata, almost all of the risk reduction (i.e., cases avoided) from sanitary surveys will be from the nondisinfecting wells. This is because for the disinfecting wells that are currently achieving 4-log removal, most of the virus present in the source water is already being inactivated so that the incremental risk reduction from eliminating the source entirely is very small and contributes very little to the total benefits achieved. Nevertheless, the risk reduction for disinfecting wells that is achieved through sanitary surveys is calculated in the risk reduction model for completeness sake.

With respect to when this reduction in virus concentration and risk occurs, it is assumed that identifying the (approximately) 8.3% of wells that are improperly constructed wells and performing a corrective action on them as a result of sanitary surveys will occur across the entire 25 year analysis period. It is assumed that no corrective actions will occur in the first three years, and that all of the corrective actions performed will be evenly distributed across the remaining years. Therefore, in the benefits model, each well that undergoes a corrective action from a sanitary survey is assigned a year between year 4 and year 25 with equal probability of it occurring in any one of the years in the time period.

Triggered Monitoring

The triggered monitoring component of the rule applies only to the nondisinfecting subset of wells and any wells that are applying disinfectant but not achieving 4-log removal of viruses. For the wells that are currently achieving 4-log removal, the sanitary survey requirements still apply and the output developed in that part of the model as described above are retained for those wells

For the triggered monitoring component of the risk reduction analysis, each well goes through a 2-step process. In the first step of the process, estimates are made of the number of TC positives–and therefore the number of source water indicator samples–that occur during the 22 years between year 4 and year 25 (it is assumed that no corrective actions will be taken during the first 3 years after rule implementation). The number of TC positives expected per year for each well of a given type and size are obtained from the DV data as described in chapter 4 (Section 4.2.7). The total number of TC positives expected through year 25 is then calculated as the number TC positives per year times 22. If, for example, a well is in the CWS size 10,000-50,000 category, the DV data indicate that these wells average 2.21 TC

positives per year; over 22 years, then, it is expected that these wells will have 48.6 TC positives and therefore take up to 49 source water indicator samples between years 4 and 25.

In the second step of the process, a simulation is performed to determine which, if any, of the indicator samples taken through year 25 is the first positive indicator result. As described in Chapter 4, in each uncertainty loop of the risk reduction model a set of values for both virus and indicator hit rates is selected. Included among this set of values is the probability that the first positive of an indicator will occur on a given assay number (contingent on these assays being performed in wells that are known to have a virus present at some time). Exhibit 4.27 showed the probability of the first indicator positive occurring on a given assays for the median and the 5th and 95th percentiles of a sample of 1,000 of these uncertainty sets of occurrence values. The curve for the median set of values shown in that exhibit indicates that there is about a 40% probability that the first indicator positive will occur on or before the 49th assay. The data for each uncertainty set provides these cumulative probabilities of observing the first positive on or before each specific assay number. In the risk reduction model, a random value between 0 and 1 is generated for each well. That value is used as a look-up value to determine what assay number would produce the first positive.

For example, if the curve shown as the median data set in Exhibit 4.27 were the set of values being used for a particular uncertainty loop, and the random number between 0 and 1 generated for a well in the CWS size 10,000-50,000 category were 0.25, the look-up function would indicate that the first indicator positive would occur on assay number 8. Since these wells are expected to take 48.6 indicator assays over the 22 year period, the 8th assay would occur in the 6th year (48.6 / 8 ~ 6). Since there are no samples taken in years 1 through 3, the 6th year of sampling corresponds to year 9 of the 25 year modeling period. Therefore, this well would be "caught" by triggered monitoring in year 9. This prediction is then compared to the year in which the well is captured (if it is) by the sanitary survey provisions. The corrective action is assigned to the rule provision (SS or TM) that occurs the earliest in the 25 year period. If both occur in the same year, one of the two is selected randomly.

It is important to note that this analysis assumes no correlation between the occurrence of total coliform in the distribution system and the occurrence of fecal contamination in the well water source. In fact, the two are positively correlated in systems that do not disinfect. Bacteria in the source water of systems that do not disinfect can directly cause total coliform positives in samples taken from the distribution system. Although this relationship is known to exist, EPA has insufficient data to include it in an occurrence model. As a result, only about 3% of TC positives are estimated to lead to indicator positives in the triggered monitoring samples. The true rate of indicator positives is expected to be greater, with more disinfecting systems taking corrective action. Not modeling the relationship between TC positives and fecal contamination at the source contributes to underestimation of the effectiveness of triggered monitoring. As a result, both benefits and costs (to a lesser degree) are underestimated.

Based on the number of TC positives expected per well across all well types and sizes, together with the expected values of indicator positives as a function of assay number across all of the uncertainty sets available to draw from for the simulation model, it can be estimated that approximately one-third

(33%) of nondisinfecting wells with virus present should be caught and corrected by the triggered monitoring provision of the rule by the 25th year of the modeling timeframe.[7]

Because there are some nondisinfecting wells that will be caught in the simulation model by both sanitary survey and triggered monitoring (where the one occurring earliest is selected for corrective action), the total wells ultimately caught by both components of this rule alternative will be less than the sum of the two individual components (i.e., ~8.3% for SS and 27.5% for TM). The expected fraction of nondisinfecting wells that are captured by either SS or TM can be estimated from the sum of these minus the product (to account for the overlap):

$$(8.3\% + 27.5\%) - (8.3\% * 27.5\%) = 33.5\%$$

Therefore, the SS + TM alternative should, by the 25th year after rule promulgation, result in corrective actions being performed at approximately 33.5% of all non-disinfecting wells and 8.3% of all (4-log) disinfecting wells that have virus present in their source water. Because most of the baseline risk is found in nondisinfecting wells, it is also, therefore, expected that this rule will result in approximately a 33.5% reduction in the baseline cases of illness and death.

5.2.5.7 Results for Risk Reduction for the Final GWR

The final GWR, the risk targeted approach, includes sanitary surveys, triggered monitoring, corrective action, and compliance monitoring. The estimated reduction in illnesses and deaths are presented by system size and type in Exhibit 5.17 and in summary in Exhibit 5.18. These values are the annual average cases avoided across the 25 year analysis timeframe, and they include the initial three years after implementation when no corrective actions are performed as a result of sanitary surveys or triggered monitoring.

Exhibit 5.19 provides a summary of the estimated cases avoided per year in the 25th year following rule implementation. This summary provides an indication of the magnitude of the annual benefits that can ultimately be achieved by the GWR. The cases of illness avoided shown here, 41,868, represent an approximately 22.6% reduction of baseline cases of 185,186 shown in Exhibit 5.13. A detailed breakdown of illnesses and deaths avoided by age group is presented in Appendix B.

[7] The effect of taking five repeat samples for any positive indicator sample is not included in this analysis. Based on repeat sampling, some wells will not be caught as described in this section (i.e., all repeat samples will be negative) and benefits will not accrue to those wells. The effect of this omission is a slight overestimate of benefits, however, the number of systems with five negative repeat samples is expected to be small.

Exhibit 5.17 Annual Viral Illnesses and Deaths Avoided for the GWR by System Size and Type

	Type A Viruses		Type B Viruses		Total	
	Illnesses	Deaths	Illnesses	Deaths	Illnesses	Deaths
	A	B	C	D	E=A+C	F=B+D
Community Water Systems (CWSs)						
<100	338	0.00	26	0.01	363	0.0
101-500	783	0.01	57	0.01	840	0.0
501-1,000	752	0.00	55	0.01	807	0.0
1,001-3,300	1,844	0.01	132	0.03	1,977	0.0
3,301-10K	4,619	0.03	327	0.06	4,946	0.1
10,001-50K	4,394	0.03	338	0.07	4,732	0.1
50,001-100K	8,832	0.06	582	0.12	9,414	0.2
100,001-1M	8,336	0.06	615	0.12	8,951	0.2
>1 Million	0	0.00	0	0.00	0	0.0
All Sizes	29,900	0.20	2,131	0.42	32,031	0.6
Nontransient Noncommunity Water Systems (NTNCWSs)						
<100	134	0.00	6	0.00	141	0.0
101-500	428	0.00	19	0.00	447	0.0
501-1,000	395	0.00	22	0.00	416	0.0
1,001-3,300	489	0.00	35	0.01	524	0.0
3,301-10K	241	0.00	14	0.00	255	0.0
10,001-50K	151	0.00	8	0.00	159	0.0
50,001-100K	52	0.00	3	0.00	55	0.0
100,001-1M	93	0.00	4	0.00	97	0.0
>1 Million	0	0.00	0	0.00	0	0.0
All Sizes	1,983	0.01	111	0.02	2,094	0.0
Transient Noncommunity Water Systems (TNCWSs)						
<100	1,806	0.01	40	0.01	1,846	0.0
101-500	2,555	0.02	62	0.01	2,617	0.0
501-1,000	1,081	0.01	30	0.01	1,111	0.0
1,001-3,300	913	0.01	24	0.01	937	0.0
3,301-10K	469	0.00	12	0.00	481	0.0
10,001-50K	491	0.00	11	0.00	501	0.0
50,001-100K	75	0.00	1	0.00	76	0.0
100,001-1M	170	0.00	3	0.00	173	0.0
>1 Million	0	0.00	0	0.00	0	0.0
All Sizes	7,560	0.05	184	0.04	7,743	0.1
Total	39,442	0.26	2,426	0.48	41,868	0.7

Note: Detail may not add to totals due to independent rounding. The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to comprise a significant portion of the overall benefits of the Final Rule and are presented in Section 5.4.

Source: Appendix B

Exhibit 5.18 Summary of Annual Viral Illnesses and Deaths Avoided for the GWR

Virus type	Illnesses per Year			Deaths per Year		
	Mean	5th Percentile	95th Percentile	Mean	5th Percentile	95th Percentile
Type A	39,442	10,093	79,925	0.3	0.1	0.5
Type B	2,426	181	8,114	0.5	0.0	1.6
Total	41,868	10,274	88,039	0.7	0.1	2.1

Note: Details may not add to totals due to independent rounding and independent statistical analyses.
Source: Appendix B

Exhibit 5.19 Viral Illnesses and Deaths Avoided in the 25th Year after Implementation of the GWR

Virus type	Illnesses per Year			Deaths per Year		
	Mean	5th Percentile	95th Percentile	Mean	5th Percentile	95th Percentile
Type A	59,126	15,387	121,578	0.4	0.1	0.8
Type B	3,583	259	12,372	0.7	0.0	2.4
Total	62,709	15,646	133,951	1.1	0.1	3.2

Note: Details may not add to totals due to independent rounding and independent statistical analyses.
Source: Appendix B

5.2.5.8 Results for Reduction in Individual Risks for the Final GWR

Exhibits 5.20a and 5.20b present the distributions of individual annual risks of infection for the population using ground water for Type A and Type B viruses, respectively. These graphs show the risks separately for individuals consuming water from CWS, NTNCWS and TNCWS systems. Baseline risks and annual risks following the full implementation (25 years) of the rule alternatives are presented. Note that curves that are further to the right indicate more risk, those to the left indicate less risk.

In general, the graphs show a relatively small reduction in individual risk from the Sanitary Survey and Corrective Action alternative, somewhat larger risk reductions for the Risk Targeted and Multi-Barrier alternatives, and substantially greater reductions for the 4-log across-the-board disinfection alternative. These changes in individual risk track well with the estimated reductions in annual cases of illness and deaths for the various rule alternatives presented in previous sections. In addition, the annual individual infection risks are substantially higher for Type A than Type B viruses, which corresponds to the differences in the dose response functions for the two types of viruses.

Also note that these graphs imply that the annual individual baseline risks for CWS consumers is lower than that for the noncommunity water systems, and that individual risk for NTNCWSs is slightly higher than that for TNCWSs. This can be understood in terms of the differences in current disinfection and differences in water consumption days and amounts. (Virus occurrence is assumed to be the same in all system types in the primary analysis.) Although there is more water consumption both in terms of days of consumption and volume per day per individual in CWSs than in either NTNCWS or TNCWS (which would tend to push individual risk up), a much larger portion of the CWS wells are currently disinfecting than the NTNCWS or TNCWS wells, which pushes the overall individual risk distribution for CWS down. Between NTNCWSs and TNCWSs, both the percent of wells disinfecting and water consumption are

lower in the TNCWSs than in NTNCWSs and this is reflected in the comparing these baseline graphs. (Note that for the 4-log rule alternative which results in all wells in all system types being disinfected, a comparison of the risk curves across the three types of systems shows the greatest risk in CWS, slightly less in NTNCWS, and much less in TNCWS. This is because with this alternative, only differences in water consumption days and volume per day drive the individual risk levels for consumers at these different systems types.

Exhibit 5.20a Comparison of Average Annual Individual Infectivity Risk Distributions for Baseline and Rule Alternatives for Type A Viruses

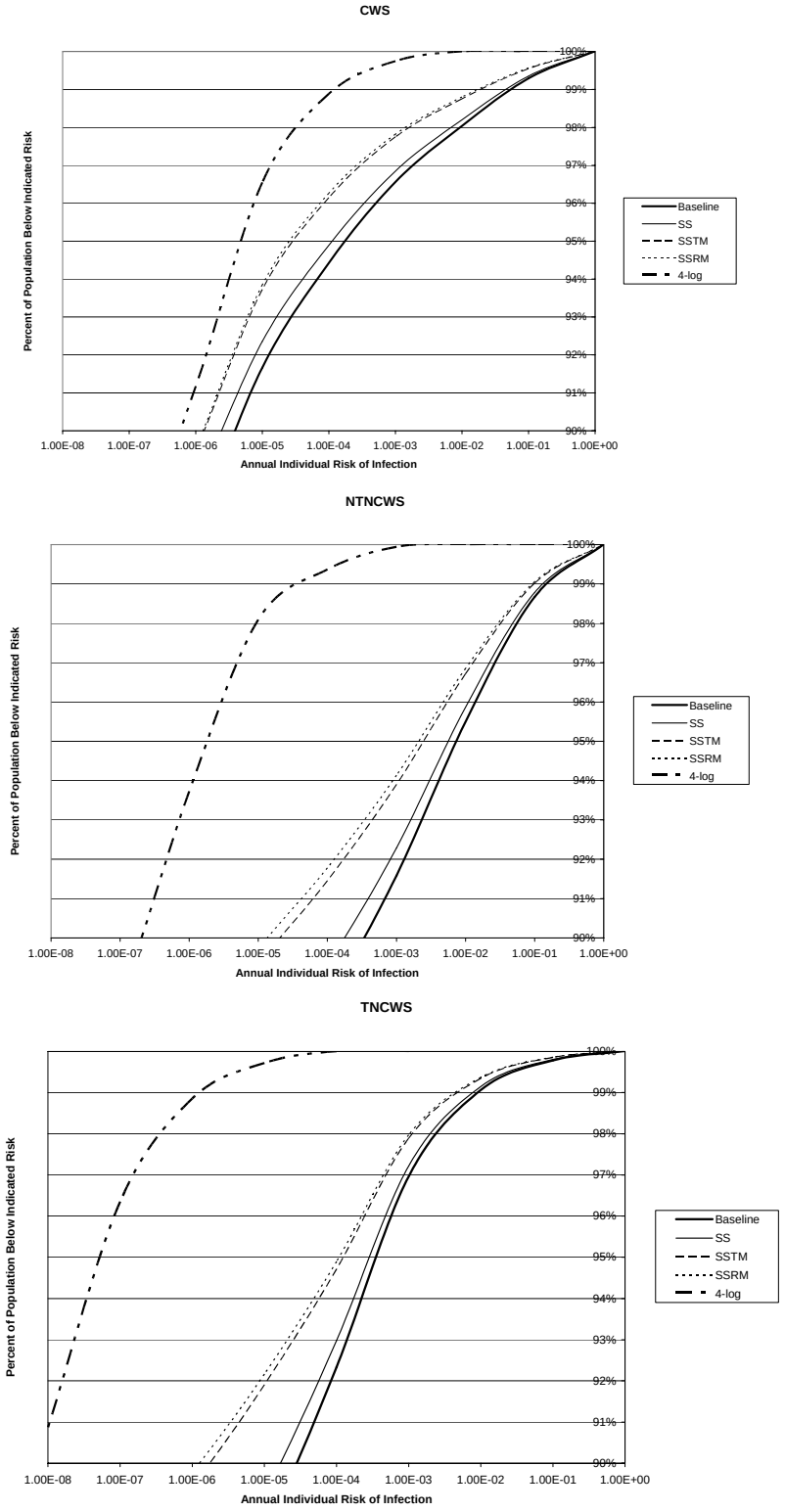
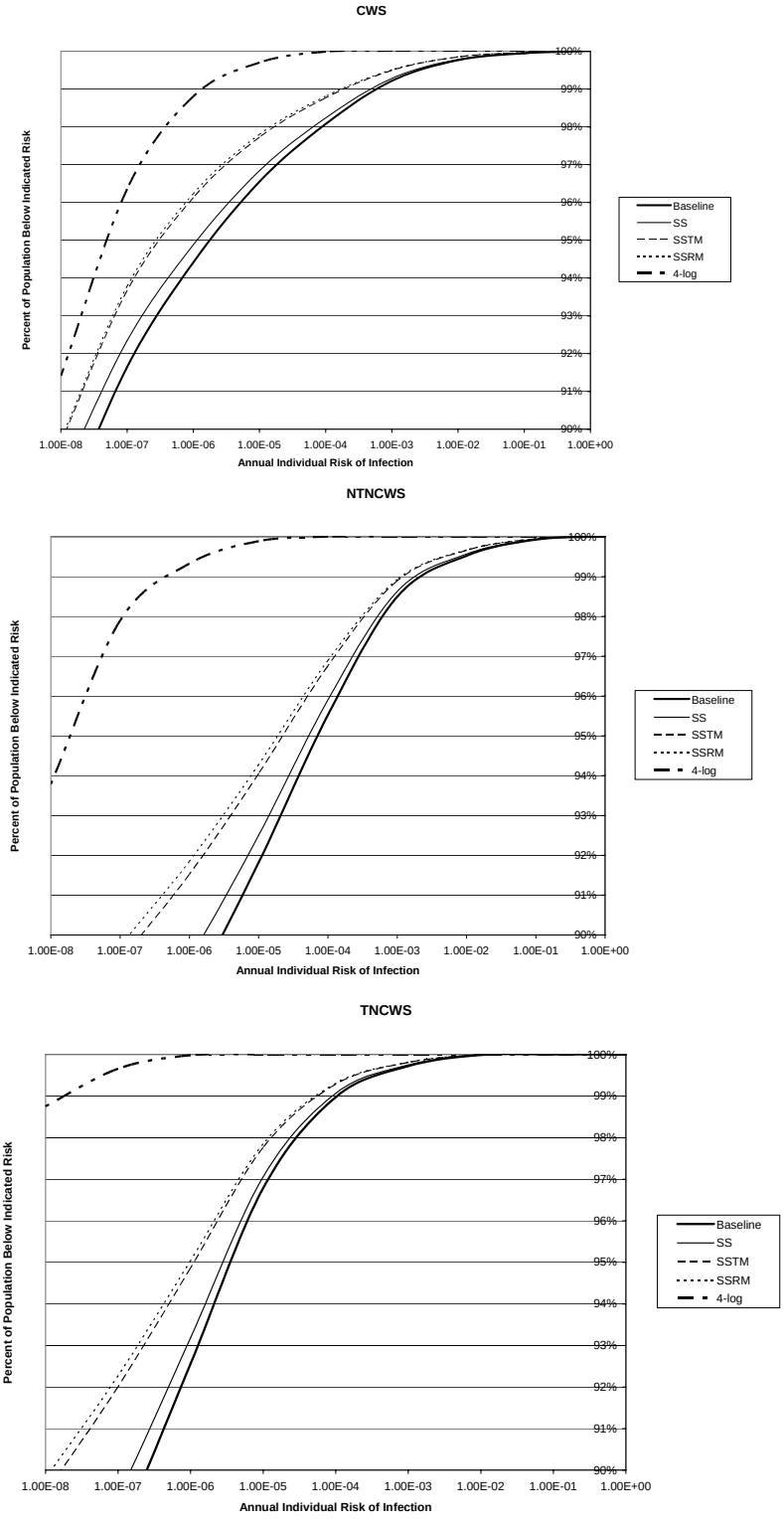


Exhibit 5.20b Comparison of Average Annual Individual Infectivity Risk Distributions for Baseline and Rule Alternatives for Type B Viruses



5.2.5.9 Potential Increases in Health Risks

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

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

5.3 Monetized Benefits from Reduction in Exposure to Waterborne Pathogens

Once the annual illnesses and deaths avoided as a result of the GWR implementation are estimated using the risk model described in the previous sections, monetary unit values can be applied to these estimates to establish the monetary benefits attributable to the rule. As discussed earlier, only a portion of the illnesses and deaths avoided are quantified. Further, the only benefits estimated and monetized for the main analysis in this EA are acute health effects of viral infections. The following sections explain how the value of reductions in illnesses and deaths was derived and presents results of the monetized benefits calculations.

5.3.1 Value of Reduction in Type A and Type B Virus Cases

5.3.1.1 Value of Viral Illnesses Avoided

The goal of this analysis is to provide as complete an accounting as possible of the social welfare impacts of the regulatory requirements under consideration. Based on the principles of welfare economics, the preferred approach for valuing reductions in the risk of Type A and Type B virus morbidity is to rely on estimates of willingness to pay (WTP) for these risk reductions. However, there are no direct studies of WTP for avoided morbidity from the viral illnesses considered in the benefits analysis. As a minimum estimate of that value, this analysis estimates the value of averted morbidity risks based on the (1) avoided medical costs and (2) the value of avoided time losses for the illness they cause. The rationale for and limitations of this approach are discussed below, and greater detail is provided in Appendix A.

The calculation of medical costs includes the costs of medical services and medications received by ill individuals. The assumption behind using these costs as a benefit measure is that a policy that reduces the incidence of illness will yield benefits at minimum equal to the costs avoided. Cost of illness (COI) estimates, however, may significantly underestimate individual willingness to pay for a variety of reasons. In particular, these estimate do not: (1) address the value of avoiding pain and suffering; (2) include costs that individuals incur to avoid the illness (i.e., defensive or averting expenditures); (3) reflect aversion to risk (the fear of becoming ill); (4) consider *ex ante* values (they are based on *ex post* costs); and (5) consider whether treatment returns individuals to their original health state (i.e., is equivalent to avoiding the illness entirely).

A number of researchers have explored the relationship between the COI and individual WTP for risk reductions. This research suggests that the ratio of these two types of values varies greatly depending on the nature of the health effect, the characteristics of the individuals studied, and the factors included in the construction of each estimate. Comparison studies result in WTP to COI ratios ranging from about a factor of 2 to as much as a factor of 79 (in one case); many of the ratios are between 3 and 6.[8] In other words, the COI estimates were typically one-third to one-sixth of the WTP estimates, but the ratio varied greatly.

[8] See Appendix B of EPA's *Handbook for Non-Cancer Health Effects Valuation* (USEPA, 2000c) for a review of these studies.

In some cases, COI studies include indirect, as well as direct costs. These indirect costs usually include lost earnings due to missed market work time, and may also include costs associated with reduced productivity while at work and/or lost nonmarket work time (e.g., child care or housekeeping). Typically, these costs are estimated using the human capital approach, which focuses on the value of goods and services that are bought and sold in the marketplace and ignores other aspects of time use that affect individual well-being.

The analysis of Type A and Type B virus-related morbidity uses two measures of the COI–referred to in this EA as Traditional and Enhanced. Both approaches include direct medical costs and the value of lost work time, but differ in the assessment of value of lost work time. They both consider the impact of time losses on foregone market production, which affects the individual worker (e.g., in terms of lost income) as well as other members of society (who benefit from the availability of the goods or services produced as well as the taxes paid), and foregone nonmarket (household and volunteer) production, which affects the individual and other household members and often has impacts outside the home. The Traditional COI includes nonmarket (unpaid) work time based on replacement costs and does not include a value for the time lost of children under 16 years of age. The other approach, the Enhanced COI, values nonmarket work time based on opportunity costs and places a value on the lost time of children. Both approaches also include values for the nonmarket time lost by friends or family members caring for those who are sick,[9] but the approaches use different values for this lost time.

The Enhanced COI also includes the value of lost leisure time and lost productivity—the reduced utility (or sense of well-being) associated with decreased enjoyment of time spent in both market and nonmarket activities. The Enhanced COI is an attempt to more completely measure the loss of welfare from an illness.

A search of the literature suggests that researchers have not attempted to estimate directly (e.g., through surveys) the difference between the value of time in a well state compared to time in an ill state. This analysis relies instead on wage and compensation data to estimate the opportunity costs of time usage. This approach recognizes that, because resources are limited, any decision to use resources for one purpose means that they cannot be used for other purposes. One minimal measure of the value of a resource, therefore, is the value of its next best use.

The application of the opportunity cost approach to paid work time is relatively clear, since compensation can be used to estimate these costs. For other (unpaid) time spent in nonmarket work or leisure activities, wage data are also used based on the assumption that (at the margin) the wage represents the opportunity cost of engaging in such activities.

More precisely, lost market work is valued at the median gross (pre--tax) wage rate plus benefits, also referred to as total compensation or employer's costs. This approach is most representative of the full social impact of lost work because it incorporates both the loss to the individual in terms of lost income and the loss to society in terms of reduced tax revenue or decreased production of goods and services. Lost nonmarket work and leisure time is valued at the median net (post-tax) wage rate. This approach reflects the assumption that, at the margin, an individual will choose to engage in nonmarket work or leisure activities only if the value of these activities exceeds the wage rate that the individual

[9] Paid care is included in the medical cost component of the analysis and hence is not discussed in the discussion of time losses.

would otherwise earn. Sleep time presents special problems in this analysis, both because data on the effect of Type A and Type B virus--related morbidity on the amount or quality of sleep time is not available and because current literature on valuing lost time has not settled on an accepted valuation method. This analysis, thus, conservatively assumes that lost sleep time has zero value.

These values are applied to both complete losses of time (time spent in illness-related activities rather than normal activities) as well as to partial losses (time spent in normal activities that is less productive or pleasurable than in the absence of illness). In the latter case, however, the dollar value of the loss is prorated to reflect the fact that the individual does not completely lose the productivity or utility associated with the activity. These values are applied to such time losses incurred by the ill individual.

The use of medical costs and the opportunity cost of time losses to value morbidity related to Type A and Type B viruses may understate the value of these risk reductions for a variety of reasons.[10] As noted earlier, COI estimates generally understate WTP for a variety of reasons, e.g., because they exclude consideration of the value of avoided pain and suffering or of risk aversion. In addition, the use of wage and compensation data to value lost time may understate the utility of time spent in its preferred use. The use of wage rates may understate the total utility associated with an activity even in the case of paid work, because individuals may derive intrinsic pleasure from the activity above and beyond the income they receive. For nonmarket work and leisure, the value of the activity to the individual may exceed the opportunity cost for similar reasons. In addition, nonmarket work and other activities can provide benefits to other members of society that are not reflected in the individual wage rate. Finally, this approach does not include the value of lost sleep time.

In addition, relying on wage data for valuing lost time presents difficulties in the case of individuals for whom these data are not available, such as children, the unemployed, and those out of the labor market. For the Enhanced COI approach, all lost time of children is valued at the median post-tax wage rate. No estimates exist, however, for the indirect cost of illness. EPA transferred the method used for days lost due to illness (equal to the duration of illness) to children. EPA further assumes that a caretaker stays home with these children, introducing additional lost caretaker days. The rationale for this approach is discussed in more detail below. It is unclear whether this approach under- or overstates the value of time losses for the individuals in these other categories, given the available information on these values. However, the Agency's *Children's Health Valuation Handbook* states: "To the extent that a caregiver is more likely to be involved when a child is recuperating, the total value of lost time is likely to be higher for a child's illness than for an adult's." (USEPA, 2002)

COI Calculations

The primary risk of illness that the GWR addresses is from endemic exposure to Type A and Type B viruses and the resulting acute cases of illnesses. Many elements of the COI come from a

[10] There are a number of other simplifying assumptions inherent in the application of this approach that may lead it to under- or overstate the value of time losses, related to factors such as the functioning of the labor market, the treatment of individuals who are not labor force participants, the use of average or median (rather than marginal) earnings data, and the possibility that substitute activities (e.g., watching TV instead of normal activities) have some positive value. It is unclear whether, in total, these practical limitations serve to increase or decrease the bias that results from the sources discussed in this paragraph.

literature review of current medical studies; other elements have been assumed. The literature review yielded information on the duration of illness from Type A and Type B viruses, the type of medical care sought, if any, and the costs associated with these services. The data from the literature review, as well as assumptions made in this analysis, are described in Appendix A.

The computation of COI involves two broad categories of costs—direct and indirect medical costs. All costs are updated to a common year (2003) used as the starting point for projecting benefits into future time periods. For Type A viruses, each cost component has a separate estimate made based on age and the health state of the individual (healthy or immunocompromised). For Type B viruses, cost components have separate estimates based both on age and on the type of care required: no medical care (93% of cases); outpatient care (6% of cases); or inpatient care (1% of cases). Detail on these breakouts is also provided in Appendix A. The next two subsections discuss the details of the computations used to derive direct and indirect medical costs.

Direct Medical Costs

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

Exhibits 5.21a – 5.21b and 5.22a – 5.22b show the weighted direct medical costs per case of Type A viral illness, ranging from an average cost of $0 (for healthy patients, 5 years or older) to an average cost of $4,486 (for immunocompromised patients younger than 5 years old). The weighted direct medical costs per case of Type B viral illness (Exhibits 5.21c–5.21e and 5.22c–5.22e) range from an average of $0 (for patients requiring no medical care) to $23,431 (for patients less than 1 year old requiring inpatient care). Costs for doctor visits, follow-up visits, and hospital stays constitute the direct medical costs. Costs for initial and follow-up doctor visits are obtained in 2000 dollars and updated to 2003 dollars using the consumer price index (CPI) for medical care services.

Exhibit 5.21a Estimates for Average Cost and Average Cost per Healthy Patient of Type A Illness, by Age (Enhanced COI)

Cost Category	Average Cost Per Patient 2003$			
	<2 years	2 to 4 years	5 to 15 years	≥16 years
Symptom duration--reported days (range) [A]	3	3	3	2.5
Direct Costs				
Outpatient costs				
Initial physician visit [B]	$114.55	$114.55	$114.55	$114.55
Average # of follow-up visits [A]	0.5 (0-9)	0.5 (0-9)	N/A	N/A
Cost per follow-up [B]	$66.18	$66.18	$66.18	$66.18
Total Unit Cost [C]	$148 $115 - $710	$148 $115 - $710	$115	$115
Percent Outpatient [A]	14%	14%	0.0%	0.0%
Weighted Unit Cost [C]	$21 $16 - $101	$21 $16 - $99	$0	$0
Inpatient costs				
Duration of hospital stay (days) [A]	5	5	N/A	N/A
Hospital cost per day [B]	$1,007.19	$1,007.19	$1,007.19	$1,007.19
Total hosptial cost [C]	$5,036	$4,029	$4,029	$4,029
Initial physician visit [B]	$152.87	$152.87	$152.87	$152.87
Average # of follow-up visits [A]	4	4	N/A	N/A
Cost per follow-up [B]	$52.25	$52.25	$52.25	$52.25
Total Unit Cost [C]	$5,398	$4,391	$4,338	$4,338
Percent Inpatient [A]	1.4%	1.4%	0.0%	0.0%
Weighted Unit Cost [C]	$76	$61	$0	$0
Total Weighted Direct Costs [C]	$97 $16 - $101	$82 $16 - $99	$0 $0 - $0	$0 $0 - $0
Indirect Costs				
Value of lost patient day [D]	$199.36	$199.36	$199.36	$227.79
Lost patient days (No Medical Care/Outpatient) [A]	3	3	1.5	1 (15.3%), 0 (84.7%) [Note 1]
Lost patient days (Inpatient) [A]	5	5	N/A	N/A
Value of caregiver day [D]	$227.79	$227.79	$227.79	$227.79
Caregiver days (No Medical Care/Outpatient) [A]	3	3	1.5	0
Caregiver days (Inpatient) [A]	5	5	N/A	N/A
Value of lost productivity day [E]	$59.81	$59.81	$59.81	$68.34
Lost productivity days [A]	0	0	0	1
Total Indirect Costs [C]	$1,293	$1,293	$641	$103
Total Cost of Illness [C]	$1,390 $1,310 - $1,395	$1,376 $1,309 - $1,393	$641	$103

Note 1: For the healthy population >16 years, the severity of symptom manifestation is dependent on the rotavirus strain and can be divided into two groups. The G2 & G9 strains represent 15.3% of illnesses, while all other strains comprise the remaining 84.7%.

Sources:

[A] Appendix A, Exhibit A.1

[B] Appendix A, Exhibit A.2

[C] Calculations based on data presented in the table.

[D] Appendix A, Exhibit A.7

[E] Weighted average per day value of time ($227.79) multiplied by percent loss productivity (30 percent, rounded from Harrington et al. 1991)

Exhibit 5.21b Estimates for Average Cost and Average Cost per Immunocompromised Patient of Type A Illness, by Age (Enhanced COI)

Cost Category	Average Cost Per Patient 2003$			
	<2 years	2 to 4 years	5 to 15 years	≥16 years
Symptom duration--reported days (range) [A]	5	3	3	2.5
Direct Costs				
Outpatient costs				
Initial physician visit [B]	$114.55	$114.55	$114.55	$114.55
Average # of follow-up visits [A]	0.5 (0-9)	0.5 (0-9)	0	0
Cost per follow-up [B]	$66.18	$66.18	$66.18	$66.18
Total Unit Cost [C]	$148 $115 - $710	$148 $115 - $710	$115	$115
Percent Outpatient [A]	100%	100%	100.0%	100.0%
Weighted Unit Cost [C]	$148 $115 - $710	$148 $115 - $710	$115	$115
Inpatient costs				
Duration of hospital stay (days) [A]	5	3	3	2.5
Hospital cost per day [B]	$1,007.19	$1,007.19	$1,007.19	$1,007.19
Total hosptial cost [C]	$4,029	$4,029	$4,029	$4,029
Initial physician visit [B]	$152.87	$152.87	$152.87	$152.87
Average # of follow-up visits [A]	4	2	2	2
Cost per follow-up [B]	$52.25	$52.25	$52.25	$52.25
Total Unit Cost [C]	$4,338	$4,338	$4,338	$4,338
Percent Inpatient [A]	100%	100%	100%	100%
Weighted Unit Cost [C]	$4,338	$4,338	$4,338	$4,338
Total Weighted Direct Costs [C]	$4,486 $4,453 - $5,049	$4,486 $4,453 - $5,049	$4,453	$4,453
Indirect Costs				
Value of lost patient day [D]	$199.36	$199.36	$199.36	$227.79
Lost patient days [A]	5	3	3	2.5
Value of caregiver day [D]	$227.79	$227.79	$227.79	$227.79
Caregiver days [A]	5	3	3	0
Value of lost productivity day [E]	$59.81	$59.81	$59.81	$68.34
Lost productivity days [A]	0	0	0	0
Total Indirect Costs [C]	$2,136	$1,281	$1,281	$569
Total Cost of Illness [C]	$6,622 $6,589 - $7,184	$5,767 $5,734 - $6,330	$5,734	$5,022

Sources:
[A] Appendix A, Exhibit A.1
[B] Appendix A, Exhibit A.2
[C] Calculations based on data presented in the table.
[D] Appendix A, Exhibit A.7
[E] Weighted average per day value of time ($227.79) multiplied by percent loss productivity (30 percent, rounded from Harrington et al. 1991)

Exhibit 5.21c: Estimates for Average Cost and Average Cost per Case of Type B Illness Requiring No Medical Care, by Age (Enhanced COI)

Cost Category	Average Cost per Patient 2003$			
	<1 Year	1 to 4 years	5 to 15 years	≥16 years
Symptom duration--reported days (range) [A]	3 (1-6)	3 (1-6)	3 (1-6)	3 (1-6)
Direct Costs				
Outpatient costs				
Initial physician visit [B]	NA	NA	NA	NA
Average # of follow-up visits [A]	NA	NA	NA	NA
Cost per follow-up [B]	NA	NA	NA	NA
Total Unit Cost [C]	NA	NA	NA	NA
Percent Outpatient [A]	0.0%	0.0%	0.0%	0.0%
Weighted Unit Cost [C]	$0.00	$0.00	$0.00	$0.00
Inpatient costs				
Duration of hospital stay [A]	NA	NA	NA	NA
Hospital cost per day	NA	NA	NA	NA
Total hosptial cost	NA	NA	NA	NA
Initial physician visit	NA	NA	NA	NA
Average # of follow-up visits [A]	NA	NA	NA	NA
Cost per follow-up	NA	NA	NA	NA
Total Unit Cost	NA	NA	NA	NA
Percent Inpatient [A]	0%	0%	0%	0%
Weighted Unit Cost [C]	$0.00	$0.00	$0.00	$0.00
Total Weighted Direct Costs [C]	$0	$0	$0	$0
Indirect Costs				
Value of lost patient day [D]	$199.36	$199.36	$199.36	$227.79
Lost patient days [A]	3 (1-6)	3 (1-6)	1.5	1.15
Value of caregiver day [D]	$227.79	$227.79	$227.79	$227.79
Caregiver days [A]	3 (1-6)	3 (1-6)	1.5	0
Value of lost productivity day [E]	$59.81	$59.81	$59.81	$68.34
Lost productivity days [A]	0	0	0	1.09
Total Indirect Costs[1] [C]	$1,281 $427 - $2,563	$1,281 $427 - $2,563	$641	$336
Total Cost of Illness [C]	$1,281 $427 - $2,563	$1,281 $427 - $2,563	$641	$336

[1] Total Indirect Costs is shown as a range for those age categories for which the duration of symptoms, and hence lost patient days, was a range determined from best available data.

Sources:

[A] Appendix A, Exhibit A.3

[B] Appendix A, Exhibit A.4

[C] Calculations based on data presented in the table

[D] Appendix A, Exhibit A.7,E] Weighted average per day value of time ($227.79) multiplied by percent loss productivity (30 percent, rounded from Harrington et al. 1991)NA: Not applicable to mild cases.

Exhibit 5.21d Estimates for Average Cost and Average Cost per Case of Type B Illness Requiring Outpatient Care, by Age (Enhanced COI)

Cost Category	Average Cost per Patient 2003$			
	<1 Year	1 to 4 years	5 to 15 years	≥16 years
Symptom duration--reported days (range) [A]	5 (2-12)	5 (2-10)	5 (2-7)	5 (2-9)
Direct Costs				
Outpatient costs				
Initial physician visit [B]	$114.55	$114.55	$114.55	$114.55
Average # of follow-up visits [A]	1	1	1	1
Cost per follow-up [B]	$66.18	$66.18	$66.18	$66.18
Total Unit Cost [C]	$181	$181	$181	$181
Percent Outpatient [A]	100%	100%	100.0%	100.0%
Weighted Unit Cost [C]	$181	$181	$181	$181
Inpatient costs				
Duration of hospital stay [A]	NA	NA	NA	NA
Hospital cost per day [B]	NA	NA	NA	NA
Total hosptial cost [C]	NA	NA	NA	NA
Initial physician visit [B]	NA	NA	NA	NA
Average # of follow-up visits [A]	NA	NA	NA	NA
Cost per follow-up [B]	NA	NA	NA	NA
Total Unit Cost [C]	NA	NA	NA	NA
Percent Inpatient [A]	0%	0%	0%	0%
Weighted Unit Cost [C]	$0.00	$0.00	$0.00	$0.00
Total Weighted Direct Costs [C]	$181	$181	$181	$181
Indirect Costs				
Value of lost patient day [D]	$199.36	$199.36	$199.36	$227.79
Lost patient days [A]	5 (2-12)	5 (2-10)	5 (2-7)	5 (2-9)
Value of caregiver day [D]	$227.79	$227.79	$227.79	$227.79
Caregiver days [A]	5 (2-12)	5 (2-10)	5 (2-7)	0
Value of lost productivity day [E]	$59.81	$59.81	$59.81	$68.34
Lost productivity days [A]	0	0	0	0
Total Indirect Costs [C]	$2,136 $ 854 - $ 5,126	$2,136 $ 854 - $ 4,272	$2,136 $ 854 - $ 2,990	$1,139 $456 - $2,050
Total Cost of Illness [C]	$2,316 $ 1,035 - $ 5,307	$2,316 $ 1,035 - $ 4,452	$2,316 $ 1,035 - $ 3,171	$1,320 $ 636 - $ 2,231

Sources:
[A] Appendix A, Exhibit A.3
[B] Appendix A, Exhibit A.4
[C] Calculations based on data presented in the table.
[D] Appendix A, Exhibit A.7
[E] Weighted average per day value of time ($227.79) multiplied by percent loss productivity (30 percent, rounded from Harrington et al. 1991)
* No data available

Exhibit 5.21e Estimates for Average Cost and Average Cost per Case of Type B Illness Requiring Inpatient Care, by Age (Enhanced COI)

Cost Category	Average Cost per Patient 2003$			
	<1 Year	1 to 4 years	5 to 15 years	≥16 years
Symptom duration--reported days (range) [A]	7 (2-14)	7 (2-14)	7 (2-14)	7 (2-14)
Direct Costs				
Outpatient costs				
Initial physician visit [B]	$114.55	$114.55	$114.55	$114.55
Average # of follow-up visits [A]	1	1	1	1
Cost per follow-up [B]	$66.18	$66.18	$66.18	$66.18
Total Unit Cost [C]	$181	$181	$181	$181
Percent Outpatient [A]	100%	100%	100.0%	100.0%
Weighted Unit Cost [C]	$181	$181	$181	$181
Inpatient costs				
Duration of hospital stay--reported days [A]	4.7	4.7	2.5	2.5
Hospital cost per day [B]	$4,869.90	$1,839.15	$1,839.15	$1,839.15
Total hosptial cost [C]	$22,889	$8,644	$4,598	$4,598
Initial physician visit [B]	$152.87	$152.87	$152.87	$152.87
Average # of follow-up visits [A]	4	4	2	2
Cost per follow-up [B]	$52.25	$52.25	$52.25	$52.25
Total Unit Cost [C]	$23,250	$9,006	$4,855	$4,855
Percent Inpatient [A]	100%	100%	100%	100%
Weighted Unit Cost [C]	$23,250	$9,006	$4,855	$4,855
Total Weighted Direct Costs [C]	$23,431	$9,187	$5,036	$5,036
Indirect Costs				
Value of lost patient day [D]	$199.36	$199.36	$199.36	$227.79
Lost patient days [A]	7 (2-14)	7 (2-14)	7 (2-14)	7 (2-14)
Value of caregiver day [D]	$227.79	$227.79	$227.79	$227.79
Caregiver days [A]	7 (2-14)	7 (2-14)	7 (2-14)	0
Value of lost productivity day [E]	$59.81	$59.81	$59.81	$68.34
Lost productivity days [A]	0	0	0	0
Total Indirect Costs [C]	$2,990 $ 854 - $ 5,980	$2,990 $ 854 - $ 5,980	$2,990 $ 854 - $ 5,980	$1,595 $456 - $3,189
Total Cost of Illness [C]	$26,421 $ 24,285 - $ 29,411	$12,177 $ 10,041 - $ 15,167	$8,026 $ 5,890 - $ 11,016	$6,631 $ 5,492 - $ 8,225

Sources:
[A] Appendix A, Exhibit A.3
[B] Appendix A, Exhibit A.4
[C] Calculations based on data presented in the table.
[D] Appendix A, Exhibit A.7
[E] Weighted average per day value of time ($227.79) multiplied by percent loss productivity (30 percent, rounded from Harrington et al. 1991)
* No data available

Exhibit 5.22a Estimates for Average Cost and Average Cost per Healthy Patient of Type A Illness, by Age (Traditional COI)

Cost Category	Average Cost Per Patient 2003$			
	<2 years	2 to 4 years	5 to 15 years	≥16 years
Symptom duration--reported days (range) [A]	3	3	3	2.5
Direct Costs				
Outpatient costs				
Initial physician visit [B]	$114.55	$114.55	$114.55	$114.55
Average # of follow-up visits [A]	0.5 (0-9)	0.5 (0-9)	N/A	N/A
Cost per follow-up [B]	$66.18	$66.18	$66.18	$66.18
Total Unit Cost [C]	$148 $115 - $710	$148 $115 - $710	$115	$115
Percent Outpatient [A]	14%	14%	0.0%	0.0%
Weighted Unit Cost [C]	$21 $16 - $101	$21 $16 - $99	$0	$0
Inpatient costs				
Duration of hospital stay (days) [A]	5	5	N/A	N/A
Hospital cost per day [B]	$1,007.19	$1,007.19	$1,007.19	$1,007.19
Total hosptial cost [C]	$5,036	$4,029	$4,029	$4,029
Initial physician visit [B]	$152.87	$152.87	$152.87	$152.87
Average # of follow-up visits [A]	4	4	N/A	N/A
Cost per follow-up [B]	$52.25	$52.25	$52.25	$52.25
Total Unit Cost [C]	$5,398	$4,391	$4,338	$4,338
Percent Inpatient [A]	1.4%	1.4%	0.0%	0.0%
Weighted Unit Cost [C]	$76	$61	$0	$0
Total Weighted Direct Costs [C]	$97 $16 - $101	$82 $16 - $99	$0 $0 - $0	$0 $0 - $0
Indirect Costs				
Value of lost patient day [D]	$0.00	$0.00	$0.00	$85.12
Lost patient days (No Medical Care/Outpatient) [A]	3	3	1.5	1 (15.3%), 0 (84.7%) [Note 1]
Lost patient days (Inpatient) [A]	5	5	N/A	N/A
Value of caregiver day [D]	$85.12	$85.12	$85.12	$85.12
Caregiver days (No Medical Care/Outpatient) [A]	3	3	1.5	0
Caregiver days (Inpatient) [A]	5	5	N/A	N/A
Value of lost productivity day [E]	$0.00	$0.00	$0.00	$25.54
Lost productivity days [A]	0	0	0	1
Total Indirect Costs [C]	$258	$258	$128	$39
Total Cost of Illness [C]	$354 $274 - $359	$340 $274 - $357	$128	$39

Note 1: For the healthy population >16 years, the severity of symptom manifestation is dependent on the rotavirus strain and can be divided into two groups. The G2 & G9 strains represent 15.3% of illnesses, while all other strains comprise the remaining 84.7%.

Sources:

[A] Appendix A, Exhibit A.1.

[B] Appendix A, Exhibit A.2.

[C] Calculations based on data presented in the table.

[D] Appendix A, Exhibit A.7

[E] Weighted average per day value of time ($85.12) multiplied by percent loss productivity (30 percent, rounded from Harrington et al. 1991)

Exhibit 5.22b Estimates for Average Cost and Average Cost per Immunocompromised Patient of Type A Illness, by Age (Traditional COI)

Cost Category	Average Cost Per Patient 2003$			
	<2 years	2 to 4 years	5 to 15 years	≥16 years
Symptom duration--reported days (range) [A]	5	3	3	2.5
Direct Costs				
Outpatient costs				
Initial physician visit [B]	$114.55	$114.55	$114.55	$114.55
Average # of follow-up visits [A]	0.5 (0-9)	0.5 (0-9)	0	0
Cost per follow-up [B]	$66.18	$66.18	$66.18	$66.18
Total Unit Cost [C]	$148 $115 - $710	$148 $115 - $710	$115	$115
Percent Outpatient [A]	100%	100%	100.0%	100.0%
Weighted Unit Cost [C]	$148 $115 - $710	$148 $115 - $710	$115	$115
Inpatient costs				
Duration of hospital stay (days) [A]	5	3	3	2.5
Hospital cost per day [B]	$1,007.19	$1,007.19	$1,007.19	$1,007.19
Total hosptial cost [C]	$4,029	$4,029	$4,029	$4,029
Initial physician visit [B]	$152.87	$152.87	$152.87	$152.87
Average # of follow-up visits [A]	4	2	2	2
Cost per follow-up [B]	$52.25	$52.25	$52.25	$52.25
Total Unit Cost [C]	$4,338	$4,338	$4,338	$4,338
Percent Inpatient [A]	100%	100%	100%	100%
Weighted Unit Cost [C]	$4,338	$4,338	$4,338	$4,338
Total Weighted Direct Costs [C]	$4,486 $4,453 - $5,049	$4,486 $4,453 - $5,049	$4,453	$4,453
Indirect Costs				
Value of lost patient day [D]	$0.00	$0.00	$0.00	$85.12
Lost patient days [A]	5	3	3	2.5
Value of caregiver day [D]	$85.12	$85.12	$85.12	$85.12
Caregiver days [A]	5	3	3	0
Value of lost productivity day [E]	$0.00	$0.00	$0.00	$25.54
Lost productivity days [A]	0	0	0	0
Total Indirect Costs [C]	$426	$255	$255	$213
Total Cost of Illness [C]	$4,912 $4,879 - $5,474	$4,741 $4,708 - $5,304	$4,708	$4,666

Sources:
[A] Appendix A, Exhibit A.1.
[B] Appendix A, Exhibit A.2.
[C] Calculations based on data presented in the table.
[D] Appendix A, Exhibit A.7
[E] Weighted average per day value of time ($85.12) multiplied by percent loss productivity (30 percent, rounded from Harrington et al. 1991)

Exhibit 5.22c Estimates for Average Cost and Average Cost per Case of Type B Illness Requiring No Medical Care, by Age (Traditional COI)

Cost Category	Average Cost per Patient 2003$			
	<1 Year	1 to 4 years	5 to 15 years	≥16 years
Symptom duration--reported days (range) [A]	3 (1-6)	3 (1-6)	3 (1-6)	3 (1-6)
Direct Costs				
Outpatient costs				
Initial physician visit [B]	NA	NA	NA	NA
Average # of follow-up visits [A]	NA	NA	NA	NA
Cost per follow-up [B]	NA	NA	NA	NA
Total Unit Cost [C]	NA	NA	NA	NA
Percent Outpatient [A]	0.0%	0.0%	0.0%	0.0%
Weighted Unit Cost [C]	$0.00	$0.00	$0.00	$0.00
Inpatient costs				
Duration of hospital stay [A]	NA	NA	NA	NA
Hospital cost per day	NA	NA	NA	NA
Total hosptial cost	NA	NA	NA	NA
Initial physician visit	NA	NA	NA	NA
Average # of follow-up visits [A]	NA	NA	NA	NA
Cost per follow-up	NA	NA	NA	NA
Total Unit Cost	NA	NA	NA	NA
Percent Inpatient [A]	0%	0%	0%	0%
Weighted Unit Cost [C]	$0.00	$0.00	$0.00	$0.00
Total Weighted Direct Costs [C]	$0	$0	$0	$0
Indirect Costs				
Value of lost patient day [D]	$0.00	$0.00	$0.00	$85.12
Lost patient days [A]	3 (1-6)	3 (1-6)	1.5	1.15
Value of caregiver day [D]	$85.12	$85.12	$85.12	$85.12
Caregiver days [A]	3 (1-6)	3 (1-6)	1.5	0
Value of lost productivity day [E]	$0.00	$0.00	$0.00	$25.54
Lost productivity days [A]	0	0	0	1.09
Total Indirect Costs [C]	$255 $85 - $511	$255 $85 - $511	$128	$126
Total Cost of Illness [C]	$255 $85 - $511	$255 $85 - $511	$128	$126

Sources:
[A] Appendix A, Exhibit A.3.
[B] Appendix A, Exhibit A.4.
[C] Calculations based on data presented in the table.
[D] Appendix A, Exhibit A.7
[E] Weighted average per day value of time ($85.12) multiplied by percent loss productivity (30 percent, rounded from Harrington et al. 1991)
NA: Not applicable to mild cases.

Exhibit 5.22d Estimates for Average Cost and Average Cost per Case of Type B Illness Requiring Outpatient Care, by Age (Traditional COI)

Cost Category	Average Cost per Patient 2003$			
	<1 Year	1 to 4 years	5 to 15 years	≥16 years
Symptom duration--reported days (range) [A]	5 (2-12)	5 (2-10)	5 (2-7)	5 (2-9)
Direct Costs				
Outpatient costs				
Initial physician visit [B]	$114.55	$114.55	$114.55	$114.55
Average # of follow-up visits [A]	1	1	1	1
Cost per follow-up [B]	$66.18	$66.18	$66.18	$66.18
Total Unit Cost [C]	$181	$181	$181	$181
Percent Outpatient [A]	100%	100%	100.0%	100.0%
Weighted Unit Cost [C]	$181	$181	$181	$181
Inpatient costs				
Duration of hospital stay [A]	NA	NA	NA	NA
Hospital cost per day [B]	NA	NA	NA	NA
Total hosptial cost [C]	NA	NA	NA	NA
Initial physician visit [B]	NA	NA	NA	NA
Average # of follow-up visits [A]	NA	NA	NA	NA
Cost per follow-up [B]	NA	NA	NA	NA
Total Unit Cost [C]	NA	NA	NA	NA
Percent Inpatient [A]	0%	0%	0%	0%
Weighted Unit Cost [C]	$0.00	$0.00	$0.00	$0.00
Total Weighted Direct Costs [C]	$181	$181	$181	$181
Indirect Costs				
Value of lost patient day [D]	$0.00	$0.00	$0.00	$85.12
Lost patient days [A]	5 (2-12)	5 (2-10)	5 (2-7)	5 (2-9)
Value of caregiver day [D]	$85.12	$85.12	$85.12	$85.12
Caregiver days [A]	5 (2-12)	5 (2-10)	5 (2-7)	0
Value of lost productivity day [E]	$0.00	$0.00	$0.00	$25.54
Lost productivity days [A]	0	0	0	0
Total Indirect Costs [C]	$426 $170 - $1,021	$426 $170 - $851	$426 $170 - $596	$426 $170 - $766
Total Cost of Illness [C]	$606 $351 - $1,202	$606 $351 - $1,032	$606 $351 - $777	$606 $351 - $947

Sources:
[A] Appendix A, Exhibit A.3.
[B] Appendix A, Exhibit A.4.
[C] Calculations based on data presented in the table.
[D] Appendix A, Exhibit A.7
[E] Weighted average per day value of time ($85.12) multiplied by percent loss productivity (30 percent. rounded from Harrington et al. 1991)
* No data available.

Exhibit 5.22e Estimates for Average Cost and Average Cost per Case of Type B Illness Requiring Inpatient Care, by Age (Traditional COI)

Cost Category	Average Cost per Patient 2003$			
	<1 Year	1 to 4 years	5 to 15 years	≥16 years
Symptom duration--reported days (range) [A]	7 (2-14)	7 (2-14)	7 (2-14)	7 (2-14)
Direct Costs				
Outpatient costs				
Initial physician visit [B]	$114.55	$114.55	$114.55	$114.55
Average # of follow-up visits [A]	1	1	1	1
Cost per follow-up [B]	$66.18	$66.18	$66.18	$66.18
Total Unit Cost [C]	$181	$181	$181	$181
Percent Outpatient [A]	100%	100%	100.0%	100.0%
Weighted Unit Cost [C]	$181	$181	$181	$181
Inpatient costs				
Duration of hospital stay--reported days [A]	4.7	4.7	2.5	2.5
Hospital cost per day [B]	$4,869.90	$1,839.15	$1,839.15	$1,839.15
Total hosptial cost [C]	$22,889	$8,644	$4,598	$4,598
Initial physician visit [B]	$152.87	$152.87	$152.87	$152.87
Average # of follow-up visits [A]	4	4	2	2
Cost per follow-up [B]	$52.25	$52.25	$52.25	$52.25
Total Unit Cost [C]	$23,250	$9,006	$4,855	$4,855
Percent Inpatient [A]	100%	100%	100%	100%
Weighted Unit Cost [C]	$23,250	$9,006	$4,855	$4,855
Total Weighted Direct Costs [C]	$23,431	$9,187	$5,036	$5,036
Indirect Costs				
Value of lost patient day [D]	$0.00	$0.00	$0.00	$85.12
Lost patient days [A]	7 (2-14)	7 (2-14)	7 (2-14)	7 (2-14)
Value of caregiver day [D]	$85.12	$85.12	$85.12	$85.12
Caregiver days [A]	7 (2-14)	7 (2-14)	7 (2-14)	0
Value of lost productivity day [E]	$0.00	$0.00	$0.00	$25.54
Lost productivity days [A]	0	0	0	0
Total Indirect Costs [C]	$596 $170 - $1,192	$596 $170 - $1,192	$596 $170 - $1,192	$596 $170 - $1,192
Total Cost of Illness [C]	$24,027 $23,601 - $24,623	$9,782 $9,357 - $10,378	$5,632 $5,206 - $6,228	$5,632 $5,206 - $6,228

Sources:
[A] Appendix A, Exhibit A.3.
[B] Appendix A, Exhibit A.4.
[C] Calculations based on data presented in the table.
[D] Appendix A, Exhibit A.7
[E] Weighted average per day value of time ($85.12) multiplied by percent loss productivity (30 percent, rounded from Harrington et al. 1991)
* No data available.

Indirect Medical Costs

For the Enhanced COI, the total indirect cost associated with a case of Type A viral illness ranges from an average of $103 (for healthy patients 16 years old and older) to $2,136 (for patients under 2 years of age). Indirect costs associated with cases of Type B viral illness range from $336 (for patients 16 years

old and older requiring no medical care) to $2,990 (for patients under 16 years of age requiring inpatient care). Total indirect cost is the sum of the value of patient days lost, the value of productivity lost, and the value of care giver days lost. Exhibit 5.21 also includes this information. The value of a lost day is set at $227.79 for adults 16 years of age and older, and $199.36 for children under 16 years of age. As described in Appendix A, the figure for adults is calculated by summing the product of hours of market work per day and the median gross (pre-tax) wage and benefits ($20.82), the product of hours of nonmarket work per day and the median post-tax wage ($12.46), and the product of hours of leisure time per day and the median post-tax wage ($12.46), and the product of hours of sleep per day and a rate of zero. The figure for children uses a median post-tax wage ($12.46) for all lost time (16 waking hours).

For the Traditional COI, the total indirect medical cost associated with a case of Type A viral illness ranges from an average of $39 (for healthy patients 16 years old and older) to $426 (for immunocompromised patients 2 years of age and younger). Indirect costs associated with cases of Type B viral illness range from $126 (for patients 16 years old and older requiring no medical care) to $596 (for patients requiring inpatient care). Total indirect cost is the sum of the value of patient days lost, the value of productivity lost, and the value of care giver days lost. Exhibit 5.22 also includes this information. The value of a lost day for adults and caregivers is set at $85.12. As shown in Appendix A, this figure is calculated by summing the product of hours of market work per day and the median gross (pre-tax) wage and benefits ($20.82), and the product of hours of nonmarket work per day and the median post-tax wage ($6.23).

While the methodology used to derive the indirect cost of illness for adults is straightforward, the valuation of children's time presents unique problems. The best approach when valuing children's health effects is the use of child-specific valuations of these effects. For direct costs, EPA has used such valuations. Indirect costs, however, prove more challenging. As noted in the *Children's Health Valuation Handbook* (USEPA, 2002), "[children's] time lost to sickness also has value, although no direct measure exists for this loss." In this instance, the *Handbook* states that, "as a second-best option, ...transfer benefit values estimated for adults to children." The Enhanced COI uses this guideline, in conjuncture with Executive Order 13045 ("Protection of Children from Environmental Health Risks and Safety Risks"), and assumes a day lost due to illness for the duration of illness for patients younger than 16 years to be valued at $199.36 (based on the median post-tax wage). In contrast, the Traditional COI assigns no value for a lost day for children under 16 years of age. Both the Traditional and Enhanced COI approaches assume that a caretaker stays home with these children, introducing additional lost caretaker days for each lost patient day. According to the Handbook, "the productivity loss of both affected individuals should be included in the valuation estimate of a child's illness." The number of days lost entirely to illness, either by the patient or care giver, is multiplied by $227.79 (for the Enhanced COI) or $85.12 (for the Traditional COI), the average value of a lost day.

Often patients return to work or school while still experiencing symptoms that affect their productivity. Because patients are only fractionally as productive at work as well people, the loss associated with the less productive days (lost productivity) is a portion of the value of a full lost day, specifically 30 percent[11] (rounded from Harrington, 1991). Since there is only a fractional productivity loss, the days with lessened productivity are multiplied by $68.34 (30 percent of $227.79 for Enhanced COI) or $25.54 (30 percent of $85.12 for Traditional COI). No productivity losses are assigned to children under 16 years of age under either the Traditional or Enhanced COI approaches.

[11] See Appendix A.

5.3.1.2 Value of Mortality Avoided

Benefits of the GWR also derive from avoiding fatalities due to Type A and Type B virus infections. The Value of a Statistical Life (VSL) is used to measure the value of these benefits. The VSL represents an estimate of the monetary value of reducing risks of premature death. The VSL, therefore, is not an estimate of the value of saving a particular individual's life. The value of a "statistical" life represents the sum of the values placed on small individual risk reductions across an exposed population. For example, if a regulation were to reduce the risk of premature death from Type B viral infection by 1/1,000,000 for one million exposed individuals, the regulation would "save" one statistical life (1,000,000 X 1/1,000,000). If each of the 1,000,000 people were willing to pay $5 to achieve the risk reduction anticipated from the regulation, the VSL would be $5 million ($5 X 1,000,000).

An EPA study characterized the range of possible VSL values as a Weibull distribution with a mean of $4.8 million (1990 price level) based on 26 individual study estimates (USEPA 1997b). This represents the value recommended for use in benefits analyses in EPA's *Guidelines for Preparing Economic Analyses* (USEPA 2000e) and endorsed by the Science Advisory Board (SAB) Arsenic review panel (USEPA 2001b). For purposes of the GWR benefits analysis, the VSL Weibull distribution (with parameters of location = 0, scale = 5.32, shape = 1.51) was incorporated into the benefits model Monte-Carlo simulation. This enables quantification of the uncertainty surrounding benefits estimates derived from the VSL. The mean VSL, after all adjustments were made, was $7.4 million in year 2003 dollars (using a CPI adjustment factor). These adjustments are explained further in the following sections, and the mean VSL by year of the analysis can be found in Appendix B (Exhibit B.6) of this EA.

5.3.1.3 Measuring Benefits Over the GWR Implementation Schedule

In order to extract benefits data from the model and present these benefits in comparable terms to a similarly calculated stream of costs, it is necessary to calculated the present value of all benefits over the lifetime of the implementation schedule. GWR implementation occurs over several years as States and PWSs learn the requirements, inform their staffs, perform sanitary surveys, and implement source water and compliance monitoring. A 25-year horizon was chosen for this analysis, because most treatment technologies evaluated in this EA are estimated to have 20-year life-cycle. In addition, systems have several years to begin treatment associated with the GWR. Calculating a shorter time frame would include less of the complete value associated with the cost of technologies. A complete schedule of when costs and benefits are estimated to be incurred is presented in Appendix B.

5.3.1.4 Adjustments for Income Elasticity

Although the price level (year 2003) is held constant across all benefits projections, real income increases over time, and therefore benefit values in future years are adjusted to reflect income elasticity or income growth, depending on the benefits category being assessed. Benefits based on potentially fatal health effects are adjusted for income elasticity and income growth. Benefits based on the value of lost time are adjusted for income growth, but not income elasticity. This section describes how these adjustments are carried out. Benefits derived from medical costs, the third broad category of benefits, are adjusted for neither income elasticity nor income growth.

In the case of avoided-death benefits, income elasticity adjustments are applied to values in future years. In general, income elasticity represents changes in valuation in relation to changes in real income. For example, if, for every 1 percent increase in real income, a particular consumer's willingness to pay for a particular item increases by 1 percent, this would be represented by an income elasticity of one. For most items, income elasticity values are actually less than one, reflecting slower growth in willingness to pay than in income.

In order to apply the income elasticity values in the benefits model, they must be combined with projections of real income growth over the time frame for analysis. To accomplish this, population and real gross domestic product (GDP) projections are combined to calculated per capita real GDP values[12] (see Appendix B, Exhibit B.5–income elasticity calculations). Percent changes in these values over time can then be combined with income elasticity figures to derive a single adjustment factor.[13] Given any two points in time, this factor is calculated as follows:

Income elasticity adjustment factor = $(E\ I_1 - E\ I_2 - I_2 - I_1) / (E\ I_2 - E\ I_1 - I_2 - I_1)$ where:

E = income elasticity
I_1 = real income (per capita GDP) in the base year
I_2 = real income (per capita GDP) in the year of analysis

When applying this formula, income elasticity adjustment factors are calculated from the same base year as the values subject to adjustment. In this case, income elasticity factors for fatal cases of viral illness are calculated from a 1990 base year (I_1 = 1990 in the above formula) because that is the base year used in the study from which VSL estimates are derived.[14]

Kleckner and Neuman (2000) identified published studies from which elasticity values could be derived for potentially fatal health effects. They suggest a triangular distribution with a mode of 0.40, and endpoints at 0.08 and 1.00. In the Monte-Carlo simulation that assigns dollar values to benefits, income elasticity values (*E* in the above equation) are drawn from this probability distribution. Based on this formula and inputs, income elasticity factors are computed and applied to avoided-death benefits in future years. At the average income elasticity value (0.49), the income elasticity factors applied range from 1.213 (2008) to 1.445 (2029).

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[12] Ideally, income elasticity and income growth measurements would be calculated using real per capita personal income growth. Real per capita GDP, however, is used as a proxy for real per capita personal income growth owing to lack of appropriate data projections for real personal income growth. Historical data suggests that GDP and personal income grow at similar rates (i.e., Table B-31 of the 2002 Economic Report of the President shows that both real per capita GDP and disposable personal income grew at an average annual rate of 2.3 percent between 1959 and 2000).

[13] See Appendix A of Kleckner and Neuman (2000) for additional information on the derivation and application of income elasticity adjustments.

[14] The distribution of VSL values used in this EA is derived based on a meta-analysis of 26 different VSL studies, all representing different year price levels. These price levels were updated to a common 1990 price level as part of the analysis in "The Benefits and Costs of the Clean Air Act, 1970-1990" (USEPA, 1997c), from which the distribution used in this EA is taken.

The second type of adjustment for income growth is applied to the portion of future benefits derived from the value of lost time. The methodology here is more straightforward. The same per capita GDP values referenced above (and presented in Appendix B) are employed to compute simple ratios (income growth factors) between the future year and the year 2003 (the baseline year for COI calculations). Lost time benefits values are then multiplied by these factors, which range from 1.15 in 2008 to 1.64 in 2029.

5.3.1.5 Present Value of Future Benefits

To allow comparison of future streams of costs and benefits, it is common practice to adjust both streams to a present value (PV) using a social discount rate. This process takes into account the time preference that society places on expenditures and benefits and allows comparison of cost and benefit streams that vary over a given time period.[15] A present value for any future period can be calculated using the following equation:

$$PV = V_t/(1 + R)t$$

where: t = the number of years from the reference period (year 0 of the benefits stream)
R = social discount rate
V_t = the benefits occurring t years from the reference period

There is much discussion among economists of the proper social discount rate to use for policy analysis. For this EA, therefore, PV calculations are made using two social discount rates thought to best represent current policy evaluation methodologies, 3 and 7 percent. Historically, the use of 3 percent is based on rates of return on relatively risk-free investments, as described in the *Ex anteGuidelines for Preparing Economic Analyses* (USEPA, 2000e). The rate of 7 percent is a recommendation of the Office of Management and Budget (OMB) as an estimate of "before-tax rate of return to incremental private investment" (USEPA, 1996c). To allow evaluation on an annual basis, the total PV of benefits are annualized using the same social discount rates.

5.3.2 Summary of Quantified Benefits of GWR

The risk assessment methodology described in this chapter estimates quantified benefits of reducing endemic acute infections caused by a portion of Type A and Type B viruses. Exhibits 5.23a-b provide a summary of the cumulative monetary benefits estimated for the GWR for all system sizes and categories (CWSs, NTNCWSs, and TNCWSs). Nonquantified benefits are discussed in Section 5.4.

The costs for rule alternatives are presented in Chapter 6, and cost/benefit comparisons are evaluated in Chapter 8.

[15] See EPA's *Guidelines for Preparing Economic Analyses* (USEPA, 2000e) for a full discussion of the use of social discount rates in the evaluation of policy decisions.

Exhibit 5.23a Annualized Quantified Benefits of Illnesses and Deaths Avoided, Final Rule, Enhanced COI, All Systems by System Size and Type ($Millions, 2003)

System Size (Population Served)	3% Discount Rate			7% Discount Rate		
	Mean Value	90 Percent Confidence Bound		Mean Value	90 Percent Confidence Bound	
		Lower (5th %ile)	Upper (95th %ile)		Lower (5th %ile)	Upper (95th %ile)
Community Water Systems (CWSs)						
<100	$ 0.2	$ 0.1	$ 0.5	$ 0.2	$ 0.0	$ 0.3
101-500	$ 0.4	$ 0.2	$ 1.0	$ 0.4	$ 0.1	$ 0.8
501-1,000	$ 0.4	$ 0.1	$ 1.0	$ 0.3	$ 0.1	$ 0.8
1,001-3,300	$ 1.0	$ 0.3	$ 2.4	$ 0.8	$ 0.3	$ 2.0
3,301-10K	$ 2.5	$ 0.9	$ 5.7	$ 2.1	$ 0.7	$ 4.8
10,001-50K	$ 2.4	$ 0.8	$ 5.3	$ 2.1	$ 0.7	$ 4.6
50,001-100K	$ 4.7	$ 1.5	$ 11.0	$ 4.1	$ 1.3	$ 9.6
100,001-1M	$ 4.3	$ 1.5	$ 10.1	$ 3.8	$ 1.3	$ 8.8
>1 Million	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.0
All Sizes	$ 16.0	$ 5.4	$ 37.0	$ 13.7	$ 4.6	$ 31.6
Nontransient Noncommunity Water Systems (NTNCWSs)						
<100	$ 0.1	$ 0.0	$ 0.1	$ 0.1	$ 0.0	$ 0.1
101-500	$ 0.2	$ 0.1	$ 0.4	$ 0.2	$ 0.1	$ 0.4
501-1,000	$ 0.2	$ 0.1	$ 0.5	$ 0.2	$ 0.0	$ 0.4
1,001-3,300	$ 0.2	$ 0.1	$ 0.6	$ 0.2	$ 0.1	$ 0.5
3,301-10K	$ 0.1	$ 0.0	$ 0.3	$ 0.1	$ 0.0	$ 0.2
10,001-50K	$ 0.1	$ 0.0	$ 0.2	$ 0.1	$ 0.0	$ 0.1
50,001-100K	$ 0.0	$ 0.0	$ 0.1	$ 0.0	$ 0.0	$ 0.0
100,001-1M	$ 0.0	$ 0.0	$ 0.1	$ 0.0	$ 0.0	$ 0.1
>1 Million	$ -	$ -	$ -	$ -	$ -	$ -
All Sizes	$ 0.9	$ 0.3	$ 2.2	$ 0.8	$ 0.2	$ 1.8
Transient Noncommunity Water Systems (TNCWSs)						
<100	$ 0.6	$ 0.2	$ 1.4	$ 0.5	$ 0.1	$ 1.1
101-500	$ 0.9	$ 0.3	$ 2.2	$ 0.8	$ 0.2	$ 1.8
501-1,000	$ 0.4	$ 0.1	$ 1.0	$ 0.3	$ 0.1	$ 0.8
1,001-3,300	$ 0.3	$ 0.1	$ 0.8	$ 0.3	$ 0.1	$ 0.6
3,301-10K	$ 0.2	$ 0.1	$ 0.4	$ 0.1	$ 0.0	$ 0.3
10,001-50K	$ 0.2	$ 0.0	$ 0.4	$ 0.1	$ 0.0	$ 0.3
50,001-100K	$ 0.0	$ 0.0	$ 0.1	$ 0.0	$ 0.0	$ 0.0
100,001-1M	$ 0.1	$ 0.0	$ 0.1	$ 0.0	$ 0.0	$ 0.1
>1 Million	$ -	$ -	$ -	$ -	$ -	$ -
All Sizes	$ 2.7	$ 0.8	$ 6.2	$ 2.3	$ 0.7	$ 5.1
TOTAL	$ 19.7	$ 6.5	$ 45.4	$ 16.8	$ 5.5	$ 38.6

Detail may not add to totals due to independent rounding. The Traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The Enhanced COI also factors in valuations for lost personal time (non-work time) such as childcare and homemaking (to the extent not covered by the Traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway.

The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to comprise a significant portion of the overall benefits of the Rule and are presented in Section 5.4.

Source: Appendix C

Exhibit 5.23b Annualized Quantified Benefits of Illnesses and Deaths Avoided, Final Rule, Traditional COI, All Systems, by System Size and Type ($Millions, 2003)

System Size (Population Served)	3% Discount Rate			7% Discount Rate		
	Mean Value	90 Percent Confidence Bound		Mean Value	90 Percent Confidence Bound	
		Lower (5th %ile)	Upper (95th %ile)		Lower (5th %ile)	Upper (95th %ile)
Community Water Systems (CWSs)						
<100	$ 0.1	$ 0.0	$ 0.3	$ 0.1	$ 0.0	$ 0.2
101-500	$ 0.2	$ 0.1	$ 0.6	$ 0.2	$ 0.0	$ 0.5
501-1,000	$ 0.2	$ 0.0	$ 0.6	$ 0.2	$ 0.0	$ 0.5
1,001-3,300	$ 0.5	$ 0.1	$ 1.4	$ 0.4	$ 0.1	$ 1.2
3,301-10K	$ 1.3	$ 0.3	$ 3.4	$ 1.1	$ 0.3	$ 2.8
10,001-50K	$ 1.2	$ 0.3	$ 3.2	$ 1.1	$ 0.3	$ 2.8
50,001-100K	$ 2.4	$ 0.5	$ 6.7	$ 2.1	$ 0.4	$ 5.9
100,001-1M	$ 2.2	$ 0.5	$ 6.0	$ 1.9	$ 0.5	$ 5.3
>1 Million	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.0
All Sizes	$ 8.2	$ 1.9	$ 22.3	$ 7.1	$ 1.6	$ 19.1
Nontransient Noncommunity Water Systems (NTNCWSs)						
<100	$ 0.0	$ 0.0	$ 0.1	$ 0.0	$ 0.0	$ 0.1
101-500	$ 0.1	$ 0.0	$ 0.3	$ 0.1	$ 0.0	$ 0.2
501-1,000	$ 0.1	$ 0.0	$ 0.3	$ 0.1	$ 0.0	$ 0.2
1,001-3,300	$ 0.1	$ 0.0	$ 0.3	$ 0.1	$ 0.0	$ 0.3
3,301-10K	$ 0.1	$ 0.0	$ 0.1	$ 0.0	$ 0.0	$ 0.1
10,001-50K	$ 0.0	$ 0.0	$ 0.1	$ 0.0	$ 0.0	$ 0.1
50,001-100K	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.0
100,001-1M	$ 0.0	$ 0.0	$ 0.1	$ 0.0	$ 0.0	$ 0.0
>1 Million	$ -	$ -	$ -	$ -	$ -	$ -
All Sizes	$ 0.5	$ 0.1	$ 1.3	$ 0.4	$ 0.1	$ 1.0
Transient Noncommunity Water Systems (TNCWSs)						
<100	$ 0.3	$ 0.1	$ 0.7	$ 0.3	$ 0.1	$ 0.6
101-500	$ 0.4	$ 0.1	$ 1.2	$ 0.4	$ 0.1	$ 1.0
501-1,000	$ 0.2	$ 0.0	$ 0.6	$ 0.2	$ 0.0	$ 0.5
1,001-3,300	$ 0.2	$ 0.0	$ 0.4	$ 0.1	$ 0.0	$ 0.4
3,301-10K	$ 0.1	$ 0.0	$ 0.2	$ 0.1	$ 0.0	$ 0.2
10,001-50K	$ 0.1	$ 0.0	$ 0.2	$ 0.1	$ 0.0	$ 0.2
50,001-100K	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.0	$ 0.0
100,001-1M	$ 0.0	$ 0.0	$ 0.1	$ 0.0	$ 0.0	$ 0.1
>1 Million	$ -	$ -	$ -	$ -	$ -	$ -
All Sizes	$ 1.3	$ 0.3	$ 3.4	$ 1.1	$ 0.2	$ 2.8
TOTAL	$ 10.0	$ 2.2	$ 27.0	$ 8.6	$ 1.9	$ 22.9

Detail may not add to totals due to independent rounding. The Traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The Enhanced COI also factors in valuations for lost personal time (non-work time) such as childcare and homemaking (to the extent not covered by the Traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway.

The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to comprise a significant portion of the overall benefits of the Rule and are presented in Section 5.4.

Source: Appendix C

5.3.3 Quantified Benefits to Sensitive Subpopulations

Exhibits 5.23a and 5.23b presented the annualized benefits of the GWR across the general population. However, a large portion of these benefits will be realized by sensitive subpopulations. As described previously in section 5.2.2.2, EPA is considering three sensitive populations for the purpose of the GWR: the immunocompromised, children (< 5 years old), and the elderly (> 65 years old). Exhibit 5.24 presents the benefits of the GWR to sensitive populations.

Exhibit 5.24 Annual Illnesses and Deaths Avoided at Full Implementation, and Quantified Benefits of the GWR in Sensitive Populations

Population	US Census[1]	Population Potentially Affected (served by GW systems)	No. of Illnesses Avoided	No. of Deaths Avoided	Annual Benefits Using 3 % Discount Rate and Enhanced COI[2] ($Millions)
Immunocompromised (0.3%)					
All ages	844,266	342,772	126	0.002	$0.62
Nonimmunocompromised Sensitive (99.7%)					
Elderly (>65 yrs)	34,791,627	14,125,401	5,559	0.10	$1.55
Children (<5 yrs)	19,079,280	7,746,187	2,780	0.06	$4.99
Children (<5 yrs) Type A:					
<2 yrs	7,587,829	3,080,659	1,684	0.01	$2.81
2-4 yrs	11,491,436	4,665,523	904	0.01	$1.51
Children (<5 yrs) Type B:					
<1 month	315,541	128,110	3	0.00	$0.01
1 month - <1 yr	3,470,952	1,409,207	37	0.01	$0.13
1-4 yrs	15,292,787	6,208,872	151	0.03	$0.52
Total Nonimmunocompromised Sensitive	53,870,907	37,363,958	8,339	0.15	$7.17
Total	54,715,173	37,706,730	8,465	0.15	$7.79

Notes: Detail may not sum due to independent statistical analyses and rounding. The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The nonquantified benefits are expected to comprise a significant portion of the overall benefits of the Rule and are presented in Section 5.4. The Immunocompromised population includes bone marrow transplant recipients, AIDS patients, and organ transplant patients.

[1] The U.S. Census data is modified to show the number of people that are estimated to be immunocompromised (0.3 % of the population) and not immunocompromised (99.7% of the population). Therefore, the U.S. Census population estimates shown above for the Elderly and Children categories are 99.7% of the estimates shown in Exhibit 5.4.

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

Source: U.S. Census Population from 2000 Census data (U.S. Bureau of the Census, 2000); Population Potentially Affected derived from SDWIS (USEPA 2003a); Number of Illnesses Avoided, Deaths Avoided, and Annual Benefits from GWR Model Output.

5.4 Nonquantified Benefits of GWR Provisions

Due to the limited availability of data, EPA was only able to quantify some of the benefits it believes are associated with the GWR. The EA for the GWR monetizes benefits associated with Type A viruses represented by rotavirus data and Type B represented by enterovirus or echovirus data. As discussed in Section 5.1., the EA quantifies only the endemic, acute illnesses due to rotavirus and enterovirus. Other benefits, not quantified, are discussed in this section. As discussed in Section 5.2 and 5.3, even in the case where benefits are quantified, data limitations remain and certain factors used in the analysis have significant associated uncertainties.

The nonquantified health benefits are: 1) decreased incidence of gastroenteritis caused by other Type A viruses such as norovirus, astrovirus and adenovirus, 2) decreased incidence of other acute disease endpoints (e.g., hepatitis, conjunctivitis), 3) decreased incidence of chronic illness sequelae associated with Type B virus (e.g., diabetes, dilated cardiomyopathy, hypertension and reduced kidney function), 4) decreased incidence of illness and death caused by bacteria, 5) decreased incidence of waterborne disease outbreaks and epidemic illness, and 6) decreased illness through minimizing treatment failures or fewer episodes with inadequate treatment.

The nonquantified non-health benefits are: 1) improved perception of ground water quality and perception about reduced risk associated with PWS wells, 2) reduced use of bottle water and point-of-use devices, 3) reduced time spent on averting behavior such as obtaining alternative water supplies, and 3) avoided costs associated with outbreak response.

EPA believes that, collectively, these benefits, both health and non-health, are likely to substantially exceed those which EPA was able to quantify, and are the primary basis for supporting the preferred regulatory alternative. Each of these major nonquantified benefits is discussed further below.

5.4.1 Decreased Incidence of Illness Caused by Other Type A Viruses

5.4.1.1 Norovirus

Noroviruses have been suggested as “the single most significant cause of intestinal infectious disease in the developed world.” (Carter, 2005) However, no cell culture method exists to recover noroviruses in stool or environmental samples, therefore published human infectivity data for norovirus were not available to use in the EA. This detection method deficiency and resulting lack of published infectivity data prevented quantification of monetized benefits for norovirus occurrence reduction in the GWR EA. In this section, the norovirus disease burden is qualitatively discussed together with information that suggests additional benefit from full implementation of the GWR.

Norovirus Disease in the United States

In recent years, numerous common source outbreaks[16] have been attributed to norovirus contamination. CDC retrospectively evaluated 4,050 U.S. common source outbreaks that occurred during 1998--2000 and determined that at a minimum, 28% could be attributable to norovirus (Turcios, et al, 2006). In another study of outbreaks occurring during the period from 2000 to 2004, fecal samples from 226 outbreaks (12 waterborne) of acute gastroenteritis suspected of calicivirus causality were analyzed by CDC for norovirus and other caliciviruses (Blanton et al, 2006). Caliciviruses (primarily norovirus but also sapovirus) were detected in 184 (81%) of those outbreaks. These data suggest that norovirus represents a large component of the total gastroenteritis epidemic disease burden in the United States. This perspective is further supported by CDC who estimated total U.S. annual illnesses from Norwalk-like (now called norovirus) viruses of 23,000,000 cases (Mead et al 1999).

The identification of the etiologic agent of a waterborne, or any common source or person-to-person outbreak depends on a number of factors: the timely recognition of the outbreak and timely stool sample collection, laboratory capacity and capability, active requests for non-routine tests, and many other factors (Lee et al., 2002). When routine analysis of stool is requested, the sample is typically tested only for some enteric bacteria and some protozoan parasites (typically *Giardia*); testing for viruses and especially norovirus, is not common. Viral agents are less easily identified than most enteric bacteria and norovirus is among the most difficult viral agents to identify (Blanton et al., 2006). It is only within the last ten years that molecular methods have become sufficiently advanced so norovirus strains can be specifically identified in stool samples. Unlike bacterial agents, no routine, commercially available test for identifying norovirus exists and therefore ill persons who submit a stool specimen are not routinely tested for norovirus (Blanton et al., 2006).

Norovirus has a low infectious dose, prolonged asymptomatic shedding, substantial strain diversity and considerable environmental stability (CDC, 2001a). As a result of a low infectious dose, a small dose readily allows infection in exposed individuals (CDC, 2001a). Prolonged shedding allows opportunity for individuals to come in contact with norovirus. Norovirus does not provide lasting immunity upon infection partly because there are many different serotypes (Carter, 2005). The substantial strain diversity may prevent individuals from acquiring a general immunity that prevents illness from any norovirus. Environmental stability allows norovirus to survive in ground water and elsewhere in the environment until acquired by another host (Schwab and Bae, 2005). Thus, norovirus-contaminated ground water or a norovirus-contaminated surface will continue to maintain infectious norovirus. Individuals can acquire primary norovirus infection by drinking that ground water or can acquire secondary infectious norovirus by contact with a contaminated surface or persons.

Although a small percentage (about 20%) of individuals in the United States are likely genetically immune to norovirus infection (Lindesmith et al., 2003), the remaining population is subject to repeated episodes of infection and illness. Norovirus is shed in appreciable numbers, at concentrations similar to enteroviruses (Carter, 2005). Because norovirus is highly infectious (Moe et al., 2001), individuals may easily acquire infection. Once infected, norovirus is easily transmitted to others. Individuals can easily

[16]Common source outbreaks arise primarily from food or water (ice is considered to be water by EPA but is commonly treated as food in outbreak compilations). Propagation by secondary (person-to-person) transmission may also occur but is not the immediate cause of the outbreak. Outbreaks that are not common source arise and propagate only by person-to-person transmission.

spread infection and illness to family members and others (both children and adults) outside the household by casual contact with asymptomatic carriers who shed for long periods.

Using molecular epidemiology tools, diverse cases may be tracked backwards in time and exposure history to identify an index case or a common source exposure. One norovirus strain, the Farmington Hills strain, is identified as a cause of multiple large outbreaks on cruise ships (Widdowson et al., 2004). The norovirus attack rates (30% of passengers became ill) resulting during cruise ships outbreaks suggests a defining character, it's capability to spread rapidly and efficiently via secondary transmission from a primary infected individual. This norovirus characteristic has significance when estimating the number of secondary cases which is illustrated further in Appendix J.

Norovirus Ground Water Outbreaks

Norovirus is recognized as the confirmed cause for some ground water outbreaks and is suspected in many others. In general, the etiological agent of many common source gastroenteritis outbreaks has not been identified. For example, of greater than 2,500 outbreaks reported to CDC from 1993 to 1997, 68% were of "unknown etiology" (Widdowson et al, 2005). Similarly, most common source outbreaks resulting from ground water fecal contamination are of unknown etiology. Of 342 ground water outbreaks in the United States between 1971 and 1994, 212 were of "undetermined" etiology (Craun and Calderon, 1997).

Two recent ground water outbreaks in Wyoming were both recognized as norovirus outbreaks. In South Pass, Wyoming, an epidemiological investigation linked illness to the well water and ice (Parshionkar et al, 2003). A total of 84 illnesses were identified. The well supplied a TNC PWS system producing water from a sensitive (fractured bedrock) aquifer. A chlorination device malfunctioned due to poor maintenance. In Big Horn, Wyoming, 35 illnesses were identified due to fecal contamination of an unchlorinated PWS well in a sensitive (fractured bedrock) aquifer (Anderson et al, 2003). In 1989, norovirus was identified in an outbreak with 110 illnesses in Sedona, AZ (Lawson et al, 1991). Most recently, norovirus illness and campylobacterois were the most common illnesses associated with fecal contamination of PWS wells on South Bass Island, OH in 2004 (Ohio EPA, 2005). It is estimated that about 1450 individuals became ill from consuming well water tapping a sensitive aquifer with widespread fecal contamination (many PWS as well as some private wells were fecally contaminated). Other norovirus ground water outbreaks are identified from Yukon, Canada (Beller et al., 1997), Braun Station, TX (D'Antonio et al., 1985), Pierce County, WA (Taylor et al, 1981), Onondaga, NY (Chatterjeee et al. 2004), Monroe County, PA (Wilson et al., 1982), Henderson County, IL (Parsonnet et al., 1989), southeastern PA (Cannon et al, 1991), South Dakota (CDC, 1988) and elsewhere. Among outbreaks that have been specifically attributed to norovirus exposure in ground water, most have occurred in sensitive aquifers (see the GWR Occurrence and Monitoring Background Document for a discussion of outbreaks in sensitive aquifers).

Norovirus Disease Burden and Severity

The health effects of norovirus illness include acute onset of nausea, vomiting, abdominal cramps, and diarrhea. Vomiting is relatively more prevalent among children. Many adults experience vomiting as well as diarrhea. Constitutional symptoms (e.g., headache, fever, chills, and myalgia) are frequently reported. Although rare, severe dehydration caused by norovirus gastroenteritis can be fatal, with this outcome occurring among susceptible persons (e.g., older persons with debilitating health

conditions). No long-term sequelae of norovirus infection have been reported (CDC, 2001a). Duration of illness is typically 12–60 hours.

Norovirus is suggested in waterborne disease when vomiting is a symptom because norovirus is fairly unique among the common gastrointestinal agents in that vomiting often accompanies diarrhea. In a prospective study of Dutch patients with norovirus in a community cohort (not an outbreak), 74% of 99 patients of all ages experienced vomiting. Vomiting enhances the ability of norovirus to spread efficiently via fomites, suspended particles and aerosols.

The avoided illnesses from Type A viruses determined quantitatively in this EA are based only on rotavirus infection and illness. There are significant differences between rotaviral and noroviral disease. The total ground water-borne disease burden would change significantly if norovirus were included in the quantitative analysis. EPA believes that, if norovirus was included in the quantified benefits, there would be significantly greater total benefits for two reasons. First, norovirus, unlike rotavirus, is a disease of older teenagers and adults (Carter, 2005) as well as of children. In a study of 1,484 norovirus patients, the mean age was 43 years (Fankhauser et al. 2002). Similarly, in a study of 1,010 norovirus cases, the median age was 47 years (Blanton et al, 2006). This distinction is important; the monetized rotavirus disease burden in this EA provides only a small benefit for adult rotaviral disease because most adults are immune to rotavirus. Thus, noroviral disease in adults, which is quite prevalent, would be a significant additional avoided illness and monetized benefit if norovirus were included in the quantified analysis in this EA.

Second, unlike rotavirus, adults with norovirus experience vomiting and some experience only vomiting (CDC, 2001a). Most individuals experienced vomiting in a norovirus outbreak. In an analysis of symptoms, Widdowson et al (2005) found that more than half the ill persons experience vomiting in almost all norovirus outbreaks (i.e., in 86 percent of 136 outbreaks, greater than 50 percent of people experienced vomiting as a clinical symptom).

In monetizing the benefits associated with rotavirus or norovirus, the clinical symptoms are important. Norovirus is unique among the waterborne etiologic agents in that large proportions of ill individuals experience vomiting. Because adults with rotavirus experience gastroenteritis only, EPA assumes that each adult ill with rotavirus has one day of lost productivity and a subset (16%) have one lost patient day. In contrast, for adults with norovirus illness that manifests as vomiting (with nausea and gastroenteritis), EPA believes that norovirus likely produces greater lost leisure time and more lost productivity days, and therefore lost patient days, as compared with rotavirus because vomiting is so debilitating. Thus, a case of noroviral disease, when monetized, would likely produce greater benefit than rotaviral disease in adults.

In an analysis of care, Widdowson et al. (2005) compiled data on 3,370 persons affected in 112 norovirus outbreaks in the United States. Of these, 329 (10%) sought care from a physician and 33 (1%) were hospitalized. Because these data are from outbreak investigations, the outbreak cases may be biased toward the more severe end of the disease spectrum. It has been hypothesized that outbreaks are more likely recognized when the disease is more severe. Conversely, endemic cases or unrecognized outbreak cases may be milder disease. Mead et al. (1999) estimated norovirus hospitalization rates at 0.2% rather than the 1% value determined from outbreaks.

This EA quantifies the benefits for Type A viruses using data only from rotavirus. Unlike rotavirus, the norovirus human challenge study data to determine norovirus infectivity are not yet

published (Moe, 2001). For this reason alone, rotavirus data are used to quantitatively determine the benefits for the Type A viruses. As discussed above, EPA believes that the more severe clinical symptoms associated with norovirus, as compared with rotavirus, suggests that the norovirus disease burden associated with PWS wells is important, especially for adults.

EPA believes that the disease burden for norovirus and rotavirus is similar, although children are more likely to experience vomiting from norovirus. However, vomiting in children does not result in additional benefits when the illness is monetized. In contrast, the person-days ill metric does not account for the clinical symptoms and disease severity in adults who experience those person-days of illness and this severity provides additional benefits when monetized. EPA believes that consideration of the more severe clinical symptoms associated with norovirus illness among adults implies that adults will have more lost-patient days, as well as more lost productivity days.

Norovirus Cost of Illness

EPA believes that the clinical severity of norovirus illness in adults is significant. While EPA has data on the proportion of cases with vomiting and on the duration of illness, EPA has no data on duration of vomiting. Consideration of vomiting for norovirus illness suggests that the lost productivity for norovirus illness in adults could be much greater than is assumed for rotavirus in the quantified benefits because vomiting is typically sufficiently debilitating (and infectious to others) that most people cannot (or should not) work. The EA currently assumes a weighted mean value of 0.16 lost patient days and one day of lost productivity for adults when ill from rotavirus. EPA believes that this value is low compared with the likely norovirus illness lost productivity and lost patient days.

5.4.1.2 Other Type A viruses

Hepatitis A Virus

Viral pathogens, other than the enteroviruses, rotavirus and the caliciviruses are also transmitted by the fecal-oral pathway and thus are potential etiologic agents for ground waterborne disease. Hepatitis A (HAV) virus is the only waterborne virus that is reportable to CDC. About 28,000 HAV cases are reported to CDC each year, although that number is expected to decline with time because children are currently vaccinated for HAV in high risk states and newer recommendations are for increased vaccination coverage. More generally, however, because HAV is more severe as an adult disease, an aging U.S. population may have greater disease burden. Mead et al (1999) estimate about 83,000 HAV cases each year, with a hospitalization rate of 13% and a mortality rate of 0.3%. Like all fecal/oral pathogens, HAV is acquired through a variety of pathways. Hepatitis has a long incubation period and the virus remains viable in the environment and especially ground water for months. Thus, the infection source is often obscure. Ground water HAV outbreaks have been identified (Georgetown, TX (Hejkal et al, 1982), Racine, MO (Missouri Department of Health, 1992); Lancaster, PA (Bowen and McCarthy, 1983); Quebec, Canada (De Serres et al., 1999); all in sensitive aquifers). HAV is not favored in typical cell lines used in cell culture and so identification is difficult in environmental samples. As a result of the relatively large hepatitis A disease burden in locales where hygiene is poor, hepatitis A virus is believed to be highly infectious, perhaps as infectious as norovirus or rotavirus. HAV tends to present more serious symptoms than other viruses discussed thus far. Unlike norovirus or rotavirus, HAV infection confers lifetime immunity. No human dose response study data are available at differing doses. Because

of this and the fact that HAV cannot be routinely identified in well water, the benefits of avoiding HAV disease through full implementation of the GWR cannot be quantified.

Hepatitis E virus

Hepatitis E (HEV) virus is another fecal oral virus that is potential transmitted via ground water. Using serology and case histories of individual patients, HEV is established as endemic within the United States (Tsang et al, 2000). However, the data suggest that only one or a few percent of the population has been infected. Unlike HAV, no ground water outbreaks of HEV have occurred in the United Sates, although they have occurred elsewhere (China and Somalia). HEV is not culturable and no data on environmental occurrence in ground water are available. The disease is severe (up to 20% mortality among pregnant women in developing countries) and thus no human dose response data are available. Because infectious HEV cannot be identified in well water and no human dose response data are available, the benefits of avoiding HEV disease through full implementation of the GWR cannot be quantified.

Adenovirus

The adenovirus are a large group of viruses that produce diverse symptoms. Two adenovirus serotypes adenovirus 40 and 41 produce primarily enteric symptoms, but several other adenoviruses are also capable of producing such symptoms. Some cause conjunctivitis. Most significantly, adenoviruses caused a fatal outcome in otherwise health young males in military settings. (CDC, 2001b) All adenoviruses, no matter the infection site and characteristic illness, are shed copiously through the gut and are thus fecal\oral viruses (Carter, 2005). Adenoviruses are not efficiently recovered using commonly available cell lines and methods and no human dose response data are available. No waterborne disease outbreaks have been reported for adenovirus in the United States, but adenovrius was among several pathogens identified in wells sampled during the South Bass Island, OH outbreak (CDC, 2005). The GWR does not quantify the benefits from avoided adenovirus illness.

Astrovirus

Astrovirus, like rotavirus, is commonly acquired in child care settings, causes mild disease in children and most children are exposed at an early age. However, like rotavirus, a small percentage of that large population suffer more significant health effects and may require in-patient care. Like rotavirus, the disease burden in older children and adult populations is underestimated because the disease is mild (Carter, 2005). Astroviruses are shed in stool at large numbers (similar to enteroviruses Carter, 2005) and, in France, prospective epidemiology studies have implicated untreated ground water as a route of infection (Gofti-Laroche, et al, 2003). Astroviruses are not favored for recovery in environmental samples using common cell lines and no human dose-response data exist. No waterborne disease outbreaks have been identified for Astrovirus in the United States. The benefits from avoiding astrovirus illness via the GWR can only be qualitatively be described.

Reovirus

Reovirus is recovered in environmental samples using the BGM cell line and is commonly found co-occurring with the enteroviruses in PWS wells. Carducci et al (2002) found that, in some cases, enterovirus detection was limited because reovirus reproduction was so highly favored. Reovirus is more closely related to rotavirus and thus has some similar characteristics. Unlike rotavirus, reovirus rarely

causes disease but it is now recognized as a human pathogen in children (Tyler et al, 2004). Although reovirus is probably not a significant component of the total disease burden, it is important because it likely reduces the enterovirus recovery efficiency[17], which is typically not greater than 50 percent under optimal conditions. No waterborne disease outbreaks have been identified for Reovirus in the United States.

5.4.2 Decreased Incidence of Other Illness Caused by Type B Viruses

Other Type B viral diseases, such as diabetes or cardiomyopathy, may lead to chronic disease. Because the causal relationship is not well established and the number of cases associated with drinking water is unknown, the Agency was not able to quantify benefits from the GWR on reducing chronic diseases. While this EA does not quantify in dollar terms the benefit of avoiding chronic illness, this section discusses the potential benefits qualitatively and illustrates the significance of these secondary benefits.

The total number of people with two types of chronic illnesses, diabetes and heart disease in the United States is substantial. Between 1990-92, there was an annual average of seven million people with diabetes (all kinds) and four million people with chronic heart disease (including myocarditis and cardiomyopathy) (Collins, 1997). Additionally, 3.5 percent of heart disease deaths in 1993 were due to cardiomyopathy (NHLBI, 1996). The potential benefits of avoiding some of these health effects cannot be overlooked, and may be significant.

An extensive literature review proved that costs of a single case of diabetes or heart disease are significant. Cost estimates for a case of diabetes and a case of chronic myocarditis (using the cost per case of an "average case of heart disease" as a proxy for chronic myocarditis) are presented below to demonstrate the magnitude of potential benefits per avoided case of chronic illness. Potential implications of diabetes, myocarditis, and cardiomyopathy through consumption of ground water are briefly discussed below.

Diabetes

There is considerable information that Type 1 diabetes may be associated with enterovirus infection, including infection with coxsackievirus and echoviruses (Maria et al. 2005; Vreugdenhil et al, 2000). Epidemiological studies have shown a strong correlation between diabetes and enterovirus infection. Individual case studies have reported diabetes development after enterovirus infection (Roivainen, 1998). A mechanism for producing disease suggests that entervirus infection triggers autoimmunity response. While these data are suggestive, they are not definitive. Recently, Maria et al (2005) reported simultaneous (on the same day) diabetes onset in mother and son coincident with enteroviral infection. With these data, it is now clear that at least some Type 1 diabetes cases result from enterovirus infection. The GWR EA considered the severe acute illnesses resulting from enterovirus infection in quantitatively determining the benefits (illnesses avoided), but only considers qualitatively

[17]The presence of reovirus in environmental samples complicates the recovery, or detection and quantification, of enteroviruses. Additionally, reovirus rarely results in illness. Therefore, reovirus occurrence can cause underestimates of enteroviral occurrence, and can elevate viral concentrations without adding to the disease burden associated with a contaminated water source. Hence, it can result in an underestimate of the quantified benefits that accrue from the GWR.

the diabetes cases avoided as a result of corrective actions performed due to enterovirus contamination of PWS wells.

The most comprehensive work regarding the economic burden of diabetes (both Type I and Type II) in the United States was conducted for the American Diabetes Association. In their report "Economic Consequences of Diabetes Mellitus in the United States in 1997," Fox et al. (1998) presented the direct medical and indirect costs attributable to diabetes, as well as a total and per capita estimate of expenditures of people with and without diabetes. Improving on their estimates and methodology from their 1992 effort (Fox et al., 1993), this national prevalence-based COI study also compares the health care expenditures of diabetics in 1997 to nondiabetics.

The authors created a holistic estimate of the health care expenditures attributable to diabetes in 1997 by including: 1) medical expenditures attributable to diabetes (i.e., the cost due to the excess prevalence of diabetes related chronic complications and general medical conditions in people with diabetes), and 2) total medical expenditures incurred among people with diabetes (i.e., the cost for all services for people with diabetes). Annual per capita expenditure estimates were also calculated and defined as the sum of the expenditures for diabetics in 1997, divided by the 1997 diabetic population. The estimates do not, however, include pain and suffering nor do they include lost productive and leisure time.

The per capita annual medical expenditures for people with diabetes was $13,092 for people with diabetes versus $3,470 among people without diabetes. Therefore, the annual cost of diabetic care is $9,622 per person.[18] The annual net productivity loss for each person due to diabetes totaled $1,650 for 18–64 year olds and $528 for those 65 and older.[19] These are sums of costs attributable to diabetes from productivity loss from work, from restricted-activity and from bed-disability.

According to the 1980–1987 Hospital Cost and Utilization Project (HCUP), a national sample of more than 500 hospitals that represent an unweighted 20 percent sample of discharges, the mean age of diagnosis for a case of diabetes mellitus within the study was 53 (Elixhauser et al., 1993). Assuming that a patient incurs treatment for diabetes each year throughout the duration of his expected life from age 53 (29.6 years)[20], the present value estimate of the direct medical costs and indirect costs of illnesses would be $227,032 using a 3 percent discount rate and $143,733 using a 7 percent discount rate. This figure could be even greater if the cost of premature death or pain and suffering were incorporated. While this is a simple approximation of the magnitude of a COI value for this illness, it captures the lifetime costs of diabetes in those who survive the first year through their life expectancy period from the age of diagnosis.

[18] Costs updated from January 1995 dollars to 2003 (annual) dollars using the CPI-U for "medical care services" (= 278.8 ÷ 219.8 = 1.3).

[19] Costs updated from January 1997 dollars to 2003 (annual) dollars using the CPI-U for "all items" (= 177.1 ÷ 159.1 = 1.1).

[20] *Life Tables*. Table 6–3. "Expectation of Life at Single Years of Age, by Race and Sex: United States, 1995." (NCHS, 1998).

Myocarditis and Dilated Cardiomyopathy

Viral infection of the heart is relatively common and usually of little consequence (Kearney et al., 2001). However, virus infection can lead to substantial cardiac damage and severe acute heart failure and can also evolve into chronic heart failure (Kearney et al, 2001). Viral infection is the most common cause of myocarditis. Viruses for which ground water is one possible route of exposure such as Coxsackie A and B virus, echovirus and adenovirus can cause myocarditis (Kim et al, 2001; Magnani and Dec, 2006; Huhn et al. 2005) with Coxsackie B virus the most often (of all viruses) associated with myocarditis (Kearney et al. 2001). In addition to myocarditis, epidemiological studies from Finland have documented an association between enterovirus infection and heart attacks (myocardial infarction) in men with no prior evidence of heart disease (Reunanen et al, 2002).

Mean age of patients with active myocarditis is 42 years (Kearney et al., 2001). Sixty percent of myocarditis patients had antecedent symptoms indicative of recent infection (Kearney et al. 2001). Myocarditis accounted for 22% of sudden unexpected death under age 30 and 11% of those between 30 and 40. Mortality is 20% at one year and 56% at four years (unless transplant occurs) (Kearney et al, 2001) largely due to chronic heart failure (dilated cardiomyopathy).

Myocarditis is included in the quantified benefits as a severe illness that can be caused by echovirus and other enterovirus infection. However, myocarditis can lead to chronic heart disease (dilated cardiomyopathy) which, like all chronic disease sequelae, are not quantified in the EA benefits. Myocarditis is a common cause of dilated cardiomyopathy, which in developed countries is the underlying etiology in about 45% of patients undergoing heart transplants (Kearney et al. 2001). The EA underestimates the benefits associated with preventing acute viral heart infections by coxsackievirus (and adenovirus) because it focuses primarily on echovirus disease endpoints. Also and perhaps most importantly, the EA quantifies only severe acute cases due myocarditis and neglects the chronic disease sequelae associated with all enteroviral heart infections.

The annual direct COI associated with an "average case of heart disease" is estimated to be $5,129[21]. This estimate is derived from data originally computed by of the National Center for Health Statistics (NCHS) for "heart disease" (which includes International Class of Diseases, 9th Revision (ICD–9) codes 391–398, 402, 404, 410–416, 420–429)(Hodgson, 1984; Hodgson, 1998). Since no specific cost data were available for chronic myocarditis, or cardiomyopathy (ICD–9 code 425), annual

[21] Cost updated from January 1995 dollars to 2003 (annual) dollars using the CPI-U for "medical care services" (= 278.8 ÷ 219.8 = 1.3).

per capita costs for an "average case of heart disease" were computed using data on "heart disease" in conjunction with prevalence numbers from the 1995 National Health Interview Survey.[22,23]

Indirect costs of "other heart disease" were estimated by Cropper and Krupnick (1990) who used information from the 1978 Social Security Survey of Disabled and Work to model the effects of disease on labor participation and earnings. Cropper and Krupnick found that the annual indirect cost ranged from $3,447 to $7,074 depending on the age of the individual and the age of illness onset.[24] Again, it is important to note that these costs do not include pain and suffering.

According to the 1980–1987 HCUP study of 500 hospitals, the mean age of diagnosis for cardiomyopathy was 60 (Elixhauser et al., 1993). Using this diagnostic category as a proxy for chronic myocarditis,[25] the lifetime COI could be substantial. For example, the present value of both direct and indirect costs for a patient with the condition would be $61,117 given an average life expectancy of 21.1 years (7 percent discount rate). This figure could be even greater if the costs of lost earnings and of premature death were incorporated.

Flaccid Paralysis

Flaccid paralysis is a rare but severe consequence of enterovirus infection. Flaccid paralysis occurs most commonly upon poliovirus infection (about 1 in 200 infections) but vaccination has eliminated almost all poliovirus cases. However there is no vaccine to prevent flaccid paralysis from echovirus, coxsackievirus or enterovirus 70 and 71 (Grimwood et al, 2003; Rotbart, 1995) infection. Flaccid paralysis is more likely with echovirus than coxsackievirus but rare. For example, no flaccid paralysis cases occurred as the result of an echovirus 18 outbreak in 2001 in 29 cases of viral meningitis from (surface) drinking water at an Alaska camp (McLaughlin et al, 2004). In an echovirus 33 outbreak in New Zealand in 2000, one healthy three-year old (of 75 infected persons) suffered flaccid paralysis (Grimwood et al, 2003); two infants died (Huang, et al. 2003). McMinn et al. 2001 report two cases of Guillain-Barre paralysis among 14 children neurologically ill from enterovirus 71 during a 1990 outbreak in Western Australia. For the period 1970-1979, CDC reports 58 paralysis cases due to enteroviruses with most cases due to echovirus (Moore, 1982). The EA does not explicitly include benefits associated with preventing flaccid paralysis because the disease is so infrequent.

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[22] Chronic illness prevalence rates (cases per 1,000 individuals) for "heart disease" were multiplied by the total U.S. population to obtain the total number of heart disease cases in 1995. The "average cost of heart disease" per person in 1995 was subsequently calculated by dividing the total cost of heart disease in 1995 by the total number of heart disease cases in 1995. Prevalence figures were from *Current Estimates of the National Health Interview Survey, 1995* (Benson and Marano, 1998), and the total U.S. population was obtained from the Census Bureau.

[23] Without more detailed information, this simplified method assumes that the cost of any heart disease, whether ischemic or other, would be the same within this major disease group. This is a major limitation of these estimates, as hospital costs for coronary heart disease may not be the same for hypertensive disease, for example.

[24] Costs updated from January 1977 dollars to 2003 (annual) dollars using the CPI-U for "all items: (= 177.1 ÷ 58.5 = 3.0).

[25] Costs updated from January 1977 dollars to 2003 (annual) dollars using the CPI-U for "all items: (= 177.1 ÷ 58.5 = 3.0).

5.4.3 Decreased Incidence of Bacterial Illness and Death

Although the EA does not quantify the benefits of bacterial illnesses that may be avoided by the GWR, EPA believes that these benefits could be substantial. EPA believes that if a fecal indicator occurs in a PWS well it demonstrates that a pathway exists for pathogens to travel from a fecal contaminant source to the well. Furthermore, if such a pathway exists, EPA believes it is only a matter of time before pathogens (viral or bacterial) excreted by infected animals or individuals reach the well. Such exposure might then cause illness among populations using undisinfected water from the well. There is a larger range for bacterial sources of contamination than sources of viral contamination because bacterial pathogens that also cause illness in humans can originate from animal reservoirs (infected livestock) whereas most viruses that cause illness in humans do not. Identifying and eliminating or treating such sources of contamination under the GWR will result in reduced exposure to bacterial pathogens and illness avoided. Bacterial contamination can occur in wells in both sensitive and non-sensitive aquifers. However, because the bacteria are larger than the viruses, they are less mobile in non-sensitive aquifers and are more likely to occur in wells in sensitive aquifers and in shallow wells in non-sensitive aquifers. The nonquantified benefits of bacterial illness avoided could be much larger than that predicted for viruses because the severity of some of the symptoms associated with bacterial illness are worse than some of the symptoms of viral illness. The following is a discussion of different bacterial pathogens found in ground water and their associated clinical symptoms if ingestion results in illness.

5.4.3.1 Bacterial Pathogen Occurrence

The bacterial pathogens can be divided into two groups; the frank pathogens such as *E. coli* O157:H7 and the opportunistic pathogens, such as Pseudomonas aeruginosa. The opportunistic bacterial pathogens found in drinking water have been well summarized by Rusin et al (1997) and will be discussed later when exposure scenarios other than contaminated source water are considered. This discussion will focus on the frank bacterial pathogens that are found in fecally contaminated ground water. Unlike the viral pathogens, the frank bacterial pathogens can be excreted by animals (typically birds and mammals) but some, such as *Helicobacter Pylori* and *Legionella pneumophila* are naturally present in ground water.

E. coli

The group of bacteria known as *E. coli* contain both pathogenic and non-pathogenic isolates. The most dangerous *E. coli* bacteria contain the gene for producing Shiga toxins. *E. coli* O157:H7 is the most widespread shiga-toxin producing *E. coli* but at least 81 serotypes have been identified (Prager et al, 2005). Release of toxins in the body can result in kidney failure, shock and death in otherwise healthy individuals, especially small children. Typically, kidney failure occurs in 2-7% of illnesses. Death or end-stage renal disease occurs in about 12% of patients four years after diarrhea-associated kidney failure (Garg et al, 2003). Twenty five percent of kidney failure survivors demonstrate long-term renal sequelae (Garg et al, 2003). For patients with moderate and severe gastroenteritis caused by *E. coli*, long-term study shows that they have an increased risk of hypertension and reduced kidney function (Garg et al. 2005). CDC estimates that drinking water is responsible for 15% of the 73,000 illnesses each year from *E. coli* O157:H7 in the United States (Rangel, 2005).

Ground water outbreaks due to *E. coli* O157:H7 are prominent because of the fatal outcomes associated with those outbreaks. In Walkerton, Ontario, 6 individuals died and 27 developed kidney

failure from ground water contaminated with *E. coli* O157:H7 (and *Campylobacter* jejuni) (Health Canada, 2000). The aquifer was sensitive (karst) and fecal contamination often occurred. The outbreak coincided with a reduction in chlorination treatment coincident with a large fecal contamination event. In Washington County, NY, two individuals (including an otherwise healthy two year old child) died from *E. coli* O157:H7 contamination of a county fair water supply system. The aquifer was thin and shallow but not sensitive. (The fair ground's water supply system was not recognized as a PWS system because it was used for less than 60 days each year.) Four individuals died in Cabool, MO due to *E. coli* O157:H7 (Swerdlow et al, 1992). This aquifer was sensitive (karst) and multiple illnesses (above normal levels) occurred before a water main break so the outbreak was likely due to source water contamination. Another *E. coli* O157:H7 outbreak occurred in ground water in Minnesota but no kidney failures resulted.

Although manure is often considered to be the source of shiga-toxin producing *E. coli*, they have also been isolated from municipal sewage (Holler et al, 1999). *E. coli* O157:H7 was found to survive on a pasture surface for almost 4 months. About 4-15% of cases are acquired via secondary transmission (Parry and Salmon, 1998). In addition to the shiga-toxin producing *E. coli*, there are a substantial number of other pathogenic *E. coli* bacteria, mostly through production of other toxins. Hunter (2003) identifies 62 *E. coli* strains capable of causing diarrheal disease. Little data are available on the hazard associated with waterborne transmission for most of the pathogenic *E. coli* other than *E. coli* O157:H7.

Although *E. coli* is monitored in PWS wells via the Total Coliform Rule, the EPA-approved methods are not capable of identifying the shiga-toxin producing *E. coli*. Because *E. coli* are often found in ground water supplies and because low doses can result in infection and secondary transmission is significant, it is likely that disease due to *E. coli* is quite prevalent in association with PWS wells. Few data on pathogenic *E. coli* in PWS wells are available. Dose response data are limited to a single point value from a carefully documented outbreak in Japan. This point value suggests that the infectious dose is very low compared with most pathogenic bacteria. Because few data are available on the occurrence of pathogenic *E. coli* in PWS wells and dose response data are limited, the benefits of avoided illness and chronic sequelae from the GWR can only be qualitatively discussed.

Shigella

Shigella bacteria are distinct because they are often associated with bloody diarrhea (bacillary dysentery). The enterohemorraghic *E. coli* bacteria acquired the capability to produce toxins by exchanging plasmids with *Shigella*. Thus, *Shigella* often also cause kidney failure and chronic kidney disease. *Shigella* contamination only results from human fecal contamination and thus it is probably less common than *E. coli* contamination, which has both human and animal sources. *Shigella* are one of the most easily recognized causes of waterborne disease outbreaks because the advent of bloody diarrhea spurs detailed investigations and often a cause is identified, even though *Shigella* are difficult to cultivate. One large ground water outbreak in a sensitive aquifer occurred recently in Island Park, Idaho due, perhaps, to an unidentified broken sewer line contaminating the well water (CDC, 1996). Because *Shigella* is associated only with human feces, there is little incentive to look for *Shigella* as compared with all the other bacterial pathogens that have both human and animal sources. As a result, no data are available on occurrence although limited dose response data are available. EPA is unable to quantify the benefits from avoided *Shigella* illness because no occurrence data are available.

Campylobacter and Arcobacter

Campylobacter (like *Salmonella*) are very common contaminants of food and water. *Campylobacter* is commonly associated with animal manure, especially cow and chicken manure. *Campylobacter* and *Salmonella* are associated with many common source (food or water) exposure deaths, probably in large part because there are a large number of illnesses. More deaths may be associated with *Campylobacter* and *Salmonella* than with viruses. Uniquely, *Campylobacter* is often associated with Guillain-Barre paralysis that can last for weeks or months. About 1 paralysis case occurs for every 1000 cases of campylobacteriosis (Altekruse et al, 1999). About 20% of paralysis patients are left with some disability and approximately 5% die. Campylobacterosis is also associated with Reiter syndrome (reactive arthritis). Approximately 1% of patients with camplybacterosis have arthritis onset in one or more joints (especially the knee) in the 7 to 10 days after diarrheal onset (Altekruse et al. 1999).

The *E. coli* O157:H7 ground water outbreak in Walkerton, Ontario was also a large outbreak of campylobacterosis. *Arcobacter* (now a separate genus from *Campylobacter*) was responsible for a ground water outbreak at a camp in Coeur d'Alene, Idaho (McMillan, 1996). The sensitive aquifer was contaminated by a septic tank. *Campylobacter* were associated with the recent outbreak in South Bass Island, Ohio due to widespread fecal contamination in a sensitive aquifer (Ohio EPA, 2005). Like all bacterial pathogens, special enrichment methods are needed to identify *Campylobacter* and *Arcobacter* in environmental samples and so no data are available on the occurrence of these ubiquitous pathogens in PWS well water. *Campylobacter*, like *Vibrio* has a viable but non-culturable environmental form which makes it difficult to detect at times in water (Rollins and Colwell, 1986; Koenraad et al., 1997). Limited dose-response data are available for Camplybacter (but not for *Arcobacter*). Because no occurrence data are available, EPA is unable to quantify the benefits associated with avoided camplybacterosis (and arcobacterosis) and their chronic sequelae (Guillane-Barre paralysis and reactive arthritis).

Salmonella

Salmonella causes typhoid fever, once a common and dangerous waterborne disease. Typhoid is no longer a problem in the United States, and in recent years, *Salmonella* has become increasingly less common as a common source outbreak agent while campylobacterosis outbreaks have correspondingly increased. The reasons for this change are unclear. *Salmonella* was identified in most fecally contaminated PWS wells during the South Bass Island, OH outbreak in 2004 (Ohio EPA, 2005). The main problems associated with *Salmonella* result from scenarios other than fecal source water contamination. For example, the seven deaths that occurred due to *Salmonella* contamination in a ground water PWS system in Gideon, Missouri were due to bird entry into a storage tank (Angulo et al., 1997). *Salmonella* resulted in a very large outbreak in a ground water utility in Riverside, California during the 1960s (16,000 illnesses, 70 hospitalizations and 3 deaths) prior to the advent of the Total Coliform Rule (Boring et al., 1971). This issue will be discussed further below. Limited dose-response data are available for *Salmonella* but no occurrence data. The GWR EA provides nonquantified benefits resulting from corrective actions such as disinfection that would mitigate against salmonellosis resulting from animal entry into the distribution system or *Salmonella* contamination of PWS wells in general.

Legionella

Legionella are opportunistic bacterial pathogens that colonize water distributions systems. An estimated 8,000-10,000 cases of Legionaires disease and Pontiac fever occur in the U.S. each year due to *Legionella*. Twenty-one of 48 known species are able to infect humans. A study of 46 PWS wells from

16 water utilities in the United States and Canada showed that 38 wells (82%) were positive for *Legionella*. Also, 33% of 114 PWS well samples were positive for *Legionella*. About half the identified *Legionella* species were pathogenic forms. The authors conclude that this is the "first study that has unambiguously proven that *Legionella* constitute a part of the microflora of ground water not known to be under the direct influence of surface waters" (Riffard et al., 2004). EPA calculates benefits associated with fecal contamination. However, *Legionella* are present in ground water in the absence of fecal contamination and constitute a potential disease hazard if the bacterium is inhaled during showering. Although nationally representative *Legionella* occurrence data are available for ground water, the methods used are not typical or standardized. Also, no dose-response data exist so it is not possible to quantify the disease burden from ground water exposure. If disinfection is required as a corrective action, it will minimize the *Legionella* contamination of the distribution system. However, the GWR EA only qualitatively accounts for the avoided illnesses from *Legionella* inhalation.

5.4.3.2 Estimate of Potentially Avoided Bacterial Caused Deaths by GWR

The quantified benefits in the EA predicts that among the 27% of the wells having sometime fecal contamination about 34% (of the 27%) of these wells will be identified by triggered monitoring and be required to take remedial action. The subsets of wells that fall into this category include 1) wells predicted to have both viral and *E. coli* presence and identified by indicator monitoring (about 2/3 of the 27%) and 2) wells predicted to have *E. coli* presence but no viral presence and identified by indicator monitoring (about 1/3 of the 27%). The quantified benefits model only addresses avoiding viral illness in the first of these categories.

Although EPA did not formally quantify the benefits of avoided bacterial illness, EPA developed a rough estimate of the potential deaths that might be prevented by reduced exposure to bacterial pathogens under the GWR (to supplement the quantified benefits from virus exposure). The following analytical steps were taken to generate such an estimate.

1) Estimate potential bacterial illnesses avoided

Analysis of outbreak data from 1991 through 2000, shows a total of 2,346 bacterial illnesses compared to 1,806 viral illnesses and 4,523 illnesses of unknown etiology (see Exhibit 2.3) in section 2.2.1, compiled from CDC 1993, Kramer et al., 1996, Levy et al., 1998, Barwick et al., 2000, and Lee et al., 2002). If the illnesses of unknown etiology are assumed to be viral[26], then a total of 6,329 waterborne viral illnesses would be associated with the waterborne outbreaks. The ratio of bacterial waterborne illness to viral waterborne illness in outbreaks is therefore 0.37:1.

If we assume that this ratio of bacterial to viral waterborne illness also pertains to the relative rate of endemic bacterial and viral illness prevented due to the GWR, then for every viral illness avoided under the GWR we will also avoid an additional 0.37 of bacterial illness; i.e., relative to the quantified cases of viral disease avoided, we would avoid 16,805 bacterial illnesses per year (41,868 predicted viral illnesses avoided per year x 0.37 = 15,491).

[26]Because viral illnesses are generally more difficult to identify than bacterial illnesses, all illnesses with unidentified causes were considered to be viral illnesses. This assumption most likely leads to an underestimate of the ratio of bacterial to viral illness associated with reported outbreaks.

It is possible that the ratio of bacterial to viral endemic illness due to ground water is lower than 0.37:1 because the likelihood of detecting an outbreak due to bacterial illness may be greater than that of detecting a viral outbreak[27]. However, any potential overestimate is likely to be compensated by the assumption that all cases of outbreak illness of unknown etiology are viral. EPA recognizes that the extrapolation from the ratio of outbreak etiology to the ratio of endemic illness etiology remains a major uncertainty in this analysis and that the impacts of the two opposing biases on the extrapolated estimate is unknown.

2) Estimate a mortality rate for waterborne bacterial illness

The approach taken for this step was to a) recognize the types and distribution of bacterial illness associated with waterborne disease, b) characterize mortality rates for the different types of bacterial illness identified in "a", and c) estimate a composite mortality rate considering "a" and "b".

For a), EPA used the same waterborne disease outbreak information from Exhibit 2.3, cited above, to inform the types and distribution of bacterial illness in ground water systems.

For b), EPA used data from Mead et al (1999) (Table 3) to estimate mortality rates for each type of bacterial illness identified in waterborne disease outbreaks in ground water systems (from Exhibit 2.3). While Table 3 in Mead et al. (1999) provides estimates for illnesses, hospitalizations and deaths caused by foodborne pathogens for specific bacterial agents, some of these agents have also been recognized as causing waterborne disease (namely *E. coli* O157:H7, *Salmonella* non-typhoidal, *Salmonella typhi*, *Shigella*, and *Campylobacter* spp). Therefore, EPA considers it appropriate to apply the calculated mortality rates from Mead et al. (1999) to the same bacterial pathogens identified in waterborne disease outbreaks. These mortality rates estimated from Mead ranged from 3.64 per 1,000 illnesses for *Salmonella typhi* to 0.055 per 1,000 illnesses for *Campylobacter* spp. Fatality rates of other illnesses caused by potentially waterborne bacterial pathogens included 0.83 per 1,000 illnesses for *E. coli* O157, 0.41 per 1000 for *Salmonella* non-typhoidal, and 0.16 per 1,000 for *Shigella*, and 2.54 for *Vibrio* the least frequently reported ground water associated waterborne bacterial illness.

For c), EPA applied the above case fatality rates, calculated from Mead et al. (1999), to the illness case rate reported in Exhibit 2.3, for each of these bacterial illnesses. EPA then calculated a weighted average mortality rate for waterborne bacterial illness of 0.64 deaths per 1000 illnesses (see Exhibit 5.25). In using mortality rates associated with foodborne illness, EPA assumes that differences in exposure scenarios do not lead to differences in illness manifestation.

EPA thinks that the above estimate is not unreasonable because the spread among the mortality rates of the different bacteria in Exhibit 5.25 is relatively small and therefore, giving a different weight (e.g. based on additional information) to one particular agent over another would not significantly change the estimate. The four most influential pathogens (*Shigella*, *Campylobacter spp.*, *E. coli* O157, *Salmonella* (non-typhoidal) in the weighted average had a relatively small difference in their case fatality rate. The illness with the lowest case fatality rate, *Vibrio*, had a very small reported incidence of waterborne disease associated with it.

[27]Bacterial illnesses are more likely to be diagnosed than viral illnesses because of their severity. However, most cases of diarrhea associated with outbreaks are not identified by etiology and identifying etiology is unnecessary in order to identify an outbreak.

With regard to *E. coli*, EPA only considered O157 in the mortality rate estimate because most of the pathogenic *E. coli* in reported waterborne disease outbreaks were identified as O157. The Mead paper reports two O157 strains with essentially the same case fatality rate and two other *E. coli* strains that are not associated with mortality. Any *E. coli* o157 before 1993 would probably not have been identified as such since it was only recognized as a pathogen in 1982 and more broadly recognized only in 1993 after a multi-state foodborne *E. coli* outbreak (Rangel et al., 2005). However, it is probable that all four strains cause sporadic cases or even unidentified outbreaks of waterborne disease. If all four strains were included in the calculation of mortality rate for pathogenic *E. coli* and weighted equally, the case fatality rate for all pathogenic *E. coli* would have dropped by approximately 50% and the composite mortality rate factor, calculated in Exhibit 5.25, would have dropped by approximately 15%.

3) Estimate potential annual bacterial deaths avoided by the GWR

EPA multiplied the composite mortality rate from (2) above (6.41×10^{-4}) by the estimated annual bacterial illnesses avoided in (1) (15,491) to estimate 10 potential deaths avoided per year. The assumptions underlying these calculations are dependent on a variety of judgements. Other assumptions are equally likely. EPA believes this calculation provides a plausible estimate of potential additional deaths avoided from exposure to bacteria in GWSs.

Exhibit 5.25 Estimated Bacterial Illnesses and Deaths Avoided

Pathogen	Illnesses (thousands)	Hospitalizations	Hospitalizations/1000 cases of illness	Cases of illness in WBDO	Fraction of WBDO illness	WBD illness hospitalizations/ 1000 cases
	A	B	C = B/A	D	E = D/Total D	F = (C/1000) * E
Campylobacter spp	2,454.0	13,174	5.37	223	0.095	5.10E-04
E. coli O157 *	73.5	2,168	29.50	807	0.344	1.01E-02
Salmonella typhi	0.8	618	750.00	124	0.053	3.96E-02
Salmonell non-typhoidal	1,412.0	16,430	11.64	625	0.266	3.10E-03
Shigella	448.0	6,231	13.91	556	0.237	3.30E-03
Vibrio other	7.9	99	12.56	11	0.005	5.89E-05
			WBDO Total Cases:	2,346	Composite case hospitalization rate:	5.68E-02

* EPA assumed that E. coli O157 represents pathogenic *E. coli* identified in drinking water because it was the *E. coli* strain identified as the etiologic agent responsible all of the pathogenic *E. coli* related ground water outbreaks. Other strains of pathogenic *E. coli* also cause waterborne illness; however, they have not been identified as the etiologic agent of a ground water associated disease outbreak in the CDC waterborne outbreak surveillance reports referenced in Exhibit 2.3.

** *vibrio* (other): i.e., not *V. cholerae* or *vulnificus*

Note: Estimated Total number of hospitalizations due to bacterial illness = estimated number of cases (15,491) x Bacterial Composite Case Hospitalization Rate (15,491x 0.0568 = 880 hospitalizations/year).

Source:

(A) Data of pathogen specific illnesses from Table 3 in Mead paper.

(B) Data of pathogen specific deaths from Table 3 in Mead paper.

(D) Cases of illness from CDC outbreak surveillance reports in Exhibit 2.3. "Etiology of Waterborne Outbreaks in Ground Water Systems, 1991 - 2000," (Kramer et al., 1996; Levy et al., 1998; Barwick et al., 2000; and Lee et al., 2002).

5.4.3.3 Estimate of a Hospitalization Rate for Waterborne Bacterial Illness

EPA used the same approach for estimating potential hospitalizations avoided by a reduction in the incidence of bacterial illness, as it did for estimating potential deaths avoided. In order to estimate a hospitalization rate due to waterborne bacterial illnesses, a composite hospitalization rate was developed that represents the hospitalization rate for all waterborne bacterial pathogens adjusted by the frequency of their occurrence as the etiologic agent in WBDOs. The data presented in Mead et al. (1999) represent bacterial illnesses and hospitalizations due to all different exposures, e.g. food, person to person spread, waterborne. By using information on the relative frequency of illness caused by different waterborne pathogens under outbreak conditions we have developed a weighting scheme specific for considering waterborne illness health effects and associated burden (hospitalization).

Exhibit 5.26 below presents the data used in the calculations and the results of the calculations described as follows: The hospitalization rates (in column 4) were calculated from the cases of illness due to all causes (column 2) and the number of hospitalizations (column 3) from Table 3 of Mead P.S. et al, (1999). In order to develop the composite waterborne bacterial hospitalization rate, the etiologic fraction was calculated by dividing cases of illness of a specific etiology from WBDOs by the total number of WBDO cases of illness. An occurrence weighted hospitalization rate is calculated by multiplying the etiologic fraction of WBDO cases (column 6) by the etiologic agent's hospitalization rate (column 4). Lastly, the composite bacterial hospitalization rate is calculated by summing the weighted rates in column 7. The result is an integrated, or composite bacterial hospitalization rate of 57 hospitalizations/ 1000 cases of waterborne bacterial illness.

EPA estimated the potential hospitalizations avoided (from reduced bacterial illness) by multiplying the estimate for bacterial illness avoided (15,491) by the composite bacterial hospitalization rate of 57/1000 cases of illness to indicate 880 annual potential hospitalizations. If the average bacterial hospitalization cost is assumed to be greater than the Type B viral illness adult hospitalization cost used in the quantified benefits section ($5,000 - see Exhibit 5.22 E), then the benefits of preventing bacterial illness would be $4.4 million or more.

Exhibit 5.26 Waterborne Bacterial Illness Hospitalization Rates

Pathogen	Illnesses (thousands)	Hospitalizations	Hospitalizations/1000 cases of illness	Cases of illness in WBDO	Fraction of WBDO illness	WBD illness hospitalizations/ 1000 cases
	A	B	C = B/A	D	E = D/Total D	F = (C/1000) * E
Campylobacter spp	2,454.0	13,174	5.37	223	0.095	5.10E-04
E. coli O157 *	73.5	2,168	29.50	807	0.344	1.01E-02
Salmonella typhi	0.8	618	750.00	124	0.053	3.96E-02
Salmonell non-typhoidal	1,412.0	16,430	11.64	625	0.266	3.10E-03
Shigella	448.0	6,231	13.91	556	0.237	3.30E-03
Vibrio other	7.9	99	12.56	11	0.005	5.89E-05
			WBDO Total Cases:	2,346	Composite case hospitalization rate:	5.68E-02

* EPA assumed that E. coli O157 represents pathogenic *E. coli* identified in drinking water because it was the *E. coli* strain identified as the etiologic agent responsible all of the pathogenic *E. coli* related ground water outbreaks. Other strains of pathogenic *E. coli* also cause waterborne illness; however, they have not been identified as the etiologic agent of a ground water associated disease outbreak in the CDC waterborne outbreak surveillance reports referenced in Exhibit 2.3.

** *vibrio* (other): i.e., not *V. cholerae* or *vulnificus*

Note: Estimated Total number of hospitalizations due to bacterial illness = estimated number of cases (16,805) x Bacterial Composite Case Hospitalization Rate (15,491x 0.0568 = 880 hospitalizations/year).

Source:

(A) Data of pathogen specific illnesses from Table 3 in Mead paper.

(B) Data of pathogen specific deaths from Table 3 in Mead paper.

(D) Cases of illness from CDC outbreak surveillance reports in Exhibit 2.3. "Etiology of Waterborne Outbreaks in Ground Water Systems, 1991 - 2000," (Kramer et al., 1996; Levy et al., 1998; Barwick et al., 2000; and Lee et al., 2002).

Summary of Nonquantified Benefits for Bacterial Illness Avoided

EPA estimated that the total benefits could increase by a factor of five by only accounting for additional deaths and hospitalizations caused by bacterial illness being avoided. The actual number of hospitalizations and deaths avoided could be higher or lower. Within the context of best available science, given all the other nonquantified benefits for chronic bacterial illnesses avoided, EPA believes that the total nonquantified benefits for bacteria could exceed a factor of four relative to the quantified benefits for viruses. If a value of $7.5 million is assumed for each death avoided (see Section 5.3.1.2), then the value of bacterial deaths avoided each year would be approximately $75 million (year 2003 dollars). If a value of $5,000 is assumed for each hospitalization avoided (see Exhibit 5.22e), then the value of bacterial hospitalizations avoided each year would be approximately $4.4 million (year 2003 dollars). Taken together, these additional benefits would result in benefits that are five times the quantified benefits for viruses (four times quantified benefits plus quantified benefits) [i.e., (75 + 4.4+ 19.7)/19.7 = 5].

5.4.4 Other Chronic and Acute Illness Potentially Avoided

As discussed in Section 5.1, the GWR EA quantifies only a small subset of the total benefits. Only acute illnesses arising from Type A virus represented by rotavirus data and Type B virus represented by enterovirus data are quantified. Acute illnesses from other viral etiologies and from bacterial infection are not quantified. Also, chronic illnesses resulting from either viral or bacterial illness are not quantified. This section addresses some of the chronic disease endpoints that are not quantified in this EA and are only qualitatively assessed.

Hypertension and Reduced Kidney Function

As a result of the large number of illnesses, hospitalizations and deaths due to *E. coli* O157:H7 and *Camplybacter* contamination at Walkerton, Ontario, a long term study was undertaken to evaluate chronic sequelae (Garg et al, 2005). This is the largest and longest study ever of chronic sequella after ground water exposure. After a mean follow-up of 3.7 years after the outbreak, patients with moderate and severe gastroenteritis had an adjusted relative risk of hypertension of 1.15 (0.97-1.35) and 1.28 (1.04-1.56) respectively. A similar association was seen for reduced kidney function. The authors (Garg et al., 2005) conclude:

> *"Adults with symptomatic bacterial gastroenteritis from drinking contaminated water were more likely than asymptomatic adults to have newly diagnosed hypertension and reduced renal function during the follow-up period of almost 4 years after infection."*

This new finding documents that an acute self-limiting bacterial gastroenteritis is likely to be followed by hypertension and reduced kidney function in a significant subset of individuals. As discussed in Section 5.4.3.1, bacterial gastroenteritis is a frequent occurrence in the U.S. resulting from both epidemic and endemic exposure. It is likely that a similar study of endemic acute self-limiting bacterial gastroenteritis would also document increased likelihood of these two chronic disease sequelae.

The GWR EA quantifies only acute illnesses resulting from some virus infection. The EA does not quantify acute bacterial disease, including acute self-limiting bacterial gastroenteritis. The EA also does not quantify the chronic disease sequelae such as hypertension and reduced renal function that can

arise from acute illness. Because bacterial disease and their chronic sequelae are considered only qualitatively, the GWR EA underestimates the benefits associated with bacterial illness.

Helicobacter pylori

Helicobacter pylori is often associated with ground water (Hegarty et al. 1999; Rolle-Kampzczyk et al, 2004) and is known to cause gastric ulcers. However, *Helicobacter* is not culturable and so occurrence data from ground water are fairly uncertain. Improved hygiene and water treatment have together reduced the number of ulcers caused by this organism over the last few decades but it is impossible to quantify that decrease. Nevertheless, corrective action and especially disinfection resulting from the GWR will likely provide a reduction in the number of intestinal colonizations by *Helicobacter pylori* and a corresponding decrease in gastric ulcers. The GWR EA does not quantify the benefits associated with avoiding bacterial disease. Because chronic infection by *Helicobacter pylori* can lead to gastric ulcers, there are significant health effects potentially avoided due to *Helicobacter pylori* infection that are considered in this EA only qualitatively.

Reactive Arthritis, Irritable Bowel Syndrome and Persistent Diarrhea

A recent study (Rees, et al, 2004) evaluated the chronic sequelae resulting from enteric infection identified but the California FoodNet Surveillance. Eight percent of respondents reported new joint pain after infection and 35% reported new gastrointestinal symptoms including persistent diarrhea and irritable bowel syndrome. Reiter's Disease is form of reactive arthritis which, as discussed in the section describing the nonquantified benefits associated with *Campylobacter*, is often associated with *Campylobacter* infection.

Primary Amoebic Meningioencephalitis (PAM)

In 2003, two five-year old boys living in the same water service area near Phoenix AZ died in the same week from Primary Amoebic Meningioencephalitis (PAM) (Marciano-Cabral et al, 2003). Both boys lived in homes supplied by untreated PWS wells. Atypically, the wells in that area provide water at elevated temperatures, representing the elevated geothermal gradient in the subsurface. Seventeen samples taken from the boys homes were positive for *Naegleria fowleri* and *N. fowleri* was also responsible for the boy's deaths from PAM. It is likely that the heated ground water provided a suitable habitat for *N. fowleri* colonization and growth either in the aquifer, the well, the distribution system or the household plumbing. *N. fowleri* is effectively treated with disinfection or chlorination. The final GWR may require systems with elevated ground water temperature to take corrective action such as disinfection if, for example, the elevated temperature is noted in a sanitary survey. However, EPA is unable to quantify the number of PAM cases that would be avoided in the future, so the benefits are presented only qualitatively.

Cryptosporidium and Giardia

Cryptosporidium and *Giardia* are associated with surface water rather than ground water PWS systems. If *Cryptosporidium* or *Giardia* are recognized in well water, the system should be considered as a surface water system (ground water under the direct influence of surface water [GWUDI]) rather than as a ground water system. As a GWUDI system, these wells are regulated by the Long Term 2 Surface Water Treatment Rule and not by the GWR. However, on several occasions, PWS wells were regulated as if they were ground water rather than as surface water until a cryptosporidiosis or *Giardiasis* outbreak

was recognized. Examples of Cryptosporidiosis outbreaks associated with ground water wells (not recognized as GWUDI wells) located in sensitive aquifers includes outbreaks in Braun Station, TX (D'Antonio et al, 1985), Reading, PA (Moore et al, 1993), Brushy Creek, TX (Lee et al., 2001) and Yakima, WA (Dworkin et al, 1996). The sanitary survey and hydrological sensitivity assessments under the GWR rule may identify some systems as being under the direct influence of surface water and thereby make such systems subject to surface water treatment technique requirements and avoid potential outbreaks. Such actions would result in both increased costs and benefits for such systems.

5.4.5 Reduction in Outbreak Risk and Response Costs

Besides reducing the endemic risk of illnesses from waterborne pathogens, the GWR will reduce the likelihood of major outbreaks from occurring. These avoided illnesses and other costs are not estimated or included in the GWR benefits estimates and would be difficult to quantify. The economic value of reducing the risk of outbreaks could be quite high when the magnitude of potential costs is considered. Other types of costs associated with outbreaks include spending by local, State, and national public health agencies; emergency corrective actions by utilities; and possible legal costs if liability is a factor. Affected water systems and local governments may incur costs through provisions of alternative water supplies and issuing customer water use warnings and health alerts. Commercial establishments (e.g., restaurants) and their customers may incur costs due to interrupted and lost service. Local businesses, institutions, and households may incur costs associated with undertaking averting and defensive actions. Cost-benefit analyses of large engineering works typically include probabilistic failure assessment to determine the likely benefits of avoiding catastrophic effects. Such analyses are not included in the EA quantified or nonquantified benefits because there are too many likely failure scenarios. Thus, to the extent that GWR reduces the likelihood of waterborne disease outbreaks, avoided response costs are potentially numerous and significant.

During outbreaks, consumers and businesses may use alternative water sources or practice behaviors to reduce risk, such as boiling water. If the rule reduces the need for these averting behaviors, an economic benefit will accrue. To give a sense of the possible scale, the expenditures on averting behaviors during an outbreak of *Giardiasis*, such as hauling in safe water, boiling water, and purchasing bottled water, were estimated at between $3.10 to $9.80 per person per day (year 2003 dollars) during the outbreak (Harrington et al., 1991). If these figures are applied to even a small drinking water system serving 10,000 customers, total expenditures on averting behavior during a waterborne disease outbreak could range between $31,000 and $98,000 per day. Determining the precise reduction in outbreak risk and the resulting benefits due to reduced or avoided averting behavior is not possible given current information, but potential benefits are expected to be substantial.

Five studies were identified that used the averting cost approach to estimate household and other costs attributable to short-term contamination of drinking water supplies (Abdalla, 1990; Abdalla et al., 1992; Harrington et al., 1991; Sun et al., 1992; Van Houtven et al., 1997). The most relevant of these for the GWR analysis is a study by Harrington et al. (1991), that analyzes the costs associated with drinking water contamination by *Giardia* in Luzerne County, Pennsylvania. The December 1983 outbreak resulted in 366 confirmed *Giardiasis* cases resulting from sewage leaking into the unfiltered source water. The total affected population was 75,000 individuals across Pittston Burough and 17 other municipalities. The Harrington study also developed a theoretical and empirical example of how outbreak costs are incurred, based on the Luzerne County example.

The four steps associated with a waterborne outbreak that may impose costs on society are discovery, survey and testing, reaction, and aftermath (Harrington et al., 1991). These are described below:

- **Discovery.** Health care providers or State, local, or hospital laboratory technicians send reports to State authorities notifying them of the need for further investigation when the rate of new cases suddenly increases above the normal rate.

- **Survey and testing.** A host of epidemiological surveys may be conducted, along with tests of the water supply, once a few cases are confirmed.

- **Reaction**. Local authorities and the water system may issue boil-water advisories, or other warnings to reduce exposure once a link is made between the drinking water supply and the disease outbreak. Businesses, as well as households, may be affected by such action, requiring government agencies to begin surveillance and enforcement activities and, in some cases, provide alternative water sources.

- **Aftermath.** This final step involves discussions of any long-term solutions to the problem, and how the costs of the outbreak and prevention of future ones may be shared. These discussions can only take place once the outbreak is contained by actions taken during the previous phase.

The Luzerne County outbreak resulted in losses due to actions taken by individuals to avoid the contaminated water that are estimated to be between $36.8 million and $109.4 million (year 2003 dollars). The predominant cost was time lost to boiling water. Losses due to averting actions for restaurants, bars, schools and other businesses during the outbreak exceeded $1.8 million. The burden for government agencies was $407,300 and the outbreak cost the water supply utility $3.2 million. These costs do not include legal fees, outbreak effects on businesses that were not investigated, leisure activities, or net losses due to substituting more expensive beverages for tap water. During a waterborne disease outbreak in Walkerton, Ontario (population 5,000), an analysis conservatively estimated the economic impact excluding medically related costs to be over $43 million in Canadian dollars (approximately $32 million in U.S. dollars) (year 2003 dollars) (Livernois, 2002).

5.4.6 Reduced Disinfection Treatment Failure Rates and Associated Waterborne Disease

Implementation of the GWR may lead to additional benefits from reductions in disinfection failures. Such benefits would stem from the increased oversight of treatment processes as part of compliance with regulatory requirements (e.g., during sanitary surveys and compliance monitoring, or with upgrades in disinfection to 4 log inactivation of viruses).

Direct data on the numbers of illnesses and deaths resulting from treatment failure are not available. However, these numbers could be substantial given that the relative rates outbreak related illness attributed to treatment deficiencies versus outbreak related illnesses attributed to source water deficiencies in untreated ground waters. Of the outbreak-related illnesses due to viral, bacterial, and unknown agents reported in GWSs during 1991–2000 (see Exhibit 4.31), 4,224 were attributable to drinking untreated ground water and 4,888 were attributable to a treatment deficiency.

EPA's baseline estimate among disinfected supplies assumes that all disinfected supplies are providing either 2 log or 4 log inactivation of viruses and does not account for occasional disinfection failures or upsets. Given this simplifying assumption, the baseline estimate for viral disease among disinfected supplies is about 2,500 cases, whereas the baseline risk for the undisinfected supplies is about 179,700 cases (approximately 1.4% of illnesses we estimate to occur in currently disinfecting wells). However, based on outbreak data, an additional 1.16 (4,888/4,224) outbreak-related illnesses occur in systems using disinfection with treatment failures for every outbreak-related illness in systems with untreated ground water. If this same ratio were to apply to endemic illness in disinfected versus undisinfected supplies, the baseline incidence of disease in disinfected supplies (taking disinfection failures into account) would be roughly 80 times higher than currently estimated, i.e., 1.16 x 179,700/2,500 additional illnesses per year. Even small percent reductions in disinfection failures or upsets resulting from this rule (e.g., 10%) could therefore lead to substantial reductions in baseline risk among disinfected supplies which is currently not accounted for in the quantified benefits.

As with the analysis of bacterial illnesses, there is no way of knowing whether the ratio of 1.16 is generally higher or lower for non-outbreak illnesses. It is possible, that outbreaks represent a larger or smaller portion of total cases for treatment deficiencies than for untreated ground water. Similarly, it is not possible to estimate with any degree of confidence the percent reduction in treatment failures that might result from this rule. In any case, benefits from reduced treatment are likely to result from this rule and would be additive to benefits estimates in the main analysis.

5.4.7 Distribution System Contamination

The GWR will lead to additional systems providing disinfection at the source and this will lead to some disinfectant residual provided in the distribution system. Opportunistic bacterial pathogens are soil and other environmental bacteria that can colonize distribution systems and typically are harbored and protected in distribution system biofilms where substantial bacterial population growth can occur. Periodic biofilm sloughing can introduce these pathogens into untreated ground water. Major groups of opportunistic bacterial include Pseudomonas, Acinetobacter, Xanthamonas, Moraxella, Mycobacterium and Serratia (Rusin et al. 1997 a, b). Each of these bacteria is capable of causing disease, typically pneumonia, meningitis and septicemia, but also other diseases, in sensitive subpopulations. Sensitive subpopulations are estimated to be 20% of the U.S. population (Gerba et al., 1996). Although sensitive subpopulations are often advised to drink only treated or bottled water, it is often difficult to know the water source for all exposures, especially water from transient systems. Corrective action, including disinfection can have substantial benefit in reducing exposure to opportunistic pathogens in untreated distribution systems. The GWR only qualitatively accounts for the benefits that might accrue for reduced exposure and illness among sensitive subpopulations due to opportunistic bacterial pathogens.

5.4.8 Benefits From the Reduction of Co-Occurring and Emerging Contaminants

While the benefits analysis for the GWR only includes reductions in illness and mortality attributable to illnesses from Type A and Type B viruses, the GWR is expected to reduce exposure to other pathogens. For example, some membrane technologies installed to remove viruses can reduce or eliminate many other drinking water contaminants including arsenic and bacteria. Strengthened regulatory requirements will translate into increased removal of additional pathogens and a resulting reduction in risk. This may prove essential, as the impact of emerging pathogens is not well established.

Unfortunately, EPA is unable to quantify the resultant benefit associated with a reduction in risk from emerging pathogens due to current data limitations.

5.4.9 Reduced Uncertainty/Costs to Households to Avert Infection

To the extent that the GWR decreases consumers' uncertainty about expected health outcomes from consumption of drinking water, the rule should provide direct benefits independent of risk reduction benefits. In other words, drinking water consumers may be willing to pay a premium for regulatory action if it reduces their uncertainty about whether they will become ill (Moore, 1990).

Conceptually, whether consumers would be willing to pay something extra to reduce uncertainty in the GWR context depends on several complicated factors, including consumers' degree of risk aversion, their perceptions about drinking water quality, and the expected probability and severity of human health effects associated with microbial contamination of drinking water. For example, risk premiums would be expected only for consumers who are risk averse. Further, the magnitude of any premium would be expected to be positively related to the probability and severity of expected health outcomes, and the degree to which consumers perceive them to be affected by regulatory action.

In addition, to the extent that the GWR can be expected to reduce a household's perceptions of the health risks associated with drinking water, regulatory action should reduce household averting actions and costs. Any such cost savings would represent a regulatory benefit. Examples of household averting actions include: 1) securing drinking water from alternative sources (e.g., bottled water), 2) installation of home treatment systems (e.g., point-of-use and point-of-entry treatment), and 3) boiling tap water used for consumption. These actions can involve significant cash outlays and implicit costs (e.g., time costs).

A number of factors, however, limit the relevance of this potential benefit in the GWR context. One is the possibility that regulatory action may not affect household perceptions of health risks enough to motivate them to forego averting actions. A related factor is that many households that undertake averting action for health reasons may be especially risk averse (e.g., households with infants or immuncompromised persons). These households might be expected to pursue averting actions regardless of the level of regulatory control if they believe such actions may provide added protection against microbial risks. However, any treatment that also improves taste and odor as well as microbial protection may likely result in households forgoing averting behavior.

5.4.10 Summary of Nonquantified Benefits

The total benefits in this EA include both quantified and nonquantified components. The quantified benefits are summarized in Exhibit 5.23. The total nonquantified benefits are captured by several additional analyses and are summarized here but discussed in more detail throughout this EA. EPA estimates that, based on avoided bacterial illnesses and deaths alone, which are discussed only in the nonquantified benefits section, the total benefits could be underestimated by a factor of five. Other benefits will also accrue but are not quantified.

The nonquantified benefits result from multiple factors. First, the quantified benefits are based on limited, well-defined data and key assumptions that restrict the input parameters in the quantified benefit

calculation. Typically, these assumptions resulted in low mean values and narrow uncertainty ranges in the benefits analysis. This EA, where applicable, discusses alternative assumptions. For example, the enterovirus morbidity fractions are, by assumption, not determined using coxsackievirus (an enterovirus) data although the enterovirus severity data use all enterovirus data. If coxsackievirus data were available, the mean morbidity values would be greater. Choosing alternative values and ranges and differing key assumptions, which might also be deemed reasonable, would increase the quantified benefits in this EA.

Second, the quantified benefits are based on data and assumptions that pertain to only partial representation of Type A and Type B viruses potentially found in PWS wells with fecal contamination. Due to limited available data, only rotavirus and some enterovirus data were used to calculate the quantified benefits. As is more completely discussed in Section 5.4. other viruses as well as pathogenic bacteria may contribute to the disease burden, both acute and chronic, associated with PWS wells with fecal contamination. Most importantly, bacterial illnesses can result in more frequent and lengthier hospitalization and more frequently have fatal outcomes. If bacterial diseases were considered in the quantified benefits, the monetized benefits could be substantially greater because bacterial disease can be more severe and can result in higher mortality rates.

Third, the quantified benefits are based on data and assumptions that limit the characterization of acute disease. For rotavirus, only acute gastroenteritis illness and fatal dehydration associated with that illness are monetized. Norovirus disease is not considered. For the enteroviruses, all acute disease endpoints are considered, but the prevalence of severe endemic cases may be substantially diluted by the large number of hand, foot, and mouth disease cases that are not likely to be waterborne. Thus, the proportion of severe cases in the quantitative benefits is likely to be underestimated. As is discussed more completely in Section 5.4, in neither instance, either for rotavirus or the enteroviruses, are chronic diseases identified or monetized in the quantitative benefits calculation.

Fourth, the quantified benefits are based explicitly on what has been directly measured in PWS wells, yet there is great difficulty in identifying and counting all infectious viral pathogens in dilute drinking water samples. Indeed, some viral pathogens like infectious norovirus can never be identified in any sample. Section 4.3.2 discusses these difficulties in more detail. Standard fecal indicator data such as total coliforms and *E. coli*, commonly used to identify water treatment deficiencies and potential human health hazards, are explicitly not used to determine human exposure for the purposes of quantifying the benefits in this EA.

Fifth, the quantified benefits are assumed to be based only on one contamination scenario, fecal contamination of source water. Other contamination scenarios are thoroughly documented in the ground water contamination and outbreak scientific literature. However, these scenarios, such as inadequate disinfection, are not explicitly considered in calculating the quantified benefits in this EA.

Sixth, the quantified benefits are assumed to be based only on avoidance of endemic disease. The GWR will likely also decrease the incidence of epidemic disease (outbreaks). If epidemic illnesses and the avoided non-health-related costs of ground waterborne disease outbreaks were included, the quantified benefits would increase.

In summary, this EA quantifies a subset of the total health and non-health related benefits. In a sample calculation, discussed in Section 5.4.3.2, EPA estimated that the total benefits could increase by a factor of five by only accounting for additional deaths and hospitalizations caused by bacterial illness being avoided. While EPA recognizes that this estimate includes substantial uncertainty, given all the

other nonquantified factors described above, EPA believes that the total benefits from the GWR are likely to be more than five times those which have been quantified.

5.5 Alternative Analyses

To quantify the effects that differences in major modeling assumptions would have on benefits analyses, several alternative analyses were performed. This section presents discussion and results for four such analyses: use of an alternative baseline for viral concentration; use of two alternative dose response functions for Type A viruses; use of an alternative dose response function for Type B viruses; and use of an alternative set of occurrence data (Exhibit 5.27).

5.5.1 Alternative Viral Concentration Baseline

The main analysis of this EA applies data on viral concentrations derived from the Abbaszadegan and Pennsylvania studies to estimate viral concentrations in those wells defined in this EA as "less vulnerable" (see Chapter 4). Data from Lieberman are used to estimate viral concentrations for those wells defined as "more vulnerable." These data are applied to each category of public water system, e.g., CWS, NTNCWS, and TNCWS in the main analysis.

As a sensitivity analysis, these same studies are applied differentially to the six categories (based on three system types and their status as more or less vulnerable): Abbaszadegan's concentration data are applied to only less vulnerable CWSs; Lieberman's concentration data are applied to more vulnerable CWSs; and the Pennsylvania study's concentration data are applied to both the more vulnerable and less vulnerable NTNCWSs and TNCWSs. This alternative would increase the quantified benefits of rule implementation by a range of $1.1 million to $1.7 million (an increase of approximately 7 to 9 percent, using a 7 percent and 3 percent discount rate, respectively) (Exhibit 5.27). Benefits would decrease for CWSs and increase for both NTNCWSs and TNCWSs.

5.5.2 Alternative Type A Dose response

Two alternative dose response models were developed by EPA for Type A viruses using the same study data (Ward et al., 1986) that were used for the dose response function in the main analysis. In both alternative analyses, only the results for the 7 subjects exposed to 0.9 viruses were used since this dose level is most similar to doses likely to be experienced by those consuming contaminated water. As described in detail in Appendix F.5.1, an exponential model form was used having the form $P = 1 - e^{-D*r}$. In this model, D is the expected daily dose of virus and r is the model parameter.

In the first analysis, a large sample of r values were generated using an MCMC method to capture uncertainty in the true value of the r parameter. This alternative leads to a higher estimate of risk and quantified benefits related to Type A viruses. The results, in terms of the monetized benefits using this alternative dose response function (with all other aspects kept the same as in the main model), are shown in Exhibit 5.27. This alternative dose response function would increase the annualized quantified benefits by a range of $1.7 million to $2.1 million (approximately 10 percent) relative to the annualized benefits for the main analysis, using a 7 percent and 3 percent discount rate, respectively.

In the second alternative dose response analysis for Type A viruses, the *r* value was estimated without consideration of uncertainty. This alternative leads to a lower estimate of risk and benefits related to Type A viruses by a range of $1.7 million to $2.0 million (approximately 10 percent in both cases) relative to the annualized quantified benefits for the main analysis, using a discount rate of 7 percent and 3 percent, respectively.

5.5.3 Alternative Type B Dose Response

An alternative dose response model was developed by EPA for Type B viruses using the same study data (Schiff et al., 1984) that were for the dose response function in the main analysis. In this alternative analysis, the two highest dose groups (33,000 and 330,000 pfu) were excluded from the analysis. As described in detail in Appendix F, an exponential model form was used having the form $P = 1 - e^{-} - D*r$. In this model, D is the expected daily dose of virus and r is the model parameter. A large sample of *r* values were generated using a MCMC method to capture uncertainty in the true value of the r parameter.

This alternative leads to a lower estimate of risk and benefits related to Type B viruses. The results, in terms of the monetized benefits using this alternative dose response function (with all other aspects kept the same as in the main model), are shown in Exhibit 5.27. This alternative dose response function would decrease the annualized benefits by a range of $3.7 million to $4.3 million (approximately 22 percent) relative to the annualized benefits for the main analysis, using a 7 percent and 3 percent discount rate, respectively.

5.5.4 Alternative Occurrence (Peer Review) Data

The Agency performed an alternative benefits analysis by running the benefits model using a subset of the studies that were the basis for the fecal indicator and viral occurrence rates in the primary analysis. This subset comprised just those studies which had undergone peer review prior to publication[28] and so consisted only of peer-reviewed data (a parallel analysis was performed for the cost model–see section 6.4.8). Compared to the primary analysis, this alternative benefits model results in an increase in the annualized benefits by a range of $10.4 million to $12.2 million (an approximately 62% increase), using 7 percent and 3 percent discount rates, respectively (Exhibit 5.27).

[28] Studies omitted from the alternative occurrence model are those used for the primary analysis (detailed in Ch. 4 of the EA) that were either not published or not peer reviewed prior to publication: Missouri Alluvial Aquifer (Vaughn, 1996), Wisconsin Migrant Worker Camp (USEPA et al., 1998), EPA Vulnerability (USEPA, 1998), New England (Doherty et al., 1998), Three-State Study #3: Minnesota (Battigelli, 1999), Three-State Study #1: Wisconsin (Battigelli, 1999), and the Montana Study (Miller and Meek, 1996).

Exhibit 5.27 Results of Alternative Analyses

Analysis	Incremental Difference in Mean Benefits from Primary	
	3% Discount Rate	7% Discount Rate
Primary Analysis	$19.7	$16.8
Alternative Viral Concentration Baseline	$1.7	$1.1
First Alternative Type A Dose Response	$2.1	$1.7
Second Alternative Type A Dose Response	($2.0)	($1.7)
Alternative Type B Dose Response	($4.3)	($3.7)
Peer Review (Subset of Data Used in Primary Analysis)	$12.2	$10.4

Notes: The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to comprise a significant portion of the overall benefits of the Rule and are presented in Section 5.4.

Source: GWR Model Output

5.6 Summary of Uncertainty

This chapter presents the data, assumptions, and methods used to estimate the baseline risks, in terms of illnesses and deaths, from the presence of viral pathogens in ground water used as source water for public drinking water systems. It also presents estimates of the reductions in those risks (benefits) resulting from the implementation of the GWR, and of the monetized value of those benefits. Throughout this chapter, an attempt has been made to address uncertainty in the inputs to and the results obtained from the baseline risk and risk reduction modeling. Exhibit 5.28 summarizes the major uncertainties for modeling GWR benefits as well as any anticipated influence on the cost model. Additional discussion of the uncertainty and variability factors influencing the benefits model follows (see Chapter 6 for additional discussion of uncertainty and variability in the cost model estimates).

Exhibit 5.28 Summary of Uncertainties Affecting GWR Estimates

(continued on next page)

Uncertainty	Section Discussion of Uncertainty	Effect on Benefits Estimates			Effect on Cost Estimates		
		Under-estimate	Over-estimate	Unknown Impact	Under-estimate	Over-estimate	Unknown Impact
Viral and indicator occurrence	Exhibit 4.32	X					X
Effectiveness of indicator monitoring	Exhibit 4.32 5.2.3.6	X					X
Rotavirus used to represent Type A infectivity	5.2.4.1			X			None
Model/data used for rotavirus dose response	Appendix F	X					None
Echovirus 12 used to represent Type B infectivity	5.2.4.1	X					None
Model/data used for echovirus dose response	Appendix F		X				None
Rotavirus Used to represent Type A morbidity	5.2.4.1	X					None
Echovirus 12 used to represent Type B morbidity	5.2.4.1	X					None
Population rates in TNCWSs	5.2.3.4		X				None
Secondary spread	5.2.4.2 5.2.4.3 Appendix E	X		X			None
Infectivity risk of sensitive subgroups	5.2.5.3	X					None
Morbidity and mortality risk for elderly or immuno-compromised	5.2.5.3	X					None
Value of health outcomes (COI)	5.2.4.2 5.4.10	X					None
Five repeat samples (not modeled)	5.2.5.6		X			X	

Uncertainty	Section Discussion of Uncertainty	Effect on Benefits Estimates			Effect on Cost Estimates		
		Under-estimate	Over-estimate	Unknown Impact	Under-estimate	Over-estimate	Unknown Impact
Treatment failure (not modeled)	5.4.7	X			X		
Distribution system risk (not modeled)	5.4.8	X			X		
Bacterial illness (not included in main benefits)	5.4.3.1	X					None

In the inputs to the exposure estimates for the risk model, the same elements of variability and uncertainty that were discussed in Chapter 4 for the viral and indicator occurrence data and modeling apply to their use here in the baseline risk and risk reduction modeling. Of particular note are the concerns that the limited monitoring data available on viral pathogen occurrence may lead to underestimates of the number of wells and the number of people potentially affected. In addition, the limited data on indicator and pathogen co-occurrence may be resulting in an underestimate of the effectiveness of indicator monitoring of source water to identify those wells that are expected to have viral pathogens present.

Uncertainty exists in the dose response functions for infectivity developed for Type A and Type B viruses based on rotavirus and echovirus challenge data, respectively. In the main analysis, this uncertainty is considered to some extent by virtue of the large set of dose response function parameters that were generated and used in the simulation model. In addition, in an effort to address the uncertainty in the risk of infection, the alternative dose response functions were developed using data from the challenge studies that was considered most representative of likely exposures via drinking water.

Variability and uncertainty are considered in the morbidity factors used in the risk model. Variability is accounted for by applying different factors for young children versus the rest of the population. Uncertainty is also considered as uniform uncertainty distributions in these morbidity factors.

Secondary spread is included in the analysis, and variability is included in secondary spread rate for Type A viruses as a function of age of the primary infected individual, while uncertainty in the secondary spread factor is included for Type B viruses. Beyond this, however, there is some concern that secondary spread is being underestimated because of limited data which required use of a metric where secondary cases are associated with primary cases of illness rather than with primary cases of infection.

In the risk and benefits analysis, there is recognition of three sensitive subgroups: young, old and immunocompromised. There are, however, only limited quantitative considerations of the potential increased impacts on these subgroups. There is no difference included for any of these subgroups with respect to infectivity risk relative to the population at large. An increased morbidity factor is included for the very young, and an increased mortality factor for neonates is included for Type B viruses. There is no

consideration of increased morbidity or mortality risk for older persons or the immunocompromised subgroups. (Note that the analysis does consider increased severity of illness for the immunocompromised in terms of medical costs incurred.)

In the valuation of benefits analysis, a cost-of-illness (COI) approach has been used rather than a willingness-to-pay (WTP) approach due to lack of available data. Generally, WTP is considered a more appropriate approach to estimating the benefits of avoiding risks and typically leads to higher benefits than the COI approach. Therefore, there is some concern that the value of the GWR benefits may be understated because they are based on COI rather than WTP.

As described previously, EPA's national occurrence dataset includes information on virus and indicator occurrence from 1309 wells among 15 studies. These wells serve community and noncommunity public water systems of different sizes and types (e.g., disinfecting/nondisinfecting), and the wells are situated in shallow and deep aquifers, located in sensitive or nonsensitive hydrogeologic settings, and are geographically dispersed across the US. Although all these types of wells are included in the dataset, their numbers in the dataset do not necessarily relate to their numbers in the population of wells that will be affected by the GWR. In other words, these 1309 wells may not be perfectly representative of the larger population of affected wells. Because the surveyed wells have not all been characterized or characterized similarly for these features (system size, hydrogeologic setting, vulnerability, etc.), EPA is not able to assess the degree to which the dataset may have overstated or understated our national occurrence estimates.

5.7 Regulatory Alternatives

In addition to model runs to calculate benefits for the Final GWR requirements, analyses were conducted for the other rule alternatives considered as part of the rule development process. The five modeled regulatory conditions are: Baseline, Final GWR, Sanitary Survey and Corrective Action, Multi-Barrier Approach, and Across-the-board Disinfection (see Chapter 3 for a full description of these alternatives). The following exhibits present the estimated illnesses and deaths remaining for each regulatory scenario (Exhibit 5.29), the reduction in illnesses and deaths for each of the regulatory scenarios (Exhibit 5.30) and the annualized value of illnesses and deaths avoided for regulatory alternatives (Exhibit 5.31). Benefits and costs of the Final GWR are compared in relation to these alternatives in Chapter 8.

Exhibit 5.29 Remaining Number of Annual Viral Illnesses and Deaths for Each Regulatory Alternative

Regulatory Alternative	Virus Type	Illnesses per Year			Deaths per Year		
		Mean	5th Percentile	95th Percentile	Mean	5th Percentile	95th Percentile
Baseline	**Type A**	175,168	32,652	435,381	1.2	0.2	2.9
	Type B	10,018	501	40,718	2.0	0.0	8.1
	Total	**185,186**	33,153	476,099	**3.2**	0.3	11.0
Final Rule Risk Targeted Approach	**Type A**	135,726	22,559	355,455	0.9	0.1	2.4
	Type B	7,592	320	32,605	1.5	0.0	6.5
	Total	**143,318**	22,879	388,060	**2.4**	0.2	8.9
Alternative 1 Sanitary Survey and Corrective Action	**Type A**	168,154	31,065	420,404	1.1	0.2	2.8
	Type B	9,535	470	38,688	1.9	0.0	7.8
	Total	**177,689**	31,535	459,092	**3.0**	0.2	10.6
Alternative 3 Multi-Barrier Approach	**Type A**	132,332	21,207	348,839	0.9	0.1	2.3
	Type B	7,435	307	32,094	1.5	0.0	6.4
	Total	**139,768**	21,514	380,933	**2.4**	0.2	8.7
Alternative 4 Across-the-Board Disinfection	**Type A**	28,295	5,248	70,474	0.2	0.0	0.5
	Type B	1,609	80	6,540	0.3	0.0	1.3
	Total	**29,904**	5,328	77,014	**0.5**	0.0	1.8

Notes: Details may not add to totals due to independent rounding and independent statistical analyses. Only endemic illnesses are estimated. The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The nonquantified benefits are expected to comprise a significant portion of the overall benefits of the Rule and are presented in Section 5.4.

Source: Appendix C

Exhibit 5.30 Comparison of Number of Annual Viral Illnesses and Deaths Avoided for Regulatory Alternatives

Regulatory Alternative	Illnesses per Year			Deaths per Year		
	Mean	5th Percentile	95th Percentile	Mean	5th Percentile	95th Percentile
Final Rule Risk Targeted Approach	**41,868**	10,274	88,039	**0.7**	0.1	2.1
Alternative 1 Sanitary Survey and Corrective Action	**7,497**	1,618	17,007	**0.1**	0.0	0.4
Alternative 3 Multi-Barrier Approach	**45,419**	11,639	95,166	**0.8**	0.1	2.3
Alternative 4 Across-the-Board Disinfection	**155,282**	27,824	399,085	**2.7**	0.2	9.2

Note: Details may not add to totals due to independent rounding. Only endemic illnesses are estimated.

Source: Appendix C.

Exhibit 5.31 Annualized Value of Viral Illnesses and Deaths Avoided for Regulatory Alternatives

Regulatory Alternative	3% Discount Rate			7% Discount Rate		
	Mean	5th Percentile	95th Percentile	Mean	5th Percentile	95th Percentile
Enhanced COI						
Final Rule	$19.7	$6.5	$45.4	$16.8	$5.5	$38.6
Alternative 1	$3.6	$0.9	$9.3	$2.9	$0.7	$7.5
Alternative 3	$21.3	$7.1	$48.7	$18.2	$6.0	$41.6
Alternative 4	$70.2	$18.3	$177.0	$61.9	$16.1	$156.3
Traditional COI						
Final Rule	$10.0	$2.2	$27.0	$8.6	$1.9	$22.9
Alternative 1	$1.9	$0.3	$5.5	$1.5	$0.2	$4.5
Alternative 3	$10.8	$2.5	$28.9	$9.3	$2.1	$24.8
Alternative 4	$35.5	$6.5	$102.4	$31.5	$5.7	$90.8

Notes: Detail may not add to totals due to independent rounding. The Traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The Enhanced COI also factors in valuations for lost personal time (non-work time) such as childcare and homemaking (to the extent not covered by the Traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway.

The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to comprise a significant portion of the overall benefits of the Rule and are presented in Section 5.4.

Source: Appendix C

6. Cost Analysis

6.1 Introduction

This chapter presents estimates for the total national and household costs for the Ground Water Rule (GWR). To estimate the national costs of the GWR, the United States Environmental Protection Agency (EPA or Agency) calculated the incremental cost for rule components that expand current State practices (e.g., sanitary surveys) and the additional cost of new activities required under the rule. Cost analyses include estimates to implement the rule, conduct sanitary surveys, perform triggered source water monitoring, implement corrective actions (including drilling a new well, installation/operation of treatment, etc.), and perform compliance monitoring. Assessment monitoring and hydrogeologic sensitivity assessments (HSAs) are optional and are not included in the cost estimates.

System costs are estimated for different system types and size categories (nine size categories are used based on population served, consistent with the Drinking Water Baseline Handbook (USEPA, 2001a)). State[1] cost analyses include estimates of the labor burdens that States would face, including staff training on GWR requirements, conducting sanitary surveys, reviewing monitoring reports, reviewing and approving corrective action plans, and recordkeeping. EPA estimated unit costs for these various components using cost models, equipment price lists and quotes, wage rates from government and engineering sources (Bureau of Labor Statistics, R.S. Means, and States), stakeholder inputs, and other relevant assumptions used in economic analyses performed for existing drinking water rules (e.g., Arsenic Rule).

The national costs are estimated using a Monte-Carlo simulation model specifically developed for the GWR. The GWR cost model was developed in a SAS© software platform utilizing a Monte-Carlo simulation. The main advantage to this modeling approach is that, in addition to providing average compliance costs, it also estimates the range of costs within each public water system (PWS) size and type category. The GWR cost model allows for variability and uncertainty in PWS configuration, current treatment in-place, and source water quality to be captured in the compliance cost estimates. This information forms the basis for examining impacts to PWSs and technology affordability.

The remainder of this chapter is organized as follows:

- **Section 6.2** describes the general costing and compliance assumptions used to estimate national costs of the GWR.
- **Section 6.3** describes the methodology of projecting costs over a 25-year period according to the GWR compliance schedule, estimating the present value of each cost, and annualizing each over a 25-year period.
- **Section 6.4** describes the methodology for developing costs for all rule activities.

[1] The term "State" in the context of this chapter refers to any State or other primacy agency that has oversight authority for drinking water programs.

- **Section 6.5** presents household cost estimates.
- **Section 6.6** presents a discussion of nonquantified costs.
- **Section 6.7** presents a discussion of uncertainties in cost estimates.
- **Section 6.8** presents the total annualized cost for the Final GWR.
- **Section 6.9** presents a comparison of cost estimates for the Final GWR to estimates for other rule alternatives considered.

6.2 General Costing Assumptions and Methodology

The GWR Cost Model incorporates several baseline data elements, including the numbers, types, and sizes of ground water systems in the United States, the percentage of ground water systems that disinfect, and the percentage of disinfecting systems that attain 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer. Because many of the assumptions apply not to systems but to entry points, where appropriate, exhibits in this chapter use entry point estimates. Derivations of these baselines for the GWR are discussed in Chapter 4. In addition to those baseline elements, there are several additional baseline costing assumptions used as inputs to the GWR Cost Model. The derivation of these inputs is discussed in detail below.

6.2.1 Labor Rates

For costing purposes, EPA estimates the labor needs and hourly labor rates of systems and States for two labor categories: managerial and technical. EPA recognizes that there may be significant variation in labor rates across all PWSs. However, for purposes of this EA, and to implement national policy, EPA uses national-level estimates from *Labor Costs for National Drinking Water Rules* (USEPA, 2003b). The technical and managerial wage rates vary with system size and include fringe benefits. The technical and managerial wage rates (2003$) are shown in Exhibit 6.1.

Exhibit 6.1 Wage Rates by System Size

Loaded Wage Rate ($2003)	System Size (Population Served)					
	25-100	101-500	500-3.3k	3.3k-10k	10k-100k	>100k
Technical Wage Rate	$ 21.44	$ 23.09	$ 24.74	$ 25.34	$ 26.05	$ 31.26
Managerial Wage Rate	$ 44.36	$ 47.78	$ 51.20	$ 51.20	$ 51.20	$ 51.20
Labor Cost (per hour)	$ 21.44	$ 23.09	$ 24.74	$ 30.51	$ 31.08	$ 35.25

Notes: EPA estimates that systems with population greater than 3,300 use a combination of operators (technical) and engineers (managerial), with an 80/20 ratio between the two, respectively. Loaded rate includes a 60 percent factor to account for the cost of fringe benefits.
Source: Labor Costs for National Drinking Water Rules (USEPA, 2003b).

To account for the general composition of staff at PWSs of smaller sizes (e.g., systems serving 3,300 people or fewer), EPA uses only the technical rate. For systems serving more than 3,300 people, EPA uses a ratio of 80 percent technical labor to 20 percent managerial labor to arrive at a labor cost, or weighted labor rate, of $30.51 for systems serving 3,301-10,000 people, $31.08 for systems serving 10,001-100,000 people, and $35.25 for systems serving greater than 100,000 people.

Labor costs attributable to States for administrative tasks are estimated based on an average annual full time equivalent (FTE) labor cost, including overhead and fringe benefits, of $65,255 (2001$). This rate was established based on data from the 2001 State Drinking Water Needs Analysis (ASDWA, 2001). For use in the GWR EA analyses, the $65,255 annual rate was updated to a year 2003 price level ($70,132) and converted to an hourly basis (1 FTE = 2,080 hours) to establish a State rate of $33.60 per hour. For sanitary surveys and corrective action plan review, the year 1998 wage rate of $31.00 for a field engineer is used. The field engineer rate comes from R.S. Means (1998) and includes a 60 percent loading factor to account for the cost of fringe benefits. This wage rate is updated to 2003 dollars, resulting in a field engineer rate of $37.34 per hour. Exhibit 6.2 displays these labor rates and their derivations.

Exhibit 6.2 State Labor Rates

Cost Element	Base Hourly Labor Cost A	ECI in Year of Data B	ECI 2003 Q4 C	2003 Labor Cost D=A*(C/B)
Field Engineer	$ 31.00	$ 139.80	$ 168.40	$ 37.34
State Employee	$ 31.37	$ 153.20	$ 164.10	$ 33.60

Sources: (A) Wage rate for a Field Engineer (1998$) from R.S. Means, 1998. Wage rate for State employee from 2001 State Drinking Water Needs Analysis ($65,255 yearly for 2080 hours per year) (ASWDA, 2001)
(B & C) Employment Cost Index (ECI) for a Field Engineer from BLS (2003) from 1998 (Civilian; Total compensation; Professional, specialty, and technical occupations). ECI for State Employee from BLS (2003) from 2001 (State and local government; Total compensation; Professional, specialty, and technical occupations). www.bls.gov.

6.2.2 Laboratory Fees

A laboratory fee, or cost per sample, is associated with source water monitoring. For the purpose of this cost analysis, EPA assumed that States will select *E. coli* as the indicator of fecal contamination for source water analysis. Since States may designate alternative indicators for some sites (e.g., coliphage or enterococci), and such analysis is more costly, this assumption may underestimate costs. EPA estimated the cost of monitoring for both the use of an in-house and a commercial laboratory[2], as shown in Exhibit 6.3. For in-house laboratories, EPA's estimate of the cost per sample includes the cost of laboratory analysis materials ($8.95) and a total of 1.0 hour of the system staff's time to collect the sample and conduct the analysis. For commercial laboratory analysis, EPA's estimate of the cost per sample includes a shipping and commercial analysis fee ($74.80) and 0.5 hours of the system staff's time to collect the sample and arrange for delivery to the laboratory. The estimated burden required to collect samples includes travel time and reflects a national average. Individual systems may realize collection burden that is either less than or greater than this average depending on the locations of sampling points in a particular system. No additional costs are assumed for installation of a tap or re-piping of wells to permit sampling, since EPA assumed all wells are equipped with existing taps for sampling.

Rates may vary due to regional variations in laboratory fees, the number of samples processed (quantity discounts), and laboratory capacity. Although laboratory costs are often lower for multiple samples, there are no estimates of the number of systems that may be able to take advantage of this savings. Therefore, the rates used in this analysis may overestimate the actual costs incurred by systems.

[2]EPA assumed that systems serving fewer than 10,000 people would conduct 25% of the laboratory analyses in-house and 75% would be sent to a commercial laboratory; for systems serving 10,000 to 50,000 people EPA assumed that 75% of the laboratory analyses would be conducted in-house and 25% would be sent to a commercial laboratory; and systems serving greater than 50,000 people were assumed to conduct all laboratory analyses in-house.

Exhibit 6.3 Source Water Monitoring Costs per Sample

Analysis Conducted		Sampling			Analysis			Total Burden (hours)	Total Cost
		Labor Cost (per hour)	Sampling Labor Burden (hours)	Total Sampling Cost	Analysis Labor Burden (hours)	Operation & Maintenance	Total Analysis Cost		
		A	B	C=A*B	D	E	F=(A*D)+E	G=B+D	H=C+F
In-house									
	25-100	$ 21.44	0.5	$ 10.72	0.5	$ 8.95	$ 19.67	1.0	$ 30.39
	101-500	$ 23.09	0.5	$ 11.55	0.5	$ 8.95	$ 20.50	1.0	$ 32.04
	500-3.3k	$ 24.74	0.5	$ 12.37	0.5	$ 8.95	$ 21.32	1.0	$ 33.69
	3.3k-10k	$ 30.51	0.5	$ 15.26	0.5	$ 8.95	$ 24.21	1.0	$ 39.46
	10k-100k	$ 31.08	0.5	$ 15.54	0.5	$ 8.95	$ 24.49	1.0	$ 40.03
	>100k	$ 35.25	0.5	$ 17.62	0.5	$ 8.95	$ 26.57	1.0	$ 44.20
Commercial laboratory									
	25-100	$ 21.44	0.5	$ 10.72	0.0	$ 74.80	$ 74.80	0.5	$ 85.52
	101-500	$ 23.09	0.5	$ 11.55	0.0	$ 74.80	$ 74.80	0.5	$ 86.35
	500-3.3k	$ 24.74	0.5	$ 12.37	0.0	$ 74.80	$ 74.80	0.5	$ 87.17
	3.3k-10k	$ 30.51	0.5	$ 15.26	0.0	$ 74.80	$ 74.80	0.5	$ 90.06
	10k-100k	$ 31.08	0.5	$ 15.54	0.0	$ 74.80	$ 74.80	0.5	$ 90.34
	>100k	$ 35.25	0.5	$ 17.62	0.0	$ 74.80	$ 74.80	0.5	$ 92.42

Sources: (A) Labor rates from Exhibit 6.1.

(B & D) Labor hours for sampling and analysis reflect EPA estimate.

(E) Operation and management costs based on best professional judgement. They are the cost of laboratory analysis materials for in-house laboratories and the total cost for commercial laboratories, respectively.

6.2.3 Technology Unit Costs and Compliance Forecasts

EPA has assumed that systems may use a variety of existing technologies to achieve 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer. These technologies include the use of hypochlorination, chlorine gas disinfection, ozonation and nanofiltration, chlorine dioxide, and anodic oxidants disinfection. Other technologies or combinations of technologies (i.e., UV and chloramines, etc.) may be used to meet rule requirements. However, technologies used in the compliance forecast (and their associated unit costs) are based on representative use by the majority of systems. Unit cost estimates for these technologies are in the form of "dollars per entry point" for initial capital and yearly operation and maintenance (O&M) activities. EPA uses population-flow equations for each of the nine system size categories (see section 4.2.4) to estimate unit costs for each technology for each system type and size category. Population used in population flow equations is based on the population served for a particular entry point. Detailed explanations of the unit cost derivations for these technologies are presented in the *Technology and Cost Document for the Final Ground Water Rule* (USEPA, 2006d).

Compliance forecasts (or technology selection forecasts) are estimates of which technologies systems undergoing corrective action will use. Sections 6.4.6.1 and 6.4.6.2 provide detail on the methodology used to generate compliance forecasts for sanitary survey corrective actions and source water contamination corrective actions.

6.2.4 Cost Model

The GWR cost model uses the system baseline data and assumptions regarding labor hours, laboratory costs, and labor rates to generate system costs for rule implementation, sanitary surveys, triggered monitoring, and compliance monitoring. It also combines unit cost estimates with the predicted number of entry points at which various corrective actions are predicted to be used to produce the cost of correcting significant deficiencies and source water contamination. Finally, the model includes State costs.

6.2.5 Modeled Variability and Uncertainty in National Costs

As noted throughout this EA, EPA recognizes that there is variability among many of the input parameters to the GWR cost model (e.g., entry points per system, population served, flow per population, labor rates, and occurrence distributions) and several rule compliance assumptions. In some cases, EPA is able to describe this variability as distributions that are used as inputs to the cost model. In other cases, there is insufficient information to fully characterize the distribution of variability on a national scale and EPA uses mean values for these latter input parameters.

EPA also recognizes that there is uncertainty in the national cost estimates, and has characterized the uncertainty around the mean unit technology costs (as described in section 6.4.9) in the GWR cost model. There is also uncertainty built into the compliance assumptions regarding whether a system chooses a treatment or nontreatment corrective action. To simulate the effect of this uncertainty on national costs, the model performs a Monte-Carlo simulation. The results for the uncertainty analysis are presented in the form of 90 percent confidence bounds around mean national cost estimates.

6.3 Projecting and Discounting National Costs

Costs must be expressed in common units so they can be added together to calculate total annual costs and compared to benefits to compute net benefits. For this rule, some activities occur once, such as installing new treatment technologies. Other O&M activities phase in as new technologies are installed, then continue each year into the future. These activities do not occur instantly or simultaneously; to make such values comparable, the year or years in which all costs are expended must be determined and the costs must be brought back to their present value. For the purposes of this EA, one-time and yearly costs were projected over a 25-year time period to coincide with the estimated life span of capital equipment and a time lag of 5 to 10 years for treatment technology installation after rule promulgation. PWSs also often finance their capital improvements over a 20-year period. The present values of costs are calculated using discount rates of 3 and 7 percent based on EPA policy and Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) guidance.[3]

[3] The choice of an appropriate discount rate is a complex and controversial issue among economists and policy makers. Therefore, the Agency compares streams of future national level costs and benefits using two alternative discount rates, 3 and 7 percent. The underlying logic for each discount rate can be found in *Guidelines for Preparing Economic Analyses* (USEPA, 2000e).

There are two adjustments made to the cost estimates in this EA. One adjustment is made when costs are being used as part of the national cost estimate. These present value costs are then annualized using the same discount rate so that the costs of each regulatory alternative can be directly compared with the corresponding annual benefits. A summary of the steps in this adjustment is as follows:

- Project all undiscounted costs (noncorrective action, corrective action, and State) over a 25-year time horizon based on the rule implementation schedule.
- Calculate total present value costs using 3 and 7 percent discount rates (the same rates were used as for the benefits calculation).
- Annualize the costs over 25 years using the same discount rates.
- Calculate ninety percent confidence bounds to reflect the bounds commonly used by statisticians to assess the overall uncertainty and variability of modeled estimates.

Appendix D contains results from each step above for the final rule. Exhibits D.1 through D.5 show the nominal costs projected over the rule schedule and the present value of each cost calculated to the expected year of rule implementation for the final regulatory alternative. Exhibits D.6 through D.8 show the results for Alternatives 1, 3, and 4.

A different adjustment is made when the cost estimates are used for the analysis of household-level costs. In this case, rather than use a discount rate for determining the present value and annualized costs, an after-tax cost-of-capital rate is used. This rate should reflect the true after-tax cost of capital PWSs face, net of any government grants or subsidies. To annualize capital costs when determining the costs to households, EPA uses different discount rates for private and public systems of different sizes (annualized household costs are presented in Exhibit 6.31). The rate differences between systems represent many factors (e.g., the different borrowing sources each type of system has available to it, bond ratings, etc.) and vary from 5.20 to 6.27 percent depending on system size and ownership. These rates are shown in Exhibit 6.4.

Exhibit 6.4 Discount Rates for Private and Public Systems

System Size (Population Served)	Public Rate	Private Rate
≤100	5.31%	6.22%
101-500	5.31%	6.22%
501-1,000	5.51%	6.22%
1,001-3,300	5.51%	6.22%
3,301-10,000	5.51%	6.22%
10,001-50,000	5.20%	5.66%
50,001-100,000	5.24%	6.27%
100,001-1,000,000	5.24%	6.27%
>1,000,000	5.24%	6.27%

Source: *Development of Cost of Capital Estimates for Public Water Systems, Final Report* (USEPA, 2000f).

6.4 Derivation of Costs for Systems and States

This section presents the methodology and unit costs used to derive national costs for systems and States to perform GWR related activities. Chapter 1 contains a summary of the GWR that describes these activities. The following subsections provide a brief summary of each activity and the assumptions used to estimate the burden and costs attributable to both systems and States for each:

This chapter uses information from the baseline analysis in Chapter 4 as a starting point for analysis of PWSs subject to each rule requirement. Exhibits 6.5a-c present key baseline information and intermediate model outputs that are referenced throughout this section. Because many of the assumptions apply not to systems but to entry points, Exhibits 6.5a and 6.5b use both system and entry point estimates where appropriate.

There are also 57 States that will incur costs as a result of the rule. As noted previously, the term "State" in the context of this chapter refers to any State or other primacy agency that has oversight authority for drinking water programs.

Exhibit 6.5a GWR Baselines: Number of Systems, Entry Points, and Wells

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

Sources:
(A) Exhibit 4.1, Column U
(B) Exhibit 4.3, Column A
(C) Wells per system from US EPA Drinking Water Baseline Handbook (2001).
(E) Exhibit 4.3, Column H
(F) Exhibit 4.3, Column W
(G) Exhibit 4.3, Column R

Exhibit 6.5b Summary of Rule Implications

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

Sources: Cost Model Outputs

Notes:
(G) indicates number of entry points with treatment corrective actions.
(F) - (G) indicates non treatment corrective actions.

Exhibit 6.5c Annualized Costs for Meeting Each of the GWR Provisions to Systems and States ($Millions, 2003$)

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

Notes: Detail may not add to totals due to independent rounding and independent cost model runs.

Source: Cost Model Outputs

6.4.1 Rule Implementation and Annual Administration

PWSs

All systems subject to the GWR will incur one-time costs that include time for staff to read the rule and become familiar with its provisions and to train employees on rule requirements. All systems subject to the GWR will perform implementation activities; the number of systems performing implementation activities is shown in column A of exhibit 6.5a. The technical and managerial labor rates presented in section 6.2.1 are used along with estimates of labor hours to generate implementation costs

for all systems. Technical rates apply to systems serving 3,300 or fewer people, and the 80/20 blend of technical and managerial labor rates apply to systems serving populations greater than 3,300. Based on previous experience with rule implementation, EPA estimates that systems will require a total of 3 hours for the implementation activities associated with sanitary surveys, and a total of 2 - 4 hours for the implementation of monitoring requirements. The planning and mobilization burden estimates under monitoring implementation activities include time required to develop a sampling plan for source water monitoring under triggered monitoring. These unit costs are presented in Exhibit 6.6.

Exhibit 6.6 PWS Unit Burden and Cost Estimates for Implementation Activities

System Size (Population Served)	Labor Cost (per hour)	Sanitary Surveys			Triggered and Compliance Monitoring			Total Unit Start-Up Burden (hours)	Total Unit Start-Up Cost
		Read and Understand Rule (hours/ system)	Planning and Mobilization (hours/ system)	Unit Cost	Read and Understand Rule (hours/ system)	Planning and Mobilization (hours/ system)	Unit Cost		
	A	B	C	D=A*(B+C)	E	F	G=A*(E+F)	H=B+C+E+F	I=A*H
Community Water Systems (CWSs)									
<100	$ 21.44	2	1	$ 64.32	1	2	$ 64.32	6	$ 129
101-500	$ 23.09	2	1	$ 69.27	1	2	$ 69.27	6	$ 139
501-1,000	$ 24.74	2	1	$ 74.22	1	2	$ 74.22	6	$ 148
1,001-3,300	$ 24.74	2	1	$ 74.22	1	2	$ 74.22	6	$ 148
3,301-10K	$ 30.51	2	1	$ 91.54	1	2	$ 91.54	6	$ 183
10,001-50K	$ 31.08	2	1	$ 93.24	1	3	$ 124.32	7	$ 218
50,001-100K	$ 31.08	2	1	$ 93.24	1	3	$ 124.32	7	$ 218
100,001-1 Million	$ 35.25	2	1	$ 105.74	1	3	$ 140.99	7	$ 247
> 1 Million	$ 35.25	2	1	$ 105.74	1	3	$ 140.99	7	$ 247
Nontransient Noncommunity Water Systems (NTNCWSs)									
<100	$ 21.44	2	1	$ 64.32	1	1	$ 42.88	5	$ 107
101-500	$ 23.09	2	1	$ 69.27	1	1	$ 46.18	5	$ 115
501-1,000	$ 24.74	2	1	$ 74.22	1	1	$ 49.48	5	$ 124
1,001-3,300	$ 24.74	2	1	$ 74.22	1	1	$ 49.48	5	$ 124
3,301-10K	$ 30.51	2	1	$ 91.54	1	1	$ 61.02	5	$ 153
10,001-50K	$ 31.08	2	1	$ 93.24	1	1	$ 62.16	5	$ 155
50,001-100K	$ 31.08	2	1	$ 93.24	1	1	$ 62.16	5	$ 155
100,001-1 Million	$ 35.25	2	1	$ 105.74	1	1	$ 70.50	5	$ 176
> 1 Million	$ 35.25	2	1	$ 105.74	1	1	$ 70.50	5	$ 176
Transient Noncommunity Water Systems (TNCWSs)									
<100	$ 21.44	2	1	$ 64.32	1	1	$ 42.88	5	$ 107
101-500	$ 23.09	2	1	$ 69.27	1	1	$ 46.18	5	$ 115
501-1,000	$ 24.74	2	1	$ 74.22	1	1	$ 49.48	5	$ 124
1,001-3,300	$ 24.74	2	1	$ 74.22	1	1	$ 49.48	5	$ 124
3,301-10K	$ 30.51	2	1	$ 91.54	1	1	$ 61.02	5	$ 153
10,001-50K	$ 31.08	2	1	$ 93.24	1	1	$ 62.16	5	$ 155
50,001-100K	$ 31.08	2	1	$ 93.24	1	1	$ 62.16	5	$ 155
100,001-1 Million	$ 35.25	2	1	$ 105.74	1	1	$ 70.50	5	$ 176
> 1 Million	$ 35.25	2	1	$ 105.74	1	1	$ 70.50	5	$ 176

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

Sources: (A) Labor rates from Exhibit 6.1.

(B,C,E, & F) Labor hours for reading and understanding rule and planning and mobilization reflect EPA estimates.

States

States will incur administrative costs while implementing the GWR. These implementation costs are not directly required by specific provisions of GWR alternatives, but are necessary for States to ensure the provisions of the GWR are properly carried out. States will need to allocate time for their staff to establish and then maintain the programs necessary to comply with the GWR, including developing and adopting State regulations and modifying data management systems to track new required system reports to the States. For those GWR requirements that include monitoring with a laboratory method not currently required by the State, the State must devote a portion of its staff time to certifying laboratories for the new method. Time requirements for a variety of State agency activities and responses are estimated in this EA and Exhibit 6.7a lists the activities required to start the program following promulgation of the GWR along with their respective costs and burden.

In addition to these one-time costs, States will use resources to continue administrative activities. On an annual basis, States must coordinate with their particular EPA Region to be certain that the State's program is consistent with federal requirements. States will also continue to train State and PWS staffs, maintain laboratories' certifications, and report system compliance information to the Safe Drinking Water Information System (SDWIS). Exhibit 6.7b lists these annual activities with their respective costs and burden.

States will also be required to spend time responding to PWSs with fecally contaminated ground water sources or significant deficiencies. These costs are beyond any items specifically described and costed as part of the cost model and include items such as time to provide additional consultation to systems, prepare violation letters, and conduct data entry, etc. Because time requirements for implementation and annual administration activities vary among State agencies, EPA recognizes that the burden and cost estimates presented in Exhibits 6.7a and 6.7b may be an over- or under-estimate for some States.

Exhibit 6.7a State Burden and Cost Estimates for Implementation Activities

Compliance Activity	Labor Cost (per hour) A	Hours B	FTEs C=B/2,080	Cost D=A*B
Read and Understand Rule	$ 33.60	60	0.03	$ 2,016
Regulation Adoption and Program Development	$ 33.60	1,040	0.50	$ 34,946
Initial Laboratory Certification	$ 33.60	800	0.38	$ 26,882
Modify Data Management Systems	$ 33.60	2,080	1.00	$ 69,892
System Training and Technical Assistance	$ 33.60	2,080	1.00	$ 69,892
Staff Training	$ 33.60	520	0.25	$ 17,473
Per State Total		6,580		$ 221,101
National Totals (57 States/Primacy Agencies)		375,060		$ 12,602,743

Notes: Detail may not add due to independent rounding.

Sources: (A) Labor rate for state employee from Exhibit 6.2.

(B) Labor hours for start-up activities reflect EPA estimate.

(C) Full-time equivalent (FTE) assumes individual working 40 hours per week, 52 weeks per year.

Exhibit 6.7b State Burden and Cost Estimates for Annual Administration

Annual Administrative Activities

Compliance Activity	Labor Cost (per hour) A	Hours B	FTEs C=B/2,080	Cost D=A*B
Coordination with EPA	$ 33.60	1,040	0.50	$ 34,946
Lab Certification	$ 33.60	1,040	0.50	$ 34,946
Ongoing Technical Assistance	$ 33.60	1,040	0.50	$ 34,946
SDWIS Reporting	$ 33.60	1,040	0.50	$ 34,946
Recordkeeping	$ 33.60	880	0.42	$ 29,570
Staff Training	$ 33.60	104	0.05	$ 3,495
Per State Total		5,144		$ 172,848
National Totals (57 States/Primacy Agencies)		293,208		$ 9,852,357

Notes: Detail may not add due to independent rounding.

Sources: (A) Labor rate for state employee from Exhibit 6.2.

(B) Labor hours for start-up activities reflect EPA estimate.

(C) Full-time equivalent (FTE) assumes individual working 40 hours per week, 52 weeks per year.

Annualized cost estimates for systems and States to perform implementation activities for the preferred regulatory alternative are presented in Exhibit 6.8.

Exhibit 6.8 PWS and State Cost Estimates for Implementation and Annual Administration Activities ($Millions, 2003$)

Annualized Costs for Implementation and Annual Administration Activities									
	Systems			States			Total		
	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)
3%	$0.93	$0.93	$0.93	$9.20	$9.20	$9.20	$10.13	$10.13	$10.13
7%	$1.33	$1.33	$1.33	$9.18	$9.18	$9.18	$10.51	$10.51	$10.51

Notes: Detail may not add to totals due to independent rounding and independent cost model runs.

Source: Cost Model Outputs

6.4.2 Sanitary Surveys

PWSs

Under the sanitary survey provision of the GWR, community water systems (CWSs) and noncommunity water systems (NCWSs) will undergo sanitary surveys once every three and five years, respectively, to address eight specific components of a PWS. The exception to these frequencies is some CWSs. Those CWSs that provide 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer, or have an outstanding performance record (i.e., no significant deficiencies) and no history of total coliform maximum contaminant level (MCL) or monitoring violations under the Total Coliform Rule (TCR) may undergo sanitary surveys every 5 years. To account for this EPA assumes, based on best professional judgement, that the number of CWSs receiving sanitary surveys every 5 years is calculated by summing 50% of the non-disinfecting and disinfecting to less than 4-log systems with the number of 4-log disinfecting systems.

Sanitary surveys may increase either in scope or in frequency or in both scope and frequency under the GWR for some systems. Systems not currently performing surveys at the frequencies specified under the GWR will incur costs for performing additional full surveys (i.e., full sanitary survey costs). The scope of sanitary surveys may also increase to completely address eight specific components of a PWS. The sanitary surveys in this case are called incremental surveys (only having an incremental increase in survey effort). Incremental surveys may also be applicable to some systems under the same survey frequencies. Although States or designated agents perform the surveys, systems will incur costs to accompany State inspectors during a review of the treatment plant and the distribution system, as well as to review and discuss the sanitary survey report. The primary increase in costs that systems will incur as a result of this rule provision is the additional number of surveys undertaken during the period of analysis (i.e., full survey costs).

EPA estimates that surveys for all PWSs currently average once every 5 years. Exceptions to this frequency are those NCWSs that may be on a 10 year schedule as allowed under TCR, because they have reliable disinfection and are deemed not vulnerable by the State. Thus, CWSs now required by the GWR to receive sanitary surveys every 3 years will either undergo an increase in full surveys or incremental surveys. For CWSs now on the three year schedule, the number of additional full surveys required to be conducted is calculated as the difference between the frequency of conducting sanitary surveys on a three year schedule and a five year schedule: 22 years/3years - 22 years/5 years = 2.9 (assuming that the first survey cycle starts as soon as compliance begins at the beginning of fourth year after the rule promulgation and the rule stays effective through the 25th year). For systems on the five year schedule that have to do incremental surveys, the number is 4.4 incremental surveys (22years/5 years).

NCWSs are either on a 5 year or a 10 year schedule as allowed for under the TCR. EPA assumes that all NCWSs serving greater than 4,400 people are on a 10 year schedule. All other NCWSs are assumed to be on a 5 year schedule. For those NCWSs on a 10 year schedule, the number of additional full surveys required to be conducted is calculated as the difference between the frequency of conducting sanitary surveys on a five year schedule and a ten year schedule: 22 years/5years - 22 years/10 years = 2.2. For systems on the five year schedule that have to do incremental surveys, the number is 4.4 incremental surveys (22years/5 years).

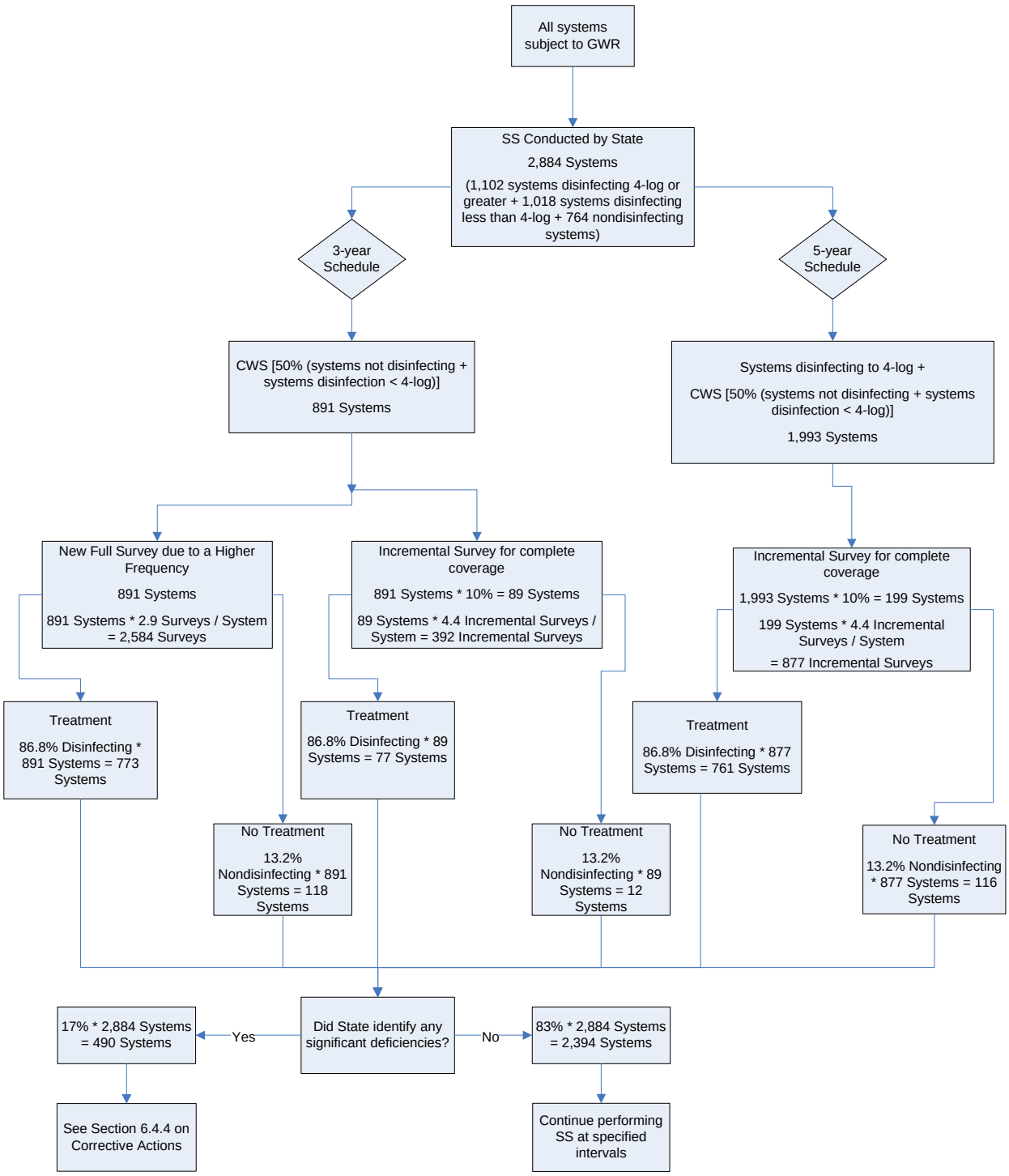
For any system incurring costs for incremental effort to comply with GWR requirements, EPA assumes that the incremental effort will be 50% of current efforts. This assumption is based on the expectation that many elements of a sanitary survey are similar to the requirements (compliance with eight elements) of the GWR. In addition, based on examination of State sanitary survey requirements, 90% of systems are already required to comply with eight elements required under the GWR. Therefore, only 10% of systems are anticipated to incur any incremental costs. These 50% and 10% factors are applied to the unit cost estimates presented in Exhibits 6.11 and 6.12 to derive a weighted unit cost which is then used in the cost model.

Exhibit 6.9 provides a schematic of the sanitary survey process for one system size and type to show the process used in the cost model. Exhibit 6.10 details the number of full and incremental sanitary surveys for systems on both the 3 and 5 year schedule. PWS unit costs to perform sanitary surveys are provided in Exhibit 6.11a for systems with treatment and in Exhibit 6.11b for systems with no treatment. Systems performing either full or incremental sanitary surveys are divided out by whether or not they perform treatment because treatment status impacts unit costs applied in the cost model (i.e., additional burden is estimated to inspect the system with treatment)[4]. All burden estimates used in the cost model are based on consultations with EPA, State, and industry professionals with significant experience conducting sanitary surveys on ground water systems. Lower unit costs are applied to NCWSs because they are normally simpler than CWSs.

[4] No differentiation in inspection burden is made between systems providing greater than or equal to 4-log treatment or less than 4-log treatment.

Exhibit 6.9 Schematic of Sanitary Survey Process

(Numbers based on 3,301 - 10,000 population category for CWSs)



States

As required by this rule, systems must provide all of necessary information and assistance requested from states for conducting surveys. The difference in costs between systems and States stems from differing unit costs for performing sanitary surveys. State unit costs are significantly higher than the system unit costs because the States are actually performing the surveys while systems are only required to provide information and assistance to support the surveys. State unit costs to perform sanitary surveys are provided in Exhibits 6.12a and 6.12b. As with the system unit costs estimates, all burden estimates used in the cost model are based on consultations with EPA, State, and industry professionals with significant experience conducting sanitary surveys on ground water systems. Lower unit costs are applied to NCWSs because they are normally simpler than CWSs.

The total annualized costs estimates for both systems and States to perform sanitary surveys are presented in Exhibit 6.13.

Exhibit 6.10 Number of Full and Incremental Sanitary Surveys for Systems

System Size (Population Served)	Number of Systems Receiving Sanitary Survey	Number of Additional Full Surveys	Number of Incremental Surveys for Systems Performing Additional Full Surveys	Number of Incremental Surveys for Systems Already on GWR Schedule
	A	B	C	D
Community Water Systems (CWSs)				
<100	12,843	2.9	4.4	4.4
101-500	14,358	2.9	4.4	4.4
501-1,000	4,649	2.9	4.4	4.4
1,001-3,300	5,910	2.9	4.4	4.4
3,301-10K	2,884	2.9	4.4	4.4
10,001-50K	1,444	2.9	4.4	4.4
50,001-100K	167	2.9	4.4	4.4
100,000-1M	103	2.9	4.4	4.4
>1,000,000	3	2.9	4.4	4.4
Nontransient Noncommunity Water Systems (NTNCWSs)				
<100	9,456	2.2	2.2	4.4
101-500	6,758	2.2	2.2	4.4
501-1,000	1,894	2.2	2.2	4.4
1,001-3,300	715	2.2	2.2	4.4
3,301-10K	73	2.2	2.2	4.4
10,001-50K	10	2.2	2.2	4.4
50,001-100K	1	2.2	2.2	4.4
100,000-1M	1	2.2	2.2	4.4
>1,000,000	0	NA	NA	NA
Transient Noncommunity Water Systems (TNCWSs)				
<100	64,448	2.2	2.2	4.4
101-500	18,993	2.2	2.2	4.4
501-1,000	1,940	2.2	2.2	4.4
1,001-3,300	585	2.2	2.2	4.4
3,301-10K	74	2.2	2.2	4.4
10,001-50K	19	2.2	2.2	4.4
50,001-100K	1	2.2	2.2	4.4
100,000-1M	1	2.2	2.2	4.4
>1,000,000	0	NA	NA	NA

Note: Incremental surveys reflect CWSs moving from a 5 year to a 3 year schedule and NCWSs moving from a 10 year to a 5 year schedule.

Exhibit 6.11a PWS Unit Burden and Cost Estimates for Performing Full and Incremental Sanitary Surveys (Treatment)

System Size (Population Served)	Labor Cost (per hour) A	Review/ Inspect Wells B	Review/ Inspect Treatment C	Review/ Inspect Distribution System D	Report Review and Discussion w/ State E	Total Unit Burden (hours) F=sum(B-E)	Unit Cost (Full Survey) G=A*F	Weighted Unit Cost (Incremental Survey) H=0.05*G
Community Water Systems (CWSs)								
<100	$ 21.44	1.1	0.8	1.2	1.1	4.3	$ 92	$ 5
101-500	$ 23.09	1.2	0.8	1.2	1.1	4.3	$ 99	$ 5
501-1,000	$ 24.74	1.5	1.1	1.7	1.2	5.4	$ 135	$ 7
1,001-3,300	$ 24.74	2.2	1.3	2.9	1.4	7.7	$ 191	$ 10
3,301-10K	$ 30.51	2.7	1.6	3.6	1.8	9.6	$ 291	$ 15
10,001-50K	$ 31.08	3.7	2.0	4.3	1.9	11.8	$ 368	$ 18
50,001-100K	$ 31.08	9.0	3.0	12.0	3.0	27.0	$ 839	$ 42
100,000-1M	$ 35.25	15.0	8.0	24.0	3.0	50.0	$ 1,762	$ 88
>1,000,000	$ 35.25	24.0	10.0	36.0	4.0	74.0	$ 1,762	$ 88
Nontransient Noncommunity Water Systems (NTNCWSs)								
<100	$ 21.44	1.0	0.8	1.0	1.3	4.0	$ 87	$ 4
101-500	$ 23.09	1.0	0.8	1.1	1.3	4.2	$ 96	$ 5
501-1,000	$ 24.74	1.1	0.9	1.3	1.2	4.5	$ 110	$ 6
1,001-3,300	$ 24.74	1.1	1.1	1.2	1.3	4.7	$ 116	$ 6
3,301-10K	$ 30.51	1.5	1.5	1.7	1.5	6.2	$ 188	$ 9
10,001-50K	$ 31.08	1.3	0.8	1.8	1.3	5.0	$ 155	$ 8
50,001-100K	$ 31.08	1.5	0.8	2.3	1.3	5.8	$ 179	$ 9
100,000-1M	$ 35.25	8.0	1.0	10.0	1.5	20.5	$ 723	$ 36
>1,000,000	$ 35.25	NA	NA	NA	NA	NA	NA	NA
Transient Noncommunity Water Systems (TNCWSs)								
<100	$ 21.44	0.7	0.6	0.6	0.9	2.7	$ 59	$ 3
101-500	$ 23.09	0.7	0.6	0.6	0.9	2.7	$ 63	$ 3
501-1,000	$ 24.74	1.0	0.8	1.0	0.9	3.7	$ 92	$ 5
1,001-3,300	$ 24.74	0.9	1.0	0.9	1.1	3.9	$ 96	$ 5
3,301-10K	$ 30.51	1.2	1.3	1.2	1.2	4.8	$ 147	$ 7
10,001-50K	$ 31.08	0.8	0.5	1.3	0.8	3.3	$ 101	$ 5
50,001-100K	$ 31.08	1.3	0.5	1.3	0.8	3.8	$ 117	$ 6
100,000-1M	$ 35.25	8.0	1.0	10.0	1.0	20.0	$ 705	$ 35
>1,000,000	$ 35.25	NA	NA	NA	NA	NA	NA	NA

Notes: Weighted unit costs equal 5% of the unit costs. This factor accounts for 50% effort for an incremental survey and 10% of systems that do not already comply with rule requirements (see text discussion).

Exhibit 6.11b PWS Unit Burden and Cost Estimates for Performing Full and Incremental Sanitary Surveys (No Treatment)

System Size (Population Served)	Labor Cost (per hour)	Review/ Inspect Wells	Review/ Inspect Distribution System	Report Review and Discussion w/ State	Total Unit Burden (hours)	Unit Cost (Full Survey)	Weighted Unit Cost (Incremental Survey)
	A	B	C	D	E=sum(B-D)	F=A*E	G=0.05*F
Community Water Systems (CWSs)							
<100	$ 21.44	1.1	1.2	1.1	3.5	$ 75	$ 4
101-500	$ 23.09	1.2	1.2	1.1	3.5	$ 81	$ 4
501-1,000	$ 24.74	1.5	1.7	1.2	4.4	$ 108	$ 5
1,001-3,300	$ 24.74	2.2	2.9	1.4	6.4	$ 159	$ 8
3,301-10K	$ 30.51	2.7	3.6	1.8	8.0	$ 243	$ 12
10,001-50K	$ 31.08	3.7	4.3	1.9	9.8	$ 305	$ 15
50,001-100K	$ 31.08	9.0	12.0	3.0	24.0	$ 746	$ 37
100,000-1M	$ 35.25	15.0	24.0	3.0	42.0	$ 1,480	$ 74
>1,000,000	$ 35.25	24.0	36.0	4.0	64.0	$ 1,480	$ 74
Nontransient Noncommunity Water Systems (NTNCWSs)							
<100	$ 21.44	1.0	1.0	1.3	3.3	$ 70	$ 4
101-500	$ 23.09	1.0	1.1	1.3	3.4	$ 79	$ 4
501-1,000	$ 24.74	1.1	1.3	1.2	3.6	$ 89	$ 4
1,001-3,300	$ 24.74	1.1	1.2	1.3	3.6	$ 89	$ 4
3,301-10K	$ 30.51	1.5	1.7	1.5	4.7	$ 142	$ 7
10,001-50K	$ 31.08	1.3	1.8	1.3	4.3	$ 132	$ 7
50,001-100K	$ 31.08	1.5	2.3	1.3	5.0	$ 155	$ 8
100,000-1M	$ 35.25	8.0	10.0	1.5	19.5	$ 687	$ 34
>1,000,000	$ 35.25	NA	NA	NA	NA	NA	NA
Transient Noncommunity Water Systems (TNCWSs)							
<100	$ 21.44	0.7	0.6	0.9	2.2	$ 46	$ 2
101-500	$ 23.09	0.7	0.6	0.9	2.2	$ 50	$ 2
501-1,000	$ 24.74	1.0	1.0	0.9	2.9	$ 72	$ 4
1,001-3,300	$ 24.74	0.9	0.9	1.1	2.9	$ 72	$ 4
3,301-10K	$ 30.51	1.2	1.2	1.2	3.5	$ 107	$ 5
10,001-50K	$ 31.08	0.8	1.3	0.8	2.8	$ 85	$ 4
50,001-100K	$ 31.08	1.3	1.3	0.8	3.3	$ 101	$ 5
100,000-1M	$ 35.25	8.0	10.0	1.0	19.0	$ 670	$ 33
>1,000,000	$ 35.25	NA	NA	NA	NA	NA	NA

Notes:

Weighted unit costs equal 5% of the unit costs. This factor accounts for 50% effort for an incremental survey and 10% of systems that do not already comply with rule requirements (see text discussion).

Exhibit 6.12a State Unit Burden and Cost Estimates for Performing Full and Incremental Sanitary Surveys (Treatment)

System Size (Population Served)	Labor Cost (per hour) A	Review/ Inspect Wells B	Review/ Inspect Treatment C	Review/ Inspect Distribution System D	Report Documentation/ File Review E	Report Development F	Data Entry G	Report Review and Discussion w/ PWS H	Travel I	Total Unit Burden (hours) J=sum(B-I)	Unit Cost (Full Survey) K=A*J	Weighted Unit Cost (Incremental Survey) L=0.05*K
Community Water Systems (CWSs)												
<100	$ 37.34	1.1	0.8	1.2	2.3	5.7	0.8	1.1	1.8	14.8	$ 551	$ 28
101-500	$ 37.34	1.2	0.8	1.2	2.3	5.8	0.8	1.1	1.8	14.9	$ 557	$ 28
501-1,000	$ 37.34	1.5	1.1	1.7	2.6	7.4	0.8	1.2	1.8	18.0	$ 671	$ 34
1,001-3,300	$ 37.34	2.2	1.3	2.9	3.4	8.8	1.2	1.4	1.8	22.8	$ 851	$ 43
3,301-10K	$ 37.34	2.7	1.6	3.6	3.7	9.6	1.3	1.8	1.8	25.9	$ 967	$ 48
10,001-50K	$ 37.34	3.7	2.0	4.3	5.3	10.1	1.4	1.9	1.8	30.3	$ 1,132	$ 57
50,001-100K	$ 37.34	9.0	3.0	12.0	12.0	12.0	2.0	3.0	1.8	54.8	$ 2,044	$ 102
100,000-1M	$ 37.34	15.0	8.0	24.0	18.0	18.0	3.0	3.0	1.8	90.8	$ 3,389	$ 169
>1,000,000	$ 37.34	24.0	10.0	36.0	18.0	18.0	4.0	4.0	1.8	115.8	$ 3,389	$ 169
Nontransient Noncommunity Water Systems (NTNCWSs)												
<100	$ 37.34	1.0	0.8	1.0	1.9	5.1	1.0	1.3	1.8	13.8	$ 515	$ 26
101-500	$ 37.34	1.0	0.8	1.1	2.0	5.3	1.0	1.3	1.8	14.2	$ 531	$ 27
501-1,000	$ 37.34	1.1	0.9	1.3	2.1	6.5	0.8	1.2	1.8	15.6	$ 583	$ 29
1,001-3,300	$ 37.34	1.1	1.1	1.2	2.1	6.2	0.8	1.3	1.8	15.6	$ 581	$ 29
3,301-10K	$ 37.34	1.5	1.5	1.7	2.2	6.7	0.8	1.5	1.8	17.6	$ 657	$ 33
10,001-50K	$ 37.34	1.3	0.8	1.8	2.5	5.0	0.8	1.3	1.8	15.0	$ 560	$ 28
50,001-100K	$ 37.34	1.5	0.8	2.3	2.5	5.0	0.8	1.3	1.8	15.8	$ 588	$ 29
100,000-1M	$ 37.34	8.0	1.0	10.0	8.0	10.0	1.0	1.5	1.8	41.3	$ 1,540	$ 77
>1,000,000	NA	NA	NA	NA	NA	NA	NA	NA	1.8	NA	NA	NA
Transient Noncommunity Water Systems (TNCWSs)												
<100	$ 37.34	0.7	0.6	0.6	1.5	5.1	0.8	0.9	1.8	11.9	$ 443	$ 22
101-500	$ 37.34	0.7	0.6	0.6	1.5	5.3	0.8	0.9	1.8	12.1	$ 452	$ 23
501-1,000	$ 37.34	1.0	0.8	1.0	1.8	5.8	0.8	0.9	1.8	13.9	$ 518	$ 26
1,001-3,300	$ 37.34	0.9	1.0	0.9	1.7	4.7	0.8	1.1	1.8	12.9	$ 480	$ 24
3,301-10K	$ 37.34	1.2	1.3	1.2	1.5	5.2	0.8	1.2	1.8	14.1	$ 526	$ 26
10,001-50K	$ 37.34	0.8	0.5	1.3	1.3	3.8	0.8	0.8	1.8	10.8	$ 401	$ 20
50,001-100K	$ 37.34	1.3	0.5	1.3	1.3	3.8	0.8	0.8	1.8	11.3	$ 420	$ 21
100,000-1M	$ 37.34	8.0	1.0	10.0	3.0	8.0	0.5	1.0	1.8	33.3	$ 1,242	$ 62
>1,000,000	NA	NA	NA	NA	NA	NA	NA	NA	1.8	NA	NA	NA

Notes: Weighted unit costs equal 5% of the unit costs. This factor accounts for 50% effort for an incremental survey and 10% of systems that do not already comply with rule requirements (see text discussion).

Exhibit 6.12b State Unit Burden and Cost Estimates for Performing Full and Incremental Sanitary Surveys (No Treatment)

System Size (Population Served)	Labor Cost (per hour) A	Review/ Inspect Wells B	Review/ Inspect Distribution System C	Report Documentation/ File Review D	Report Development E	Data Entry F	Report Review and Discussion w/ PWS G	Travel H	Total Unit Burden (hours) I=sum(B-H)	Unit Cost (Full Survey) J=A*I	Weighted Unit Cost (Incremental Survey) K=0.05*J
Community Water Systems (CWSs)											
<100	$ 37.34	1.1	1.2	2.3	5.7	0.8	1.1	1.8	13.9	$ 521	$ 26
101-500	$ 37.34	1.2	1.2	2.3	5.8	0.8	1.1	1.8	14.1	$ 526	$ 26
501-1,000	$ 37.34	1.5	1.7	2.6	7.4	0.8	1.2	1.8	16.9	$ 631	$ 32
1,001-3,300	$ 37.34	2.2	2.9	3.4	8.8	1.2	1.4	1.8	21.5	$ 803	$ 40
3,301-10K	$ 37.34	2.7	3.6	3.7	9.6	1.3	1.8	1.8	24.3	$ 909	$ 45
10,001-50K	$ 37.34	3.7	4.3	5.3	10.1	1.4	1.9	1.8	28.3	$ 1,058	$ 53
50,001-100K	$ 37.34	9.0	12.0	12.0	12.0	2.0	3.0	1.8	51.8	$ 1,932	$ 97
100,000-1M	$ 37.34	15.0	24.0	18.0	18.0	3.0	3.0	1.8	82.8	$ 3,090	$ 155
>1,000,000	$ 37.34	24.0	36.0	18.0	18.0	4.0	4.0	1.8	105.8	$ 3,090	$ 155
Nontransient Noncommunity Water Systems (NTNCWSs)											
<100	$ 37.34	1.0	1.0	1.9	5.1	1.0	1.3	1.8	13.0	$ 487	$ 24
101-500	$ 37.34	1.0	1.1	2.0	5.3	1.0	1.3	1.8	13.5	$ 503	$ 25
501-1,000	$ 37.34	1.1	1.3	2.1	6.5	0.8	1.2	1.8	14.8	$ 551	$ 28
1,001-3,300	$ 37.34	1.1	1.2	2.1	6.2	0.8	1.3	1.8	14.5	$ 540	$ 27
3,301-10K	$ 37.34	1.5	1.7	2.2	6.7	0.8	1.5	1.8	16.1	$ 601	$ 30
10,001-50K	$ 37.34	1.3	1.8	2.5	5.0	0.8	1.3	1.8	14.3	$ 532	$ 27
50,001-100K	$ 37.34	1.5	2.3	2.5	5.0	0.8	1.3	1.8	15.0	$ 560	$ 28
100,000-1M	$ 37.34	8.0	10.0	8.0	10.0	1.0	1.5	1.8	40.3	$ 1,503	$ 75
>1,000,000	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Transient Noncommunity Water Systems (TNCWSs)											
<100	$ 37.34	0.7	0.6	1.5	5.1	0.8	0.9	1.8	11.3	$ 421	$ 21
101-500	$ 37.34	0.7	0.6	1.5	5.3	0.8	0.9	1.8	11.5	$ 431	$ 22
501-1,000	$ 37.34	1.0	1.0	1.8	5.8	0.8	0.9	1.8	13.0	$ 487	$ 24
1,001-3,300	$ 37.34	0.9	0.9	1.7	4.7	0.8	1.1	1.8	11.9	$ 443	$ 22
3,301-10K	$ 37.34	1.2	1.2	1.5	5.2	0.8	1.2	1.8	12.8	$ 476	$ 24
10,001-50K	$ 37.34	0.8	1.3	1.3	3.8	0.8	0.8	1.8	10.3	$ 383	$ 19
50,001-100K	$ 37.34	1.3	1.3	1.3	3.8	0.8	0.8	1.8	10.8	$ 401	$ 20
100,000-1M	$ 37.34	8.0	10.0	3.0	8.0	0.5	1.0	1.8	32.3	$ 1,204	$ 60
>1,000,000	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Notes: Weighted unit costs equal 5% of the unit costs. This factor accounts for 50% effort for an incremental survey and 10% of systems that do not already comply with rule requirements (see text discussion).

Exhibit 6.13 PWS and State Cost Estimates for Sanitary Survey Performance ($Millions, 2003$)

Annualized Costs for Sanitary Survey Activities									
	Systems			States			Total		
	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)
3%	$0.21	$0.11	$0.31	$1.45	$0.66	$2.23	$1.66	$0.77	$2.54
7%	$0.20	$0.10	$0.30	$1.39	$0.63	$2.14	$1.59	$0.74	$2.44

Notes: Detail may not add to totals due to independent rounding and independent cost model runs.

Source: Cost Model Outputs

6.4.3 Triggered Source Water Monitoring

PWSs

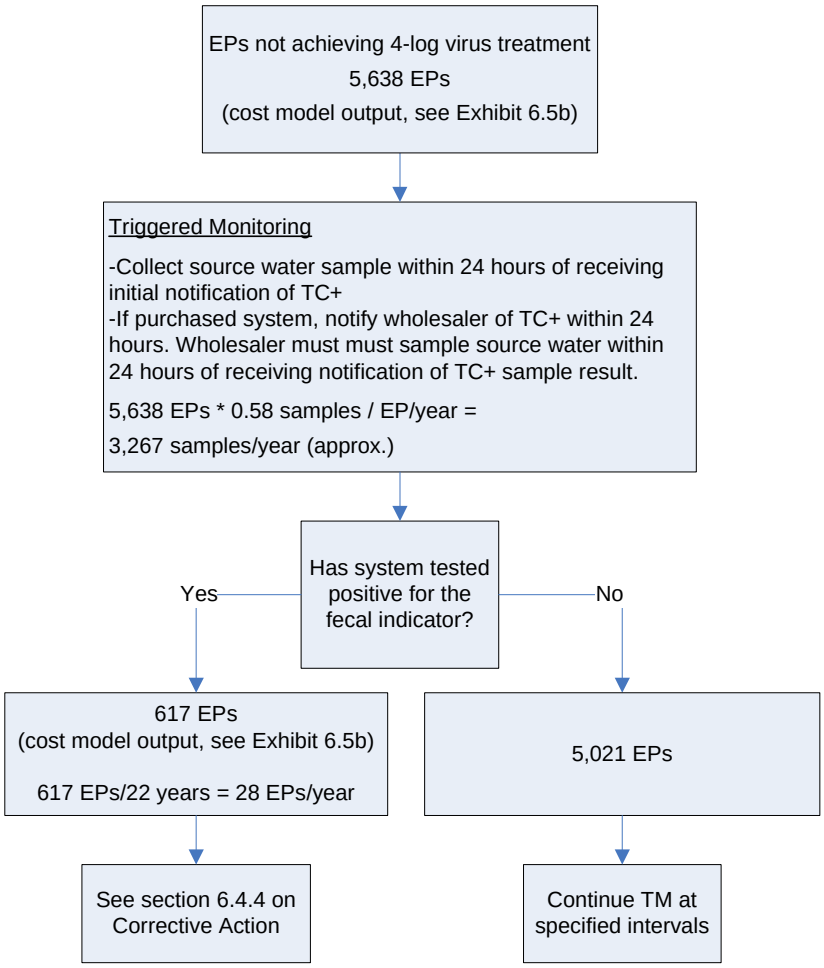
Systems that do not achieve 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer will be subject to triggered source water monitoring. Under this provision, systems are required to collect and analyze samples at the ground water source following the detection of total coliform (TC) in one or more samples collected for compliance with the TCR.[5] Systems are not required to conduct triggered source water monitoring if, according to State criteria or a State determination, the cause of the total coliform-positive sample collected under the TCR directly relates to the distribution system. While States have the option of requiring the triggered monitoring samples to be tested for the presence of a State-specified fecal indicator, for the purpose of this cost analysis, EPA assumed that States will select *E. coli* as the indicator for analysis.

If a system detects the State-specified fecal indicator at its source, then the system must take five additional samples within 24 hours unless the State determines that corrective action must be taken immediately. If any of the additional samples is positive, the system must implement a corrective action. Corrective actions fall into two major categories: non-treatment and treatment (see Section 6.4.4 for detailed discussion). Several compliance estimates were considered to develop estimates of the cost associated with triggered monitoring: the frequency with which systems will have to perform triggered monitoring; the frequency that a TC positive is deemed to be related to the distribution system; the year in which the triggered monitoring occurs; and the number of systems that are expected to test positive for the fecal indicator. These factors are discussed in greater detail below. Exhibit 6.14 presents a schematic of the triggered monitoring process as applied in the cost model.

[5] If TC is detected in more than one sample collected at a single location during the same sampling event, only one triggered monitoring sample is required to be taken from a water source directly related to that location.

Exhibit 6.14 Schematic of Triggered Monitoring Process

(Numbers based on 3,301 - 10,000 population category for CWSs)



* Each positive sample corresponds to either one entry point predicted to have treatment corrective action or one well per entry point to have a nontreatment corrective action. Systems must provide corrective actions if a source water positive sample is also followed by a positive additional source water sample. The State, at its discretion, may require corrective action based on the initial positive source water sample (See sections 6.4.3 and 6.6 for discussion).

Frequency of Performing Triggered Monitoring: EPA estimated the number of times per year that a ground water system's total coliform sampling produced a positive result, which would trigger the GWR source water monitoring requirements. The GWR allows States to determine which well within a system may be related to each TC-positive. EPA makes the simplifying assumption that monitoring at one EP within a system will approximate this rule provision. Due to the uncertainty in DV data, this assumption may over- or under-estimate the number of EPs subject to triggered monitoring (see Appendix I for further discussion). A summary of the methodology used to estimate the annual number of TC-positive samples per system is presented in Section 4.2.7 and additional detail on the analysis is presented

in Appendix I. The results presented in that Section 4.2.7 (Exhibit 4.11) are repeated in Exhibit 6.15 below for convenience. These estimates reflect the annual number of samples taken by systems of different sizes and types. Sampling costs for triggered monitoring are calculated by multiplying the annual number of triggered monitoring samples taken by the sampling unit costs presented previously in Exhibit 6.3.

Exhibit 6.15 Estimated Number of Triggered Samples Per Year Per Entry Point

System Type	System Size (Population Served)							
	<100	101-500	501-1K	1,001-3,300	3,301-10K	10,001-50K	50,001-100K	>100K
CWS	0.38	0.41	0.49	0.22	0.58	2.2	6.6	10.6
NTNCWS	0.22	0.23	0.28	0.70	1.8	7.0	20.8	33.7
TNCWS	0.47	0.48	0.60	1.1	2.9	11.0	32.6	52.8

Source: Exhibit 4.11

Total Coliform Positive Samples Related to the Distribution System: Systems are not required to conduct triggered source water monitoring if, according to State criteria or a State determination, the cause of the total coliform-positive sample collected under the TCR directly relates to the distribution system. Since it is difficult to predict the number of TC positives that are due to source water versus distribution system contamination, EPA assumes each TC positive will result in a triggered source water monitoring sample. The assumption likely overestimates triggered monitoring sample costs.

The Five Additional Samples Following an Initial Indicator Positive Sample: Neither the schematic nor this cost analysis includes additional sampling (the cost model assumes that systems take corrective action based on the first positive indicator sample result). EPA expects about 3% of the initial triggered monitoring assays will be positive and therefore require additional sampling. The total number of assays (triggered plus additional samples) would therefore be about 15% greater than the total number of initial triggered monitoring samples that are included in the cost analysis. EPA believes that this factor (understating the cost of triggered plus additional monitoring by $200,000 per year) is more than offset by including costs for samples that are already collected and assayed under the Total Coliform Rule (estimated value of more than $3 million per year).[6] The GWR allows selected samples that are collected under the TCR to be used in satisfying both the TCR repeat sample requirements and (per State approval) the initial source water fecal indicator under this GWR. The costs of these assays can therefore be attributed to the TCR rather than the GWR. By attributing all of these costs to the GWR, this analysis has

[6] Estimated costs for additional triggered monitoring ($200,000) are calculated as the product of all entry points (by system size and type) taking corrective action for triggered monitoring (Exhibit 6.5b, column D) and sampling unit costs (Exhibit 6.3). Estimated costs savings from samples already taken under the TCR are calculated as the product of all entry points serving 1,000 or fewer people (by system size and type) subject to triggered monitoring (Exhibit 6.5b, column C), the average number of TC positive samples per year under TCR routine monitoring (Exhibit 6.15), and sampling unit costs (Exhibit 6.3). Under both scenarios, costs are apportioned on an annual basis and final costs are calculated as annualized present values using a three percent discount rate.

probably overestimated the triggered monitoring costs by more than $3 million. In addition, although additional sampling will add to the total cost of monitoring, it will cause a decrease in the cost estimate for providing corrective actions (i.e., some systems with an initial positive sample will not have any positive additional samples). Since the costs of corrective actions are higher than the costs of additional sampling, the net cost may be an overestimate. This overestimation coupled with the TCR-related overestimation more than offsets the underestimation due to not including additional samples (approximately $200,000) and the net effect is an overestimation of costs.

Percent of EPs Testing Positive: The triggered monitoring component of the model applies only to the nondisinfecting subset of EPs (and any EPs that are applying disinfectant but not achieving 4-log treatment of viruses using inactivation, removal, or State-approved combination of these technologies, before or at the first customer). It is assumed that no triggered monitoring samples are taken during the first three years following rule promulgations, but may be taken during any of the 22 years from year 4 through year 25.

For the triggered monitoring component of the cost analysis, each EP not achieving 4-log treatment of viruses using inactivation, removal, or State-approved combination of these technologies, before or at the first customer, goes through a 2-step process similar to that described in Chapter 5 for the risk reduction model. In the first step of the process, estimates are made of the number of TC positives - and therefore the number of source water indicator samples - that occur during the 22 years of the compliance period between year 4 and year 25. The number of TC positives expected per year for each EP of a given type and size are obtained from the DV data as described in chapter 4. The number of TC positives per year, and therefore the expected number of triggered indicator samples taken per year, are summarized in Exhibit 6.15. The total number of TC positives expected through year 25 is then calculated as the number of TC positives per year times 22. If, for example, an EP is in the CWS size 10,000-50,000 category, the DV data indicate that these EPs average 2.21 TC positives per year; over 22 years, then, it is expected that each EP in this system size category will have 48.6 TC positives and therefore take up to 49 source water indicator samples between years 4 and 25.

In the second step of the process, a simulation is performed to determine which, if any, of the indicator samples taken through year 25 is the first fecal positive indicator result. In each uncertainty loop of the cost model a set of values is selected reflecting the probability that the first positive of an indicator will occur on a given assay number. Exhibit 4.21 showed the probability of the first fecal indicator positive occurring on a given assay for the median and the 5^{th} and 95^{th} percentiles of a sample of 1,000 of these uncertainty sets of occurrence values.

The data for each uncertainty set provide the cumulative probabilities of observing the first fecal positive on or before each specific assay number. In the cost model, a random value between 0 and 1 is generated for each EP. That value is used as a look-up value to determine what assay number would produce the first fecal positive.

For example, if the curve shown as the median data set in Exhibit 4.26 were the set of values being used for a particular uncertainty loop, and the random number between 0 and 1 generated for an EP in the CWS size 10,000-50,000 category were 0.095, the look-up function would indicate that the first fecal indicator positive would occur on assay number 8. Since these EPs are expected to take 48.6 fecal indicator assays over the 22 year period, the 8^{th} assay would occur in the 4^{th} year [(22 years/48.6 assays)*8 assays ~ 3.6]. Since there are no triggered monitoring samples taken in years 1 through 3

following promulgation, the 4th year of sampling corresponds to year 7 of the 25 year modeling period. Therefore, this well would be "caught" by triggered monitoring in year 7.

EPs that test positive (both with initial and additional samples) for an indicator of fecal contamination must perform corrective action. Costs for performing corrective actions are discussed in Section 6.4.4. In addition, a report must be submitted to the State notifying them of the problem. EPA estimates that this report will require, on average, 2.5 hours to complete and submit. EPA has developed and systems will have access to automated forms that will minimize the burden to systems in complying with this reporting requirement. Exhibit 6.16 below presents system unit costs for triggered monitoring reporting requirements.

Based on the number of TC positives expected per EP across all EP types and sizes, together with the expected values of fecal indicator positives as a function of assay number across all of the uncertainty sets available to draw from for the simulation model, it can be estimated that approximately 10.2% (90% confidence bounds of 7.4% - 13.4%) of all nondisinfecting EPs will have a fecal indicator positive from the triggered monitoring provision of the rule by the 25th year of the modeling timeframe. The 10.2% of all nondisinfecting EPs that are identified over the 25-year timeframe as having fecal indicator occurrence comprise nearly 40% of the subset of those EPs that are expected to have fecal contamination at some time. This is because the occurrence analysis shows that about 26.2% of all EPs are believed to have some fecal contaminant occurrence. The estimate of 26.2% of EPs having some fecal contaminant occurrence is based on the mean values of P2 and P3 from a sample of 10,000 estimates, where P2 (~16.5%) is the fraction of EPs having both viral and fecal indicator occurrence and P3 (~9.7%) is the fraction having fecal indicator, but no viral occurrence. Therefore the fraction of all fecally contaminated wells that are identified over the 25-year period can be estimated as 10.2% / 26.2% = 38.9% = ~40%. See Chapter 4, Section 4.3.4.1 for the derivation of P2, P3, and other viral and fecal indicator hit rate parameters.

Invalidation of Samples: The GWR allows a State to invalidate a positive source water sample if it believes that the positive is due to improper analysis. States may also invalidate positive source water samples that are due to circumstances not reflecting source water quality. Systems must resample after a sample is invalidated. For costing purposes, EPA, based on best professional judgement, estimates that States will invalidate a minimal number of samples resulting in a negligible cost and burden.

Exhibit 6.16 PWS Unit Costs for Triggered Monitoring

System Size (Population Served)	Entry Points Triggered Monitoring	Mean Number of Samples per EP per Year	Triggered Monitoring Samples/year	Average Fecal Positive Triggered Monitoring Entry Points/year	Reporting/Positive Triggered Monitoring Sample		
					Report Prep (hours)	Labor Cost (per hour)	Unit Cost
	A	B	C=A*B	D	E	F	G=E*F
Community Water Systems (CWSs)							
<100	12,797	0.38	4,842	57	2.5	$ 21.44	$ 53.60
101-500	14,819	0.41	6,076	74	2.5	$ 23.09	$ 57.73
501-1,000	5,578	0.49	2,760	28	2.5	$ 24.74	$ 61.85
1,001-3,300	8,910	0.22	1,975	32	2.5	$ 24.74	$ 61.85
3,301-10K	5,638	0.58	3,267	28	2.5	$ 30.51	$ 76.28
10,001-50K	4,357	2.21	9,609	30	2.5	$ 31.08	$ 77.70
50,001-100K	1,295	6.56	8,492	10	2.5	$ 31.08	$ 77.70
100,001-1 Million	749	10.63	7,958	6	2.5	$ 35.25	$ 88.12
> 1 Million	-	10.63	-	-	2.5	$ 35.25	$ 88.12
Totals	**54,142**		**44,979**	**265**			
Nontransient Noncommunity Water Systems (NTNCWSs)							
<100	8,609	0.22	1,887	31	2.5	$ 21.44	$ 53.60
101-500	6,149	0.23	1,384	24	2.5	$ 23.09	$ 57.73
501-1,000	1,724	0.28	485	7	2.5	$ 24.74	$ 61.85
1,001-3,300	651	0.70	457	4	2.5	$ 24.74	$ 61.85
3,301-10K	66	1.84	122	0	2.5	$ 30.51	$ 76.28
10,001-50K	9	6.99	64	0	2.5	$ 31.08	$ 77.70
50,001-100K	1	20.78	19	0	2.5	$ 31.08	$ 77.70
100,001-1 Million	1	33.67	31	0	2.5	$ 35.25	$ 88.12
> 1 Million	-	33.67	NA	NA	NA	$ 35.25	NA
Totals	**17,209**		**4,447**	**67**			
Transient Noncommunity Water Systems (TNCWSs)							
<100	63,295	0.47	29,605	314	2.5	$ 21.44	$ 53.60
101-500	18,648	0.48	8,955	92	2.5	$ 23.09	$ 57.73
501-1,000	1,905	0.60	1,144	9	2.5	$ 24.74	$ 61.85
1,001-3,300	574	1.10	633	3	2.5	$ 24.74	$ 61.85
3,301-10K	73	2.88	209	1	2.5	$ 30.51	$ 76.28
10,001-50K	19	10.97	205	0	2.5	$ 31.08	$ 77.70
50,001-100K	1	32.60	32	0	2.5	$ 31.08	$ 77.70
100,001-1 Million	1	52.83	52	0	2.5	$ 35.25	$ 88.12
> 1 Million	-	52.83	NA	NA	NA	$ 35.25	NA
Totals	**84,515**		**40,835**	**420**			
Grand Total	**155,867**		**90,261**	**752**			

Notes: Detail may not add to totals due to independent rounding.
NA Not applicable (no NCWSs of this size category).
Costs of repeat samples are not included. See Section 6.6 for discussion.

Source: (A) Number of entry points from Exhibit 6.5b.
(B) Mean triggered samples per system calculated from Exhibit 6.15.
(D) Values in Column D, Exhibit 6.5b are divided by 22 years to obtain postive triggered monitoring EPs/year.
(E) Labor hours for report preparation based on EPA experience with similar rule requirements.
(F) Labor rates from Exhibit 6.1.

States

State costs for triggered monitoring are assumed to be solely administrative. States incur costs to review several paperwork requirements: reports of positive samples (including the results of additional samples) and sample invalidation documentation. Each of these reports and associated costs is explained below.

Review Reports of Source Water Positives: The GWR requires systems that find a source water sample positive for fecal contamination to report this to the State. Based on its experience with similar reporting requirements, EPA estimates that States will require 3.5 hours to review the report. Using a labor cost of $33.60 per hour, EPA estimates a unit cost of $117.61 to review the report. This estimate is greater than the burden estimated for systems to prepare and submit the report because it is anticipated that the State will have less familiarity with any particular system and will be required to look up additional historical information to make any assessments/determinations regarding the report.

Invalidation of Samples: As noted above, the GWR allows a State to invalidate a fecal positive source water sample result that is due to improper analysis. States may also invalidate a fecal positive source water sample results that are due to circumstances not reflecting source water quality. For costing purposes, EPA estimates that States will invalidate a minimal number of samples, resulting in a negligible cost and burden.

Annualized cost estimates for systems and States to perform triggered monitoring are presented in Exhibit 6.17.

Exhibit 6.17 PWS and State Cost Estimates for Performing Triggered Monitoring ($Millions, 2003$)

Annualized Costs for Triggered Monitoring Performance									
	Systems			States			Total		
	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)
3%	$5.44	$5.32	$5.56	$0.09	$0.06	$0.12	$5.52	$5.38	$5.67
7%	$5.39	$5.27	$5.51	$0.10	$0.07	$0.13	$5.48	$5.34	$5.64

Notes: Detail may not add to totals due to independent rounding and independent cost model runs.

Source: Cost Model Outputs

6.4.4 Corrective Actions

The purpose of conducting sanitary surveys is to identify significant deficiencies in PWSs that need correction. Systems also conduct source water monitoring to detect fecal contamination in source water. Identification of significant deficiencies as well as the detection of fecal indicators requires systems to take corrective action under the GWR. National costs of these corrective actions comprise the majority of the costs associated with the GWR. This section explains the methodology used for estimating the national costs of implementing corrective actions under the GWR. This section includes discussions of the compliance forecast used to determine the corrective actions undertaken by PWSs, estimation of the burden and costs of corrective action plans, and the derivation of capital and O&M costs associated with the various corrective actions. Where available, existing data on treatment practices were used to determine compliance forecasts, burden, and cost estimates. In the absence of data, EPA used best professional judgement based on consultations with Agency, industry, and State experts and representative organizations (e.g., ASDWA) to make estimates.

6.4.4.1 Sanitary Survey Corrective Actions

Compliance Forecast

The GWR requires each PWS to correct any significant deficiencies found during a sanitary survey. Because States have the authority to define significant deficiencies under the GWR, EPA predicted the types of deficiencies that will be found and corrected as a result of the rule. EPA consulted with experts from within the Agency and from States to develop a list of corrective actions to address deficiencies that are likely to be identified in sanitary surveys of ground water systems (USEPA, 1996b). Potential significant deficiencies identified can occur at the source of water, in a treatment plant, or in the distribution system.

EPA lacks adequate data to quantify the number of significant deficiencies that will be detected and corrected in the distribution system as well as in the treatment processes. Therefore, costs associated with these deficiencies are not included in the cost model (see section 6.6 for further discussion of the nonquantified costs). Similarly, the associated benefits are not included in the benefits model. To estimate costs for significant deficiencies detected at or near the source, the following corrective actions are used in the cost model.

- Replace a sanitary well seal
- Rehabilitate an existing well

By limiting the corrective actions considered to the two options listed above, EPA has created a simplified, but representative estimate of actions that may be taken by systems. In general, EPA believes the costs for these significant deficiencies represent the range of costs systems would be expected to incur for providing correction of significant deficiencies. Many other specific corrective actions may be taken to adequately address significant deficiencies identified at or near the source. Some actions, such as drilling a new well or purchasing water from another supplier, would be more expensive than these options. However, based on discussions with experts, EPA believes that a majority of corrective actions (e.g., fencing off or providing other limited access to infrastructure to protect wells) may actually be less expensive than the two used in the cost model. Other well repairs that could correct source contamination

such as installation of pump block seals, pump block/well pad repair, or correcting runoff and drainage problems would be less expensive, and as such, be the first consideration for any system looking to most cost-effectively correct a problem. This is especially true for small systems which often have to address such issues with limited resources.

To further account for uncertainty in the corrective actions that will be taken, PWSs are assigned one of the two potential significant deficiencies listed above according to one of two probability distributions. Exhibit 6.18 presents these distributions. Because the corrections of significant deficiencies are dependent upon the deficiencies defined as significant by States and the conditions of specific systems, both of which are highly variable, EPA used a high scenario/low scenario estimating procedure to bound the cost estimates. The low-cost scenario assumes a greater percentage of the systems with significant deficiencies will have deficiencies that are less expensive to correct (e.g., more systems will have to replace their sanitary well seal than will have to perform a complete rehabilitation of their well). This high/low bounding provides an estimate of the uncertainty with respect to the percentages of each type of defect to be corrected.

Exhibit 6.18 Estimated Distribution of Significant Deficiency Corrective Actions

Corrective Action	Low Cost Distribution		High Cost Distribution	
	Percentage	Number	Percentage	Number
	A	B	C	D
Replace a sanitary well seal	60	15,028	40	10,018
Rehabilitate an existing well	40	10,018	60	15,028

Source: (A,C) Distribution of corrective actions based on best professional judgement.
(B,D) based on (A,C), 147,330 total number of systems subject to the GWR (Exhibit 4.1), and 17% percent of systems not constructed according to applicable State regulations (ASDWA survey).

The number of PWSs identifying a significant deficiency during a sanitary survey is determined based on survey data from the Association of State Drinking Water Administrators (ASDWA) (1997). Based on responses to the ASDWA survey, it was determined that 17% of systems had wells that were not constructed according to applicable State regulations. This percentage is used as an estimate of the number of systems that will find significant deficiencies at or near the source over the 25-year cost model analysis period. Within the cost model, the assignment of significant deficiencies is applied equally in years 4 - 25 of the analysis, resulting in approximately 0.77% of systems (17% / 22 years) being assigned a corrective action in each of those years.

Unit Cost Estimates

Once a corrective action has been selected, a unit cost for that change is applied based on system size. The costs for correction of significant deficiencies identified during sanitary surveys are dependent upon the nature of the deficiency. Costs were developed based on the *Technology and Cost Document for the Final Ground Water Rule* (USEPA, 2006d) to correct each of the identified significant deficiencies

and are presented in Exhibit 6.19 below. These costs are considered one-time expenditures that occur in the year the significant deficiency is found.

Exhibit 6.19 Estimated Unit Costs of Significant Deficiency Corrective Actions

Corrective Action	Size Category (Population Served)								
	<100	101-500	501-1,000	1,001-3,300	3,301-10,000	10,001-50,000	50,001-100,000	100,001-1 Million	>1 Million
Replace a Sanitary Well Seal	$3,627	$3,627	$3,627	$3,627	$3,627	$3,627	$3,627	$3,627	$3,627
Rehabilitate an Existing Well	$11,986	$11,986	$11,986	$11,986	$11,986	$11,986	$11,986	$11,986	$11,986

Source: GWR Technology and Cost Document

Corrective Action Plans

All systems are required to take corrective action for a significant deficiency that is identified during sanitary surveys. Systems must consult with States and develop a corrective action plan, submit it to the State for approval, and implement the corrective action (or combination of actions) approved by the State. Exhibit 6.20a details the burden and cost to systems to prepare corrective action plans, as well as the burden and cost to States to review them. EPA has developed and systems and States will have access to automated forms that will minimize the burden to systems in complying with this reporting requirement. These costs also apply for corrective actions due to source water contamination, discussed below. It is assumed that large systems will have more technical and managerial staff compared to small systems, and will therefore have less interaction with States than small systems. This assumption is reflected in column D of Exhibit 6.20a; State burden is incurred on a 1:1 ratio to system burden for small systems, and on a 0.5:1 ratio for large systems.

Exhibit 6.20a PWS and State Unit Costs for Corrective Action Plans

System Size (Population Served)	PWSs: Corrective Action Plan (hours) A	PWSs: Plan Labor Cost (per hour) B	PWSs: Unit Plan Cost C=A*B	States: Review Plan (hours) D	States: Review Labor Cost (per hour) E	States: Unit Plan Review Cost F=D*E
Community Water Systems (CWSs)						
<100	12	$ 21.44	$ 257.28	12	$ 37.34	$ 448.10
101-500	13	$ 23.09	$ 300.17	13	$ 37.34	$ 485.44
501-1,000	19	$ 24.74	$ 470.06	19	$ 37.34	$ 709.50
1,001-3,300	29	$ 24.74	$ 717.46	29	$ 37.34	$ 1,082.92
3,301-10K	58	$ 30.51	$ 1,769.70	58	$ 37.34	$ 2,165.83
10,001-50K	60	$ 31.08	$ 1,864.80	30	$ 37.34	$ 1,120.26
50,001-100K	70	$ 31.08	$ 2,175.60	35	$ 37.34	$ 1,306.97
100,001-1 Million	74	$ 35.25	$ 2,608.35	37	$ 37.34	$ 1,381.65
> 1 Million	74	$ 35.25	$ 2,608.35	37	$ 37.34	$ 1,381.65
Nontransient Noncommunity Water Systems (NTNCWSs)						
<100	12	$ 21.44	$ 257.28	12	$ 37.34	$ 448.10
101-500	13	$ 23.09	$ 300.17	13	$ 37.34	$ 485.44
501-1,000	19	$ 24.74	$ 470.06	19	$ 37.34	$ 709.50
1,001-3,300	29	$ 24.74	$ 717.46	29	$ 37.34	$ 1,082.92
3,301-10K	58	$ 30.51	$ 1,769.70	58	$ 37.34	$ 2,165.83
10,001-50K	60	$ 31.08	$ 1,864.80	30	$ 37.34	$ 1,120.26
50,001-100K	70	$ 31.08	$ 2,175.60	35	$ 37.34	$ 1,306.97
100,001-1 Million	74	$ 35.25	$ 2,608.35	37	$ 37.34	$ 1,381.65
> 1 Million	NA	$ 35.25	NA	NA	NA	NA
Transient Noncommunity Water Systems (TNCWSs)						
<100	12	$ 21.44	$ 257.28	12	$ 37.34	$ 448.10
101-500	13	$ 23.09	$ 300.17	13	$ 37.34	$ 485.44
501-1,000	19	$ 24.74	$ 470.06	19	$ 37.34	$ 709.50
1,001-3,300	29	$ 24.74	$ 717.46	29	$ 37.34	$ 1,082.92
3,301-10K	58	$ 30.51	$ 1,769.70	58	$ 37.34	$ 2,165.83
10,001-50K	60	$ 31.08	$ 1,864.80	30	$ 37.34	$ 1,120.26
50,001-100K	70	$ 31.08	$ 2,175.60	35	$ 37.34	$ 1,306.97
100,001-1 Million	74	$ 35.25	$ 2,608.35	37	$ 37.34	$ 1,381.65
> 1 Million	NA	$ 35.25	NA	NA	NA	NA

Notes: Detail may not add due to independent rounding.
NA= Not applicable (no NCWSs of this size category).

Sources: (A) Labor hours for preparing plan reflect EPA estimate based on best professional judgement.
(B) Labor rates from Exhibit 6.1.
(D) Labor hours for corrective action plan review reflect EPA estimate.
(E) Labor rate for field engineer from Exhibit 6.2.

Annualized cost estimates for systems and States to perform sanitary survey corrective actions (including capital, O&M, and corrective action plan costs) are presented in Exhibit 6.20b.

Exhibit 6.20b PWS and State Cost Estimates for Sanitary Survey Corrective Action Activities ($Millions, 2003$)

Annualized Costs for Sanitary Survey Corrective Action Activities									
	Systems			States			Total		
	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)
3%	$8.46	$5.74	$11.60	$0.56	$0.52	$0.61	$9.02	$6.25	$12.21
7%	$8.13	$5.51	$11.14	$0.54	$0.50	$0.59	$8.67	$6.01	$11.73

Notes: Detail may not add to totals due to independent rounding and independent cost model runs.

Source: Cost Model Outputs

6.4.4.2 Source Water Contamination Corrective Actions

Compliance Forecast

As discussed in section 6.4.3, unless a system that detects fecal contamination in its source water from triggered monitoring is directed by the State to take immediate corrective action, the systems must collect and test an additional five source water samples for the presence of the same State-specified fecal indicator within 24 hours. If any one of the five additional source water samples tests positive for the State-specified fecal indicator (*E. coli*, enterococci, or coliphage), this rule requires the system to take corrective action. For costing purposes, EPA assumes that the initial indicator positive sample will correspond to either one entry point predicted to have corrective treatment or one well per entry point to have a nontreatment corrective action. EPA believes this may underestimate treatment and nontreatment corrective action costs if more than one entry point or well in a given system requires corrective action. However, corrective action costs may be overestimated because if none of the five additional samples are positive, no corrective action is required under the rule.

Similar to sanitary survey corrective actions, systems must consult with States and develop a corrective action plan, submit it to the State for approval, and implement the corrective action (or combination of actions) approved by the state (see Section 6.4.4.1 for estimates of corrective action plan costs).

EPA assumed that corrective actions fall into four categories: fixing the deficiency that may lead to contamination; eliminating the contamination from the source; obtaining an alternative source of water; or providing disinfection treatment that achieves 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer.

EPA considered four nontreatment alternatives in the cost estimate for eliminating contamination identified during source water monitoring:

- Rehabilitate an existing well
- Drill a new well
- Purchase water
- Eliminate contamination source

For systems that employ nontreatment corrective actions, the GWR model assumes interim disinfection will be installed until the nontreatment corrective action is completed and the cost model includes the interim disinfection costs for this scenario. While interim disinfection would also apply to systems installing disinfection as a permanent strategy prior to completion of the permanent strategy, EPA assumes that the additional costs of interim disinfection for the systems projected to install permanent disinfection as their corrective actions are insignificant because the long-term disinfection is assumed in the model to occur immediately after the corrective action is required. Costs for setting up a temporary chlorine disinfection process depend on the duration of interim disinfection, which is determined by the nontreatment corrective action chosen. Based on best professional judgement, EPA estimates that interim disinfection will be performed for a duration of one year for systems rehabilitating an existing well, for two years for systems either drilling a new well or purchasing water, and for six months for systems eliminating the source of contamination.

For systems that employ treatment as a corrective action, the Agency developed costs for the following six disinfection technologies:

- Hypochlorination (with and without additional storage)
- Chlorine gas (with and without additional storage)
- Chlorine dioxide (with and without additional storage)
- Anodic oxidants[7] (with and without additional storage)
- Ozone
- Nanofiltration

To estimate the corrective action chosen by each system, the cost model uses a five-step compliance forecast. Systems may incur costs that differ from these if the State specifies an alternative treatment technology (e.g., ultraviolet light). Each step is explained below, and summarized in Exhibits 6.21a and 6.21b.

[7] EPA estimated the cost of adding Anodic oxidation in the *Technology and Cost Document for the Final Ground Water Rule* (USEPA, 2006d) as a representative technology for mixed oxidants.

Step 1—Current Treatment Practices: The first step divides entry points requiring corrective action for source water contamination into those that already have some treatment in place (i.e., <4-log) and those without treatment. EPA assumes that the ratio of correcting entry points that have disinfection treatment in place to nondisinfecting entry points performing a corrective action is identical to the ratio of entry points that disinfect but do not achieve 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer to nondisinfecting entry points, by system type and size category. Entry points that have some disinfection treatment but do not achieve 4-log are estimated to choose their corrective action based on the distribution in step five.

Step 2—Current Implementation of Treatment Types: For entry points which do not currently apply disinfection, EPA assumes that the percentage of entry points that will choose disinfection as a corrective action for source water contamination is based on a range. The high end of the range is based on the percentage of CWS entry points currently employing disinfection by system size using information from the Community Water Systems Survey (CWSS) (USEPA, 1997a). The low end of the range is assumed to be 10% based on discussions with State representatives, who indicated that the use of the CWSS data would overestimate the percentage of entry points using disinfection in response to fecally-contaminated source water. The remaining percentage of non-disinfecting entry points are predicted to employ nontreatment corrective actions in response to fecal contamination of the source water. Because of the uncertainty inherent in projecting the number of entry points that would employ each nontreatment corrective action, EPA assigns equal proportions of the nontreatment corrective actions into the high- and low-cost scenarios for significant deficiencies.

Step 3—Distribution of Nontreatment Corrective Actions: Each non-disinfecting entry point that is predicted to require a nontreatment corrective action (from step two), having been assigned to either the high- or the low-cost scenario, is then assigned a corrective action according to the corresponding percentages in that distribution, as shown in Exhibit 6.21b.

Step 4 - Distribution of Treatment Corrective Actions: The compliance forecast assigns each non-disinfecting entry point predicted to require a treatment corrective action (from step two) to one of the ten possible treatment scenarios based on the percentage of CWSs currently engaged in those treatment practices, which are estimated with the CWSS results (USEPA 1997a).

Step 5 - Distribution of Corrective Actions for Disinfecting Entry Points: Finally, for those entry points with disinfection that do not achieve 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer, the compliance forecast assigns them a corrective action (i.e., add storage or increase disinfectant dose). EPA bases this probability distribution on AWWA survey data (AWWA, 1998).

Exhibit 6.21a Summary Flow Chart
Estimated Distribution of Source Water Contamination Corrective Actions
(Numbers based on 3,301 - 10,000 population category for CWSs)

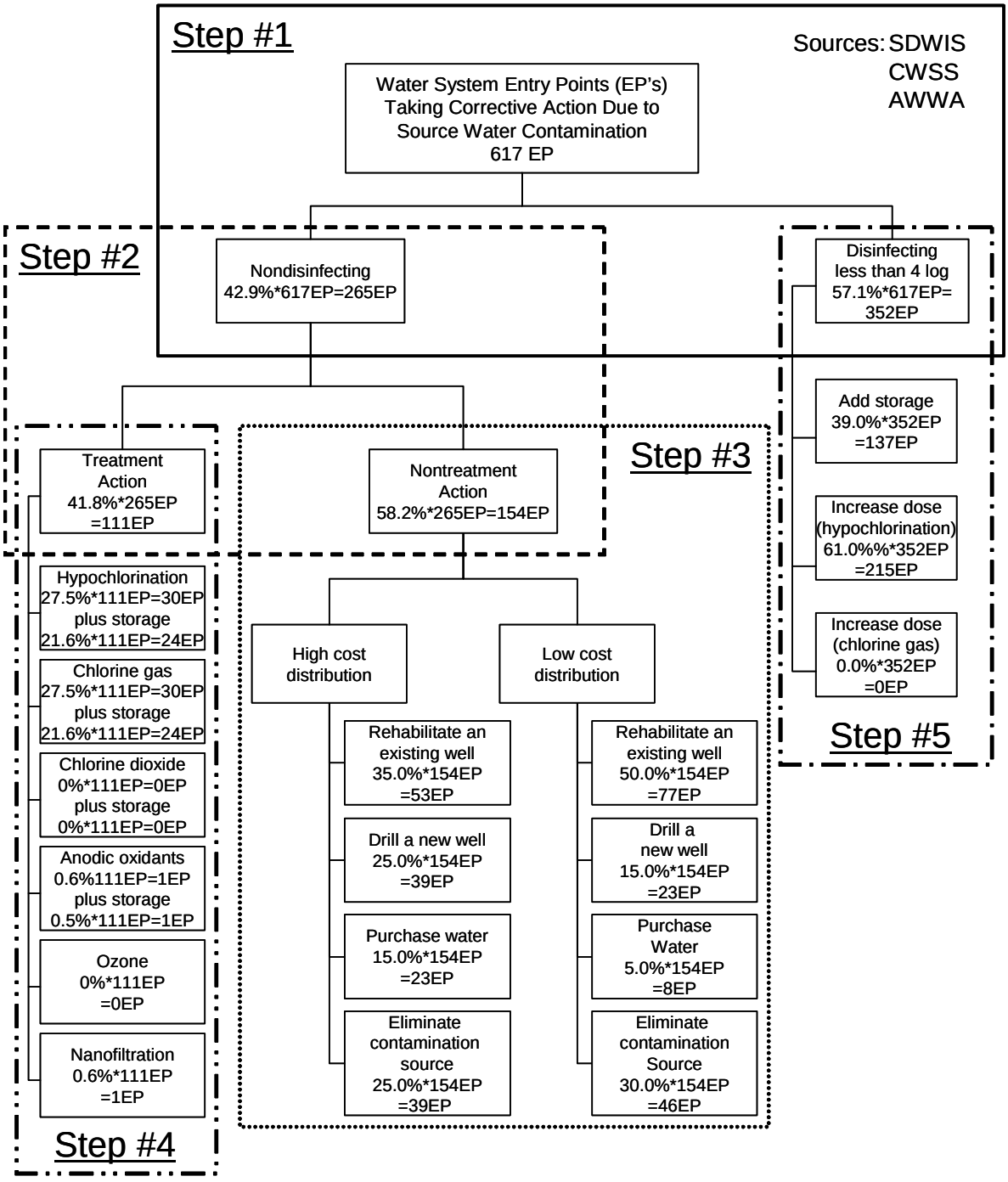


Exhibit 6.21b Estimated Distribution of Source Water Contamination Corrective Actions *(continued on next page)*

Step 1: Current Treatment Practice

System Type/ Disinfection Practice	System Size (Population Served)							
	<100	101-500	501-1,000	1,001-3,300	3,301-10,000	10,001-50,000	50,001-100,000	>100,000
CWSs								
Disinfecting less than 4 log	28.7%	56.4%	59.1%	55.4%	57.1%	83.6%	41.2%	68.9%
Nondisinfecting	71.3%	43.6%	40.9%	44.6%	42.9%	16.4%	58.8%	31.1%
NTNCWSs								
Disinfecting less than 4 log	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%	22.0%
Nondisinfecting	78.0%	78.0%	78.0%	78.0%	78.0%	78.0%	78.0%	78.0%
TNCWSs								
Disinfecting less than 4 log	16.5%	16.5%	16.5%	16.5%	16.5%	16.5%	16.5%	16.5%
Nondisinfecting	83.5%	83.5%	83.5%	83.5%	83.5%	83.5%	83.5%	83.5%

Source: Derived from Exhibit 4.3. Taken as percentages of all entry points not achieving 4-log disinfection.

Step 2: Current Implementation of Treatment Types

Category of Corrective Action	System Size (Population Served)							
	<100	101-500	501-1,000	1,001-3,300	3,301-10,000	10,001-50,000	50,001-100,000	>100,000
Nontreatment action	54.4% - 90%	27.1% - 90%	24.9% - 90%	27.9% - 90%	26.5% - 90%	8.6% - 90%	40.7% - 90%	11.8% - 90%
High cost distribution	36.1%	29.3%	28.7%	29.5%	29.1%	24.7%	32.7%	25.5%
Low cost distribution	36.1%	29.3%	28.7%	29.5%	29.1%	24.7%	32.7%	25.5%
Treatment action	10% - 45.6%	10% - 72.9%	10% - 75.1%	10% - 72.1%	10% - 73.5%	10% - 91.4%	10% - 59.3%	10% - 88.2%

Note: EPA assumes that systems points will make treatment corrective action in proportion to entry points' current disinfection practices.

Source: Derived from Exhibit 4.3.

Step 3: Distribution of Nontreatment Corrective Actions

Corrective Action	System Size (Population Served)							
	<100	101-500	501-1,000	1,001-3,300	3,301-10,000	10,001-50,000	50,001-100,000	>100,000
High Cost Distribution								
Rehabilitate an existing well	46.3%	33.3%	33.3%	33.3%	35.0%	46.2%	50.0%	50.0%
Drill a new well	27.8%	40.0%	25.0%	25.0%	25.0%	30.8%	26.2%	37.5%
Purchase water	5.6%	10.0%	12.5%	12.5%	15.0%	0.0%	0.0%	0.0%
Eliminate contamination source	20.4%	16.7%	29.2%	29.2%	25.0%	23.1%	23.8%	12.5%
Low Cost Distribution								
Rehabilitate an existing well	55.6%	50.0%	50.0%	50.0%	50.0%	61.5%	59.5%	62.5%
Drill a new well	18.5%	20.0%	12.5%	12.5%	15.0%	15.4%	19.0%	25.0%
Purchase water	1.9%	3.3%	4.2%	4.2%	5.0%	0.0%	0.0%	0.0%
Eliminate contamination source	24.1%	26.7%	33.3%	33.3%	30.0%	23.1%	21.4%	12.5%

Note: Percentage of those entry points performing nontreatment corrective action.

Exhibit 6.21b Estimated Distribution of Source Water Contamination Corrective Actions *(continued)*

Step 4: Distribution of Treatment Corrective Actions

Corrective Action	System Size (Population Served)							
	<100	101-500	501-1,000	1,001-3,300	3,301-10,000	10,001-50,000	50,001-100,000	>100,000
Hypochlorination	55.1%	54.8%	56.0%	55.3%	27.5%	0.0%	0.0%	0.0%
Hypochlorination plus storage	43.3%	43.0%	44.0%	43.4%	21.6%	0.0%	0.0%	0.0%
Chlorine gas	0.0%	0.0%	0.0%	0.0%	27.5%	53.8%	54.1%	55.7%
Chlorine gas plus storage	0.0%	0.0%	0.0%	0.0%	21.6%	42.3%	42.5%	43.7%
Chlorine dioxide	0.7%	0.6%	0.0%	0.0%	0.0%	0.3%	1.7%	0.0%
Chlorine dioxide plus storage	0.6%	0.4%	0.0%	0.0%	0.0%	0.3%	1.4%	0.0%
Anodic oxidants	0.2%	0.3%	0.0%	0.4%	0.6%	1.5%	0.0%	0.0%
Anodic oxidants plus storage	0.1%	0.2%	0.0%	0.3%	0.5%	1.2%	0.0%	0.0%
Ozone	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.6%
Nanofiltration	0.0%	0.7%	0.0%	0.6%	0.6%	0.6%	0.3%	0.0%

Note: EPA assumes that systems will choose treatment in proportion to current treatment practices. Estimates for hypochlorination and chlorine gas based on remainder of entry points not performing other treatment practices.
Source: CWSS, Table 1-23 (1997) data. Nanofiltration substituted for all membranes based on professional engineering judgement.

Step 5: Distribution of Corrective Actions for Disinfecting Entry Points

Corrective Action	System Size (Population Served)							
	<100	101-500	501-1,000	1,001-3,300	3,301-10,000	10,001-50,000	50,001-100,000	>100,000
Add storage	39%	39%	39%	39%	39%	39%	39%	39%
Increase dose - hypochlorination	61%	61%	61%	61%	61%	0%	0%	0%
Increase dose - chlorine gas	0%	0%	0%	0%	0%	61%	61%	61%

Note: EPA assumes that systems add storage or increase dose based on AWWA study.

Unit Cost Estimates

Unit cost estimates for the four nontreatment corrective actions and interim disinfection as described above are presented in Exhibit 6.22a. Unit costs for installing and operating each of the six treatment scenarios (and variations) in the compliance forecast are presented in Exhibit 6.22b. For each corrective action, costs generally increase corresponding to system size. However, some corrective actions are assumed to be constant (on average) over the range of system sizes (e.g., costs for actions such as rehabilitating a well or drilling a new well are heavily influenced by factors such as hydrogeologic setting and well depth that are independent of system size). For further description of the assumptions and methodologies used to develop all corrective action unit costs see the *Technology and Cost Document for the Final Ground Water Rule* (USEPA, 2006d).

Exhibit 6.22a Estimated Unit Costs of Nontreatment Corrective Actions for Source Water Contamination

Corrective Action	Size Category (Population Served)								
	<100	101-500	501-1,000	1,001-3,300	3,301-10,000	10,001-50,000	50,001-100,000	100,001-1 Million	>1 Million
Nontreatment Corrective Actions									
Rehabilitate an Existing Well	$11,986	$11,986	$11,986	$11,986	$11,986	$11,986	$11,986	$11,986	$11,986
Drill a New Well	$30,172	$30,172	$30,172	$30,172	$30,172	$30,172	$30,172	$30,172	$30,172
Purchase Water									
Capital	$173,180	$173,180	$198,599	$198,599	$242,618	$242,618	$353,697	$390,999	$390,999
O&M ($ per kgal)	$1.12	$1.18	$0.63	$1.44	$2.09	$1.35	$1.39	$0.91	$0.91
Eliminate Source of Contamination	$16,533	$16,533	$16,533	$16,533	$16,533	$16,533	$16,533	$16,533	$16,533
Interim Disinfection									
Rehabilitate an Existing Well									
Capital	$1,874	$1,874	$1,874	$1,874	$1,874	$1,874	$1,971	$2,302	$20,774
Total O&M	$2,636	$2,887	$3,356	$3,936	$4,259	$5,210	$7,579	$19,177	$135,513
Drill a New Well									
Capital	$1,874	$1,874	$1,874	$1,874	$1,874	$1,874	$1,971	$2,302	$20,774
Total O&M	$5,272	$5,774	$6,712	$7,871	$8,517	$10,420	$15,158	$38,354	$271,026
Purchase Water									
Capital	$1,874	$1,874	$1,874	$1,874	$1,874	$1,874	$1,971	$2,302	$20,774
Total O&M	$5,272	$5,774	$6,712	$7,871	$8,517	$10,420	$15,158	$38,354	$271,026
Eliminate Source of Contamination									
Capital	$1,874	$1,874	$1,874	$1,874	$1,874	$1,874	$1,971	$2,302	$20,774
Total O&M	$1,318	$1,444	$1,678	$1,968	$2,129	$2,605	$3,790	$9,589	$67,757

Note: Based on best professional judgement, EPA estimates that interim disinfection will be performed for a duration of one year for systems rehabilitating an existing well, for two years for systems either drilling a new well or purchasing water, and for six months for systems eliminating the source of contamination.

Source: *Technology and Cost Document for the Final Ground Water Rule* (USEPA, 2005d)

Exhibit 6.22b Estimated Unit Costs of Treatment Corrective Actions for Source Water Contamination

Corrective Action	System Size (Population Served)								
	<100	101-500	501-1,000	1,001-3,300	3,301-10,000	10,001-50,000	50,001-100,000	100,001-1 Million	> 1 Million
Systems Adding Treatment									
Chlorine gas feed capital cost	$ 29,868	$ 29,868	$ 29,868	$ 29,868	$ 29,868	$ 58,781	$ 65,006	$ 96,958	$ 337,511
Chlorine gas feed annual O&M cost	$ 6,192	$ 6,227	$ 6,307	$ 6,456	$ 6,857	$ 16,951	$ 18,197	$ 21,854	$ 61,772
Chlorine gas feed & storage capital cost	$ 31,216	$ 33,354	$ 37,960	$ 46,039	$ 66,058	$ 152,883	$ 266,275	$ 541,906	$ 2,192,279
Chlorine gas feed & storage annual O&M cost	$ 6,192	$ 6,227	$ 6,307	$ 6,456	$ 6,857	$ 16,951	$ 18,197	$ 21,854	$ 61,772
Hypochlorite feed capital cost	$ 8,970	$ 8,970	$ 15,072	$ 24,402	$ 24,402	$ 72,631	$ 79,658	$ 96,180	$ 187,445
Hypochlorite annual O&M cost	$ 1,585	$ 2,076	$ 4,180	$ 6,582	$ 7,326	$ 7,558	$ 7,909	$ 19,177	$ 135,513
Hypochlorite feed & storage capital cost	$ 10,318	$ 12,456	$ 23,164	$ 40,573	$ 60,593	$ 166,733	$ 280,927	$ 541,128	$ 2,042,213
Hypochlorite & storage annual O&M cost	$ 1,585	$ 2,076	$ 4,180	$ 6,582	$ 7,326	$ 7,558	$ 7,909	$ 19,177	$ 135,513
Chlorine Dioxide System capital cost	N/A	N/A	$ 35,011	$ 39,299	$ 42,363	$ 80,836	$ 82,091	$ 202,017	$ 371,828
Chlorine Dioxide annual O&M cost	N/A	N/A	$ 15,261	$ 16,897	$ 17,901	$ 19,878	$ 21,705	$ 25,983	$ 59,412
Chlorine Dioxide System & storage capital cost	N/A	N/A	$ 46,196	$ 61,792	$ 89,439	$ 191,678	$ 307,085	$ -	$ -
Chlorine Dioxide & storage annual O&M cost	N/A	N/A	$ 16,251	$ 17,720	$ 18,733	$ 20,392	$ 22,257	$ -	$ -
Anodic Oxidant capital cost	$ 47,219	$ 65,151	$ 87,450	$ 110,256	$ 151,129	$ 255,055	$ 354,880	$ 745,098	$ 2,188,039
Anodic Oxidant annual O&M cost	$ 2,911	$ 5,471	$ 7,480	$ 9,791	$ 12,855	$ 17,479	$ 22,181	$ 38,439	$ 179,932
Anodic Oxidant & storage capital cost	$ 48,568	$ 68,637	$ 95,543	$ 126,427	$ 187,320	$ 349,157	$ 556,149	$ 1,190,046	$ 4,042,807
Anodic Oxidant & storage annual O&M cost	$ 2,911	$ 5,471	$ 7,480	$ 9,791	$ 12,855	$ 17,479	$ 22,181	$ 38,439	$ 179,932
Ozonation capital cost	N/A	N/A	$ 347,027	$ 431,809	$ 622,023	$ 903,927	$ 1,175,442	$ 1,991,127	$ 6,518,099
Ozonation annual O&M cost	N/A	N/A	$ 55,668	$ 59,028	$ 60,789	$ 63,718	$ 67,004	$ 87,225	$ 253,317
Nanofiltration capital cost	$ 62,691	$ 104,856	$ 182,768	$ 304,122	$ 573,460	$ 1,086,398	$ 1,872,457	$ 5,140,179	$ 29,028,479
Nanofiltration annual O&M cost	$ 7,520	$ 10,253	$ 20,140	$ 37,037	$ 63,670	$ 133,397	$ 194,361	$ 541,543	$ 3,873,384
Systems upgrading from less than 4-log to 4-log or greater									
Add storage capital cost	$ 1,349	$ 3,486	$ 8,093	$ 16,171	$ 36,191	$ 94,102	$ 201,269	$ 444,947	$ 1,854,768
Increase dose - hypochlorination annual O&M cost	$ 72	$ 179	$ 179	$ 195	$ 470	NA	NA	NA	NA
Increase dose - chlorine gas annual O&M cost	NA	NA	NA	NA	NA	$ 1,342	$ 2,108	$ 3,846	$ 17,838

Source: *Technology and Cost Document for the Final Ground Water Rule* (USEPA, 2005d)

Annualized cost estimates for systems and States to perform source water contamination corrective actions are presented in Exhibit 6.23.

Exhibit 6.23 PWS and State Cost Estimates for Triggered Monitoring Corrective Action Activities ($Millions, 2003$)

Annualized Costs for Triggered Monitoring Corrective Action Activities									
	Systems			States			Total		
	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)
3%	$25.64	$14.90	$38.39	$0.46	$0.32	$0.61	$26.10	$15.22	$39.00
7%	$27.20	$15.89	$40.96	$0.52	$0.36	$0.69	$27.72	$16.26	$41.65

Notes: Detail may not add to totals due to independent rounding and independent cost model runs.

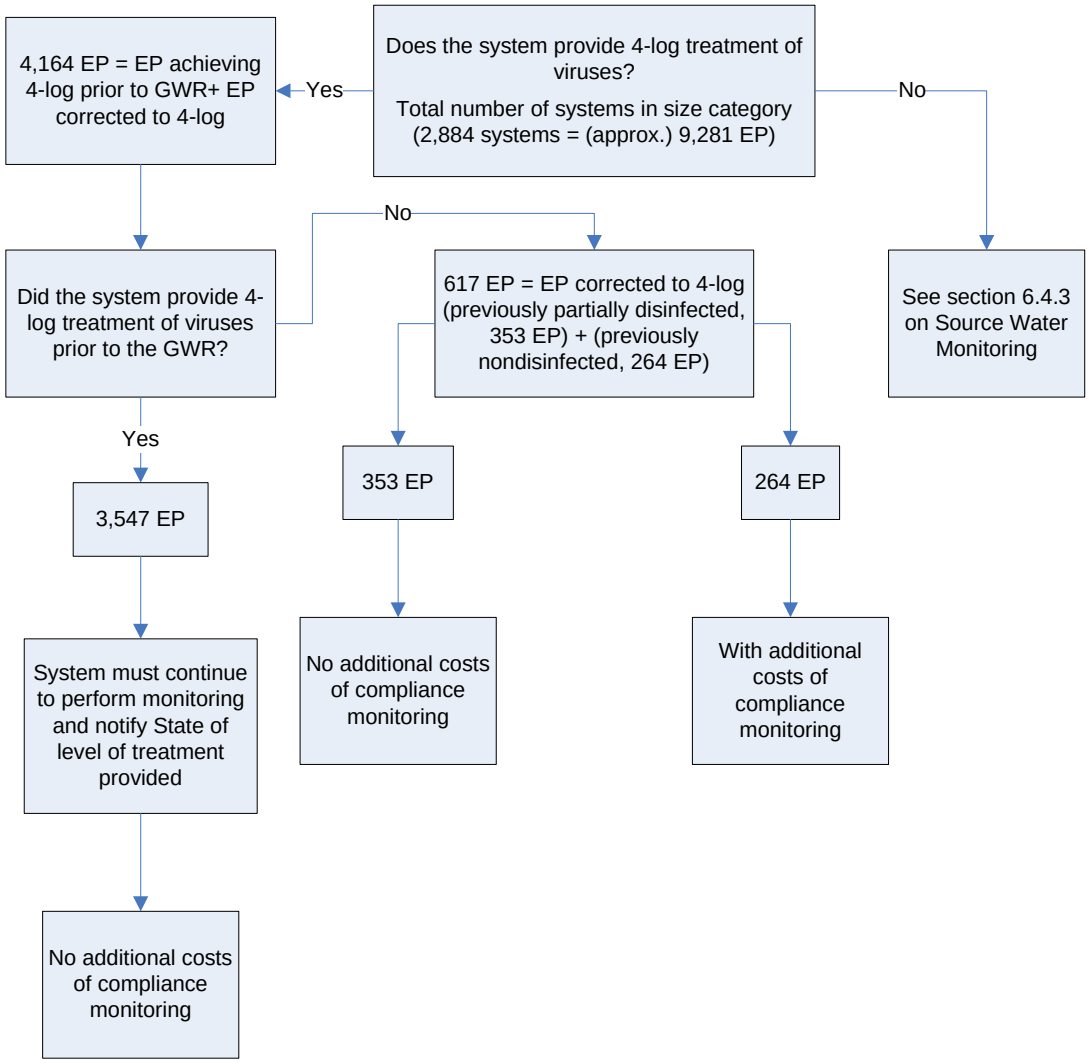
Source: Cost Model Outputs

6.4.5 Compliance Monitoring

PWSs that provide 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer to meet requirements of the GWR must monitor the effectiveness and reliability of their treatment. This section presents the assumptions used to estimate the burden and costs attributable to compliance monitoring. Exhibit 6.24 provides a schematic of the compliance monitoring process.

Exhibit 6.24 Schematic of Compliance Monitoring Process

(Numbers based on 3,301 - 10,000 population category for CWSs)



PWSs

Different cost assumptions were needed for systems engaged in compliance monitoring of disinfection treatment in place prior to promulgation of the GWR versus systems having technology installed as a result of corrective action required by the GWR. The numbers of entry points subject to each situation are presented in Exhibit 6.25.

Systems Disinfecting Prior to GWR: EPA assumed that systems already employing chemical disinfection treatment for purposes other than compliance with the GWR, or prior to the Rule's promulgation, would already have the monitoring program and monitoring equipment in place to monitor the disinfection. These systems include systems currently disinfecting to 4-log as well as systems currently disinfecting to less than 4-log. Therefore, systems which are already disinfecting would incur no costs for adding disinfection monitoring equipment. EPA bases this assumption on the language obtained from the pre-existing State disinfection requirements. Most States specify in the State regulations that systems which disinfect must maintain the prescribed level of disinfection in no less than 5% of monthly samples (suggests at least 20 samples per month), or the system's disinfectant level may not be below the prescribed disinfectant level for more than four hours. Furthermore, some States specify that disinfecting systems must monitor the disinfection at a specified frequency, such as daily or continuously. This type of language suggests monitoring at a frequency consistent with that specified in the GWR, resulting in no monitoring equipment purchases for these systems.

For systems using nanofiltration technology, the monitoring capability is built into the technology's core process. Therefore, EPA assumes that systems using nanofiltration technology prior to implementation of the GWR will incur no treatment monitoring costs to comply with the Rule by using nanofiltration.

Before beginning compliance monitoring, however, systems must inform the State that they achieve 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer. For costing purposes, EPA assumes that preparing and submitting notification for the State requires 0.5 hours. Systems must also notify the State each time the treatment technology used fails to maintain 4-log treatment for more than 4 hours (see Chapter 3 for more detail on requirements for each treatment technology). For costing purposes, EPA assumes a disinfection failure rate of 5 percent of entry points engaged in 4-log source water virus treatment. EPA assumes that preparing and submitting a treatment failure report to the State requires 2.5 hours. EPA has developed and systems will have access to automated forms that will minimize the burden to systems in complying with these reporting requirements. Exhibit 6.26 presents the unit burdens and costs for these reporting requirements.

Exhibit 6.25 Assumptions for Entry Points Subject to Compliance Monitoring

System Size (Population Served)	Systems Subject to Compliance Monitoring	Entry Points Subject to Compliance Monitoring	Entry Points Achieving 4-log Prior to GWR	Entry Points Corrected to 4-log; partially disinfected	Entry Points Corrected to 4-log; previously nondisinfected
	A	B=C+D+E	C	D	E
Community Water Systems (CWSs)					
<100	3,998	5,246	3,996	358	891
101-500	6,440	10,499	8,873	917	709
501-1,000	2,127	4,155	3,547	360	248
1,001-3,300	2,509	6,090	5,378	396	317
3,301-10K	1,294	4,164	3,547	353	264
10,001-50K	803	4,511	3,856	548	107
50,001-100K	72	810	583	93	133
100,001-1 Million	55	681	545	94	42
> 1 Million	3	34	34	-	-
Totals	**17,300**	**36,189**	**30,359**	**3,118**	**2,712**
Nontransient Noncommunity Water Systems (NTNCWSs)					
<100	1,537	1,537	850	150	537
101-500	1,141	1,141	608	119	415
501-1,000	320	320	170	33	117
1,001-3,300	150	150	64	19	67
3,301-10K	17	17	7	2	8
10,001-50K	2	2	1	0	1
50,001-100K	0	0	0	0	0
100,001-1 Million	0	0	0	0	0
> 1 Million	-	-	-	-	-
Totals	**3,167**	**3,167**	**1,700**	**323**	**1,144**
Transient Noncommunity Water Systems (TNCWSs)					
<100	8,075	8,075	1,160	1,143	5,772
101-500	2,368	2,368	342	337	1,689
501-1,000	243	243	35	35	174
1,001-3,300	86	86	11	12	63
3,301-10K	13	13	1	2	10
10,001-50K	4	4	0	1	3
50,001-100K	0	0	0	0	0
100,001-1 Million	0	0	0	0	0
> 1 Million	-	-	-	-	-
Totals	**10,790**	**10,790**	**1,549**	**1,530**	**7,711**
Grand Total	**31,257**	**50,146**	**33,608**	**4,971**	**11,567**

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

Source: (C) Number of entry points from Exhibit 4.3.
(D) Exhibit 6.5b, Column E
(E) Exhibit 6.5b, Column, F

Systems Treating As a Corrective Action: Systems that adopt treatment as a corrective action for source water fecal contamination must also install monitoring equipment to perform compliance monitoring. The unit capital and O&M costs[8] are presented in Exhibit 6.27a (for systems serving 3,300 and fewer people) and Exhibit 6.27b (for systems serving more than 3,300 people). These system size categories are costed differently due to different compliance monitoring requirements (see Chapter 1 for a full description of compliance monitoring requirements).

EPA assumes that all systems serving 3,300 or fewer people will conduct daily grab samples for chlorine residual measurement and incur 0.5 hours labor burden per day. Because nanofiltration technologies have monitoring capability incorporated into their core processes, systems that adopt these treatment techniques are assumed to incur no capital or O&M costs for compliance monitoring.

As noted above, systems must also notify the State each time the treatment technology used fails to maintain 4-log treatment of virus for more than 4 hours. EPA assumes that preparing and submitting a treatment failure report to the State requires 2.5 hours. This cost is the same as reported for systems disinfecting prior to the GWR as listed in Exhibit 6.26.

[8] Systems may choose to install monitoring systems that are more complicated and costly (i.e., SCADA systems) than those presented here. However, this level of monitoring is not required under the rule and therefore is not included as part of the cost analysis.

Exhibit 6.26 PWS Unit Costs for Compliance Monitoring for Initial State Notification and Disinfection Failure Reports

System Size (Population Served)	Initial State Notification for Systems Treating Prior to GWR			Treatment Failure Report for All Systems Treating		
	Notification Preparation (hours)	Labor Cost (per hour)	Unit Report Cost	Report Preparation (hours)	Labor Cost (per hour)	Unit Report Cost
	A	B	C=A*B	D	E	F=D*E
Community Water Systems (CWSs)						
<100	0.5	$ 21.44	$ 10.72	2.5	$ 21.44	$ 53.60
101-500	0.5	$ 23.09	$ 11.55	2.5	$ 23.09	$ 57.73
501-1,000	0.5	$ 24.74	$ 12.37	2.5	$ 24.74	$ 61.85
1,001-3,300	0.5	$ 24.74	$ 12.37	2.5	$ 24.74	$ 61.85
3,301-10K	0.5	$ 30.51	$ 15.26	2.5	$ 30.51	$ 76.28
10,001-50K	0.5	$ 31.08	$ 15.54	2.5	$ 31.08	$ 77.70
50,001-100K	0.5	$ 31.08	$ 15.54	2.5	$ 31.08	$ 77.70
100,001-1 Million	0.5	$ 35.25	$ 17.62	2.5	$ 35.25	$ 88.12
> 1 Million	0.5	$ 35.25	$ 17.62	2.5	$ 35.25	$ 88.12
Nontransient Noncommunity Water Systems (NTNCWSs)						
<100	0.5	$ 21.44	$ 10.72	2.5	$ 21.44	$ 53.60
101-500	0.5	$ 23.09	$ 11.55	2.5	$ 23.09	$ 57.73
501-1,000	0.5	$ 24.74	$ 12.37	2.5	$ 24.74	$ 61.85
1,001-3,300	0.5	$ 24.74	$ 12.37	2.5	$ 24.74	$ 61.85
3,301-10K	0.5	$ 30.51	$ 15.26	2.5	$ 30.51	$ 76.28
10,001-50K	0.5	$ 31.08	$ 15.54	2.5	$ 31.08	$ 77.70
50,001-100K	0.5	$ 31.08	$ 15.54	2.5	$ 31.08	$ 77.70
100,001-1 Million	0.5	$ 35.25	$ 17.62	2.5	$ 35.25	$ 88.12
> 1 Million	NA	$ 35.25	NA	NA	$ 35.25	NA
Transient Noncommunity Water Systems (TNCWSs)						
<100	0.5	$ 21.44	$ 10.72	2.5	$ 21.44	$ 53.60
101-500	0.5	$ 23.09	$ 11.55	2.5	$ 23.09	$ 57.73
501-1,000	0.5	$ 24.74	$ 12.37	2.5	$ 24.74	$ 61.85
1,001-3,300	0.5	$ 24.74	$ 12.37	2.5	$ 24.74	$ 61.85
3,301-10K	0.5	$ 30.51	$ 15.26	2.5	$ 30.51	$ 76.28
10,001-50K	0.5	$ 31.08	$ 15.54	2.5	$ 31.08	$ 77.70
50,001-100K	0.5	$ 31.08	$ 15.54	2.5	$ 31.08	$ 77.70
100,001-1 Million	0.5	$ 35.25	$ 17.62	2.5	$ 35.25	$ 88.12
> 1 Million	NA	$ 35.25	NA	NA	$ 35.25	NA

Notes: Detail may not add to totals due to independent rounding.
NA Not applicable (no NCWSs of this size category).

Sources: (A, D) Labor hours for initial notification and treatment failure report reflect EPA estimate.
(B, E) Labor rate from Exhibit 6.1.

Exhibit 6.27a PWS Compliance Monitoring Unit Costs for Systems Serving 3,300 or Fewer People

Component	Unit Cost (1998)	PPI (1998)	PPI (2003)	Unit Cost (2003)	Labor burden (per day)	Annual Cost Frequency	Annual Labor Burden	Annual Total Cost
	A	B	C	D=A*(C/B)	E	F	G=E*F	H=D*E*F
Compliance Monitoring Labor								
25-100	N/A	N/A	N/A	$ 21.44	0.50	365	183	$ 3,913
101-500	N/A	N/A	N/A	$ 23.09	0.50	365	183	$ 4,214
500-3.3k	N/A	N/A	N/A	$ 24.74	0.50	365	183	$ 4,515
Chlorine Test Kits								
25-100	$ 34.00	143.7	150.1	$ 35.50	N/A	3.65	N/A	$ 130
101-500	$ 34.00	143.7	150.1	$ 35.50	N/A	3.65	N/A	$ 130
500-3.3k	$ 34.00	143.7	150.1	$ 35.50	N/A	3.65	N/A	$ 130
Totals								
25-100							183	$ 4,042
101-500							183	$ 4,344
500-3.3k							183	$ 4,645

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

Sources: (A) Unit cost for test kit from Products for Analysis, 1998 Hach Co. Model 2231-02. Unit cost derivation for system operator in section 6.2.1.
(B & C) Producer Price Index (PPI) Commodity Code 3500 (Finished goods less food and energy) from BLS (www.bls.gov).
(D) Labor rate from section 6.2.1.
(E) Labor hours for compliance monitoring reflect EPA estimate.
(F) Monitoring performed daily. New test kit needed every 100 days.

Exhibit 6.27b PWS Compliance Monitoring Capital Unit and O&M Costs for Systems Serving More than 3,300 People

Component	Unit Cost (1998)	PPI (1998)	PPI (2003)	Unit Cost (2003)	Quantity Purchased	Total Cost
	A	B	C	D=A*(C/B)	E	F=D*E
Capital Costs						
Chlorine analyzer (Hach CL17)	$ 2,375	121.0	114.7	$ 2,251	1	$ 2,251
Power cord	$ 10	121.0	114.7	$ 9	1	$ 9
Chart recorder (Honeywell 10" round)	$ 665	121.0	114.7	$ 630	1	$ 630
Installation labor (System Operator)						
3.3k-10k	N/A	N/A	N/A	$ 25.34	8	$ 203
10k-100k	N/A	N/A	N/A	$ 26.05	8	$ 208
>100k	N/A	N/A	N/A	$ 31.26	8	$ 250
Total Capital Cost						
3.3k-10k						$ 3,094
10k-100k						$ 3,100
>100k						$ 3,141
Annual Operation and Maintenance						
Compliance monitoring						
3.3k-10k	N/A	N/A	N/A	$ 25.34	80	$ 2,027
10k-100k	N/A	N/A	N/A	$ 26.05	80	$ 2,084
>100k	N/A	N/A	N/A	$ 31.26	80	$ 2,501
Maintenance kit	$ 140	143.7	150.5	$ 147	1	$ 147
Monthly reagents	$ 18	143.7	150.5	$ 19	12	$ 226
Charts	$ 15	143.7	150.5	$ 16	1	$ 16
Recorder pens	$ 52	143.7	150.5	$ 54	1	$ 54
Total Annual Operation and Maintenance Costs						
3.3k-10k						$ 2,470
10k-100k						$ 2,527
>100k						$ 2,944

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

Sources: (A) Unit costs for equipment (both capital and O&M) from Products for Analysis, 1998 Hach Co.

(B & C) Producer Price Index Commodity Code 117 (Electrical machinery and equipment) for Capital Costs and Commodity Code 3500 (Finished goods less food and energy) for Annual O & M, BLS (www.bls.gov). December values.

(D) Labor rate from Exhibit 6.1.

(E) 80 hours per year for O&M compliance monitoring.

States

States incur costs to document the initial notification from systems that achieve 4-log treatment of viruses (using inactivation, removal, or State-approved combination of these technologies) before or at the first customer, as well as to review the systems' disinfection failure reports, presented in Exhibit 6.28. For costing purposes, EPA assumes that documenting the PWSs' notifications requires 0.5 hours and that reviewing disinfection failure reports requires 3.5 hours. The burden estimate for States to review a disinfection failure reports is greater than the burden estimated for systems to prepare and submit the report because it is anticipated that the State will have less familiarity with any particular system and will be required to look up additional historical information to make any assessments/determinations regarding the report. EPA has developed and States will have access to automated forms that will minimize the burden to systems in complying with this reporting requirement.

Exhibit 6.28 State Unit Costs for Compliance Monitoring

Cost Component	Labor Hours A	Labor Cost (per hour) B	Unit Cost C=A*B
Document Initial Notification	0.5	$ 33.60	$ 16.80
Review Disinfection Failure Report	3.5	$ 33.60	$ 117.61

Notes: Detail may not add to totals due to independent rounding.
Sources: (A) Labor hours for rule activities reflect EPA estimate.
(B) Labor rate from Exhibit 6.2.

Annualized costs for systems and States to perform compliance monitoring is presented in Exhibit 6.29.

Exhibit 6.29 PWS and State Cost Estimates for Compliance Monitoring Activities ($Millions, 2003$)

Annualized Costs for Compliance Monitoring Activities									
	Systems			States			Total		
	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)	Mean	Lower Bound (5th %ile)	Upper Bound (95th %ile)
3%	$9.35	$3.02	$16.97	$0.00	$0.00	$0.01	$9.36	$3.02	$16.98
7%	$8.32	$2.65	$15.17	$0.00	$0.00	$0.01	$8.32	$2.65	$15.18

Notes: Detail may not add to totals due to independent rounding and independent cost model runs.
Source: Cost Model Outputs

6.4.6 Total Capital and One-Time Costs

Exhibit 6.30 presents total capital and one-time costs of the GWR. Note, the bulk of capital costs are incurred by transient noncommunity water systems (TNCWSs) serving 10,000 or fewer people. One-time costs for PWSs and States are limited to rule implementation.

Exhibit 6.30 Total Initial Capital and One-Time Costs ($Millions, 2003$)

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

Notes: Detail may not add to totals due to independent rounding.
The mean and confidence bounds are equal for both systems and state implementation costs because EPA derived these costs from point estimates.
Source: Appendix D, Exhibits D.1, D.2, and D.3.

6.4.7 Uncertainty in Unit Costs

As stated in section 6.2.6, EPA recognizes that there are both variability and uncertainty in unit cost estimates for treatment. Variability is expected in the actual costs that will be experienced by different water systems with similar flows installing the same treatment technology. Otherwise similar systems may experience different capital and/or O&M costs due to site-specific factors. Inputs to unit costs such as water quality conditions, labor rates, and land costs can be highly variable and increase the system-to-system variability in unit costs. In developing the unit cost estimates, there is insufficient information to fully characterize what the distribution of this variability will be on a national scale for all of the treatments and all possible conditions.

The unit costs for this EA are developed as average or representative estimates of what these unit costs will be nationally. That is, in developing unit costs, design criteria for the technologies were selected to represent typical, or average, conditions for the universe of systems. As a result, there is uncertainty inherent in these unit cost estimates as they are based on independent assumptions with supporting data and vendor quotes, where available, rather than on a detailed aggregation of State, regional, or local estimates based on actual field conditions. In this EA, uncertainty in these national

average unit cost factors for specific technologies is characterized as a triangular distribution with minimum and maximum values set at the following percentages relative to the best estimate:

- Capital costs: +/- 30 percent
- O&M costs: +/- 15 percent

These percentages were developed by EPA based on input from engineering professionals and reflect recommendations from the National Drinking Water Advisory Council (NDWAC) (2001) in their review of the national cost estimation methodology for the Arsenic Rule. EPA believes that the uncertainties in capital and O&M costs for a given treatment technology are independent of one another and that uncertainties across all technologies are independent.

The uncertainty in unit costs is reflected in the 90 percent confidence bounds shown in the national cost summary exhibit in section 6.4.6 and later in this chapter.

6.4.8 Alternative Cost Analysis

The Agency performed an alternative cost analysis by running the cost model using a subset of the studies that were the basis for the fecal indicator and viral occurrence rates in the primary analysis. This subset comprised just those studies which had undergone peer review prior to publication[9] and so consisted only of peer-reviewed data. This cost model run parallels the alternative benefits model run described in section 5.5.4. Compared to the primary analysis, this alternative cost model run results in an increase in the annualized costs by a range of $29.1 million to $29.4 million (an approximately 47% increase), using 3 percent and 7 percent discount rates, respectively.

6.5 Household Costs

EPA assumes that systems may pass some or all costs of a new regulation on to their consumers in the form of rate increases. Household costs, which are in units of *$ per household per year*, are estimated in this section to provide a measure of the increase in water bills that is expected to result from the GWR. These cost increases incorporate the costs of rule implementation, sanitary surveys, triggered monitoring, corrective actions, and compliance monitoring. Exhibit 6.31 presents the mean expected increases in annual household costs for all CWSs, including those systems that do not have to take corrective action for significant deficiencies or source water contamination. Exhibit 6.31 also presents the same information for CWSs that must take corrective action. Household costs tend to decrease as system size increases, due mainly to the economies of scale for the corrective actions.

[9] Studies omitted from the alternative occurrence model are those used for the primary analysis (detailed in Ch. 4 of the EA) that were either not published or not peer reviewed prior to publication: Missouri Alluvial Aquifer (Vaughn, 1996), Wisconsin Migrant Worker Camp (USEPA et al., 1998), EPA Vulnerability (USEPA, 1998), New England (Doherty et al., 1998), Three-State Study #3: Minnesota (Battigelli, 1999), Three-State Study #1: Wisconsin (Battigelli, 1999), and the Montana Study (Miller and Meek, 1996).

To calculate household costs, the CWS population subject to each rule requirement is divided by 2.59 people per household (U.S. Bureau of the Census, 2001a) to calculate a number of households subject to each requirement. The cost of the rule, by size category, is then divided by that number of households to determine a per-household cost. To annualize capital costs when determining the costs to households, EPA uses different discount rates for private and public systems and for systems of different sizes. The rate differences between systems represent the different borrowing sources each type of system has available to it, differences in risk, and expectations regarding inflation. The rates vary from 5.20 to 6.27 percent depending on system size and ownership, and are summarized in Exhibit 6.4.

As shown in Exhibit 6.31, annual household costs for all CWSs (including both those that do and those that do not add treatment) range from $0.21 to $16.54, depending on system size. Household costs for the subset of systems that undertake corrective actions range from $0.45 to $52.38, depending on system size. EPA estimates that, as a whole, households subject to the GWR face minimal increases in their annual costs. Approximately 66 percent of the households potentially subject to the rule are customers of systems serving at least 10,000 people; these systems experience the lowest increases in costs due to significant economies of scale. Households served by small systems that undertake corrective actions will face the greatest increases in annual costs. Only CWSs are included in this analysis because they are the only systems that serve households directly.

Exhibit 6.31 Summary of Annual Per-Household Costs for the GWR (2003$/Year)

Systems Size (Population Served)	Households	Mean	Median	90th Percentile
All Community Water Systems (CWSs)				
<100	289,222	$ 16.54	$ 2.81	$ 9.31
101-500	1,303,890	$ 3.51	$ 0.64	$ 6.11
501-1,000	1,278,081	$ 0.97	$ 0.16	$ 1.70
1,001-3,300	4,196,105	$ 0.37	$ 0.04	$ 0.61
3,301-10K	6,271,380	$ 0.27	$ 0.03	$ 0.43
10,001-50K	11,468,813	$ 0.21	$ 0.04	$ 0.49
50,001-100K	4,204,584	$ 0.34	$ 0.10	$ 1.02
>100,000	9,755,817	$ 0.21	$ 0.04	$ 0.62
Total	38,767,890	$ 0.51	$ 0.09	$ 0.88
Corrective Action Community Water Systems (CWSs)				
<100	70,563	$ 52.38	$ 18.99	$ 82.21
101-500	312,484	$ 12.00	$ 4.52	$ 25.76
501-1,000	302,557	$ 3.23	$ 1.33	$ 6.56
1,001-3,300	919,133	$ 1.33	$ 0.47	$ 2.59
3,301-10K	1,487,159	$ 0.80	$ 0.25	$ 2.18
10,001-50K	2,871,250	$ 0.45	$ 0.18	$ 1.18
50,001-100K	1,215,544	$ 0.53	$ 0.26	$ 1.36
>100,000	2,283,144	$ 0.68	$ 0.39	$ 1.65
Total	9,461,833	$ 1.51	$ 0.60	$ 3.20

Source: GWR model output.

6.6 Nonquantified Costs

Although EPA has quantified the significant costs of the GWR, there are some costs that the Agency did not quantify. Overall, EPA believes that these nonquantified costs are much smaller than the nonquantified benefits. These nonquantified costs result from uncertainties surrounding rule assumptions and from modeling assumptions. For example, EPA estimated that some systems may need to acquire land if they need to build a treatment facility or drill a new well. This was not considered for most systems because EPA expects that the majority of the technologies that systems will use to comply with this rule will fit within the existing plant footprint. In addition, if the cost of land is prohibitive, a system may choose another lower cost alternative such as connecting to another source. EPA has also not quantified costs for systems already using disinfection to conduct compliance monitoring because EPA believes such systems are already incurring these costs.

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

EPA did not include compliance monitoring costs for systems improving disinfection from less than 4-log to greater than 4-log inactivation because EPA believes that essentially all of these systems are already measuring their residuals and recording such information on a daily basis as standard operating procedures. However, there may be some systems that are not doing this, and if so, additional costs would need to be incurred.

For some systems, further investigation into problems identified through implementation of GWR requirements could lead to a determination that the source is more appropriately classified as GWUDI. In such instances, systems will need to work closely with the State to clarify the source classification. If a source is reclassified as GWUDI, the system may incur significant additional costs to comply with the requirements (e.g., filtration) under the various regulations applicable to GWUDI/surface water systems. Although a reclassification may be prompted by GWR requirements, the actual costs for complying with GWUDI requirements fall under the applicable regulations governing GWUDI supplies and are not included in this EA.

The optional assessment monitoring provision was not included in the quantitative cost analysis. However, EPA was not able to quantify either the benefits or costs of this program.

Due to lack of information, EPA was unable to quantify the costs (as well as benefits) from the correction of sanitary survey deficiencies in distribution systems and treatment plants.

6.7 Uncertainty Analysis

Many uncertain values are used to derive estimates of costs of this rule. Most, but not all, of these are mathematically modeled so that a "realization" is selected for them in each "uncertainty iteration" of this EA. These uncertainties then propagate through the derivation of final estimates so the total uncertainty of those final estimates can be understood. The paragraphs that follow discuss the most important of these uncertain quantities.

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

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

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

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

For the Sanitary Survey Provisions, the Percent of Systems Identified as Having Significant Deficiencies, the Percent of These Deficiencies That Are Corrected, and Associated Costs and Benefits

For the sanitary survey provisions, EPA estimated the impacts associated with well deficiencies. EPA used data from the 1998 ASDWA survey to estimate the percent of wells with deficiencies (ASDWA, 1997). To estimate benefits, EPA assumed that if a correction of a well defect occurred at a

virally contaminated well, some, but not all of these virally contaminated wells would no longer have viral contamination. EPA used an uncertainty distribution for this estimate.

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

While the sanitary survey provisions will also result in identification and correction for deficiencies associated with treatment or distribution system deficiencies, due to insufficient data, EPA did not quantify either costs or benefits for these types of deficiencies.

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

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

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

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

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

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

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

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

Optional Assessment Monitoring

The Agency was not able to estimate the benefits or costs resulting from the optional assessment monitoring program. States can determine what systems they deem most vulnerable to fecal contamination and require these systems to conduct assessment monitoring. Systems would incur additional costs from monitoring and reporting results as well as any corrective action associated with fecal indicator positives. States would incur additional costs for determining what systems would be required to monitor, assisting systems with corrective actions decisions, and recordkeeping.

Corrective Actions and Significant Deficiencies

The Agency also did not develop costs for corrective actions for all conceivable significant deficiencies that a system may encounter. Instead, representative actions that span the range of low cost to expensive actions were used. The corrective actions that are a result of significant deficiencies identified during sanitary surveys do not include the ones performed within the treatment plant or in the distribution system due to lack of adequate data. Exclusion of these costs from the cost analysis results in an underestimate of potential rule costs, though the magnitude of the underestimate is unknown.

In addition, EPA also recognizes that some costs (as well as benefits) from the correction of sanitary survey deficiencies identified in the distribution systems and treatment plant have not been quantified.

Uncertainty Summary

Overall, EPA recognizes that there is uncertainty in various parts of its estimates that could result in either an over- or underestimate of the costs as presented in this chapter. Exhibit 6.32 presents a summary of these issues, references the section or appendix where the information is introduced, and estimates the effects that each may have on national costs. The Agency has been careful to use the best available data, to account for uncertainty quantitatively when possible, and to avoid any consistent biases in assumptions and the use of data. The primary known bias is that some benefits and costs have not been quantified, and therefore are not included in the quantitative comparison of regulatory alternatives.

Exhibit 6.32 Cost Uncertainty Summary

Uncertainty	Section With Full Discussion of Uncertainty	Most Likely Effect of Current Assumptions on Estimate of National Costs		
		Underestimate	Overestimate	Unknown Impact
Percentage of systems finding TC positive samples	6.4.3			X
Number of triggered monitoring samples attributable to TC positives under the GWR	6.4.3		X	
Percentage of triggered monitoring systems receiving indicator-positive source water	6.4.3			X
Uncertainty in compliance forecasts for corrective actions	6.4.4			X
Percentage of disinfection failures	6.4.5			X
Unit Costs	6.4.7			X
Sanitary Survey corrective actions	6.6	X		
Compliance with multiple rules	6.7			X

6.8 Total Annualized Cost for Final GWR Regulatory Alternative

Based on information presented previously in this chapter, EPA developed national cost estimates for the Final GWR. Exhibit 6.33 presents the total annualized costs to PWSs for the final GWR at 3 and 7 percent discount rates. Exhibit 6.34 presents the total annualized cost for the final GWR by system size and type at 3 and 7 percent discount rates.

Exhibit 6.33 Total Annualized Present Value Costs ($Millions, 2003$)

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

Notes: Detail may not add to totals due to independent rounding.
Source: Cost Model Outputs

Exhibit 6.34 Total Annualized Costs to Systems by System Size and Type ($Millions, 2003$)

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

Notes: Detail may not be consistent with summary presentations due to independent statistical analysis.
Source: Cost Model Outputs, Exhibit 6.6.

6.9 Comparison of Regulatory Alternatives

During the development of the GWR, the Agency considered several regulatory alternatives. Exhibit 6.35 provides a comparison of the total annual cost of compliance across the four regulatory alternatives evaluated for the GWR. The cost of the final rule lies between the least costly and most costly alternatives. The costs increases, however, by more than a factor of ten from the final rule to the across-the-board disinfection alternative. This increase in costs results from the fact that the final rule and Alternatives 1 and 3 first are tailored to focus on PWSs that have a demonstrated risk of providing their customers fecally contaminated drinking water. Across-the-board disinfection, as the name implies, requires all PWSs to treat their source water, even if there is no demonstrated potential or actual fecal

contamination. This means that costs are being incurred by many more PWSs under this alternative than the others.

The burden associated with State oversight and administration varies among the different regulatory alternatives. State burden and cost estimates for implementation and annual administration for the final regulatory alternative are presented in Exhibits 6.7a and 6.7b. These costs are estimated to be similar for Alternatives 2 and 3. States incur less burden from oversight and administration of Alternatives 1 and 4 because these alternatives do not have monitoring components of the rule. Additionally, laboratory certification is eliminated in Alternatives 1 and 4, and due to limited numbers and complexity of rule components, the burden for the remaining activities is reduced by 50% compared to Alternatives 2 and 3. For Alternative 4, technology selection is allocated in accordance with the compliance forecast for all systems choosing treatment technologies.

EPA used the same process for developing costs for the final rule to develop costs for the other alternatives. Unit costs were multiplied by the number of systems performing various components of each alternative, and results were summed for all components.

Exhibit 6.35 Comparison of National Annual Costs by Regulatory Alternative ($Millions, 2003$)

Rule Alternative	Total Annualized Cost ($Millions)					
	3 Percent Discount Rate			7 Percent Discount Rate		
		90 Percent			90 Percent	
	Mean Estimate	Lower (5th %tile)	Upper (95th %tile)	Mean Estimate	Lower (5th %tile)	Upper (95th %tile)
Alternative 1 Sanitary Survey Only	$ 15.3	$ 11.8	$ 19.2	$ 15.3	$ 11.9	$ 19.0
Alternative 2 - Risk-Targeted Approach (Final Rule) Sanitary Survey and Triggered Monitoring	$ 61.8	$ 45.2	$ 81.4	$ 62.3	$ 46.1	$ 81.6
Alternative 3 - Multi-Barrier Approach Sanitary Survey, Hydrogeologic Sensitivity Assessment, Assessment Monitoring, and Triggered Monitoring	$ 67.9	$ 49.4	$ 89.5	$ 69.4	$ 51.0	$ 90.6
Alternative 4 Across-the-Board Disinfection	$ 686.4	$ 636.8	$ 735.4	$ 665.3	$ 612.3	$ 717.0

Source: Cost Model Outputs

7. Economic Impact Analysis

7.1 Introduction

As part of the rulemaking process, EPA is required to address the direct and indirect burdens that the GWR may place on certain types of governments, businesses, and populations. This chapter presents the analyses performed by EPA in accordance with the following 12 Federal mandates.

1) The Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.
2) An analysis of small system affordability to determine variance technologies in accordance with Section 1415(e)(1) of the SDWA Amendments.
3) Feasible technologies available to all systems as required by Section 1412(b)(4)(E) of the SDWA Amendments.
4) A Technical, Financial, and Managerial Capacity Assessment as required by Section 1420(d)(3) of the 1996 Amendments to the SDWA.
5) Paperwork Reduction Act (a separate Information Collection Request document contains the complete analysis).
6) Unfunded Mandates Reform Act (UMRA) of 1995.
7) Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments).
8) Impacts on sensitive subpopulations as required by Section 1412(b)(3)(c)(i) of the Safe Drinking Water Act (SDWA) Amendments.
9) Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks).
10) Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations).
11) Executive Order 13132 (Federalism).
12) Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use).

Many of the requirements and executive orders listed above call for an explanation of why the rule is necessary, the statutory authority for the rule, and the primary objectives that the rule is intended to achieve (refer to Chapter 2 for more information regarding the objectives of the rule). More specifically, they are designed to assess the financial and health effects of the rule on sensitive, low-income, and Tribal populations as well as on small systems. The chapter also examines how much additional capacity systems will need to meet GWR requirements and whether there are existing, feasible technologies and treatment techniques available to meet rule requirements.

7.2 Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or other statute, unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (5 U.S.C. 602(a)). Small entities include small businesses, small organizations, and small governmental jurisdictions.

Defining Small Entities Affected by the Rule

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

The RFA references the definition of "small business" found in the Small Business Act, which authorizes the SBA to define "small business" further by regulation. The SBA defines small businesses by category using the North American Industry Classification System (NAICS). The NAICS code for public water supplies (PWSs) is 22131 (Water Supply and Irrigation Systems), and State agencies that include drinking water programs are classified as 92411 (Administration of Air and Water Resource and Solid Waste Management Programs) or 923120 (Administration of Public Health Programs). Ancillary systems (i.e., those that supplement the function of other establishments like factories, power plants, mobile home parks, etc.) cannot be categorized in a single NAICS code. For ancillary systems, the NAICS code is that of the primary establishment or industry. Examples of small businesses include small, privately-owned PWSs and for-profit businesses where provision of water may be ancillary, such as mobile home parks or day-care centers. Examples of small organizations include churches, schools, and homeowner associations.

The GWR applies to all PWSs that use ground water. Although the SBA and the RFA provide clear definitions for small businesses, organizations, and governmental jurisdictions, small entities are not necessarily small water systems. The size of the entity has no relation to the number of people it serves as a water supply. Furthermore, data are not collected on businesses, organizations, and governmental jurisdictions in terms of the number of water customers they serve. Therefore, EPA chose to use an alternative definition for small entities.

For purposes of assessing the impacts of the GWR on small entities, EPA considered small entities to be PWSs serving fewer than 10,000 people. This is the cut-off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. As required by the RFA, EPA proposed using this alternative definition in the *Federal Register* (63 FR 7620; February 13, 1998), requested public comment, consulted with the SBA, and finalized the alternative definition for all future drinking water regulations in the Consumer Confidence Reports regulation (63 FR 44511; August 19, 1998). As stated in that final rule, the alternative definition would be applied to this regulation as well.

Measuring Significant Impacts

EPA has not revised its determination at proposal that the GWR will have a substantial impact upon a significant number of small water systems. EPA assessed the potential impact of today's rule on small entities. There are 147,330 CWSs, NTNCWSs, and TNCWSs providing potable ground water to the public, 145,580 (99 percent) are classified by EPA as small entities. EPA has determined that all small ground water systems are impacted by the sanitary survey requirement and a substantial number these systems will be impacted by additional requirements of today's final rule including the source water monitoring requirements and the corrective action requirements. Exhibit 6.5b provides a detailed summary of the numbers of systems and entry points impacted by each GWR requirement.

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

Small Entity Outreach and Small Business Advocacy Review Panel

Section 609(b) of the RFA, as amended by SBREFA, and Section 203 of UMRA require EPA to provide small governments with an opportunity for timely and meaningful participation in the regulatory development process. In addition, the Agency must consult with small entity stakeholders and convene an Small Business Advocacy Review (SBAR) Panel prior to publication of a proposed rule.

EPA convened an SBAR Panel for the proposed rule. The SBAR Panel members for the GWR included the Small Business Advocacy Chair of EPA, 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 OMB, and the Chief Counsel for Advocacy of the SBA. The SBAR Panel convened on April 10, 1998 and met seven times before the end of the 60-day period on June 8, 1998. The culmination of these meetings was 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 stakeholder comments on components of the GWR and the background information provided to the SBAR Panel and the small entity stakeholders are available for review in the water docket. This information and the Agency's response to the SBAR Panel's recommendations in developing the GWR are summarized below.

Prior to convening the SBAR Panel, OGWDW consulted with a group of 22 small entity stakeholders likely to be impacted by a GWR. The small entity stakeholders small system operators, local government officials, small business owners (e.g., a bed and breakfast with its own water supply), and small nonprofit organization (e.g., a church with its own water supply). The small entity stakeholders were provided with background information on the rule, on the need for the rule, and the potential requirements. The small entity stakeholders were asked to provide input on the potential impacts of the rule from their perspective. All 22 small entity stakeholders commented on the information provided in the IRFA. These comments were provided to the SBAR Panel when it convened. After a teleconference between the small entity stakeholders and the SBAR Panel, the small entity stakeholders were invited to provide additional comments on the information provided. Three small entity stakeholders provided additional comments on the rule components after the teleconference.

In general, the small entity stakeholders 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 (HSA) or sanitary survey. There was also considerable discussion about whether the source data was nationally representative. Small entity stakeholders suggested providing flexibility to the States/Primacy Agencies implementing these provisions and opposed mandatory disinfection across-the-board. Small entity stakeholders 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 SBAR Panel evaluated the assembled materials and small entity comments related to the elements of the IRFA. A copy of the SBAR Panel report is available in the Office of Water docket for the GWR. The SBAR Panel suggested that, given the number of systems that could be affected by the rule, EPA consider focusing compliance requirements on those systems most at risk of fecal contamination. From this perspective, the SBAR Panel suggested that EPA evaluate whether it would be appropriate to establish different rule requirements for systems based

on system type, size, or location. The SBAR Panel also suggested providing States/Primacy Agencies with maximum flexibility, consistent with ensuring an appropriate minimum level of public health protection, to tailor specific requirements to individual system needs and resources. The SBAR Panel's recommendations to address the small entity stakeholders' concerns about the GWR were considered in developing the regulatory alternatives analyzed in this final rulemaking.

7.3 Small Drinking Water System Variances

Section 1415(e) of SDWA allows States/Primacy Agencies to grant variances to small water systems that cannot afford to comply with a National Primary Drinking Water Regulation. Section 1415(e)(6)(B) of SDWA, however, states that a variance shall not be available for a "national primary drinking water regulation for a microbial contaminant (including a bacterium, virus, or other organism) or an indicator or treatment technique for a microbial contaminant." Therefore, this provision does not apply, because the GWR is a regulation to control a microbial contaminant.

7.4 Feasible Treatment Technologies for All Systems

In accordance with Section 1412(b)(4)(E) of the 1996 SDWA Amendments, EPA examined whether there were existing, feasible technologies and treatment techniques available that would allow systems to meet the GWR requirements. EPA determined that ground water systems of all sizes can meet the requirements of 4-log virus inactivation by using chlorine (hypochlorination or gas disinfection), which is also relatively inexpensive and simple for systems to install and operate.

7.5 Effect of Compliance with the GWR on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of the SDWA, as amended, requires that, in promulgating a NPDWR, the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, managerial, and financial (TMF) capacity of PWSs. The following analysis fulfills this statutory obligation by identifying the incremental impact that the GWR will have on the TMF of regulated water systems. Analyses presented in this document reflect only the impact of new or revised requirements, as established by the GWR; the impacts of previously established requirements on system capacity are not considered.

Overall water system capacity is defined in *Guidance on Implementing the Capacity Development Provisions of the Safe Drinking Water Act Amendments of 1996* (USEPA 1998a) as the ability to plan for, achieve, and maintain compliance with applicable drinking water standards. Capacity encompasses three components: technical, managerial, and financial. Technical capacity is the operational ability of a water system to meet those SDWA requirements. Key issues of technical capacity include the following:

1) Source Water Adequacy—Does the system have a reliable source of water with adequate quantity? Is the source generally of good quality and adequately protected?

2) Infrastructure Adequacy—Can the system provide water that meets SDWA standards? What is the condition of its infrastructure, including wells or source water intakes, treatment, storage, and distribution? What is the infrastructure's life expectancy? Does the system have a capital improvement plan?

3) Technical Knowledge and Implementation—Are the system's operators certified? Do the operators have sufficient knowledge of applicable standards? Can the operators effectively implement this technical knowledge? Do the operators understand the system's technical and operational characteristics? Does the system have an effective operation and maintenance (O&M) program?

Managerial capacity is the ability of a water system's managers to make financial, operating, and staffing decisions that enable the system to achieve and maintain compliance with SDWA requirements. Key issues include:

- Ownership Accountability—Are the owners clearly identified? Can they be held accountable for the system?

- Staffing and Organization—Are the operators and managers clearly identified? Is the system properly organized and staffed? Do personnel understand the management aspects of regulatory requirements and system operations? Do they have adequate expertise to manage water system operations? Do personnel have the necessary licenses and certifications?

- Effective External Linkages—Does the system interact well with customers, regulators, and other entities? Is the system aware of available external resources, such as technical and financial assistance?

Financial capacity is a water system's ability to acquire and manage sufficient financial resources to allow the system to achieve and maintain compliance with SDWA requirements. Key issues include:

- Revenue Sufficiency—Do revenues cover costs?

- Creditworthiness—Is the system financially healthy? Does it have access to capital through public or private sources?

- Fiscal Management and Controls—Are adequate books and records maintained? Are appropriate budgeting, accounting, and financial planning methods used? Does the system manage its revenues effectively?

7.5.1 Requirements of the Final GWR

This capacity analysis is presented only for the Final Rule, although EPA took similar considerations into account in the selection of the Final Rule over the other alternatives. This process led to the incorporation of less expensive rule features for systems having fewer capabilities. For example, EPA allowed flexibility in the triggered monitoring requirements for certain small systems. Very small systems that must take four repeat samples following a total coliform (TC) positive sample under the TCR may designate one of the repeat samples as a source water sample, which covers both TCR repeat sampling and GWR triggered monitoring requirements. In addition, the requirement for performing assessment monitoring, which was part of the preferred regulatory alternative at proposal, is now a State option as part of the Final Rule. Flexibility was also built into the GWR through extended compliance time frames for NCWSs, which are primarily small systems.

The GWR establishes four major requirements that may affect the TMF capacity of affected PWSs:

1) Sanitary surveys

2) Triggered source water monitoring

3) Corrective actions

4) Compliance monitoring

In addition, personnel from systems regulated under the GWR will need to familiarize themselves with the rule and its requirements.

7.5.2 Systems Subject to the GWR

The GWR will apply to all PWSs that use ground water and may affect 42,361 CWSs, 18,908 NTNCWSs, and 86,061 TNCWSs—147,330 systems in all. While most will not, some systems may require increased TMF capacity to comply with the new requirements, or will need to tailor their compliance approaches to match their capacities. Refer to section 7.5.4 for a detailed discussion of the changes in TMF capacity for small and large systems.

7.5.3 Impact of the GWR on System Capacity

The estimates presented in Exhibits 7.1a and 7.1b reflect the anticipated impact of the GWR on system capacity based on the expected measures that systems will be required to adopt. The extent of the expected impact of a particular requirement on system capacity is estimated using a scale of 0-5, where 0 represents a requirement that is not expected to have any impact, 1 represents a requirement that is expected to have a minimal impact, and 5 represents a requirement that is expected to have a very significant impact on system capacity. Criteria used to develop the scores and associated impacts are discussed further in section 7.5.4.

These impacts are assessed separately for small systems (Exhibits 7.1a) and for large systems (Exhibit 7.1b). This distinction is necessary because most large systems will face fewer challenges in implementing the rule than smaller systems. For both large and small systems, EPA evaluated the capacity impact of each requirement on those systems affected by that particular requirement. Because in many cases the requirements only affect a small percentage of systems/entry points, the exhibits also display the number of systems and percentage of systems/entry points (of the subset of small or large systems/entry points) estimated to be affected by each specific requirement.

Exhibit 7.1a Estimated Impact of the GWR on Small System's Technical, Managerial, and Financial Capacity

(0 = no impact, 1 = minimal impact, and 5 = very significant impact)

Requirement	Number and Percent of Small Systems	Technical Capacity			Managerial Capacity			Financial Capacity		
		Source Water Adequacy	Infrastructure Adequacy	Technical Knowledge & Implementation	Ownership Accountability	Staffing & Organization	Effective External Linkages	Revenue Sufficiency	Credit Worthiness	Fiscal Mgmt. & Controls
Familiarization with rule requirements	145,580 (100%)	0	0	0	1	2	1	1	1	1
Sanitary surveys	145,580 (100%)	0	0	0	0	0	0	0	0	0
Triggered monitoring	128,711 (88%)	0	0	0	1	1	1	1	1	1
Corrective actions for significant deficiencies	24,749 (17%)	4	4	4	4	4	4	4	4	4
Compliance monitoring	3,685 (3%)	2	2	2	2	2	2	2	2	2

Notes: (1) To analyze the impact of these requirements on system capacity, the requirements believed to have the most and the least impact on affected systems were analyzed first. These initial analyses were then used as the bases against which the relative impact of the remaining requirements were assessed. The impact estimates developed for each requirement were also compared to those developed for the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) and the Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBPR) to ensure cross-rule consistency and to enable cross-rule comparisons.
(2) The scores presented above represent the worst case scenario; the requirements of this rule are expected to have less impact on the capacity of most systems affected by each requirement.

Source: Number and percent of systems subject to each rule activity from Exhibit 6.5b. Impact on capacity is determined relative to previous regulations based on the cost and number of systems/plants that require additional capacity to comply with each requirement, as described in section 7.5.4.

Exhibit 7.1b Estimated Impact of the GWR on Large System's Technical, Managerial, and Financial Capacity

(0 = no impact, 1 = minimal impact, and 5 = very significant impact)

Requirement	Number and Percent of Large Systems	Technical Capacity			Managerial Capacity			Financial Capacity		
		Source Water Adequacy	Infrastructure Adequacy	Technical Knowledge & Implementation	Ownership Accountability	Staffing & Organization	Effective External Linkages	Revenue Sufficiency	Credit Worthiness	Fiscal Mgmt. & Controls
Familiarization with rule requirements	1,750 (100%)	1	1	1	1	1	1	1	1	1
Sanitary surveys	1,750 (100%)	0	0	0	0	0	0	0	0	0
Triggered monitoring	964 (55%)	0	0	0	0	0	0	0	0	0
Corrective actions for significant deficiencies	298 (17%)	3	3	3	3	3	3	3	3	3
Compliance monitoring	123 (7%)	2	2	2	2	2	2	2	2	2

Notes: (1) To analyze the impact of these requirements on system capacity, the requirements believed to have the most and the least impact on affected systems were analyzed first. These initial analyses were then used as the bases against which the relative impact of the remaining requirements were assessed. The impact estimates developed for each requirement were also compared to those developed for the LT2ESWTR and the Stage 2 DBPR to ensure cross-rule consistency and to enable cross-rule comparisons.
(2) The scores presented above represent the worst case scenario; the requirements of this rule are expected to have less impact on the capacity of most systems affected by each requirement.

Source: Number and percent of systems subject to each rule activity from Exhibit 6.5b. Impact on capacity is determined relative to previous regulations based on the cost and number of systems/plants that require additional capacity to comply with each requirement, as described in section 7.5.4.

7.5.4 Derivation of GWR Scores

EPA developed a 5-point scoring system to analyze the impact compliance with all new regulations will have on the TMF capacity of PWSs. For each regulation, it is necessary to complete the following steps:

1. Determine the type and number of PWSs to which the regulation applies.

2. List all of the requirements of the regulation.

3. Determine the type and number of PWSs to which each requirement applies.

4. Evaluate the impact of each requirement on the capacity of affected PWSs.

The determination of the universe of affected systems and the evaluation of the capacity impact of individual requirements requires the use of the cost and technical information contained in SDWIS, EAs developed for other rules, information collection requests, and other supporting documentation for the rule. These data sources are also used to develop a qualitative description of the expected response of affected systems to each requirement.

The overall evaluation of the impact of a requirement on the affected systems, presented in Exhibit 7.2, is based on the impact each requirement has on nine sub-categories of capacity—three sub-categories under each of the broader divisions of TMF capacity. Within these sub-categories, a professional engineer with extensive water system experience reviewed the costs, number of systems affected, and complexity of each requirement. After estimating the technical, managerial, and financial impacts within each sub-category, the professional engineer assigned the scores using best professional judgment. Costs were considered cumulatively for each requirement for small and large systems. This score reflects the additional capacity that systems will need to develop to comply with each requirement. Due to a lack of available information on operating budgets, this analysis does not include a quantitative component.

To ensure the ability to make cross-rule comparisons, to standardize the assignment of numerical scores, and to minimize the subjectivity of the scoring system, the requirements made on systems by the regulation in question are compared to the requirements of those regulations for which capacity impact analyses have already been conducted (e.g., Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR), LT2ESWTR, Stage 2 DBPR). Similar requirements are assigned similar impact scores.

These group assignments are reviewed by the EPA Rule Manager and other EPA staff cognizant of small system issues to ensure that they accurately reflect the cumulative impact of the rule requirements on system capacity. Any disagreements over the assignments are discussed. The EPA Rule Manager and other EPA staff discuss the rationale for the disagreement and evaluate whether the assignments need to be adjusted. EPA adjusts the assignments only after review of the rule support documents and an analysis of the expected system response to the rule requirements.

7.5.4.1 Small Water Systems (Those Serving 10,000 or Fewer People)

Small systems will likely face only a minimal challenge to their technical and managerial capacity as a result of efforts to familiarize themselves with the GWR and aid the State in conducting sanitary surveys. Total coliform sampling is already required under the TCR and, therefore, it is not expected to pose any new technical or managerial capacity issues for systems. On average, PWSs serving fewer than 3,000 people will only need to take less than 1 triggered samples a year, and small systems

serving fewer than 1,000 people will be able to use one of their required TCR repeat samples to satisfy triggered monitoring requirements, eliminating any extra burden or cost.

Small system technical and managerial capacity may be affected by requirements to monitor the effectiveness and reliability of their disinfection or removal, especially systems not currently using disinfection. Ground water systems serving 3,300 people or fewer and using disinfection can conduct daily grab samples to measure disinfection levels instead of installing more costly continuous monitoring equipment. However, this may also require the system to increase staffing levels in addition to providing training to ensure that system staff understand the compliance monitoring requirements. Reporting, record-keeping, and data administration requirements will also affect the managerial capacity of small systems.

Small systems that are required to take corrective action are expected to experience the most significant financial challenge since many corrective actions consist of a large, one-time capital expenditure to resolve the problem. Changes in treatment may also significantly impact the managerial and technical capacity of the system.

7.5.4.2 Large Water Systems (Those Serving at Least 10,000 People)

Large systems will likely not face more than a minimal challenge to their technical and managerial capacity as a result of efforts to familiarize themselves with the GWR and assist the State with sanitary surveys. Although larger systems may need to take many source water samples a year to meet the triggered monitoring requirements, most larger systems are familiar with total coliform monitoring and already have the TMF capacity to address this increased burden.

Many larger systems already have the TMF capacity to address additional monitoring of the effectiveness and reliability of disinfection or removal. These systems will be affected less significantly than smaller systems, especially since some may already be disinfecting and conducting monitoring. Large systems are expected to face the most significant challenge meeting the technical, managerial, and financial requirements associated with corrective action. However, this requirement is only necessary when a sanitary survey identifies a significant deficiency or when a source water monitoring sample tests positive for fecal indicators.

7.6 Paperwork Reduction Act

The information collection requirements for the GWR have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. The information collected as a result of this rule will allow the States/Primacy Agencies and EPA to determine appropriate requirements for specific systems and evaluate compliance with the rule.

The Paperwork Reduction Act requires EPA to estimate the burden on public water systems (PWSs) and States/Primacy Agencies of complying with the rule. Burden means the total time, effort, and financial resources required to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This burden includes the time needed to conduct these activities:

- Review instructions.
- Develop, acquire, install, and employ technology and systems for the purposes of collecting, validating, verifying, processing, maintaining, and disclosing information.

- Adjust the existing ways to comply with any previously applicable instructions and requirements.
- Train personnel to respond to information collected.
- Search data sources.
- Complete and review the collection of information.
- Transmit or otherwise disclose the information.

For the first 3 years after publication of the final GWR in the *Federal Register*, the major information requirements are for States/Primacy Agencies and PWSs to prepare for implementation of the rule. The information collection requirements are mandatory under Part 141 for systems and Part 142 for States/Primacy Agencies. The calculation of GWR information collection burden and costs can be found in the *Information Collection Request for National Primary Drinking Water Regulations: Final Ground Water Rule* (USEPA 2006c).

The total burden associated with GWR requirements over the 3 years covered by the Information Collection Request is 1,155,791 hours, an average of 385,264 hours per year. This is based on an estimate that 57 States and territories will each need to provide 1 response each year with an average of 2,193 hours per response, and that 49,110 systems will each provide 2 responses each year with an average burden of 2.6 hours per response.

The total reporting and recordkeeping cost over the 3-year clearance period of the Information Collection Request is $30.3 million, an average of $10.1 million per year (simple average over 3 years). The average annual cost per response is $103. The recordkeeping and reporting burden does not include any capital costs for the first 3-year Information Collection Request period. Exhibit 7.2 provides a summary of the results of the Information Collection Request calculations.

Exhibit 7.2 Average Annual Burden Hours and Costs for the GWR Information Collection Request 3-Year Approval Period

	Responses	Burden Hours	Labor Costs	O&M Costs	Capital Costs	Total Annual Costs
PWSs	98,220	260,244	$5,890,508	$0	$0	$5,890,508
States & Territories	57	125,020	$4,200,914	$0	$0	$4,200,914
Total	**98,277**	**385,264**	**$10,091,422**	**$0**	**$0**	**$10,091,422**

Note: Data represent burden and cost for only the 3-year Information Collection Request approval period. Data are based on nominal (or undiscounted) values. Detail may not add due to independent rounding.

Source: *Information Collection Request for the National Primary Drinking Water Regulations: Final Ground Water Rule* (USEPA 2006c).

7.7 Unfunded Mandates Reform Act

The UMRA of 1995, Public Law 104-4, consists of four Titles and numerous sections. Sections 201 through 205 of Title II, entitled "Regulatory Accountability and Reform," are relevant to the GWR and are discussed in this section. Title II, Section 201 of the UMRA, requires Federal agencies to assess the effects of their regulatory actions on State, Local, and Tribal governments, and the private sector. Under UMRA Section 202, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, Local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any 1 year. Section 203 requires the Agency to establish a small government agency plan before establishing any regulatory requirements that may significantly or uniquely affect small governments.

Section 204 of the UMRA requires the Agency to develop an effective process to permit elected officers of State, Local, and Tribal governments to provide meaningful and timely input in the development of regulatory proposals that contain significant Federal intergovernmental mandates. Finally, Section 205 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 before promulgating a rule for which a written statement is needed under Section 202. 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.

EPA has determined that this rule will not result in expenditures of $100 million or more for State, Local, and Tribal governments, in the aggregate or the private sector in any 1 year, as shown in Exhibit 7.3.

Exhibit 7.3 Ground Water System, State, and Tribal Estimated Costs

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

Note: Detail may not add due to independent rounding. All values annualized in millions of 2003$.

Source: State Costs from Appendix D; Total Public and Private Costs from GWR Cost Model Output.

Although the GWR is not subject to the requirements of Sections 202 and 205 of UMRA, EPA has prepared a written statement addressing the following items:

- The authorizing legislation (Chapter 2)
- Benefit-cost analysis including an analysis of the extent to which the costs of State, Local and Tribal governments will be paid for by the Federal government (Chapter 8, section 7.7.1)
- Estimates of future compliance costs and disproportionate budgetary effects (Chapter 6, section 7.7.2)
- Macroeconomic effects (section 7.7.3)
- A summary of EPA's consultation with State, Local, and Tribal governments and their concerns, including a summary of the Agency's evaluation of those comments and concerns (sections 7.2, 7.7.7, 7.8, 7.11)
- Identification and consideration of regulatory alternatives and the selection of the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule (Chapters 3 and 8)

7.7.1 Social Benefits and Costs

The social benefits are those that primarily accrue to the public through an increased level of protection from viral and bacterial illness due to exposure to microbial pathogens in drinking water. To assign a monetary value to the illness, EPA used cost-of-illness (COI) estimates by age categories to estimate the benefits from the reduction in acute viral illnesses and deaths avoided. This is considered to be 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. Chapter 5 presents the benefits analysis, which includes both qualitative and monetized benefits of improvements to health and safety. The estimated annualized benefit of the GWR using a 3 percent discount rate and the Enhanced COI approach is $19.7 million under the Final GWR.

In addition to reducing the number of viral illnesses and deaths, the GWR will also decrease bacterial illness associated with fecal contamination of ground water. EPA did not directly calculate the actual numbers of illnesses 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 illnesses from fecally contaminated ground water, the Agency developed an alternative calculation. This analysis of nonquantified benefits from avoided bacterial illnesses and deaths is presented in section 5.4. This rule also considered but did not monetize the health benefit from the reduction in chronic illness associated with some viral and bacterial infections.

Measuring the social costs of the rule requires identifying affected entities by ownership (public or private), considering regulatory alternatives, calculating regulatory compliance costs, and estimating any disproportionate impacts. Chapter 6 of this document details the cost analysis performed for the GWR. Under the Preferred Alternative, the likely compliance scenario is expected to result in total annualized costs of approximately $61.8 million using a 3 percent discount rate (or $62.3 million using a 7 percent discount rate). Exhibit 7.4 summarizes the range of annualized costs and benefits for each regulatory alternative.

Exhibit 7.4 Mean Total Annualized Benefits and Costs of Regulatory Alternatives ($Millions, 2003$)

Regulatory Alternative	Enhanced Annualized Benefits (3%) ($Millions)	Traditional Annualized Benefits (3%) ($Millions)	Enhanced Annualized Benefits (7%) ($Millions)	Traditional Annualized Benefits (7%) ($Millions)	Annualized Costs (3%) ($Millions)	Annualized Costs (7%) ($Millions)
Final GWR (Risk Targeted Approach)	$19.7	$10.0	$16.8	$8.6	$61.8	$62.3
Alternative 1 (Sanitary Survey and Corrective Action)	$3.6	$1.9	$2.9	$1.5	$15.3	$15.3
Alternative 3 (Multi-barrier Approach)	$21.3	$10.8	$18.2	$9.3	$67.9	$69.4
Alternative 4 (Across-the-Board Disinfection)	$70.2	$35.5	$61.9	$31.5	$686.4	$665.3

Source: Benefits from Exhibit 5.31. Costs from Exhibit 6.35.

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/Primacy Agencies that have primary enforcement responsibility for their drinking water programs through the Public Water Systems Supervision (PWSS) Grants Program. States/Primacy Agencies may use these funds to develop primacy programs or to contract with other State agencies to assist in the development or implementation of their primacy programs. However, they may not use these funds to contract with regulated entities (i.e., water systems). States/Primacy Agencies may use PWSS Grants to set up and administer a State program that includes such activities as public education, testing, training, technical assistance, development and administration of a remediation grant and loan or incentive program (excluding the actual grant or loan funds), or other regulatory or nonregulatory measures.

Additional funding is available from other programs administered by EPA or other Federal agencies. These include EPA's Drinking Water State Revolving Fund (DWSRF), the U.S. Department of Agriculture's Rural Utilities' Loan and Grant Program, and the Department of Housing and Urban Development's Community Development Block Grant (CDBG) Program.

SDWA authorizes the EPA Administrator to award capitalization grants to States/Primacy Agencies, which in turn can provide low-cost loans and other types of assistance to eligible PWSs. The DWSRF assists PWSs with financing the costs of infrastructure needed to achieve or maintain compliance with SDWA requirements. Each State has considerable flexibility to determine the design of its DWSRF Program and to direct funding toward its most pressing compliance and public health protection needs. States/Primacy Agencies may also, on a one-to-one 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/Primacy Agencies have the flexibility to transfer a portion of funds from their Clean Water State Revolving Fund accounts to their DWSRF accounts.

A State/Primacy Agency can use the financial resources of the DWSRF to assist small systems. In fact, a minimum of 15 percent of a State/Primacy Agency's DWSRF grant must be used to provide infrastructure loans to systems serving 10,000 or fewer people. Two percent of the State/Primacy Agency's grant is set-aside funding that can only be used to provide technical assistance to small systems. In addition, up to 14 percent of the State/Primacy Agency's grant may be used to provide TMF assistance to all system sizes. For small systems that are disadvantaged, up to 30 percent of a State/Primacy Agency's DWSRF may be used for increased loan subsidies. Tribes have separate set-aside funding that they can use under the DWSRF.

In addition to the DWSRF, money is available from the Department of Agriculture's Rural Utility Service (RUS) and Housing and Urban Development's CDBG Program. RUS provides loans, guaranteed loans, and grants to improve, repair, or construct water supply and distribution systems in rural areas and towns with a population of up to 10,000 people. In fiscal year 2003, RUS had over $1.5 billion of available funds for water and environmental programs. Also, three sources of funding exist under the CDBG program to finance building and improvements of public faculties such as water systems. These include: 1) direct grants to communities with populations over 200,000; 2) direct grants to States/Primacy Agencies, which in turn are awarded to smaller communities, rural areas, and coloñas in Arizona, California, New Mexico, and Texas; and 3) direct grants to U.S. territories and trusts. The CDBG budget for the formula program for fiscal year 2003 totaled over $4.4 billion.

7.7.2 Disproportionate Budgetary Effects

UMRA is intended to reduce the burden on State, Local, and Tribal governments of Federal mandates that are not accompanied by adequate Federal funding. Section 202 of UMRA requires an analysis of possible disproportionate budgetary effects of certain classes of rules, in which the GWR falls.[1] EPA believes that the cost estimates presented in Exhibit 7.5 accurately characterize future compliance costs of the GWR. EPA explored possible disproportionate impacts of the GWR on particular geographic areas and groups of customers. In general, the costs that a PWS, whether publicly- or privately-owned, will incur to comply with this rule will depend on many factors that are not generally

[1] "...[T]he agency shall prepare a written statement containing. . . (3) estimates by the agency, if and to the extent that the agency determines that accurate estimates are reasonably feasible, of. . . (B) any disproportionate budgetary effects of the Federal mandate upon any particular regions of the nation or particular State, Local, or Tribal government, urban or rural or other types of communities, or particular segments of the private sector..."

based on location. However, the data needed to confirm this assessment and to analyze other impacts of this problem are not available; therefore, EPA looked at two other factors:

- The impacts of the rule on small versus large systems and the impacts within the five small system size categories
- The costs to publicly-owned versus privately-owned water systems

It is also possible that some States or EPA regions may face greater challenges from the GWR than other States or regions because they have comparatively more ground water systems. However, costs are not expected to be highly focused on a particularly geographic region or sector. In addition, States that have a larger percentage of systems also receive a greater share of money under the PWSS Grants Program and the DWSRF.

One measure performed of disproportionate impact is 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 total cost to the small ground water systems is due to the large number of these types of systems (i.e., 99 percent of ground water systems serve fewer than 10,000 people). Other reasons for the disparity include the following: 1) large systems are more likely to already be disinfecting their ground water (disinfection exempts a system from triggered monitoring); 2) they typically have greater technical and operational expertise; and 3) they are more likely to engage in source protection programs. The total impacts on small systems (those serving fewer than 10,000 people) as well as large and medium systems (those serving at least 10,000) are presented in Exhibit 7.5 for 3 percent and 7 percent discount rates.

Exhibit 7.5 Annualized Compliance Costs by Type of Ground Water System

Source Water Category	Annualized Cost to Systems Serving ≤ 10,000 People ($ Millions)		Annualized Cost to Systems Serving > 10,000 People ($ Millions)	
	3 Percent	7 Percent	3 Percent	7 Percent
CWSs				
Non-tribal Systems	12.0	12.0	6.5	7.0
Tribal Systems	0.2	0.2	0	0
Total	**12.2**	**12.1**	**6.5**	**7.1**
NTNCWSs				
Non-tribal Systems	4.8	4.8	0.1	0.1
Tribal Systems	0.0	0.0	0	0
Total	**4.9**	**4.8**	**0.1**	**0.1**
TNCWSs				
Non-tribal Systems	26.3	26.4	0.1	0.1
Tribal Systems	0.0	0.0	0	0
Total	**26.3**	**26.4**	**0.1**	**0.1**
Grand Total	**$ 43.4**	**$ 43.4**	**$ 6.7**	**$ 7.2**

Source: Total Costs from Appendix D minus Tribal Costs; Tribal Costs calculated from Appendix D.

The mean cost *per system* for compliance is shown for large and small systems in Exhibit 7.6. The cost per system is greater for larger systems, due to increased costs of disinfection and other costs that increase with the size of the system. Among the small systems, the potential system-level economic impact will be the greatest for systems serving 3,301 to 10,000 people.

Exhibit 7.6 Mean Annualized Compliance Cost per Ground Water System by System Size and Type

System Size	CWSs	NTNCWSs	TNCWSs
≤100	$ 226	$ 187	$ 275
101-500	$ 251	$ 275	$ 372
501-1,000	$ 312	$ 354	$ 506
1,001-3,300	$ 331	$ 646	$ 721
3,301-10,000	$ 773	$ 1,361	$ 1,741
10,001-50,000	$ 1,973	$ 3,769	$ 4,127
50,001-100,000	$ 10,622	$ 5,813	$ 5,320
100,001-1 Million	$ 18,369	$ 8,383	$ 11,921
>1 Million	$ 14	$ -	$ -

Source: Derived from Appendix D.

A second measure of impact performed on small systems is the total cost to privately-owned water systems compared to that incurred by publicly-owned water systems. Exhibit 7.3 reveals that 55 percent of small system compliance costs are borne by publicly-owned PWSs, while 45 percent is borne by privately-owned PWSs. This difference results from the fact that more than 55 percent of small PWSs using ground water are owned by public entities. EPA, therefore, expects publicly-owned systems as a group to have a slightly larger share of the total costs of the rule, but it does not expect cost per system to differ systematically with ownership. Most importantly, the rule protects the health of customers of all covered drinking water systems regardless of the size or type of system.

7.7.3 Macroeconomic Effects

Under UMRA Section 202, EPA is required to estimate the potential macroeconomic effects of the regulation. These include effects on productivity, economic growth, full employment, and Gross Domestic Product (GDP) (USEPA 2000e). Macroeconomic 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 GDP. In 2003, real GDP was $10,321 billion (U.S. Department of Commerce BEA 2004); thus, a rule would have to cost at least $26 billion annually 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 GWR should not have a measurable effect on the national economy; the total annualized costs for the rule range from $61.8 to $62.3 million using a 3 and 7 percent discount rate, respectively. Using these annualized figures as a measure, the annual cost of the GWR is an insignificant fraction of a $26 billion annual cost that would be considered a measurable macroeconomic impact. Thus, annualized GWR costs measured as a percentage of the national GDP will only decline over time as GDP grows.

7.7.4 Consultation with Small Governments

Before the Agency establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed, under Section 203 of UMRA, a small government agency plan. The plan must provide for the notification of potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates and informing, educating, and advising small governments on compliance with the regulatory requirements. EPA consulted with small governments to address impacts of regulatory requirements in the GWR that might significantly or uniquely affect small governments. A variety of stakeholders, including small governments, were provided with several opportunities to participate early in the regulatory development process, as described in section 7.4.

7.7.5 Consultation with State, Local, and Tribal Governments

Section 204 of UMRA requires the Agency to develop an effective process to permit elected officers of State, Local, and Tribal governments (or their designated authorized employees) to provide meaningful and timely input in the development of regulatory proposals that contain significant Federal intergovernmental mandates. Consistent with these provisions, EPA held consultations with affected governmental entities prior to proposal of the rule, as described in sections 7.4 and 7.7. EPA conducted four public meetings for all stakeholders and two Association of State Drinking Water Administrators (ASDWA) early involvement meetings. Because of the GWR's impact on small entities, the Agency convened a SBAR Panel in accordance with the RFA as amended by the SBREFA to address small entity concerns, including small local governments specifically. EPA consulted with small entity stakeholders prior to convening the SBAR Panel to get their input on the GWR. Of the 22 small entity participants, five represented small governments. EPA also made presentations on the GWR to the national and 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 the proposed rule and requested comment from the public through an informal process. Specifically, on February 3, 1999, EPA posted a draft proposal on their webpage and mailed out over 300 copies to people who had attended the 1997 and 1998 public stakeholder meetings, as well as people on the EPA workgroup. EPA received 79 letters or electronic responses to this draft: 34 from State governments (representing 30 different States), 25 from local governments, 10 from trade associations, 6 from Federal government agencies, and 4 from other people/organizations. No comments were received from Tribal governments. EPA reviewed the comments and carefully considered their merit. The GWR reflects many of the commentors' points and suggestions.

EPA will educate, inform, and advise small systems, including those operated by small governments, about the GWR requirements. One of the most important components of this process will be the Small System GWR Implementation Guidance, which is required by SBREFA of 1996. This plain-English guide will explain what actions a small entity must take to comply with the rule. The Agency is also developing fact sheets that concisely describe various aspects and requirements of the GWR. Additional details on Tribal involvement in the rulemaking process can be found in section 7.7.

7.7.6 Regulatory Alternatives Considered

As required under Section 205 of UMRA, EPA considered several regulatory alternatives and numerous methods that would reduce microbial contamination in ground water systems. Chapter 3 provides a detailed discussion of these alternatives. EPA believes that Alternative 2, the risk targeted approach, is the most cost effective alternative that achieves the rule's objective to reduce the risk of illness and death from microbial contamination in PWSs relying on ground water. This alternative 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.

7.7.7 Impacts on Small Governments

In developing this rule, EPA consulted with small governments pursuant to Section 203 of UMRA to address impacts of regulatory requirements in the rule that might significantly or uniquely affect small governments. In preparation for the GWR, EPA conducted an analysis on small government impacts and included small government officials or their designated representatives in the rulemaking process. 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 attended public stakeholder meetings. Through participation and exchange in the SBREFA process and various meetings, 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.

EPA has determined that this rule contains regulatory requirements that might significantly or uniquely affect small governments. As shown in Exhibit 7.6, estimated annual expenditures per small system for the GWR range from $226 to $773 for CWSs, $187 to $1,361 for NTNCWSs, and $275 to $1,741 for TNCWSs (at a 3 percent discount rate).

7.8 Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249; November 6, 2000), requires EPA to develop "an accountable process to ensure meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications." The Executive Order defines "policies that have Tribal implications" to include regulations that have "substantial direct effects on one or more Indian Tribes, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes."

Under Executive Order 13175, EPA may not issue a regulation that has Tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by Tribal governments, or EPA consults with Tribal officials early in the process of developing the proposed regulation and develops a Tribal summary impact statement.

EPA performed an analysis to estimate the impact of the GWR on Tribal systems. More than 87 percent of PWSs in Indian Country (727 systems) are ground water systems and will, therefore, be affected by the GWR. Based on the analysis, EPA concluded that the GWR may have Tribal implications because it may impose substantial direct compliance costs on Tribal governments, and the Federal

government will not provide the funds necessary to pay the direct costs incurred by the Tribal governments in complying with the rule. Accordingly, EPA provides the following Tribal summary impact statement as required by Section 5(b) of Executive Order 13175.

As described in section 7.5.5, EPA held extensive public meetings that provided tribes with the opportunity for meaningful and timely input into the development of the GWR. Summaries of the meetings have been included in the public docket for this rulemaking. In addition, the Agency presented the rule and asked for comment at three Tribal conferences. Two outreach efforts were conducted at national conferences; one for the National Indian Health Board and the other for the National Tribal Environmental Council. The third outreach effort took place in conjunction with the Inter-Tribal Council of Arizona, Inc.

Tribal Summary Impact Statement

EPA performed an analysis to estimate the impact of the GWR on Tribal systems. EPA has identified 727 Indian Tribal systems that might be subject to the GWR. As seen in Exhibit 7.7, all but three Tribal systems are classified as small systems (serving fewer than 10,000 people).

Exhibit 7.7 Annual Cost of Compliance for Tribal Systems by System Type and Size (Annualized at 3 Percent)

System Size/Type	Number of Systems Affected by GWR	Systems Conducting Implementation Activities		Systems Conducting Santitary Surveys		Systems Conducting HSAs		Systems Conducting Triggered Monitoring		Systems Conducting Assessment Monitoring		Sytems Taking Corrective Action		Systems Conducting Compliance Monitoring		Mean Annualized Cost per System	Estimated Total Tribal Costs
		%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.		
	A	B	C = B * A	D	E = D * A	F	G = F * A	H	I = H * A	J	K = J * A	L	M = L * A	N	O = N * A	P	Q = A * P
Primarily Disinfecting Ground Water CWSs																	
≤100	171	100%	171	100%	171	0%	0	76%	130	0%	0	24%	42	31%	53	$ 226	$ 38,686
101-500	223	100%	223	100%	223	0%	0	62%	138	0%	0	24%	53	45%	100	$ 251	$ 56,084
501-1,000	69	100%	69	100%	69	0%	0	61%	42	0%	0	24%	16	46%	32	$ 312	$ 21,562
1,001-3,300	69	100%	69	100%	69	0%	0	63%	43	0%	0	22%	15	42%	29	$ 331	$ 22,851
3,301-10,000	21	100%	21	100%	21	0%	0	62%	13	0%	0	24%	5	45%	9	$ 773	$ 16,230
10,001-50,000	3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
50,001-100,000	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
100,001-1 Million	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
> 1 Million	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
Subtotal	556		553		553		0		367		0		132		224		$ 155,413
Primarily Disinfecting Ground Water NTNCWSs																	
≤100	34	100%	34	100%	34	0%	0	91%	31	0%	0	24%	8	16%	6	$ 187	$ 6,371
101-500	28	100%	28	100%	28	0%	0	91%	25	0%	0	25%	7	17%	5	$ 275	$ 7,689
501-1,000	13	100%	13	100%	13	0%	0	91%	12	0%	0	25%	3	17%	2	$ 354	$ 4,607
1,001-3,300	21	100%	21	100%	21	0%	0	91%	19	0%	0	29%	6	21%	4	$ 646	$ 13,568
3,301-10,000	2	100%	2	100%	2	0%	0	91%	2	0%	0	31%	1	23%	0	$ 1,361	$ -
10,001-50,000	0	100%	0	100%	0	0%	0	91%	0	0%	0	33%	0	25%	0	$ 3,769	$ -
50,001-100,000	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
100,001-1 Million	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
> 1 Million	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
Subtotal	98		98		98		0		89		0		25		17		$ 32,235
Primarily Disinfecting Ground Water TNCWSs																	
≤100	57	100%	57	100%	57	0%	0	98%	56	0%	0	28%	16	13%	7	$ 275	$ 15,688
101-500	11	100%	11	100%	11	0%	0	98%	11	0%	0	28%	3	12%	1	$ 372	$ 4,096
501-1,000	3	100%	3	100%	3	0%	0	98%	3	0%	0	28%	1	13%	0	$ 506	$ 1,517
1,001-3,300	1	100%	1	100%	1	0%	0	98%	1	0%	0	30%	0	15%	0	$ 721	$ 721
3,301-10,000	1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
10,001-50,000	0	100%	0	100%	0	0%	0	98%	0	0%	0	35%	0	20%	0	$ 4,127	$ -
50,001-100,000	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
100,001-1 Million	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
> 1 Million	0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	$ -	$ -
Subtotal	73		72		72		0		71		0		20		9		$ 22,022
TOTALS	727		723		723		0		527		0		177		250		**$ 209,670**

Source: Derived from Appendix D.

EPA has estimated costs for Indian Tribal systems to comply with the GWR, based on the assumption that the percentages of systems expected to incur costs for each size category will be the same for Tribal systems as for systems nationwide. The costs for Tribal systems are calculated in two steps. First, the number of Indian Tribal systems in each size category is multiplied by the percentage of systems nationally in each size category expected to incur costs for various rule activities. Second, the average cost of each rule requirement is multiplied by the number of Tribal systems expected to incur costs. Exhibit 7.7 shows the percentage of systems expected to incur costs for various compliance activities. These costs result in an estimated total annualized cost to Indian Tribes of $209,670 for the GWR.

7.9 Impacts on Sensitive Subpopulations

EPA's Office of Water has historically considered risks to sensitive subpopulations (including children) in establishing drinking water assessments, advisories or other guidance, and standards. Generally, the health effects of many pathogens and viruses on sensitive subpopulations is much more severe and debilitating than on the general population. These sensitive subpopulations include the young, elderly (especially those weakened by other conditions), malnourished and disease-impaired (especially those with diabetes), and a broad category of those with compromised immune systems, such as Acquired Immune Deficiency Syndrome (AIDS) patients, individuals with Lupus or cystic fibrosis, transplant recipients, and individuals on chemotherapy (Rose 1997). In total, these subgroups represent almost 20 percent of the current population of the United States.

Pregnant and lactating women may be at an increased risk from enteric viruses as well as act as a source of infection for neonates. Infection during pregnancy may also result in the transmission of infection from the mother to the child *in utero*, during birth, or shortly thereafter. Since very young children do not have fully developed immune systems, they are at increased risk and are particularly difficult to treat.

Infectious diseases are also a major problem for the elderly because immune function declines with age. As a result, outbreaks of waterborne diseases can be devastating on the elderly community (e.g., nursing homes) and may increase the possibility of significantly higher mortality rates in the elderly than in the general population.

Immunocompromised individuals are a growing proportion of the population with the relatively new and severe problem magnified by the AIDS epidemic and the escalation in organ and tissue transplantations. Enteric pathogens take advantage of the impaired immune systems of these individuals and set up generalized and persistent infections in the immunocompromised host. These infections are particularly difficult to treat and can result in a significantly higher mortality than in immunocompetent persons.

With regard to sensitive sub-populations, EPA explicitly examined the effects of the GWR on young children, the elderly, and immunocompromised individuals. Exhibit 5.24 in Chapter 5 shows the estimated number of illnesses and deaths avoided in each of these categories and the values of the associated benefits. In addition to the information presented in Chapter 5 of this EA, research outlining the potential health benefits of the GWR to both sensitive subpopulations and the general public is discussed in greater detail in the *Occurrence and Monitoring Document for the Final Ground Water Rule* (USEPA 2006b).

7.9.1 Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885; April 23, 1997) applies to any rule initiated after April 21, 1998, that (1) is determined to be "economically significant" as defined under Executive Order 12866; and (2) concerns an environmental, health, or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA 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 final rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866. As a matter of policy, EPA has examined the environmental health or safety effects of viruses on children.

The risk of illness and death due to viruses depends on several factors, including the type of virus, age, nutrition, exposure, genetic variability, presence of disease, and the immune status of the individual. Rotavirus infections can occur in people of all ages, but they primarily affect young children. In addition, infants and young children have higher rates of infection and disease from enteroviruses than other age groups (USEPA 1999). Several viruses that can be transmitted through water, including poliovirus, coxsackievirus, and echovirus, can have serious health consequences in children, which are discussed in detail in Chapter 5.

In developing the risk and benefits analysis for the GWR, the effects on children, both in terms of unique risk and cost-of-illness estimates, were explicitly taken into consideration, as discussed in Chapter 5 of this EA. This analysis suggests that the rule provides a greater per capita health benefit to children than to adults, mostly due to the high cost-of-illness associated with viral illnesses avoided in young children. In other words, the analysis suggests that the viral and bacterial illnesses of concern to the GWR disproportionately affect children, and therefore, the benefits of the proposed rule accrue disproportionately to children.

7.10 Environmental Justice

Executive Order 12898 (59 FR 7629) establishes a Federal policy for incorporating environmental justice into Federal agency missions by directing agencies to identify and address disproportionately high adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. The Agency has considered environmental justice related issues concerning the potential impacts of this action and consulted with minority and low-income stakeholders.

Two aspects of the GWR comply with the order that requires the Agency to consider environmental justice issues in the rulemaking and to consult with stakeholders representing a variety of economic and ethnic backgrounds. These are: (1) the overall nature of the rule, and (2) the convening of a stakeholder meeting specifically to address environmental justice issues.

The GWR applies uniformly to CWSs, NTNCWSs, and TNCWSs that use ground water as their source. Consequently, this rule provides health protection from pathogen exposure equally to all income and minority groups served by ground water systems. Existing regulations, such as the Surface Water Treatment Rule (SWTR) and the Interim Enhanced Surface Water Treatment Rule (IESWTR), provide similar health benefit protection to communities that use surface water or GWUDI.

The Agency built on the efforts conducted during the IESWTR's development to comply with Executive Order 12898. On March 12, 1998, the Agency held a stakeholder meeting to address various

components of pending drinking water regulations and how they might impact sensitive subpopulations, minority populations, and low-income populations. This meeting was a continuation of stakeholder meetings that started in 1995 to obtain input on the Agency's Drinking Water Programs. Topics discussed included treatment techniques, costs and benefits, data quality, health effects, and the regulatory process. Participants were national, State, Tribal, municipal, and individual stakeholders. EPA conducted the meeting by video conference call among 11 cities. The major objectives for the March 12, 1998 meeting included the following:

- Solicit ideas from stakeholders on known issues concerning current drinking water regulatory efforts.
- Identify key areas of concern to stakeholders.
- Receive suggestions from stakeholders concerning ways to increase representation of communities in OGWDW regulatory efforts.

In addition, EPA developed a plain-English guide for this meeting to assist stakeholders in understanding the multiple and sometimes complex issues surrounding drinking water regulations.

The GWR and other drinking water regulations are expected to have a positive effect on human health regardless of the social or economic status of a specific population. The GWR serves to provide a similar level of drinking water protection to all groups. To the extent that levels of bacteria and viruses in drinking water might be disproportionately high now among minority or low-income populations (which is unknown), the GWR will work to remove those differences. Thus, the GWR meets the intent of Federal policy requiring incorporation of environmental justice into Federal agency missions.

The GWR applies uniformly to PWSs that use ground water as their source. Consequently, this rule provides health protection from pathogenic bacteria and viruses exposure equally to all income and minority groups served by ground water systems.

7.11 Federalism

Executive Order 13132, "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" are 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(b) 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.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to 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 Executive Order 13132 in a meaningful and timely manner.

EPA has concluded that this rule does not have Federalism implications because it does not impose substantial direct compliance costs on State and Local governments. The cost to State, Local, and Tribal governments in the aggregate is $41.5 million (see Exhibit 7.3) on average annually at a 3 percent discount rate.

Nonetheless, as discussed in section 7.5.4, 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 GWR. Summaries of the meetings have been included in the public record for this rulemaking. EPA consulted extensively with State and Local governments. For example, four public stakeholder meetings were held in Washington, DC, Portland, OR, Madison, WI, and Dallas, TX. EPA also held three early involvement meetings with ASDWA. Several key issues were raised by stakeholder regarding the GWR provisions, many of which were related to reducing burden and increasing flexibility by creating a targeted risk based approach that builds upon existing State programs. Its 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.

Initial consultation of the GWR occurred before November 2, 1999, the effective date of Executive Order 13132. However, EPA initiated discussions with State and Local elected officials regarding the implications of the rule during the public comment period and took their recommendations under consideration during the development of the final rule requirements.

7.12 Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355; May 22, 2001), provides that agencies shall prepare and submit to the Administrator of the Office of Information and Regulatory Affairs, OMB, a Statement of Energy Effects for certain actions identified as "significant energy actions." Section 4(b) of Executive Order 13211 defines "significant energy actions" as "any action by an agency (normally published in the *Federal Register*) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) that is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action."

The GWR has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This determination is based on the analysis presented below.

Energy Supply

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

In response to the GWR, some water utilities are expected to increase their energy use, and those impacts are discussed later in this section.

Energy Distribution

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

Energy Use

The third consideration is whether the GWR would adversely affect the use of energy. Because some PWSs are expected to add treatment technologies and security that use electrical power, this potential impact of the GWR on the use of energy requires further evaluation. The analyses that underlay the estimation of costs in Chapter 6 are national in scope and do not identify specific plants or systems that may install treatment in response to the GWR. As a result, no analysis of the effect on specific energy suppliers is possible with the available data. The approach used to estimate the impact of energy use, therefore, focuses on national-level impacts. It estimates the additional energy use due to the GWR and compares that to the national levels of power generation in terms of average and peak loads.

The first step is to estimate the energy used by the technologies or corrective action expected to be installed as a result of the GWR. Energy use is not directly estimated in *Technology and Cost Document for the Final Ground Water Rule* (USEPA 2006d), but the annual cost of energy for each technology and corrective action addition or upgrade necessitated by the GWR is provided. An estimate of plant-level energy use is derived by dividing the total energy cost per plant for a range of flows by an average national cost of electricity of $0.076 per kilowatt hour per year (kWh/y) (USDOE EIA 2004a[2]). The energy use per plant for each flow range and technology or corrective action is then multiplied by the number of plants

[2] EPA is aware that DOE has updated its 2003 "average national cost of electricity per kilowatt hour per year" from $0.076 to $0.074. However, EPA continues to use the $0.076 value to maintain consistency with the *Technology and Cost Document for the Final Ground Water Rule* (USEPA 2006d).

predicted to install each technology in a given flow range. The energy requirements for each flow range are then added to produce a national total. No electricity use is subtracted to account for the technologies that may be replaced by new technologies, resulting in a conservative estimate of the increase in energy use. An incremental national annual energy usage is estimated at 4,521 megawatt hours (MWh); results of the analysis are shown in Exhibit 7.8.

Exhibit 7.8 Total Increased Annual National Energy Usage Attributable to the GWR

Technology/Corrective Action	Plants Selecting Technology	Total Annual Energy Required (kWh/yr)
	A	B
Gas Chlorination	177	190,099
Hypochlorination	3,565	3,726,479
ClO_2	39	11,928
Anodic Oxidation	16	95,342
Ozonation	0	17,229
NF	10	479,477
Total	3,808	4,520,555

Sources:
[A] Plants selecting technology taken from Exhibits 6.5b and 6.21b.
[B] ClO_2, Ozonation, and NF - Total annual energy required calculated from energy costs given in the *Technology and Cost Document for the Final Ground Water Rule* (USEPA 2006d) assuming $0.076/kWh. Gas Chlorination, Hypochlorination, and Anodic Oxidation - Total annual energy required obtained from the Water and W/W Models.

Exhibit 7.9 provides a sample calculation for chlorine dioxide showing the increase in energy usage as a result of the GWR.

To determine if the additional energy required for systems to comply with the rule would have a significant adverse effect on the use of energy, the numbers in Exhibit 7.9 are compared to the national production figures for electricity. According to the U.S. Department of Energy's Information Administration, electricity producers generated 3,848 million MWh of electricity in 2003 (USDOE EIA 2004b[3]). Using the assumed energy use for the GWR (4,520,555 kWh/y), the rule would result in only a 0.0001 percent increase in annual average energy use when fully implemented. This calculation is shown below:

4,521 MWh/y ÷ 3,848,000,000 MWh/y * 100 = 0.0001%

[3] EPA is aware that DOE has updated its estimate of total electricity produced in 2003 from 3,848 million to 3,883 million. However, EPA continues to use the 3,848 million estimate to maintain consistency with related electricity estimates used in this EA and the *Technology and Cost Document for the Final Ground Water Rule*.

Exhibit 7.9 Sample Calculation for Determining Increase in Energy Usage: Chlorine Dioxide (ClO_2 Dose = 1.25 mg/L)

System Size (population served)	Average Daily Flow Flow (MGD)	Total No. of Entry Points	Number of Entry Points Selecting	Annual Energy Cost per Entry Point ($/EP/yr)	Annual Energy Requirement (kWhr/EP/yr)	Total Energy Usage for Entry Points Selecting (kWhr/year)
	A	B	C	D	E = D/$0.076 per kWhr	F=C*E
CWSs						
≤ 100	0.004	12,857	3	-	-	-
101 - 500	0.014	14,534	3	-	-	-
501 - 1,000	0.037	5,536	-	261	3,437	-
1,001 - 3,300	0.081	8,966	-	261	3,437	-
3,301 - 10,000	0.199	5,734	-	261	3,437	-
10,001 - 50,000	0.441	4,257	0	262	3,444	1,114
50,001 - 100,000	0.718	1,308	1	263	3,455	4,919
100,001 - 1 Million	2.263	730	-	272	3,576	-
> 1 Million	18.107	-	-	378	4,973	-
NTNCWSs						
≤ 100	0.004	8,606	2	-	-	-
101 - 500	0.022	6,150	2	261	3,437	5,839
501 - 1,000	0.071	1,724	-	261	3,437	-
1,001 - 3,300	0.175	651	-	261	3,437	-
3,301 - 10,000	0.637	66	-	262	3,452	-
10,001 - 50,000	2.856	9	0	276	3,626	14
50,001 - 100,000	9.918	1	0	310	4,080	6
100,001 - 1 Million	17.188	1	-	370	4,868	-
> 1 Million	-	-	-	-	-	-
TNCWSs						
≤ 100	0.003	63,288	21	-	-	-
101 - 500	0.017	18,651	7	-	-	-
501 - 1,000	0.068	1,905	-	261	3,437	-
1,001 - 3,300	0.159	574	-	261	3,437	-
3,301 - 10,000	0.619	73	-	262	3,451	-
10,001 - 50,000	2.124	19	0	273	3,587	31
50,001 - 100,000	7.649	1	0	297	3,908	6
100,001 - 1 Million	19.724	1	-	416	5,475	-
> 1 Million	-	-	-	-	-	-
TOTALS		**155,641**	**39**		**75,392**	**11,928**

Notes: Detail may not add due to independent rounding.

Sources: [A] Flows taken from Exhibit 4.6
[B] Total number of entry points taken from Exhibit 4.3
[C] Number of entry plants selecting chlorine dioxide taken from Exhibit 6.21b
[D] Energy cost per entry point interpolated from ClO2 energy costs in the *Technology and Cost Document for the Final Ground Water Rule* (USEPA 2006d)
[E] Electricity cost is $0.076/KWh, as presented in the *Technology and Cost Document for the Final Ground Water Rule* (USEPA 2006d).

In addition to average energy use, the impact at times of peak power demand is important. To examine whether increased energy usage might significantly affect the capacity margins of energy suppliers, their peak-season generating capacity reserve was compared to an estimate of peak incremental power demand by water utilities. Both energy use and water use peak in the summer months, so the most significant effects on supply would be seen then. During the summer of 2003, U.S. generation capacity exceeded consumption by 15 percent, or approximately 160,000 MW (USDOE EIA 2004b[4]). Assuming around-the-clock operation of water treatment plants, the total energy requirement for technologies can be divided by 8,760 hours per year. Twelve hours of operation per day was assumed for the of security system light bulbs. The sum of these two average power demands was 0.52 MW. Assuming that power demand is proportional to water flow through the plant and that peak flow can be as high as twice the average daily flow during the summer months, about 1.03 MW could be needed for treatment technologies and security installed to comply with the GWR. This is only 0.001 percent of the capacity margin available at peak use. This calculation is presented below:

1. Treatment Technologies: 4,520,555 kWh/y * (y/8,760 hr) * (MW/1,000 kW) * 2 = 1.03 MW

2. 1.03 MW ÷ 160,000 MW * 100 = 0.001%

Although EPA recognizes that not all regions have a 15 percent capacity margin and that this margin varies across regions and through time, this analysis reflects the effect of the rule on national energy supply, distribution, and use. While certain areas have experienced shortfalls in generating capacity in the recent past, a peak incremental power requirement of 1.03 MW nationwide is not likely to significantly change the energy supply, distribution, or use in any given area.

Conclusion

The GWR is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355; May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy (as a function of annual average use and conditions of peak power demand).

The total increase in energy usage by water systems as a result of the GWR is predicted to be approximately 4.5 million kWh/y, which is only one-ten-thousandth of 1 percent of the total energy produced in 2003. While the rule may have some adverse energy effects, EPA does not believe that this constitutes a significant adverse effect on the energy supply.

[4] EPA is aware that DOE has updated its estimate of capacity exceeding consumption in the summer of 2003 from 160,000 to 159,000 MW. However, EPA continues to use the estimate of 160,000 MW to maintain consistency with related electricity estimates used in this EA and the *Technology and Cost Document for the Final Ground Water Rule* (USEPA 2006d).

8. Comparison of Quantified Benefits and Costs of the GWR

8.1 National Quantified Benefits and Costs of the GWR

This chapter presents a summary of the quantified benefits and costs of the Ground Water Rule (GWR). The nonquantified benefits are summarized in Chapter 5, Section 5.4. EPA estimates that the quantified benefits are small compared with the nonquantified benefits. In particular, EPA estimates that the nonquantified benefits associated with bacterial illness would increase total benefits to about five times the quantified benefits associated with viral illness from Type A virus (represented by data from rotavirus) and Type B virus (represented by data from enterovirus and echovirus). Other non-bacterial health and non-health benefits also accrue but are not quantified.

The following sections present summary results from the quantified economic analysis, followed by a discussion of the results based on evaluation of the total benefits, both quantified and nonquantified. The first sections of this chapter focus on analysis of the final GWR, followed by a comparison of these requirements to the other regulatory alternatives considered.

8.1.1 National Quantified Benefits Summary

The quantified benefits of the GWR derive from the reduction in risk of endemic, acute illness, specifically the morbidity and mortality from viral illness attributable to consumption of drinking water from the PWSs affected by the rule. The quantified acute viral illnesses are those associated with Type A (represented by data from rotavirus) and Type B (represented by data from enterovirus and echovirus) and are a subset of the total illnesses, both acute and chronic, from all waterborne bacteria and viruses.

The quantified benefits are presented in two forms. Exhibit 8.1 presents a summary of quantified benefits in terms of the annual endemic, acute illnesses and deaths avoided after full implementation. Exhibit 8.2 monetizes estimates of endemic, acute illnesses and deaths avoided into annualized present values using both the Enhanced and the Traditional COI approaches to allow comparison to cost estimates. The mean annualized value of quantified benefits of reduced risk ranges from $8.6 million to $19.7 million, depending on the COI approach and the discount rate used.

There are substantial benefits attributable to the GWR that are not quantified within this EA as part of the main analyses because of data limitations. Beneficial aspects of the rule not quantified are characterized as either health benefits or non-health benefits. Nonquantified health-related benefits include reducing other acute viral illness (other than those caused by rotavirus and enterovirus); endemic, acute bacterial illnesses and deaths; and epidemic bacterial and viral acute illness and death (associated with outbreaks, disinfection failures, and distribution system contamination). Chronic illness, both bacterial and viral, are also not quantified. The rule will also result in many nonhealth benefits such as reduced costs for responding to outbreaks, costs for averting behavior, and reduced uncertainly regarding drinking water safety (see Exhibit 8.3).

Exhibit 8.1 Summary of Annual Avoided Viral Illnesses and Deaths by System Type

System Type	Annual Viral Illnesses Avoided			Annual Viral Deaths Avoided		
		90% Confidence Bounds			90% Confidence Bounds	
	Mean	5th	95th	Mean	5th	95th
CWS	32,031	8,704	68,994	0.62	0.07	1.81
NTNCWS	2,094	533	4,308	0.03	0.00	0.09
TNCWS	7,743	1,037	14,738	0.09	0.01	0.21
Total	41,868	10,274	88,039	0.74	0.08	2.11

Note: Detail may not add due to independent forecasting. Values presented are average annual illnesses and deaths avoided over the 25 year period of analysis following rule promulgation.

Source: Appendix C

As mentioned above, there are substantial benefits attributable to the GWR that are not quantified within this EA as part of the main analyses. These nonquantified benefits are shown in relation to quantified benefits as part of the total benefits of the GWR in Exhibit 8.3. The nonquantified benefits result from multiple factors. First, the quantified benefits are based on limited, well-defined data and key assumptions that restrict the input parameters in the quantified benefit calculation. Typically, these assumptions resulted in low mean values and narrow uncertainty ranges in the benefit analysis. This EA, where applicable, discusses alternative assumptions. For example, the enterovirus morbidity fractions are, by assumption, not determined using coxsackievirus (an enterovirus) data although the enterovirus severity data use all enterovirus data. If coxsackievirus data were available, the mean morbidity values would be greater. Choosing alternative values and ranges and differing key assumptions, which might also be deemed reasonable, would increase the quantified benefits in this EA.

Second, the quantified benefits are based on data and assumptions that pertain to only partial representation of Type A and Type B viruses potentially found in PWS wells with fecal contamination. Due to limited available data, only rotavirus and some enterovirus data were used to calculate the quantified benefits. As is more completely discussed in Section 5.4. other viruses as well as pathogenic bacteria may contribute to the disease burden, both acute and chronic, associated with PWS wells with fecal contamination. Most importantly, bacterial illnesses can result in more frequent and lengthier hospitalization and more frequently have fatal outcomes. If bacterial diseases were considered in the quantified benefits, the monetized benefits could be substantially greater because bacterial disease can be more severe and can result in higher mortality rates.

Third, the quantified benefits are based on data and assumptions that limit the characterization of acute disease. For rotavirus, only acute gastroenteritis illness and fatal dehydration associated with that illness are monetized. Norovirus disease is not considered. For the enteroviruses, all acute disease endpoints are considered, but the prevalence of severe endemic cases may be substantially diluted by the large number of hand, foot, and mouth disease cases that are not likely to be waterborne. Thus, the proportion of severe cases in the quantitative benefits is likely to be underestimated. As is discussed more completely in Section 5.4, in neither instance, either for rotavirus or the enteroviruses, are chronic diseases identified or monetized in the quantitative benefits calculation.

Fourth, the quantified benefits are based explicitly on what has been directly measured in PWS wells, yet there is great difficulty in identifying and counting all infectious viral pathogens in dilute drinking water samples. Indeed, some viral pathogens like infectious norovirus can never be identified in any sample. Section 4.3.2 discusses these difficulties in more detail. Standard fecal indicator data such as total coliforms and *E. coli*, commonly used to identify water treatment deficiencies and potential human health hazards, are explicitly not used to determine human exposure for the purposes of quantifying the benefits in this EA.

Fifth, the quantified benefits are assumed to be based only on one contamination scenario, fecal contamination of source water. Other contamination scenarios are thoroughly documented in the ground water contamination and outbreak scientific literature. However, these scenarios, such as inadequate disinfection, are not explicitly considered in calculating the quantified benefits in this EA.

Sixth, the quantified benefits are assumed to be based only on avoidance of endemic disease. The GWR will likely also decrease the incidence of epidemic disease (outbreaks). If epidemic illnesses and the avoided non-health-related costs of ground waterborne disease outbreaks were included, the quantified benefits would increase.

In summary, this EA quantifies a subset of the total health and non-health related benefits. In a sample calculation, discussed in Section 5.4.3.2, EPA estimated that the total benefits could increase by a factor of five by only accounting for additional deaths and hospitalizations caused by bacterial illness being avoided. While EPA recognizes that this estimate includes substantial uncertainty, given all the other nonquantified factors described above, EPA believes that the total benefits from the GWR are likely to be more than five times those which have been quantified. See Exhibit 8.5b for estimates of net benefits that incorporate nonquantified benefits.

Exhibit 8.2 Summary of Annualized Present Value Quantified Benefits ($Millions, 2003$)

System Type	Annualized Benefits at 3% Discount Rate			Annualized Benefits at 7% Discount Rate		
		90% Confidence Bounds			90%Confidence Bounds	
	Mean	5th	95th	Mean	5th	95th
Enhanced COI						
CWS	$ 16.0	$ 5.4	$ 37.0	$ 13.7	$ 4.6	$ 31.6
NTNCWS	$ 0.9	$ 0.3	$ 2.2	$ 0.8	$ 0.2	$ 1.8
TNCWS	$ 2.7	$ 0.8	$ 6.2	$ 2.3	$ 0.7	$ 5.1
Total	$ 19.7	$ 6.5	$ 45.4	$ 16.8	$ 5.5	$ 38.6
Traditional COI						
CWS	$ 8.2	$ 1.9	$ 22.3	$ 7.1	$ 1.6	$ 19.1
NTNCWS	$ 0.5	$ 0.1	$ 1.3	$ 0.4	$ 0.1	$ 1.0
TNCWS	$ 1.3	$ 0.3	$ 3.4	$ 1.1	$ 0.2	$ 2.8
Total	$ 10.0	$ 2.2	$ 27.0	$ 8.6	$ 1.9	$ 22.9

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

The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to comprise a significant portion of the overall benefits of the Rule and are presented in Section 5.4 of Ch. 5 of the EA.

Source: Exhibit 5.23a, 5.23b

Exhibit 8.3 Summary of Benefits of the GWR

Benefit Category	Total Benefits	GWR EA Quantified Benefits
Health Benefits		
Reduction in endemic illness incidence	• viral exposure risk reduction (morbidity and mortality) • bacterial exposure risk reduction (morbidity and mortality) • chronic sequelae reduction • reduction in secondary transmission of viral or bacterial illness from symptomatic and asymptomatic individuals	• acute rotavirus (Type A) illnesses and deaths avoided • acute enterovirus (Type B) illnesses and deaths avoided • reduction in secondary transmission of viral illness from symptomatic individuals
Reduction in epidemic (outbreak) illness incidence	• viral exposure risk reduction (morbidity and mortality) • bacterial exposure risk reduction (morbidity and mortality) • chronic sequelae reduction • reduction in secondary transmission of viral or bacterial illness from symptomatic and asymptomatic individuals	Not quantified
Reduction in treatment failures	Decreased illness through minimizing treatment failures or fewer episodes with inadequate treatment	Not quantified
Non-Health Benefits		
Outbreak responses avoided	Avoided costs to affected water systems, local governments (provision of alternate water, issuing warnings and alerts), and community (decreased tourism due to bad press).	Not quantified
Avoided costs of averting behavior	• reduced need or perceived need to use bottled water, point-of-use devices, etc. (includes time and material costs) • less time spent on averting behavior: hauling/boiling water, etc.	Not quantified
Increased confidence	Perceived reduction in risk associated with perceived improvement in drinking water quality	Not quantified

8.1.2 National Cost Summary

The national annual cost of the GWR results from activities associated with rule implementation, sanitary surveys, triggered source water monitoring, corrective actions, and compliance monitoring. The estimated annualized cost of the GWR is $61.8 million at a three percent discount rate and $62.3 million at a seven percent discount rate. Exhibit 8.4 presents these costs further broken out by system type.

Exhibit 8.4 Summary of Quantified Costs, Final Rule ($Millions, 2003$)

System Type	Annualized Costs at 3% Discount Rate			Annualized Costs at 7% Discount Rate		
	Mean	90% Confidence Bounds		Mean	90%Confidence Bounds	
		5th	95th		5th	95th
CWS	$ 18.7	$ 12.4	$ 26.3	$ 19.2	$ 13.0	$ 26.9
NTNCWS	$ 4.9	$ 3.3	$ 6.8	$ 4.9	$ 3.4	$ 6.7
TNCWS	$ 26.4	$ 18.6	$ 35.7	$ 26.5	$ 18.8	$ 35.5
States	$ 11.8	$ 10.9	$ 12.6	$ 11.7	$ 10.9	$ 12.6
Total	$ 61.8	$ 45.2	$ 81.4	$ 62.3	$ 46.1	$ 81.6

Notes: Detail may not add due to independent rounding.

Source: Exhibits 6.33 and 6.34

8.1.3 Comparison of National Quantified Benefits and Costs

Exhibit 8.5a compares estimated quantified benefits with estimated costs. Based on the comparison of these values, the estimated quantified benefits of the rule range from approximately one-third to about one-seventh of the value of the costs, depending on the discount rate and COI approach. The estimated quantified benefits for the Enhanced COI approach are greater than the corresponding estimated benefits for the Traditional COI approach. The quantified estimate of the benefits significantly understates the true benefit of the rule. As discussed in Section 8.1.1 and Exhibit 8.3, the nonquantified health and non-health benefits far exceed those that EPA was able to quantify, and are the primary basis for supporting the preferred regulatory alternative. Section 5.4.3 of the EA discusses the potential value of nonquantified benefits, in particular avoided bacterial illnesses and deaths, which would significantly increase the net benefits of the final GWR. Exhibit 8.5b presents these estimates based on primary benefits using the Enhanced COI approach.

Exhibit 8.5a Estimated Annualized National Benefits and Costs for the GWR ($Millions, 2003$)

Estimate Category	3% Discount Rate			7% Discount Rate		
	Mean	90% Confidence Bounds		Mean	90%Confidence Bounds	
		5th	95th		5th	95th
Enhanced COI						
Benefits	$ 19.7	$ 6.5	$ 45.4	$ 16.8	$ 5.5	$ 38.6
Costs	$ 61.8	$ 45.2	$ 81.4	$ 62.3	$ 46.1	$ 81.6
Net Benefits	$ (42.1)	Note 1	Note 1	$ (45.5)	Note 1	Note 1
Traditional COI						
Benefits	$ 10.0	$ 2.2	$ 27.0	$ 8.6	$ 1.9	$ 22.9
Costs	$ 61.8	$ 45.2	$ 81.4	$ 62.3	$ 46.1	$ 81.6
Net Benefits	$ (51.8)	Note 1	Note 1	$ (53.7)	Note 1	Note 1
Nonquantified Benefits	Decreased incidence of other acute viral disease endpoints Decreased incidence of bacterial illness and death Decreased incidence of chronic bacterial and viral illness sequelae Decreased incidence of waterborne disease outbreaks and epidemic illness Decreased illness through minimizing treatment failures or fewer episodes with inadequate treatment Decreased use of bottle water and point-of-use devices (material costs) Decreased time spent on averting behavior Avoided costs associated with outbreak response Perceived improvement in drinking water quality and reduction in risk associated with ingestion Benefits from optional Assessment Monitoring Benefits from correction of sanitary survey deficiencies identified in the distribution systems and treatment plant					
Nonquantified Costs	Costs for optional Assessment Monitoring Costs from correction of sanitary survey deficiencies identified in the distribution systems and treatment plant Costs for compliance monitoring for some systems that already disinfect Some land costs depending on the treatment technology Cost for five repeat samples but this is small compared to the overestimate of cost for the initial fecal-indicator sample that systems would take.					

Note 1: Because benefits and costs are calculated using different model modules, bounds are not calculated on net benefits.
Notes: Detail may not add due to independent rounding. The Traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The Enhanced COI also factors in valuations for lost personal time (non-work time) such as childcare and homemaking (to the extent not covered by the Traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway.

Source: Exhibts 8.2 and 8.4

Exhibit 8.5b Estimated Net Benefits Including Annual Bacterial Illness and Death Avoidance Estimate ($Millions 2003$)

Estimate Category	Discount Rate	
Benefits	**3%**	**7%**
Quantified Benefits (ECOI)	$ 19.7	$ 16.8
Bacterial Illness and Death Avoidance Benefits	$ 98.6	$ 83.8
Total	$ 118.3	$ 100.6
Costs	$ 61.8	$ 62.3
Net Benefits	$ 56.5	$ 38.3

Notes: Costs and Quantified Benefits are output from the GWR model as annualized estimates that incorporate annual adjustments for income elasticity, changes in real income, and a CPI increase factor (all affecting the VSL). The GWR model also incorporates a schedule for implementation that affects the timing of benefits accrual throughout the analysis period for the GWR, which affects all components of benefits (direct and indirect). The model also discounts both costs and benefits (shown above at 3 and 7 percent). See Ch. 5 and Appendix B of the EA for detail on these adjustments. The estimated value of avoiding bacterial illness and death is not generated in the primary analysis model but is calculated as shown in Ch. 5, Sec. 5.4.3. Therefore, the components of the estimated value of avoiding bacterial illness and death (affecting VSL and Direct Medical Costs) are not adjusted for these factors.

8.2 Effect of Uncertainties and Nonquantified Benefit/Cost Estimates on the Estimation of Net National Benefits

Detailed discussions of the assumptions and uncertainties associated with national benefits and costs are contained in Chapters 4, 5, and 6. Several of the most important assumptions and data uncertainties, and the effect of those uncertainties on the benefits and cost analyses, are discussed below.

The GWR EA attempted to capture the full range of uncertainty in the analysis. In the quantified analysis, parameters were described using a distribution rather than a point value where sufficient information is available. Where information is limited, distributions are chosen based on informed professional judgment. Otherwise, distributions were determined by statistical models that allowed the data to inform the distribution. Choice of statistical models were based on examining the data combined with use of scientific principles. Alternative assumptions were tested and described in alternative analyses. The EA also includes detailed discussion of the additional uncertainty associated with nonquantified factors and untested assumptions.

The quantified GWR benefits are calculated using Monte Carlo sampling of the parameter distributions and are expressed in monetary terms. The calculated results are presented as ranges with means and confidence bounds. The most likely quantified value is within this calculated range but the total benefit range, considering the non quantified benefits, is greater than the calculated benefit range. As summarized in Exhibit 5.32 and described throughout Chapter 5, because of limited available data, almost all of the factors in the quantified analysis were chosen to provide a conservative estimate of benefit, thus underestimating the quantified benefits. Furthermore, the factors discussed but not quantified in the benefits analysis primarily act to provide additional GWR benefits, albeit nonquantified. Based on these two uncertainty sources, EPA concludes that the total mean benefits are expected to be several times greater than the quantified mean benefits and are likely to be greater than the calculated upper confidence bound as well. The formal peer review of the GWR EA yielded comments and summary statements that endorse EPA's conclusion that the GWR EA quantified benefits are small compared to the total benefits.

Most of the significant costs that EPA has identified have been quantified. The only significant costs that have not been quantified are for certain corrective actions that are a result of significant deficiencies identified during sanitary surveys. Exclusion of these costs from the EA cost analysis results in an underestimate of potential rule costs. However, as described in Chapter 6 of the EA, the impact on the overall cost/benefit ratios from excluding costs for correction of treatment or distribution system significant deficiencies is minimal since data limitations also exclude quantifying any benefits that may be realized for correcting these significant deficiencies.

There is uncertainty in the cost analysis that could result in either an over- or underestimate of the costs as presented in this chapter. Exhibit 6.32 in Chapter 6 of the EA presents a summary of these issues and estimates the effects that each may have on national costs. The greatest uncertainties affecting the costs of the GWR are in the percentages used to estimate compliance and costs for each regulatory alternative. However, by using a Monte-Carlo analysis, a best estimate (mean of range of estimates) of costs can be calculated as well as the uncertainty bounds around that estimate.

Overall, EPA believes that the nonquantified costs are much smaller than the nonquantified benefits and the estimates of the national net benefits are conservative. Detailed discussion of nonquantified benefits and costs are presented in chapters 5 and 6, respectively.

8.3 Breakeven Analysis

In the face of uncertainties, it is helpful to evaluate the range over which the regulation meets the critical test of benefits exceeding costs. Thus, the number of illnesses or deaths that would have to be avoided annually to compensate for costs, or for the GWR to "break even," can be calculated. If the estimated present annual cost of the rule is $61.8 million using a three percent discount rate and $62.3 million using a seven percent discount rate, then 131,234 or 155,609 illnesses, respectively, would need to be avoided annually using the Enhanced COI approach. Using the Traditional COI approach, 257,887 or 304,696 illnesses would have to be avoided annually. The breakeven number of illnesses that need to be avoided for both the Enhanced and Traditional COI approaches is above the estimated number of quantified illnesses (41,868 as shown in Exhibit 8.1) avoided by the final GWR. To "break even" using deaths avoided as a measure, approximately 8 deaths would have to be avoided for either a three or seven percent discount rate. Although this number of deaths exceeds the bounds of the quantified number of deaths avoided in the primary analysis, it is small in absolute terms when considering potential effects of viruses and bacteria not quantified as part of the analysis. Section 5.4.3.2 describes the methodology for estimating ten additional deaths due to bacterial illness from contaminated PWS wells. Bacterial illness and death is not considered in the breakeven analysis.

It must be noted, again, that this analysis does not account for the nonquantified health and non-health benefits, which far exceed those that EPA was able to quantify, and are the primary basis for supporting the preferred regulatory alternative. The nonquantified benefits of the final GWR include all of the nonquantified benefits that accrue to each alternative, as described in Chapter 5.

Exhibit 8.6 Estimated Breakeven Points

Measure	Estimated Number of Cases to Avoid to Break Even[1]	
	3% Discount Rate	7% Discount Rate
Ilnesses		
Enhanced COI	131,234	155,609
Traditional COI	257,887	304,696
Deaths		
VSL	8.3	8.4

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

[1] Breakeven illnesses and deaths are derived by dividing the regulation cost by an estimate of the average benefit per illness or death avoided as shown in Exhibit 8.1. Illnesses or deaths avoided may be of bacterial or viral etiology; since this analysis is based on the viral COI described in Ch. 5 of the EA for Type A and Type B viruses, for reasons also explained in Ch. 5 the COI could be an underestimate for cases of other types of viral or bacterial illness avoided. This could result in an overestimate of the number of illnesses or deaths that need to be avoided in order to break even with the costs of the rule.

Source: Derived from Exhibits 8.1 and 8.5a

8.4 Comparison of Regulatory Alternatives

As discussed in Chapter 3, the development and evaluation of several regulatory alternatives was undertaken as part of a consultation process that included stakeholder meetings and public comments. The four alternatives in the final EA are listed below.

Alternative 1—Sanitary surveys and corrective action.

Final GWR—Risk Targeted Approach (Sanitary surveys, triggered monitoring, optional assessment monitoring, corrective action, and compliance monitoring).

Alternative 3—Multi-Barrier Approach (Sanitary surveys, triggered monitoring, optional hydrogeologic sensitivity assessment, assessment monitoring, corrective action, and compliance monitoring).

Alternative 4—Across-the-board disinfection (Sanitary surveys, install/upgrade and maintain treatment).

The following sections evaluate the benefits and costs for the Final GWR requirements in comparison to the three other alternatives.

8.4.1 Comparison of Benefits and Costs

To make meaningful comparisons between regulatory alternatives, it is first necessary to look at the final benefit and cost numbers derived for each. Exhibit 8.7 presents the annualized present value costs for each alternative considered, followed by presentations of benefits in Exhibits 8.8 and 8.9.

Exhibit 8.7 Annualized Costs, by Regulatory Alternative ($Millions, 2003$)

	Annualized Costs at 3% Discount Rate			Annualized Costs at 7% Discount Rate		
		90% Confidence Bounds			90% Confidence Bounds	
Rule Alternative	Mean	5th	95th	Mean	5th	95th
Alternative 1	$ 15.3	$ 11.8	$ 19.2	$ 15.3	$ 11.9	$ 19.0
Final Rule	$ 61.8	$ 45.2	$ 81.4	$ 62.3	$ 46.1	$ 81.6
Alternative 3	$ 67.9	$ 49.4	$ 89.5	$ 69.4	$ 51.0	$ 90.6
Alternative 4	$ 686.4	$ 636.8	$ 735.4	$ 665.3	$ 612.3	$ 717.0

Source: Exhibit 6.35

Exhibit 8.8 Number of Annual Quantified Viral Illnesses and Deaths Avoided Regulatory Alternatives

	Illnesses Avoided			Deaths Avoided		
		90% Confidence Bounds			90% Confidence Bounds	
Rule Alternative	Mean	5th	95th	Mean	5th	95th
Alternative 1	7,497	1,618	17,007	0.14	0.01	0.44
Final Rule	41,868	10,274	88,039	0.74	0.08	2.11
Alternative 3	45,419	11,639	95,166	0.80	0.09	2.33
Alternative 4	155,282	27,824	399,085	2.67	0.21	9.25

Source: Exhibit 5.30

Exhibit 8.9 Annualized Value of Quantified Viral Illnesses and Deaths Avoided, by Regulatory Alternative ($Millions, 2003$)

Rule Alternative	At 3%			At 7%		
	Mean	90% Confidence Bounds		Mean	90% Confidence Bounds	
		5th	95th		5th	95th
Enhanced COI						
Alternative 1	$ 3.6	$ 0.9	$ 9.3	$ 2.9	$ 0.7	$ 7.5
Final Rule	$ 19.7	$ 6.5	$ 45.4	$ 16.8	$ 5.5	$ 38.6
Alternative 3	$ 21.3	$ 7.1	$ 48.7	$ 18.2	$ 6.0	$ 41.6
Alternative 4	$ 70.2	$ 18.3	$ 177.0	$ 61.9	$ 16.1	$ 156.3
Traditional COI						
Alternative 1	$ 1.9	$ 0.3	$ 5.5	$ 1.5	$ 0.2	$ 4.5
Final Rule	$ 10.0	$ 2.2	$ 27.0	$ 8.6	$ 1.9	$ 22.9
Alternative 3	$ 10.8	$ 2.5	$ 28.9	$ 9.3	$ 2.1	$ 24.8
Alternative 4	$ 35.5	$ 6.5	$ 102.4	$ 31.5	$ 5.7	$ 90.8

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

The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to compose a significant portion of the overall benefits of the Rule and are presented in Section 5.4 of Ch. 5 of the EA.

Source: Exhibit 5.31

Net benefit is the difference between the monetized benefit and cost estimates. Exhibit 8.10a presents net benefits based on the annualized present value of quantified benefits at three and seven percent discount rates, using both the Enhanced and the Traditional COI approach. The data are based on the average benefits less the average values for costs. As discussed in Section 8.1.1 and Exhibit 8.3, the nonquantified health and nonhealth benefits far exceed those that EPA was able to quantify, and their incorporation into the quantified analysis would result in substantial increases in net benefits. Exhibit 8.10b demonstrates how by using a multiplier (based on bacterial hospitalizations and deaths avoided), the net benefits of the final GWR are positive using the enhanced COI and are very close to positive using the traditional COI. Based on consideration of the large number of nonquantified benefits, EPA believes that this level of additional nonquantified benefits in relation to quantified benefits will be easily achieved. Therefore, consideration of these nonquantified benefits provides a basis for supporting the preferred regulatory alternative. To the extent that additional benefits are realized, those populations at greatest risk from ground water contamination (e.g., sensitive sub-populations, including children and the immunocompromised) will be better protected.

Exhibit 8.10a Annualized Net Benefits by Regulatory Alternative ($Millions, 2003$)

Rule Alternative	Annualized Value 3%	Annualized Value 7%
Enhanced COI		
Alternative 1	$ (11.7)	$ (12.4)
Final Rule	$ (42.1)	$ (45.5)
Alternative 3	$ (46.6)	$ (51.2)
Alternative 4	$ (616.2)	$ (603.4)
Traditional COI		
Alternative 1	$ (13.5)	$ (13.8)
Final Rule	$ (51.8)	$ (53.7)
Alternative 3	$ (57.1)	$ (60.1)
Alternative 4	$ (650.9)	$ (633.8)

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

The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to compose a significant portion of the overall benefits of the Rule and are presented in Section 5.4 of Ch. 5 of the EA.

Source: Derived from Exhibits 8.7 and 8.9

Exhibit 8.10b Annualized Mean Net Benefits for Final Rule Including Estimates for Nonquantified Benefits ($Millions, 2003$)

Multiple of Benefits Representing Nonquantified Benefits	Annualized Net Benefit Value - Final Rule 3%	Annualized Net Benefit Value - Final Rule 7%
Enhanced COI		
Quantified Net Benefits Only	$ (42.1)	$ (45.5)
Nonquantified = 5X Quantified	$ 56.5	$ 38.3
Traditional COI		
Quantified Net Benefits Only	$ (51.8)	$ (53.7)
Nonquantified = 5X Quantified	$ (1.6)	$ (10.9)

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

Source: Derived from Exhibits 8.7 and 8.9

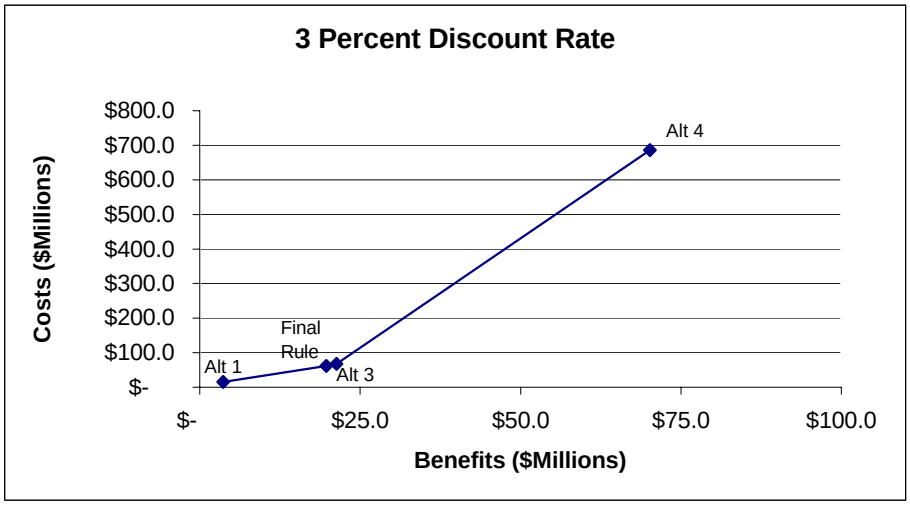
8.4.2 Cost-Effectiveness Measures

Cost-Effectiveness–Traditional Approach

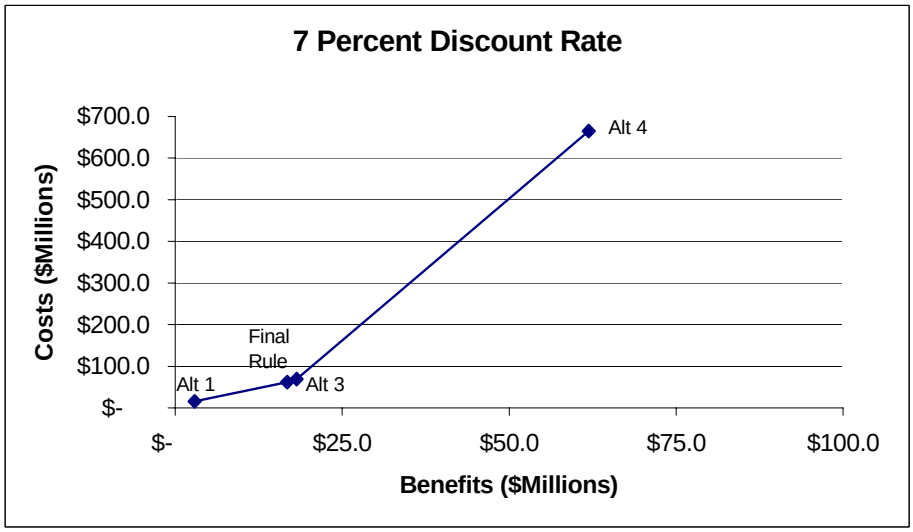
Cost-effectiveness analysis is a policy evaluation tool that allows comparisons of regulatory alternatives. The concept of cost-effectiveness can be defined simply as getting the greatest benefits for a given expenditure or imposing the least cost for a given level of benefits. In Exhibits 8.11a and 8.11b, the test is to see if any alternative falls to the right and completely below any other alternative on the graph. If so, the alternative to the right and below would be more cost-effective and "dominate" the alternative that provided fewer benefits at higher costs.

In the strict sense, each of the regulatory alternatives is cost effective—no regulatory alternative provides more benefits at the same or a lower cost than another, and no alternative can achieve lower costs for the same or a greater level of benefits than another. Thus, no alternative dominates any other or is more cost effective. Instead, the alternatives offer increasing levels of benefits at increasing levels of cost, as seen in Exhibits 8.11a and 8.11b.

Exhibit 8.11a Mean Annualized Costs at Mean Benefit Level, Enhanced COI, by Regulatory Alternative



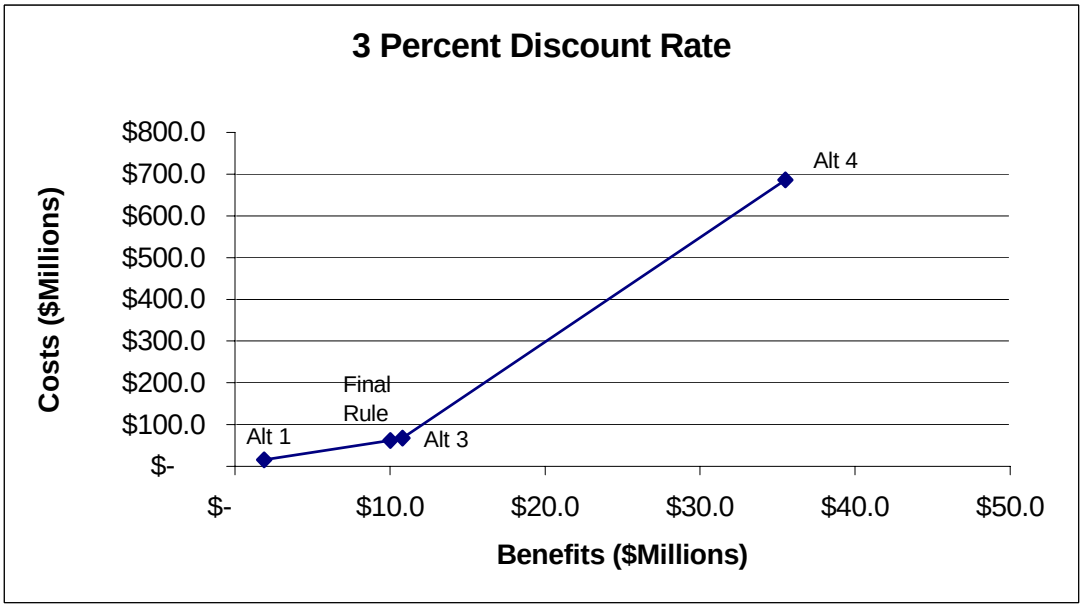
Source: Exhibits 8.7 and 8.9

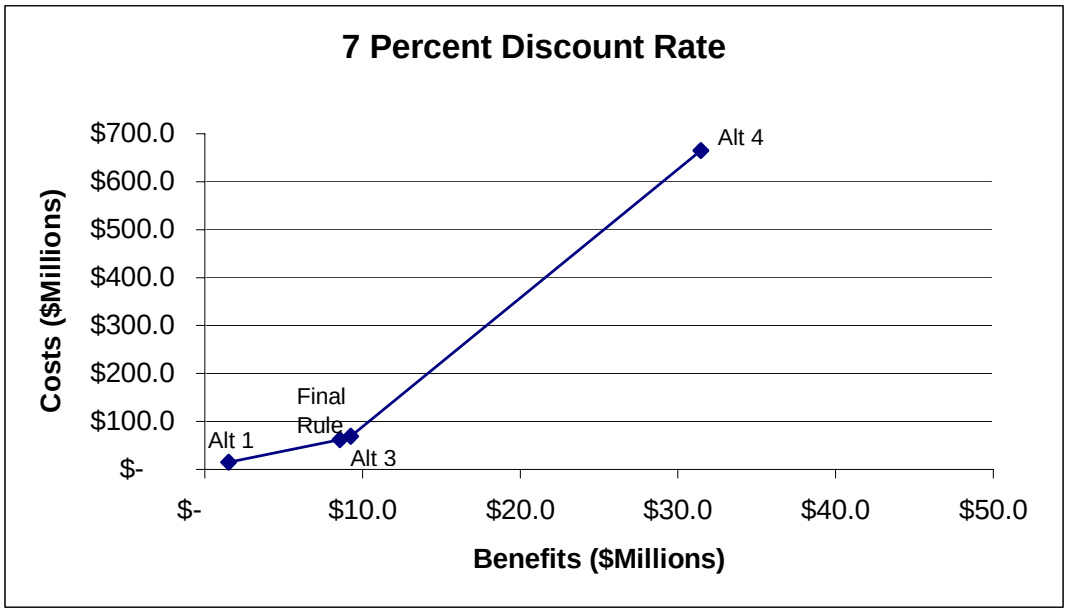


Source: Exhibits 8.7 and 8.9

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

Exhibit 8.11b Mean Annualized Costs at Mean Benefit Level, Traditional COI, by Regulatory Alternative





Source: Exhibits 8.7 and 8.9

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

Cost per Case of Illness or Death Avoided

Another measure related to cost-effectiveness that EPA used to evaluate the regulatory alternatives is the cost for each case of illness and death avoided. EPA has performed this analysis for the quantified benefits of the GWR. For purposes of evaluating the alternatives, the lower the cost per case or death avoided, the more cost-effective the alternative is believed to be. Exhibit 8.12 presents the average cost per case of viral illness and death avoided for each regulatory alternative.

Exhibit 8.12 Cost Per Viral Illness or Death Avoided by Regulatory Alternative (2003$)

Rule Alternative	Cost per Viral Illness Avoided ($)		Cost per Viral Death Avoided ($Millions)	
	3%	7%	3%	7%
Alternative 1	$ 2,045	$ 2,044	$ 107.4	$ 107.4
Final Rule	$ 1,476	$ 1,488	$ 83.1	$ 83.8
Alternative 3	$ 1,495	$ 1,527	$ 85.0	$ 86.9
Alternative 4	$ 4,420	$ 4,284	$ 257.4	$ 249.5

Note: The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to compose a significant portion of the overall benefits of the Rule and are presented in Section 5.4 of Ch. 5 of the EA.

Source: Derived from Exhibits 8.7 and 8.8

Exhibit 8.12 shows that the cost per case avoided for the final GWR is lower than the cost per case avoided for each of the other alternatives considered. Thus, the Final GWR is the most efficient alternative by this measure. Given the substantial nonquantified benefits of the final GWR as described in Chapter 5, the actual cost per case is lower than calculated in Exhibit 8.12.

Incremental Net Benefits

EPA also assessed the incremental net benefits of the regulatory alternatives. Incremental costs and benefits are those that are incurred or realized in reducing viral illness, bacterial illness, and outbreaks from one rule alternative to the next. Estimates of incremental costs and benefits are useful in considering the economic efficiency of different regulatory options considered by the Agency. Generally, the goal of an incremental analysis is to identify the option where incremental benefits most closely equal incremental costs (net social benefits are maximized). However, the usefulness of this analysis is limited because the benefits from the rule that are not quantified or monetized far exceed those that EPA was able to quantify, and these nonquantified benefits are the primary basis for supporting the preferred regulatory alternative.

Exhibit 8.13 presents the four regulatory alternatives in order of increasing level of reduction in waterborne pathogens, or increasing levels of protection from illness. As a result, it is possible to compare incremental net benefits from the baseline and alternative to alternative. As shown in Exhibits 8.13a and b, incremental net benefits for all alternatives are negative. The benefits of non-quantified bacterial illness and death avoided would add benefits to all alternatives without any increase in costs.

EPA estimated that the total benefits are likely to increase by more than a factor of five by accounting for additional deaths and hospitalizations caused by reduced bacterial illness and death alone. These non-quantified benefits have a significant positive impact on the incremental benefits and net incremental benefits. Both Alternative 3 and Alternative 2 would have positive net incremental benefits if the bacterial benefits are considered. The next highest alternative, Alternative 4, has such highly negative incremental net benefits, and the difference is so substantial that non-monetized benefits would be unlikely to compensate. However, comparisons between Alternative 4 and the other alternatives may be between two separate sets of benefits, in the sense that they may be distributed to somewhat different populations. However, based on consideration of all factors, EPA has determined that the final GWR provides the maximum benefits at a cost that is justified.

The cost-effectiveness of the final GWR and alternatives was also considered in terms of the quality-adjusted life years (QALYs) saved for avoided viral illnesses or deaths. The QALYs analysis shows that the final GWR performs the best in terms of this measure. Appendix H provides the detail of this analysis.

Exhibit 8.13a Incremental Net Quantified Benefits by Rule Alternative - Enhanced COI (Annualized Present Value Mean, $Millions, 2003$)

Rule Alternative	Annual Costs A	Annual Benefits B	Incremental Costs C	Incremental Benefits D	Incremental Net Benefits E=D-C
3% Discount Rate					
Alternative 1: Sanitary Survey and Corrective Action	$ 15.3	$ 3.6	$ 15.3	$ 3.6	$ (11.7)
Alternative 2 (Final Rule): Risk Targeted Approach	$ 61.8	$ 19.7	$ 46.5	$ 16.1	$ (30.4)
Alternative 3: Multi-Barrier Approach	$ 67.9	$ 21.3	$ 6.1	$ 1.6	$ (4.5)
Alternative 4: Across-the-board Disinfection	$ 686.4	$ 70.2	$ 618.5	$ 48.9	$ (569.6)
7% Discount Rate					
Alternative 1: Sanitary Survey and Corrective Action	$ 15.3	$ 2.9	$ 15.3	$ 2.9	$ (12.4)
Alternative 2 (Final Rule): Risk Targeted Approach	$ 62.3	$ 16.8	$ 47.0	$ 13.9	$ (33.1)
Alternative 3: Multi-Barrier Approach	$ 69.4	$ 18.2	$ 7.1	$ 1.4	$ (5.7)
Alternative 4: Across-the-board Disinfection	$ 665.3	$ 61.9	$ 595.9	$ 43.8	$ (552.2)

Notes: The Traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The Enhanced COI also factors in valuations for lost personal time (non-work time) such as childcare and homemaking (to the extent not covered by the Traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway. All values are annualized in 2003$.

The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to compose a significant portion of the overall benefits of the Rule and are presented in Section 5.4 of Ch. 5 of the EA.

Sources: (A) Exhibit 8.7, (B) Exhibit 8.9

Exhibit 8.13b Incremental Net Quantified Benefits by Rule Alternative - Traditional COI (Annualized Present Value Mean, $Millions, 2003$)

Rule Alternative	Annual Costs A	Annual Benefits B	Incremental Costs C	Incremental Benefits D	Incremental Net Benefits E=D-C
3% Discount Rate					
Alternative 1: Sanitary Survey and Corrective Action	$ 15.3	$ 1.9	$ 15.3	$ 1.9	$ (13.5)
Alternative 2 (Final Rule): Risk Targeted Approach	$ 61.8	$ 10.0	$ 46.5	$ 8.2	$ (38.3)
Alternative 3: Multi-Barrier Approach	$ 67.9	$ 10.8	$ 6.1	$ 0.8	$ (5.3)
Alternative 4: Across-the-board Disinfection	$ 686.4	$ 35.5	$ 618.5	$ 24.7	$ (593.8)
7% Discount Rate					
Alternative 1: Sanitary Survey and Corrective Action	$ 15.3	$ 1.5	$ 15.3	$ 1.5	$ (13.8)
Alternative 2 (Final Rule): Risk Targeted Approach	$ 62.3	$ 8.6	$ 47.0	$ 7.1	$ (39.9)
Alternative 3: Multi-Barrier Approach	$ 69.4	$ 9.3	$ 7.1	$ 0.7	$ (6.4)
Alternative 4: Across-the-board Disinfection	$ 665.3	$ 31.5	$ 595.9	$ 22.2	$ (573.7)

Note: The Traditional COI only includes valuation for medical costs and lost work time (including some portion of unpaid household production). The Enhanced COI also factors in valuations for lost personal time (non-work time) such as childcare and homemaking (to the extent not covered by the Traditional COI), time with family, and recreation, and lost productivity at work on days when workers are ill but go to work anyway. All values are annualized in 2003$.

The figures presented in this exhibit represent only the quantifiable benefits of the GWR. The unquantified benefits are expected to compose a significant portion of the overall benefits of the Rule and are presented in Section 5.4 of Ch. 5 of the EA.

Sources: (A) Exhibit 8.7, (B) Exhibit 8.9

8.5 Summary of Conclusions

The Agency also performed a number of other analyses related to the final rule. This process included an analysis of net benefits, as well as cost effectiveness and efficiency analyses. In addition, the Agency performed a number of comparisons among the four regulatory alternatives that are described in more detail earlier in this chapter. The following is a summary of these analyses.

The GWR likely passes economic threshold criteria:

- The GWR has positive net benefits when both quantified and nonquantified benefits are considered. For the Enhanced COI approach, the quantified benefits alone are approximately 27 to 32 percent of the costs of the GWR (Exhibit 8.5a) depending on discount rate. For the Traditional COI approach, the quantified benefits are approximately 14 to 16 percent of the costs of the GWR. Considering that nonquantified benefits are expected to be significantly larger than the quantified benefits, it appears likely that the final GWR would have positive net benefits regardless of the discount rate or cost of illness approach used. Section 5.4.3.2 presents a discussion of nonquantified benefits and estimates a portion of their value, based only on bacterial illnesses avoided, at four times the primary analysis benefits (resulting in

total benefits that are five times the primary benefits). This includes consideration of the value of deaths and hospitalization costs avoided for ground water borne cases of bacterial illness prevented by the rule. Including only these estimated bacterial illness and death benefits, the total net benefits of the GWR would be positive using the Enhanced COI approach. Total net benefits would still be slightly negative using the Traditional COI approach, however, other nonquantified benefits such as indirect (non-medical) costs associated with waterborne bacterial illness or the value of avoiding other chronic (either bacterial or viral) or other viral illnesses (not accounted for in this analysis) would most likely make this value positive.

- The number of illnesses that must be avoided to break even with costs (Exhibit 8.6) is well above the estimated number of viral cases avoided (Exhibit 8.1), but is most likely within the bounds of cases avoided once nonquantified cases (both bacterial and viral) are considered. The number of deaths that must be avoided to break even, while outside the bounds of the quantitative analysis, is small in absolute terms. Consideration of all nonquantified benefits is predicted to result in favorable break even results.

- The GWR is cost-effective (using either the Enhanced or the Traditional COI approach): no other alternative achieves greater benefits at the same cost or the same benefits at lower cost (Exhibit 8.11).

Final GWR determinations:

- The economic analysis for this rule, considering quantified and nonquantified benefits, supports the basis for selecting the final GWR over other alternatives. However, the distinction between Alternative 2 and 3 on an economic basis, is not great.

- EPA chose the final GWR because EPA believes it is more flexible, targeted, and cost-effectively protective than Alternative 3. Optional assessment monitoring allows States to most effectively target those systems at greatest risk and minimize unnecessary monitoring. EPA took the following considerations into account in making this judgment:

    1) Under Alternative 3, some States may not be able to conduct HSAs and thereby require systems in nonsensitive aquifers to conduct assessment monitoring unnecessarily. For systems not at risk this additional monitoring would provide no benefit.

    2) Systems with frequent TC positives in the distributions system (and subsequent frequent triggered monitoring) would benefit little from assessment monitoring regardless if they were sensitive or not because the source water would already be thoroughly evaluated. Under Alternative 3, such systems in sensitive (or undetermined) aquifers would be required to do assessment monitoring.

    3) Systems identified as having significant risk factors pertaining to potential fecal contamination at their source (e.g., aquifer condition, well characteristics, proximity to sewage or septic), but infrequent triggered monitoring source water samples, would benefit from assessment monitoring. States will be able to identify such systems on an ongoing basis through a variety of tools and information readily available to them.

- The EPA believes that the final rule is a logical outgrowth of the proposed rule, that it is supported by comments, and that it provides public health benefits while apportioning costs in a more flexible targeted manner.

As a result of all of these considerations, EPA has determined that the final GWR will provide important protection against illnesses and deaths attributable to fecally contaminated ground water. EPA also believes that the GWR will provide a desired level of protection from ground water pathogen contamination at a justifiable cost.

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